TEXAS SENATE
COMMITTEE ON HEALTH AND HUMAN SERVICES

INTERIM REPORT
TO THE
87TH LEGISLATURE

January 2021

THE SENATE OF TEXAS
COMMITTEE ON HEALTH AND HUMAN SERVICES

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January 11, 2021

The Honorable Dan Patrick
Lieutenant Governor of Texas
P.O. Box 12068
Austin, TX 78711

Dear Governor Patrick,

The Senate Committee on Health and Human Services submits this report in response to the interim charges you assigned to this committee, as well as topics related to the COVID-19 public health emergency.

Respectfully submitted,

Senator Lois Kolkhorst, Chair

Senator Charles Perry, Vice-Chair

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LOIS W. KOLKHORST
STATE SENATOR
DISTRICT 18

January 11, 2021

The Honorable Dan Patrick
Lieutenant Governor of Texas
P.O. Box 12068
Austin, TX 78711

Dear Governor Patrick,

The interim that followed the 86th Texas Legislature was unlike any other. Beginning in March of 2020, the COVID-19 global pandemic became the primary focus of the Senate Health and Human Services Committee, the Texas Senate as well as the entire Legislature. Our efforts to manage COVID-19 have resulted in hundreds of hours of research and countless conference calls with important leaders such as yourself, as well as Governor Abbott, the White House, state agencies, local governments, public health experts, along with many others.

A great deal has been learned from this pandemic but there is much more to discover during the months ahead. As was the case with Hurricane Harvey, it is my hope that lawmakers will use the lessons learned from COVID-19 to create legislation and budget priorities that help us be prepared for future health events. Following the response to Harvey, we crafted Senate and House legislation that resulted in Texas leading the nation in natural disaster recovery. In the same manner, Texas can set in motion bold policies that will lead our nation post-pandemic.

The COVID-19 pandemic profoundly interrupted how the Texas Senate conducted interim business. As Chair, I truly appreciate your leadership in directing this Committee to study and identify solutions to our state's greatest health and human services challenges. However, due to the pandemic and resulting restrictions, the Committee was unable to hold full public hearings on these interim charges:

- **Health Care Costs:** Examine the state health and human services finance system including, but not limited to, the following programs and methods of finance: Local Provider Participation Funds, the Delivery System Reform Incentive Payment Program, Medicaid 1115 waivers and Section 1332 State Innovation waivers, Pay for Quality programs, the Quality Incentive Payment Program, and other state and local funding used to finance health care systems in Texas. Identify ways to streamline functions and reduce unnecessarily burdensome and costly requirements in the Texas Medicaid program. Provide

recommendations to ensure the sustainability of the state's health and human services system and judicious use of taxpayer dollars.

- **Heart Health:** Analyze the prevalence and cost impact of heart disease to state health care programs. Provide recommendations to increase program collaboration and reduce the long-term costs associated with heart disease, stroke, and related risk factors. Identify and recommend ways to address the impact of heart disease on women's health.

- **Rural Health:** Examine and determine ways to improve health care delivery in rural and medically underserved areas of the state. Determine whether additional funding provided during the 86th Legislative Session has helped to ensure more accessible and quality health care in rural areas.

- **Strengthening Families:** Examine Department of Family Protective Services procedures and grounds for placing a child into the child welfare system and the termination of parental rights. Make recommendations on ways to protect children who are involved with the child welfare system while preserving families under state law. Identify ways faith-based and other community organizations can assist in preserving or reunifying families involved with the child welfare system.

- **Monitoring:** Monitor the implementation of legislation addressed by the Senate Committee on Health and Human Services passed by the 86th Legislature, as well as relevant agencies and programs under the committee's jurisdiction. Specifically, make recommendations for any legislation needed to improve, enhance, or complete implementation of the following:
    - The continued implementation of Senate Bill 11 (85th Legislature) and Community-Based Care by the Department of Family and Protective Services;
    - Behavioral health programs, including implementation of the Texas Child Mental Health Care Consortium (Senate Bill 11), state hospitals, and strategies to address substance abuse and opioid addiction;
    - Child care quality and safety;
    - Medicaid medical transportation program relating to House Bill 1576;
    - Maternal mortality and infant health initiatives, including the women's health programs administered by the Health and Human Services Commission;
    - Initiatives to reduce Medicaid fraud, waste and abuse, as well as other cost containment strategies; and
    - Medicaid managed care oversight and accountability.

While the pandemic prevented us from holding public hearings on these extremely important topics, I am proud that the Committee staff, myself and the members of the Committee have

consistently monitored these issues over the interim, and we will strive to directly address each challenge during the 87th Legislature. It is also encouraging to report the Committee was able to recently convene in the Capitol to hold hearings on December 7 and 8, when we discussed COVID-19 and heard from experts on issues related to data, clinical treatments and therapeutics, as well as the way our response to the virus has impacted our most vulnerable Texans.

The enclosed report reflects our work on these COVID-19 topics, as well as our earlier focus on e-cigarettes and health care costs, which were covered in hearings held prior to the pandemic.

Sincerely,

Senator Lois W. Kolkhorst

Please direct questions or comments to:

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Interim Topic

Interim Topic Language: *Analyze the procedures for collecting, modeling, and reporting data on COVID-19 tests, cases, hospitalizations, and fatalities. Examine the role of state agencies, local governments, and private entities.*

Hearing Information

The Senate Health and Human Services Committee held a hearing on December 7, 2020 to discuss this interim topic. Individuals representing the Texas Department of State Health Services, Harris County Public Health, Houston Health Department, Northeast Texas Public Health System, Southwest Texas Regional Advisory Council, Quest Diagnostics, Memorial Hermann Health System, Parkland Health & Hospital System, UT Southwestern Medical Center, and UT Health School of Public Health provided invited testimony.[1]

Introduction

Public health data is used by health officials, providers, private entities, and state, local, and federal governments to make decisions related to health and safety. During the COVID-19 public health emergency, information about cases, hospitalizations, tests, and fatalities has been used to inform decisions about business and school closures, prevention measures, testing, messaging, and resource allocation. The accuracy, timeliness, and completeness of public health data is essential to informing such decision-making.

The Texas Department of State Health Services (DSHS) launched the public-facing state COVID-19 dashboard on March 24, 2020. Data elements including regional hospital capacity, county-level counts and trends of tests, cases, hospitalizations, and fatalities, and estimates of active and recovered cases are added daily. Case and fatality demographic data are added weekly. The dashboard is a primary source of COVID-19 data for the state. Many local public health jurisdictions also publish local data publicly. Prior to the COVID-19 pandemic, DSHS did not finalize infectious disease case numbers until six months after the calendar year, after rigorous quality checks. The pandemic was the first time the department has reported infectious disease numbers daily.[2]

Sourcing of Data Elements

COVID-19 data elements are sourced from health care providers, laboratories, hospitals, medical certifiers, and any entity conducting testing. The data is provided via electronic or other means, either by law or through voluntary information-sharing. State law requires medical providers, laboratories, and other entities to report "notifiable conditions" such as COVID-19 to the local health authority.[3] Governor Abbott's March 24th Executive Order (GA-10) required entities to

submit positive, negative, and indeterminate COVID-19 test results immediately.[4] Prior to the pandemic, only reporting of positive results was required.

National Electronic Disease Surveillance System (NEDSS)

NEDSS is the basis of disease surveillance and response in Texas. The system processes and categorizes infectious disease laboratory results. Sixty jurisdictions across the state also rely on NEDSS to access disease information pertinent to their area.[5] Messages are submitted in a specific HL7 format, consistent with nationally-specified standards. DSHS and other entities receive lab results through several pipelines, including electronic lab reports (ELRs) in HL7 format, CSV files, and faxes.

Prior to the pandemic, the system's capacity was limited to 2,000 tests per day, and about 70 laboratory facilities were registered to submit data, including commercial labs, hospitals, and public health labs.

In 2019, DSHS described NEDSS as "at risk for failure."[6] In response, the 86th Legislature appropriated $3.5 million for system upgrades, as well as several full-time equivalents (FTEs). The upgrades were in progress prior to the arrival of COVID-19, but had not yet been completed. In August 2020, DSHS successfully completed the NEDSS upgrades, including the migration to a cloud server and an increase in system capacity of nearly 10,000%.[7]

Testing: Before/During COVID-19		
	Pre-COVID	**During COVID**
Testing result focus for public health purposes	Positive results	Positive, negative, and indeterminate results
Reporting system daily capacity (all conditions)	2,000	200,000 (+9,990%)
Number of labs submitting data to DSHS	~70	~3,362 (+4,702%)

NEDSS Backlog and Issues

Before the completion of the upgrade, NEDSS' limited capacity had resulted in a backlog of hundreds of thousands of lab results. When the upgrade was completed, these older tests were processed for the first time, resulting in an artificial spike in the number of newly confirmed COVID-19 cases.

The backlog also skewed the calculation of the test positivity rate, which is the ratio of positive cases to the number of tests conducted. In August, the rate artificially spiked to nearly 25%. Prior to September 14, the positivity rate was calculated using the date the test results were received, which convoluted the calculation by combining older cases with new cases. Upon consultation with a contractor, DSHS began reporting the positivity rate using the specimen collection date as well.[8]

Onboarding of New Labs

During the pandemic, the number of facilities registered to submit lab results to NEDSS grew by 4,702% due to an increased availability and demand for COVID-19 testing.[9] These new facilities included physicians' offices, federally qualified health centers, clinics, emergency rooms, urgent cares, pharmacies, and long-term care facilities. Additional labs and hospitals began reporting as well. Many of these providers did not have previous experience reporting infectious disease lab reports and lacked the resources, infrastructure, IT support, or regulatory knowledge to submit all data fields correctly in an electronic format. Missing data fields, such as patient addresses or phone number, impede public health officials' ability to assign a case to the correct county of residence or follow up with the patient.

As demand for testing increased during the summer, the number of days between specimen collection and lab report submission to DSHS grew. The delay peaked in September, when it took an average of 24.8 days. Also in September, DSHS hired a contractor to onboard new labs to submit test results to NEDSS electronically. This effort in combination with the technology upgrades has resulted in faster and more complete lab submissions. In November, the average number of days between specimen collection and lab report submission was 7.64 days.[10]

Changes to Electronic Laboratory Reports Submission and Onboarding in NEDSS		
	Pre-COVID	**During COVID**
File format	Only Health Level 7 International (HL7) standard file format	Developed alternative comma separate value (CSV) file format for facilities unable to submit via HL7
System enhancements	-	Coded, tested, mapped, and created new Rhapsody engine integration routes to validate CSV data
Validation	-	New team of epidemiologists created to review ELRs failing validation
Time required to onboard	Months to years	Can be as quick as a few days. Longer for newer labs with fewer resources and less experience.
Facility types	Commercial labs, hospitals, public health labs	Addition of many non-traditional labs, including long-term care facilities, physician's offices, ERs, urgent cares, and pharmacies
Number of lab facilities registered	70	3,362 (+4,702%)

Despite efforts to improve the timeliness and completeness of lab report submission, older cases (14+ days old) continue to be reported daily. For example, on December 21, DSHS reported 8,107 new confirmed cases and 902 older cases.[11] As more labs are onboarded and successfully transmitting via ELR, facilities may bundle older ELRs to process in NEDSS, resulting in a

significant infusion of case data at one time. When those older cases are received, DSHS must notify local and regional public health jurisdictions regarding the number of labs pending and the date for processing.[12] Older cases are included in the statewide total, but excluded from the statewide and county-level new case counts.

Texas Health Trace

In April 2020, DSHS began building Texas Health Trace (THT), a case management and Public Health Follow Up platform and call center to support the volume of case investigations and contact notification at statewide, regional, and local jurisdiction level. Jurisdictions may opt to:

- Use their own public health follow up systems, but work with DSHS to import data into THT regularly *(primarily larger, better-resourced health departments)*;
- Use THT, but work all cases and exposed contact investigations themselves; or
- Use THT and use the state call center for exposed contacts.[13]

However, by the time the integration with existing systems became available in June, many larger local health departments had already implemented their own systems. For example, Harris County Public Health built a "Coronavirus Response Platform" (CRP) system from scratch.[14] This has resulted in a patchwork of systems and processes for public health follow up across the state.

Local Health Departments

Texas's public health system is managed through a decentralized structure, whereby local municipalities determine both the level of funding invested in public health efforts, as well as what services their local health departments (LHDs) provide. There are 64 LHDs operating within the state. In areas where no LHD exists (194 counties), DSHS Public Health Regions (PHRs) are responsible for providing public health services.

Data Sourcing

Like DSHS, LHDs receive COVID-19 lab results through multiple pipelines, including electronic lab reports, CSV files, secure email, faxes, phone calls, and secure file transfer.[15] Prior to the pandemic, some LHDs reported that about 60% of lab reports were submitted through fax or other paper means, though the number reporting electronically has increased since the start of the pandemic.[16] When non-electronic results are received, staff must clean and manually enter the data into an electronic system. The week of November 10, 70 facilities were reporting via fax to the Houston Health Department.[17]

Testimony by the Northeast Texas Public Health District describes the different formats by which the department receives lab reports:

"Some reports are only one page long, while others are over 100 pages long. Some come in spreadsheets with hundreds of patients listed but not all are COVID-19 positive. We have to sift through this list to find the positive cases. Some are one line of a spreadsheet, sent across multiple pages. Others are sent as screenshots and pictures of the patient's lab results from a phone app or medical record screen. . . it takes a considerable amount of physical manpower time to clean up this data…"[18]

Timeliness and Completeness of Lab Reports

Timeliness and completeness of lab reports is a major challenge for LHDs and PHRs. Under Title 25, Chapter 97, Texas Administrative Code, laboratory reports must include comprehensive patient data, including name, address, phone number, birth date, sex, race and ethnicity, as well as information about the specimen, specimen submitter and test completed.[19] However, many labs are not in compliance when submitting COVID-19 results.

Results with missing information such as names, addresses, or contact information hinder public health officials' ability to ascribe a case to the correct jurisdiction and conduct public health follow-up activities. Missing demographic information impedes the ability to provide a full and complete picture of impacted populations to the public. As noted by Quest Diagnostics, oftentimes a laboratory is not able to submit complete information because the health care provider submitting the specimen for testing does not provide it. Quest works with providers to improve collection of addresses and demographic information.[20]

LHDs have undertaken various efforts to address incomplete lab data. For example, Harris County Public Health contracts with Thompson Reuters and CLEAR to run background searches to find missing addresses and contact information.[21]

Jurisdictional Issues

LHDs regularly receive COVID-19 lab and fatality reports from outside their jurisdiction. This may occur because the patient was tested or died outside their county of residence. Tests, cases, and fatalities are assigned to counties and local public health jurisdictions based upon the patient address, rather than location where the test was performed or the death occurred. When a LHD receives a case, staff must review the address and re-send the results to the correct LHD or PHR. There is no automatic process for directing or re-assigning a case to the correct jurisdiction. This causes delays in public health follow up and public reporting of the case.

Alignment Between State and Local Reporting

Publicly reported daily COVID-19 case and fatality numbers often differ between LHDs and DSHS, although trends over time do align. For example, on December 22, Austin Public Health reported 672 new cases in Travis County, while DSHS reported 537 cases. DSHS and LHDs identified several factors contributing to these discrepancies:

- **Timing—**Some counties or other public health jurisdictions may require hospitals or other entities to report directly to them, in addition to the state. A LHD may have information about a case or a death before the state has the information.

- **Calculation and presentation—**LHDs and DSHS could potentially differ on several points: the time period captured by the counts, the case classifications (confirmed, probable, or confirmed and probable together), how jurisdiction is determined (based on zip code, county, etc.), or sources of the data used to produce the numbers (ELR, faxed lab reports, hospital records, etc.).

- **Jurisdictional issues—**A hospital or lab may report a case or fatality to the wrong local jurisdiction, resulting in a delay while the information is sent to the correct local jurisdiction.

Hospitalization and Hospital Capacity Data

On March 24, Governor Greg Abbott issued Executive Order GA-10, requiring hospitals to submit daily reports of hospital bed capacity to DSHS.[22] Hospitalization data, including capacity data, is reported daily on a regional level; the state is divided into 22 Trauma Services Areas (TSAs). DSHS partners with Regional Advisory Councils (RACs) through the Hospital Preparedness Program (HPP) to gather data on bed and ICU capacity and availability of therapeutics, staffing, personal protective equipment (PPE), and ventilators, as well as patient information. RACs use two electronic systems, EMResource and WebEOC, to collect and provide the information to DSHS.[23] At the start of the pandemic, some RACs were better-positioned to be able to collect more comprehensive information than others, such as demographic data on hospitalized patients.

DSHS uses hospital data to inform decision-making in the COVID-19 response, including determinations about hospital-requested staffing, allocation of therapeutics, PPE, and other resources.

Hospitals faced significant difficulty with the frequent changes and volume of reporting requirements early on in the pandemic.[24] As of December, every facility must report approximately 120 data elements daily.[25] While some hospitals were later able to automate some reporting requirements, others still must devote significant staff time to manual data entry.[26] At the federal level, those who fail to report risk Medicaid reimbursement status.[27]

Notably, while hospitals are required to report information about COVID-19 patient demographics and length of stay, the state does not have comprehensive collection, review, and analysis methods for this data, and does not post it publically. This exclusion limits decision-makers' ability to have a complete picture of COVID-19 patients in Texas hospitals.

Federal Reporting Requirement Changes

The U.S. Department of Health and Human Services (HHS) expanded mandatory data reporting guidance for hospitals and laboratories at several points during the pandemic. On June 4, HHS announced new data reporting guidance, requiring labs to report demographic data such as race, ethnicity, age, and sex.[28]

In July, HHS significantly expanded daily hospital reporting requirements to include dozens of new data elements. The agency also transitioned the reporting recipient agency from the Centers for Disease Control and Prevention (CDC) directly to HHS.[29] Testing data must still be submitted to the CDC.[30] On July 22, Texas received authorization from the Assistant Secretary for Preparedness and Response (ASPR) regional administrator to submit the required data elements on behalf of Texas hospitals, rather than requiring hospitals to report to the state and federal governments separately.[31]

Prior to the July changes, Texas hospitals reported directly to the federal government using a portal called TeleTracking. As of December, hospitals report to HPP providers using the EMResources portal, and the data is then reported to the federal government on the hospital's behalf. While this change reduced duplicative reporting requirements, many hospitals experienced difficulty in the transition. Memorial Hermann Health System described the switch from TeleTracking to EMResources as "going back 10 years."[32] On the day of the transition (June 23), nearly 15% of Texas hospitals did not submit a complete dataset, resulting in an artificial decrease in the number of COVID-19 hospitalizations reported.[33]

Fatality Data

Until July, DSHS reported COVID-19-associated deaths using completed case investigations by PHRs and LHDs and local reporting of mortality data as local jurisdictions updated public information. However, these methods had several limitations:

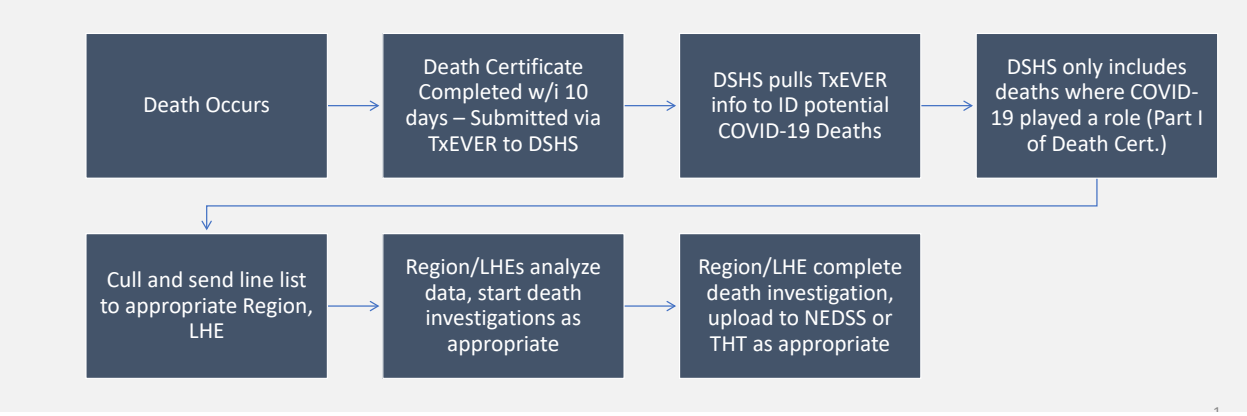
- Unclear when the death actually occurred
- Unclear whether death was for a resident of that jurisdiction or died within a different jurisdiction
- Limited demographic information
- Delays in case investigations led to delayed reporting of deaths[34]

On July 27, 2020, DSHS transitioned to a death certificate-driven reporting process. Death certificates are required to be completed within 10 days, allowing for more systematic, standardized, and timely reporting of fatalities. Death certificates also include demographic information, place of residence, location of death, and other information related to a COVID-19 death, including other observed/related medical conditions.

Certifying COVID-19 Deaths

A vast majority (90-95%+) of COVID-19 deaths are certified by physicians.[35] Early in the pandemic, DSHS began releasing information to medical certifiers about how to correctly report COVID-19 if the certifier determines that virus played a role in the sequence of events leading to a person's death. The department communicates reminders about how to correctly code, as well as to remove potentially extraneous information so that a death is not improperly coded as a COVID-19 fatality.

Current Process: Death Certificate-Driven Reporting Process[36]



Epidemiological Modeling

Epidemiological modeling is a public health tool that supports scientists and public health officials in answering questions about where and how an infectious disease is spreading, and the potential impacts of interventions. For example, models are used "to predict when the next flu season will start and to decide which flu strains to include in the flu shot each year."[37] During the COVID-19 pandemic, Texas health systems and Health-Related Institutes of higher education have developed models to study disease transmission and attempt to forecast trends in confirmed cases, positivity rates, hospitalizations, and deaths by taking into account prevention and clinical measures, population information, and existing data trends.

Institutions and outside entities may use models to make policy and operational decisions. For example, UT Southwestern uses their model of the Dallas-Fort Worth area to inform internal decisions on phases of opening and closing and screening guidelines for patients, visitors, and staff.[38] The model also helps the institution make staffing plans by estimating health care worker impact.

Predictions become more accurate as more data accumulates. Epidemiologic models early in the COVID-19 pandemic predicted a significantly higher number of deaths than what has actually occurred. Some of these early models did not assume the implementation of non-pharmaceutical

interventions, such as social distancing and mask-wearing. When the public began practicing these prevention measures, the models were rendered obsolete.[39] Epidemiologists today have significantly more information about the virus than they did early in the pandemic, including information about lethality and contagiousness.

Conclusion

The COVID-19 pandemic has brought into public view the importance of public health data in aiding decision-making during an emergency. Accurate, timely, and consistent data are essential in ensuring public trust in the state's leaders. Data challenges related to technology, coordination, and regulations have impeded the state public health response at several points during the pandemic. To ensure improvements in data collection and reporting in future public health emergencies, the state must invest in improving reporting systems and direct significant attention to addressing standardization and coordination issues.

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[1] Senate Committee on Health and Human Services, *Interim Hearing Witness List*, December 7, 2020.
[2] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[3] Chapter 97, Title 25, Texas Administrative Code
[4] Exec. Order GA-10, March 24, 2020
[5] Texas Department of State Health Services Exceptional Items: Reference Materials. Senate Finance committee, 86th Legislature. February 5, 2019.
[6] Ibid.
[7] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[8] Texas Department of State Health Services COVID-19 dashboard
[9] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[10] Ibid.
[11] Texas Department of State Health Services COVID-19 dashboard
[12] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[13] Ibid.
[14] Dr. Umair Shah, Harris County Public Health, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[15] Ibid.
[15] Ibid.
[16] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[17] Dr. David Persse, Houston Health Department, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[18] George Roberts, Northeast Texas Public Health District, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[19] Chapter 97, Title 25, Texas Administrative Code
[20] Christine Sabol, Quest Diagnostics, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[21] Dr. Umair Shah, Harris County Public Health, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[22] Exec. Order GA-10, March 24, 2020
[23] "COVID-19: Texas Hospital Reporting Requirements." Texas Department of State Health Services. July 23, 2020.

[24] Georgia Thomas, Memorial Hermann Health System, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[25] Information received from the Texas Department of State Health Services. December 2020.
[26] Information received from Baylor Scott & White Health. December 2020.
[27] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[2828] "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115." U.S. Department of Health and Human Services. June 4, 2020.
[29] "COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting." U.S. Department of Health and Human Services. December 8, 2020.
[30] Ibid.
[3131] "COVID-19: Texas Hospital Reporting Requirements." Texas Department of State Health Services. July 23, 2020.
[32] Georgia Thomas, Memorial Hermann Health System, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[33] @TexasDSHS, Twitter Post, July 23, 2020, 3:39pm. http://twitter.com/TexasDSHS
[34] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[35] Information received from the Department of State Health Services. December 2020.
[36] Texas Department of State Health Services, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[37] "Staying Ahead of the Curve: Modeling and Public Health Decision-Making" Centers for Disease Control and Prevention. January 19, 2016.
[38] Dr. Mujeeb Basit, UT Southwestern, *Testimony before the Senate Committee on Health and Human Services*, December 7, 2020.
[39] Ibid.

Interim Topic

Interim Topic Language: *Examine clinical best practices, including therapeutics, for treating COVID-19 patients at each stage of the disease. Monitor the status of vaccine development and distribution.*

Hearing Information

The Senate Health and Human Services Committee held a hearing on December 7, 2020 to discuss this interim topic. Individuals representing the Texas Biomedical Research Institute, Parkland Hospital, Memorial Hermann Health System, the Texas Department of State Health Services, and Pfizer provided invited testimony.[1]

Introduction

Clinical practices for treating COVID-19 have evolved since the beginning of the public health emergency. As of December, there is only one drug, Remdesivir, approved by the U.S. Food and Drug Administration for the treatment of COVID-19. Numerous other drugs or biological products have received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), and other drugs are being used off-label. As of December 2020, over 500 therapies are being studied.[2]

Additionally, vaccines for COVID-19 are being developed, manufactured, and distributed at record speeds. As of December, two vaccines have ben granted EUAs.

Treatment of Early-Stage Patients

The vast majority of COVID-19 patients have only mild to moderate symptoms (or no symptoms) and are able to manage their illness from their home or in ambulatory settings.[3] Patients with risk factors such as underlying medical conditions or age are more likely to later progress to severe or critical stages of the disease.

There is a notable absence of approved or authorized treatments for patients with early infections, though clinical trials are ongoing. As of December 28, monoclonal antibodies are the only treatment covered by an EUA from the FDA for treatment in non-hospitalized patients. Monoclonal antibody infusion treatments are manmade versions of antibodies that the body produces naturally to fight viruses. For example, Bamlanivimab attacks the virus's spike protein, making it more difficult for the virus to attach to and enter human cells. The drug should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset.[4] Monoclonal antibody treatments have been shown to reduce virus levels and shown promise in reducing COVID-19 hospital admissions.[5]

As of December 28, Texas has received a significant supply of these therapeutics and is distributing doses to health care providers.[6] On December 17, Governor Abbott announced the establishment of an infusion center in Cameron County to treat outpatient cases of COVID-19 with Bamlanivimab.[7]

Treatment decisions reside with the patient and their health care provider. Off-label uses of FDA-approved medications are delegated to the medical judgement of the prescriber. Some doctors in Texas report success in using off-label drugs and vitamins and mineral supplements for the treatment of COVID-19 in outpatient settings, as well as for prevention. For example, some physicians use corticosteroids, anti-parasitics, immunosupressents, antibiotics, and/or Zinc.[8]

However, there is a lack of consistency and consensus within medical communities.[9] Under Texas Medical Board (TMB) rules, physicians may prescribe drugs for off-label use, so long as a full disclosure is provided to the patient.[10] However, the lack of clarity around the Board rules as well as media stories led physicians to fear disciplinary action for prescribing off-label drugs. In response, the TMB issued a statement clarifying that the Board "does not prohibit any drug or treatment," and that "licensees should not fear disciplinary action from the TMB simply for expressing their support of specific COVID-19 treatments."[11] While a physician is free to use medical judgement when treating patients, a licensee cannot legally claim a treatment is a "cure" to COVID-19, as there is currently no known cure and such statements may be considered deceptive advertising.[12]

Treatment of Severely Ill and Critically Ill Patients

Oxygenation and Ventilation

Dyspnea (difficulty breathing) and hypoxemia (low level of oxygen in the blood) are the most common symptoms of severe COVID-19.[13] It is typical for severely ill and critical patients to require supplemental oxygen. In the most severe cases, patients may progress to acute respiratory distress syndrome (ARDS). Physicians may provide respiratory support via non-invasive ventilation, high flow nasal cannula (HFNC), or intubation and mechanical ventilation, depending on the level of oxygen support needed. There is also evidence that prone positioning can improve oxygenation and outcomes in non-intubated patients experiencing ARDS.[14]

Clinical best practices regarding respiratory support have evolved since the beginning of the pandemic. For example, early in the pandemic, it was recommended that mechanical ventilation be initiated early. This was driven by reports of patients experiencing rapid decline and the belief that non-invasive ventilation and HFNC were insufficient interventions. However, it is now generally accepted that intubations can often be avoided using other supplemental oxygen tools.[15]

Drug and Biological Products

Remdesivir− Remdesivir is an antiviral agent and the only drug approved by the FDA for the treatment of COVID-19. The drug was approved in October 2020 after receiving an EUA in May 2020.[16] Clinical trials conducted by the National Institute of Allergy and Infectious Disease found that intravenous infusions of the drug reduced recovery time for hospitalized patients.[17] While supplies were extremely limited in May, the drug has since become more widely available.[18]

Convalescent Plasma− Antibody-containing plasma from recovered patients has been used to treat a variety of illness historically, including measles, polio, chickenpox, and Severe Acute Respiratory Syndrome (SARS). Some data suggest that use of convalescent plasma may be effective in reducing mortality in hospitalized patients.[19] The FDA granted an EUA for this treatment in August 2020.[20]

Steroids− Patients with severe COVID-19 can develop a systemic inflammatory response that can result in lung injury and organ dysfunction. Corticosteroids such as Dexamethasone can reduce such an inflammatory response, and are often used in combination with an antiviral agent such as Remdesivir. Dexamethasone has been found to improve survival in hospitalized patients who require supplemental oxygen.[21]

Anti-coagulants− Some patients with severe COVID-19 may develop signs of a hypercoagulable state, putting them at risk for clots, deep vein thrombosis, pulmonary embolism, strokes, or heart attacks. Patients who show such signs may receive anti-coagulant drugs.[22]

Vaccines

Operation Warp Speed

In May 2020, the federal government officially announced a public-private partnership to facilitate and accelerate COVID-19 vaccine development, manufacturing, and distribution. Congress has directed almost $10 billion to support this effort.[23] Operation Warp Speed has allowed development to proceed more quickly by allowing steps to proceed simultaneously, such as manufacturing and demonstration of vaccine efficacy. While this is a non-traditional approach to vaccine development, no steps have been eliminated, and normal standards for safety and efficacy have been maintained.[24]

On December 11, the FDA issued the first EUA for a vaccine for the prevention of COVID-19. This authorization allows the Pfizer-BioNTech vaccine to be distributed in the U.S. Shortly after, on December 18, the Moderna vaccine was granted an EUA.[25][26]

Operation Warp Speed Candidates[27]

Manufacturer	Platform	Dose	Timing	Storage/Handling	Status (Dec. 30, 2020)
Pfizer/BioNTech	mRNA	2	0, 22 days	Ultra Cold frozen; 5 days refrigerated	EUA granted December 11
Moderna	mRNA	2	0, 28 days	Frozen; 30 days refrigerated	EUA granted December 18
Oxford/AstraZeneca	Non-replicating Viral Vector	2	4 weeks apart	Refrigerated 6 months	Phase III clinical trials
Janssen/Johnson & Johnson	Non-replicating Viral Vector	1	N/A	Frozen 6 months	Phase III clinical trials
Novavax	Recombinant Protein Subunit	2	0, 21 days	Refrigerated	Phase III clinical trials
Sanofi/GSK	Recombinant Protein Subunit	2	0, 21 days	Refrigerated	Delayed

Vaccine Allocation and Distribution

Texas is taking a phased approach to vaccine administration, using several key assumptions:

- Limited doses may be available by December 2020, but supply will increase substantially in 2021;
- Initial supply will either be approved as a licensed vaccine or authorized under an EUA issued by the FDA;
- Cold chain storage and handling requirements are likely to vary from refrigerated to ultra-cold storage; and
- Two doses from the same manufacturer, separated by 21 or 28 days, will be needed for immunity for most COVID-19 vaccines.

Providers wishing to receive vaccine allocations must register with the DSHS Immunization Program, and are required to report doses administered to ImmTrac2, the state's vaccination registry. Texas law required that vaccines and therapeutics administered as part of a declared disaster be reported. The data is kept for 5 years following the end of the disaster, unless the

patient elects to keep it in the system.[28] In addition to reporting via ImmTrac2, vaccine providers must also report total vaccine doses administered via the Texas Department of Emergency Management's (TDEM) Therapeutics & Vaccine Reporting Portal.[29]

In order to help inform where and to whom vaccine doses should be distributed and administered, the state established a 17-member Expert Vaccine Allocation Panel (EVAP), made up of internal and external subject matter experts. The EVAP makes recommendations to the Commissioner to establish prioritization of critical populations and reviews weekly data to guide allocation recommendations. Vaccines are allocated based on EVAP guiding principles, federal and state vaccine distribution requirements, provider capabilities, and priority populations and related vulnerabilities.[30] The state Infectious Disease Task Force also held a public hearing on October 18 to receive public comment on proposed critical populations and guiding principles for allocation and distribution.[31]

As of December 2020, the state is in Phase I of vaccine distribution, when there is a limited supply of COVID-19 vaccine doses available. As of December 30, 2020 Providers are vaccinating members of Phases 1A and 1B with either the Pfizer-BioNTech or Moderna vaccine. Vaccines are shipped directly to registered providers for administration to priority populations. During this phase, health care workers and populations vulnerable to severe illness from COVID-19 are prioritized. The phases and tiers were recommended by the EVAP and approved by the Commissioner.

Phase 1A– Health care workers and long-term care residents

Tier 1

1. Hospital staff working directly with patients who are positive or at high risk for COVID-19
2. Long-term care staff working directly with vulnerable residents
3. EMS providers who engage om 9-1-1 emergency services like pre-hospital care and transport
4. Home health care workers, including hospice care, who directly interface with vulnerable and high-risk populations
5. Residents of long-term care facilities

Tier 2

1. Staff in outpatient care offices who interact with symptomatic patients.
2. Direct care staff in freestanding emergency medical care facilities and urgent care clinics
3. Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID-19.
4. Public health and emergency response staff directly involved in administration of testing and vaccinations.
5. Last responders who provide mortuary or death services to decedents with COVID-19
6. School nurses who provide health care to students and teachers

Phase 1B– People over 65 and individuals with comorbidities

1. People 65 years of age and older
2. 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

As of December 30, 163,700 Texans have received first dose of a COVID-19 vaccine and 611,850 doses have been distributed.[32] On December 24, DSHS Commissioner Dr. John Hellerstedt published a letter to vaccine providers, noting that there appear to be unnecessary delays in administering all allocated doses. The commissioner urged providers to add a sense of urgency to their priorities in vaccine planning and operations, and noted that facilities may begin vaccinating Phase 1B populations if there are no readily available Phase 1A populations.[33]

Conclusion

The authorization of COVID-19 vaccines is an important milestone in the state and nation's fight against COVID-19. The faster these vaccines are manufactured, distributed, and administered, the faster Texas can return to normalcy. The legislature should continue to monitor the vaccine roll-out to ensure efficiency. While the vaccines indicate the end of the public health emergency is in sight, researchers, physicians, and their partners must continue to study and pursue therapeutics and other treatments that can reduce the prevalence of severe illness and mortality from COVID-19.

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Interim Topic

Interim Topic Language: *Evaluate the effects of the COVID-19 public health emergency and the impact of the COVID-19 response on behavioral health, child abuse, family violence, long-term care residents, and delayed medical care.*

Hearing Information

The Senate Health and Human Services Committee held a hearing on December 8, 2020 to discuss this interim topic. Individuals representing Meadows Mental Health Policy Institute, Association of Substance Abuse Programs of Texas, Cook Children's Medical Center, Texas CASA, Texas Council on Family Violence, Health and Human Services Commission, AARP, Coalition of Texans with Disabilities, Texas Oncology, and Texas Pediatric Society provided invited testimony.[1]

Introduction

Texans have experienced the effects of the COVID-19 public health emergency in ways not directly caused by the virus. Measures taken to prevent infections, including stay-at-home orders, school and business closures, and long-term care visitation restrictions, have had far reaching consequences. The state has seen upsurges in mental and behavioral health issues, increases in child abuse and domestic violence, isolation in long-term-care facilities, and detrimental changes to health care-seeking behavior.

Mental and Behavioral Health

Data collected during the COVID-19 public health emergency has demonstrated an increased need for mental and behavioral health services. The Centers for Disease Control and Prevention (CDC) tracks mental health needs weekly, and as of early November 2020, symptoms of anxiety and depression were both up four-fold from the previous year, with symptoms of anxiety disorders increasing from 8.2% to 36.3% and symptoms of depression increasing from 6.6% to 27.7%.[2] A majority of behavioral organizations across the state have experienced an increase in demand.[3] Moreover, a November Lancet study found that mental illness increases the risk of COVID-19 by 65% and that illness from COVID-19 exacerbates mental illness.[4]

Drug and alcohol misuse have also seen an increase during the public health emergency. Restrictions such as business and school closures lead to isolation and increased unemployment, which are triggers for alcohol and drug use.[5] According to an analysis by the U.S. Office of National Drug Control Policy, there was an 11.4% year-over-year increase in drug overdose deaths in the first four months of 2020.[6] Additionally, by the end of summer 2020, many states

were already approaching their 2019 overdose totals.[7] Notably, this was before the additional increase in stay-at-home restrictions and the resurgence of COVID-19 cases beginning in October 2020.

The number of people seriously considering suicide has doubled during the pandemic.[8] In late June 2020, 40% of U.S. adults reported struggling with mental health or substance use issues, with 11% of those people seriously considering suicide, according to a CDC survey.[9] The survey showed even higher risk for suicide among certain groups, including 18- to 24-year-olds (25.5%), Hispanics (18.6%), Blacks (15.1%), self-reported unpaid caregivers for adults (30.7%), and essential workers (21.7%).[10] The Meadows Mental Health Policy Institute estimates that an additional 4,000 Americans, including 300 Texans, could be lost to suicide for every 5% increase in unemployment that occurs.[11]

From mid-March through October 2020, the number of mental health-related emergency room visits increased 24% among children aged 5- to11- years old and 31% among adolescents aged 12- to 17- years old.[12] In September 2020, Cook Children's Medical Center in Fort Worth saw the highest number of patients (37) admitted for attempted suicide.[13] Among other reasons, this was attributed to stressors of the pandemic, virtual schooling, and limited or a lack of access to care and resources for mental health concerns.[14]

Child Welfare

With the implementation of stay-at-home orders and the transition from in-person learning to virtual platforms, many children's lives across the state have been dramatically impacted. There has been a notable decrease in reports of abuse and neglect, as well as Child Protective Services removals, during the PHE..[15] Specifically, in March, April, and May, reports of child abuse dropped to the lowest levels in the past five years. When reports did occur during this time, they were typically more severe and came from law enforcement or hospitals.[16] Experts attribute these shifts to the fact that children were being seen outside their homes less frequently. July 2020 brought a large uptick in reports, as mandatory child abuse reporters, including child care center workers and teachers, began seeing children more regularly again. Child advocates have concerns that intakes and removals will continue to increase as vaccines become more widely available, and families and children continue returning to work and school.[17]

COVID-19 has also dramatically impacted youth already in the foster care system. Specifically, many children in congregant care settings are unable to visit with their families or classmates in person, resulting increased isolation. Additionally, children in foster care, most notably residential treatment centers (RTCs), have faced significant challenges relating to education. Special education curriculum and accommodations are especially difficult to implement virtually, which disproportionally impacts children in foster care as they are 2.7 times more likely to require these services.[18]

To mitigate the impacts of COVID-19, Texas courts pivoted to allow court proceedings to occur virtually, resulting in greater and more active participation by parents.[19] Additionally, increased telehealth capabilities have made numerous court ordered services more readily available to parents and children, especially in rural areas.[20] Notably. one shortcoming of virtual court proceedings is that many dockets are beginning to back up and cases that need to go to trial have been delayed.[21]

At the beginning of the PHE, the Health and Human Services Commission (HHSC) issued new protocols for childcare centers and nursing facilities, but none were issued for general residential operations, including emergency shelters and RTCs.[22] The Department of Family and Protective Services (DFPS) issued documents outlining best practices for safety, however it was incumbent upon each facility to create specific policies, including visitation guidelines and staff protocols.[23] A statewide total of the number of children in foster care who have tested positive for COVID-19 has not been available, and child advocates struggle to communicate with facilities where outbreaks occur.[24]

Due to increased health and safety regulations put in place by the state, congregant care facilities, including RTCs, have been forced to maintain summer staffing levels since March 2020 due to the pandemic.[25] Additional requirements, increased staffing needs, the difficulty in hiring new staff amidst the PHE, have resulted in a shortage of capacity and an increase in children in the foster care systems without a placement.[26]

Youth currently transitioning out of foster care during the pandemic are facing an increasingly difficult time as well. Nationwide, there has been an upsurge in homelessness and unemployment among this population, as many entry-level jobs are unavailable due to COVID-19.[27]

Family Violence

Similar to what was seen during and following Hurricane Harvey, domestic violence increased during the pandemic due to increased stress from job loss and accompanying financial strain, limited access to resources, and disconnection from social support systems.[28] Many stressors associated with COVID-19 exacerbate negative mental health consequences and substance use coercion, as well as the coping mechanisms already associated with intimate partner violence victimization.[29] Texas survivors, at rates higher than survivors across the country, report financial and resource challenges due to COVID 19 including trouble getting food, difficulty paying bills, lack of transportation, and challenges with accessing public benefits. [30]

During the COVID-19 pandemic, over 80% of victims reported increased relationship difficulties, and 40% said their safety decreased.[31] Early analysis of Texas Crime reports indicated an 8.8% increase in calls to law enforcement for family violence in the first six months of the pandemic, with a notable increase in the use of firearms in these incidents.[32]

Isolation that accompanies stay-at-home orders and closures leads to increased disconnection from opportunities for support and healing. Given this disconnection, abusers were able to use the pandemic to start or escalate impairing their partner's ability to work or study.[33] COVID-19 increased barriers to survivors' ability to reach out and seek support, as there was oftentimes not a private and safe way to do so.[34] Additionally, children are present for and exposed to domestic violence at even higher frequency than prior years.[35]

COVID-19 has caused the landscape of family violence services and the needs of victims to rapidly evolve. Specifically, shelters rapidly transformed their spaces to reduce capacity and provide recommended physical distancing.[36] Family violence programs struggle to obtain personal protective equipment (PPE) and the need to create contingency plans for quarantining when staff or clients test positive, or come in contact with COVID-19, have left programs understaffed, with frontline advocates experiencing high stress, anxiety, and exhaustion.[37] Given this pivot, increased virtual and telephone services are required to ensure staff and survivors have adequate access to connect, often requiring navigation of technology safety and data security concerns.[38]

Long-Term Care Residents

As of December 2020, more than 98% of Texas nursing homes have had at least one resident or staff member diagnosed with COVID-19. This includes more than 48,000 cases of COVID-19 among nursing home residents.[39]. Nearly 72% of all deaths related to COVID-19 have occurred in individuals over the age of 65.[40]

Since 2015, the last year data is available, infection control has been the most frequently cited violation in Texas nursing homes, and these challenges were exacerbated by COVID-19.[41] Staffing is at the center of infection control failures, and nursing facilities have regularly reported staffing shortages during the pandemic. In August and September 2020 when case counts were spiking, 33% of nursing homes reported staffing shortages relative to their pre-COVID-19 staffing levels.[42] In October 2020, 16 % of Texas nursing homes reported a shortage of care staff.[43] When there are not enough staff to perform essential tasks, even well-trained caregivers cannot perform their jobs, with care, in the time allotted. These challenges have resulted in reports of residents not receiving basic care, such as using a toilet, getting a bath, or brushing teeth.[44]

Specific examples of frequently reported resident care concerns attributed to insufficient staffing levels include:

- Improper or missed medicines that resulted in confusion, seizures, loss of vision, falls, and overall decline in health conditions.

- Poor personal care, such as residents not being bathed regularly, not having hands washed properly, and not having nails trimmed, which occasionally resulted in serious pressure ulcers or bed sores.
- Not enough staff to accompany residents to the bathroom who need help or the leaving of residents sitting in soiled undergarments for extended periods of time.
- Malnutrition and dehydration because residents did not get the necessary assistance from staff during meal time.
- Poor communication from facility staff regarding residents wellbeing.[45]

Federal, state, and local emergency policies enacted during the pandemic significantly restricted resident mobility and access to loved ones, with some likening the experience to incarceration. [46] Since March, many residents have had limited access to the outdoors or areas outside their rooms, and some have not been able to leave the facility. These mobility and visitation restrictions are often called "lockdown" by residents, families, and facility staff.[47] Family members repeatedly expressed concerns and frustration that they were locked out for months, the virus still got in, and yet visitors were allowed only infrequent and brief visits.[48]

HHSC promulgated several emergency rules related to long-term care facilities in response to the public health emergency. Direction was issued over a variety of topics including visitation, and specifically end-of-life visits. Guidance from HHSC dictated that a resident was only entitled to this type of visit when actively dying, and moreover, it was at the facility's discretion to make this determination and notify the resident's loved ones.[49] In some cases, the determination of a resident actively dying was not made in time for loved ones to say goodbye in person, and occasionally a facility wrongly restricted family, friends, or clergy from access to the resident.[50]

Out of approximately 1,220 nursing facilities, roughly 551 were approved for visitation as of December 2020, resulting in thousands of family members being isolated from their loved ones in nursing facilities since March 2020.[51] Effective September 24, 2020, HHSC updated emergency rules to allow residents to designate up to two essential caregivers to provide supportive, hands-on care to facility residents who do not have COVID-19.[52] These individuals are provided necessary training to allow them to safely go inside a facility for a scheduled visit, including in the resident's room, to help ensure their loved one's physical, social and emotional needs are being met. While there are no physical distancing limitations for these caregivers, there is a requirement that only one may visit a resident at a time.[53]

Delayed Medical Care

Fear of contracting the virus, clinician availability, increases in unemployment, and elective surgery restrictions have all dramatically impacted medical care in Texas during the pandemic.[54] Over 25% of Texans aged 19- to 65- years old are uninsured and this specific barrier to care has intensified during the pandemic due to loss of employment and contingent health insurance.[55]

The Texas Cancer Registry estimates more than 127,000 new cancer diagnoses in the state during 2020, and anticipates that at least half of these patients will experience delays in diagnosis and care as a result of the pandemic.[56] Between March and July of 2020 (when compared to 2019) cancer screenings for breast, colon, lung, and prostate cancer were substantially reduced.[57] In April 2020, breast cancer screening decreased 85%, colon cancer screening decreased 75%, lung cancer screening decreased 74%, and prostate cancer screening decreased 56%.[58] Similar declines were observed in biopsies to diagnose cancer, surgeries to remove cancer, and some therapies to treat and cure cancer.[59] While there is month to month variability, new cancer diagnoses during the time period were down 30-70% and as of December had showed no recovery that would capture the diagnoses missed in the early months of the pandemic.[60]

The natural consequence of this amount of cancers growing undiagnosed and untreated will translate into increased morbidity and mortality for years to come.[61] In June 2020, Dr. Ned Sharpless, the National Cancer Institute director, stated that the delays in diagnosis would translate to an increase in more than 10,000 cancer deaths in the United States due to breast and colon cancers alone.[62]

The COVID-19 pandemic has also led to a decline in children utilizing health care services – namely routine preventive care such as well-child visits and vaccinations.[63] On September 23, 2020, the Centers for Medicaid and Medicare Services (CMS) issued a Call to Action following the drastic decline in care for children in Medicaid and Children's Health Insurance Program (CHIP).[64] From March to May 2020 nationwide:

- 22% fewer vaccinations were provided to children up to age two,
- 44% fewer developmental screenings to assess cognitive delay and early detection of autism were provided,
- 69% fewer dental services were administered, and
- 44% fewer outpatient mental health services were provided.[65]

The latest release of the Texas Department of State Health Services' (DSHS) *Impacts of COVID-19 on Texas Vaccine for Children (TVFC) Program Vaccines* report shows the number of doses administered in Texas in 2020, compared to the same months in 2019:

- Decreased substantially in April (-43%),
- Began to rebound somewhat in May (-24%) and June (-14%),
- Remained low during some of the busy back to school months in July (-27.5%) and August (-32.2%).[66]

The TVFC program provides approximately half of all Texas children vaccines.[67] Many sites include school-based clinics, many of which have suspended operations due to inactivity.[68] While there has been a rebound of in-person visits, an unknown number of parents have decided to put off routine preventive care altogether – including vaccinations.[69]

In the early days of COVID-19, the dramatic decrease in patient volume and cash flow forced many pediatrics and primary care practices near or to closure.[70] A recent survey by the Physicians Foundation found that an estimated 8% of all physician practices nationally – around 1,600 – have closed under the stress of the pandemic.[71]

Pediatric primary care offices in particular play a large role in the State's developmental delay and mental health surveillance system.[72] A reduction in Medicaid practices could result in children going without vital developmental screenings, which detect early delays in cognition and developmental disabilities.[73] Texas Early Childhood Intervention (ECI) – the state program that provides services to children ages 0 to 3- years old with developmental delays and disabilities – has seen a notable decrease in physician referrals to state contracted community programs.[74] The effects of COVID-19 and its impact on primary care pediatrics could result in a high number of Texas children who had not been identified with developmental delays being unprepared to attend school when they come of age.[75]

Similar to other areas, the primary care sector has seen a remarkable leap forward in the adoption of telemedicine care.[76] Over 368,000 clients utilized telehealth/telemedicine services during April 2020. This equates to 79.98 per 1,000 clients receiving telehealth/telemedicine services, which is a significant increase from the 3.64 per 1,000 clients that received similar services in April 2019.[77] According to the Texas Pediatric Society, without this transformation, many families would have been without access to the health care system at all, putting off ailments that would otherwise become exacerbated and lead to more dangerous health conditions.[78] State and federal policy flexibilities enabled during the pandemic were vital in ensuring this rapid transformation.[79] The availability of telemedicine well-visits with an in-person follow-up appointment has benefited both children and pediatric practices and have preserved the continuity of care between patients and their primary care medical home.[80] The pandemic has been especially detrimental to the social and emotional health of teens, and telemedicine has been extremely effective and particularly well-received by this age group.[81]

Some patients and health care providers have reported being significantly burdened by the state's elective surgery restrictions. On March 22, Governor Greg Abbott issued Executive Order GA-09. Part of this order directed licensed health care professional and licensed health care facilities to "postpone all surgeries and procedures that are not immediately medically necessary to correct a serious medical condition or, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient's physician."[82] The goal of this order was to preserve the state's limited supplies of PPE; however the order and resulting Texas Medical Board rules resulted in significant confusion for medical communities. While this restriction was lifted and superseded by a different order on April 27, it was partially reinstated in September and October by GA-31 and GA-32. GA-32 allows hospitals to conduct elective surgeries only if

COVID-19 hospitalized patients make up less than 15% of a Trauma Service Area's (TSA) hospital capacity.[83] The lack of clarity in the definition of "elective," has resulted in patients not receiving needed procedures.

Conclusion

The COVID-19 pandemic has affected the lives of millions of Texans in more ways than could have been predicted at the onslaught of the public health emergency. Efforts to contain the spread of the virus have not come without a cost to mental and behavior health, child and family welfare, the well-being of long-term-care residents, and the timeliness of numerous other medical diagnoses and treatments. The state must recognize these impacts and make necessary efforts to minimize and remediate them whenever possible.

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[63] Dr. Seth Kaplan, Texas Pediatric Society; *Testimony before the Senate Committee on Health and Human Services,* December 8, 2020.
[64] Ibid.
[65] Ibid.
[66] Ibid.
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[68]Ibid.
[69] Ibid.
[70] Ibid.

[71] Ibid.
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[73] Ibid.
[74] Ibid.
[75] Ibid.
[76] Ibid.
[77] Information Provided by HHSC. January 6, 2020.
[78] Dr. Seth Kaplan, Texas Pediatric Society; *Testimony before the Senate Committee on Health and Human Services,* December 8, 2020.
[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] Exec. Order GA-09, March 22, 2020
[83] Exec. Order GA-32, October 8, 2020

Interim Charge

Interim Charge Language: *Examine the emerging public health concerns from the rise in e-cigarette use and "vaping," especially among minors. Determine if additional policies or laws are needed to protect the public's health.*

Hearing Information

The Senate Health and Human Services Committee held a hearing on December 3, 2019 to discuss this interim charge. Individuals representing the Department of State Health Services (DSHS), the National Conference of State Legislatures, Dallas County Health and Human Services, MD Anderson Cancer Center, Texas A&M University, the Comptroller of Public Accounts, University of Texas School of Public Health, Texas Association of School Boards, and Hempstead High School provided invited testimony.[1]

Introduction

Electronic cigarettes are also called "e-cigs," "vapes," "vape pens," or "electronic nicotine delivery systems" (ENDS). "Vaping" refers to the use of these devices to inhale substances including nicotine, cannabinoids (such as CBD or THC), flavors, and/or other substances. The product heats a liquid substance (usually containing nicotine) and produces an aerosol, which users inhale.

E-cigarettes come in many forms, including disposable, rechargeable, battery-based, and modifiable. Some reusable products have "open systems," which allow users to refill the liquid. Others are closed-system, where the cartridges (or "pods") must be replaced when empty.

National attention was brought to this topic when over 2,500 U.S. e-cigarette users were hospitalized with e-cigarette, or vaping, product use associated lung injury (EVALI) beginning in August 2019.

Health Effects of E-Cigarettes

There is insufficient research on the long-term effects of e-cigarette use. When compared to combustible cigarettes, e-cigarette aerosols contain fewer harmful chemicals than cigarette smoke. However, e-cigarettes are not harmless, and are known to be harmful to young people and pregnant women.[2]

Nicotine and other additives

Most e-cigarettes contain nicotine, which is a highly addictive stimulant with adverse cardiovascular, cognitive, and reproductive effects. Nicotine intake from e-cigarettes can be the same or greater than nicotine intake from combustible cigarettes.[3] It is especially harmful for adolescent brain development and developing fetuses.[4] Adolescents can become addicted to nicotine more quickly than adults, and exposure during adolescent brain development can result in long-term deficits in cognitive function, such as reduced memory and attention span.

Besides nicotine, e-cigarettes can contain other harmful chemicals like lead, volatile organic compounds, ultrafine particles, and cancer-causing agents.[5]

E-cigarettes as a smoking cessation aid

Many cigarette smokers report using e-cigarettes to help quit smoking.[6] If e-cigarettes are used as a complete substitute for combustible cigarettes, they may help adult smokers. However, available research shows mixed results. Over half of adult e-cigarette users also smoke cigarettes.[7] The U.S. Preventative Services Task Force, responsible for making recommendations regarding preventative health care, concluded there is insufficient evidence to recommend e-cigarettes for tobacco cessation in adults.[8] There is also some evidence to suggest that e-cigarette use can lead to future cigarette smoking among youth.[9] The CDC recommends that individuals who do not smoke should not start using e-cigarettes, or any other tobacco products.

E-cigarette Use and Access

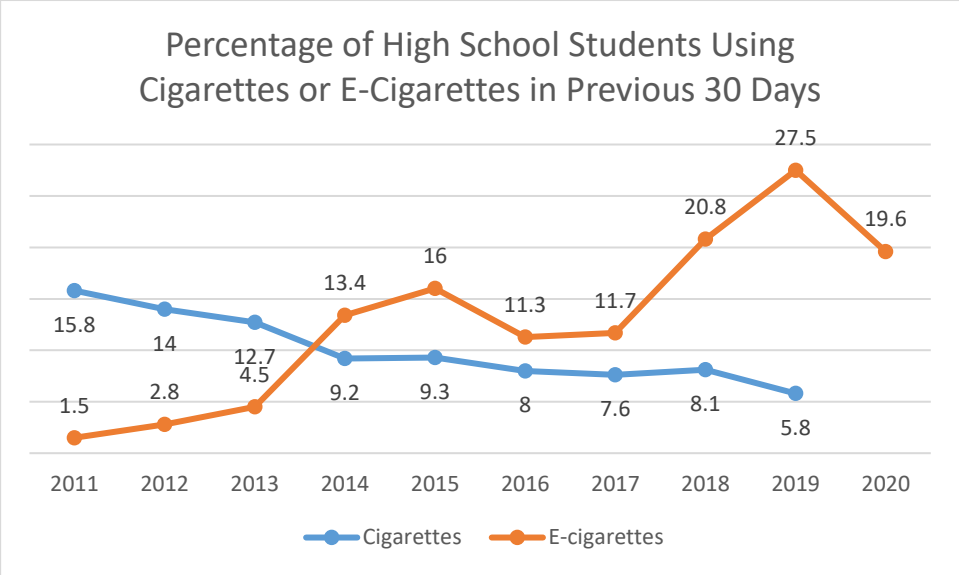
Use Among Adults

In the U.S., adults are less likely than youth to use e-cigarettes.[10] In 2018, 3.2% of U.S. adults reported using e-cigarettes "every day" or "some days." Comparatively, 13.7% of adults smoke cigarettes.[11] Over half of adult e-cigarette users are also smokers.[12] Among e-cigarette users age 45 and older in 2015, most were current or former regular cigarette smokers, and 1.3% had never been cigarette smokers. In contrast, among e-cigarette users age 18–24 years, 40% have never been regular cigarette smokers.[13]

Use and Access Among Youth

In 2018, the Surgeon General declared that the use of e-cigarettes by youth is at epidemic levels.[14] While combustible cigarette consumption among youth has fallen over the past two decades, e-cigarette use has increased dramatically. According to the 2019 National Youth Tobacco Survey (NYTS), 5 million high school and middle school students used e-cigarettes in the past 30 days −10.5% of middle school students and 27.5% of high school students. A majority (59.1%) of high school users reported JUUL as their usual brand. [15]

Notably, the 2020 NYTS found that e-cigarette use declined compared with 2019 data. In the 2020 survey, 5% of middle school students and 19.6% of high school students reporting using these products in the past 30 days.[16] This decease may be a result of school closures due to the COVID-19 pandemic.



According to the 2018 NYTS, a majority of underage users acquire e-cigarette products from social sources. However, retail stores and vape shops may also sell to minors. In 2018, 14.8% of users under age 18 reported obtaining e-cigarettes from a vape shop and 8.4% reported obtaining them from a gas station or convenience store.[17] Additionally, some youth obtain these products online. While some online retailers have multi-step age verification processes, some simply require the buyer to check a box affirming their age.[18] In January 2020, the FDA released guidance stating that as part of the agency's enforcement activities, it would assess whether manufacturers are taking adequate measures to prevent minors' access. This may include whether the manufacturer uses adequate age verification technology.[19]

Marketing

Youth are extremely likely to see e-cigarette advertisements in retail stores, television, social media or elsewhere online. Manufacturers--JUUL Labs in particular--have faced criticism regarding marketing practices, including allegations that the company targeted youth. In September 2018, the FDA issued letters to five national brands who make up a vast majority of the products popular with minors. The agency requested that each company submit a plan for how they will address and curb youth use of their products.[20] In October 2019, the Federal trade Commission opened an inquiry into the industry's marketing practices.[21] In September 2019, JUUL ceased all advertising.[22]

The Texas Office of the Attorney General is leading a multi-state investigation into JUUL's marketing and sales practices. The investigation will focus on the promotion of products to youth, claims about nicotine content, effectiveness as a smoking aid, and health and safety risks of the products.[23]

Flavors

Most youth e-cigarettes users report vaping fruit, candy, or mint flavors.[24] JUUL, the brand most popular with youth in 2019, removed its fruity and dessert flavors from brick-and-mortar retail locations in November 2018, and removed them from their e-commerce platform altogether in October 2019.[25]

In January 2020, following direction from President Trump, the FDA announced it would begin removing all pod-based flavored e-cigarette products other than tobacco and menthol flavors from the market.[26] However, flavored products were still widely available in the form of disposable and open-system e-cigarettes. Some states have announced plans to ban disposable flavored products in response.[27]

Data show that following the ban, youth use of disposable e-cigarettes increased. In 2019, 2.4% of high school regular users reported using disposable products, compared with 26.5% in 2020.[28] Public health experts note that disposable e-cigarettes are attractive to youth due to flavorings (pink lemonade and blueberry ice, for example) and low price point ($8-$11 each).

In July 2020, the FDA issued warning letters requiring several companies to cease the sale of flavored disposable products. The agency found that these products were likely to be underage-appealing.[29]

Federal Regulation of E-cigarettes

Congress provided the FDA jurisdiction over tobacco products via the Tobacco Control Act (TCA) in 2009. Under this statute, the FDA has the authority to "deem" other tobacco products to be subjected to the agency's regulatory authority.[30] The FDA extended its scope to include e-cigarettes in August 2016. The TCA created a pre-market review process by which new tobacco products may be introduced and sold. This application must provide scientific data demonstrating a product is appropriate for the protection of public health. In developing the pre-market review process for e-cigarettes, the FDA announced that all manufacturers or importers of e-cigarette devices on the market prior to August 2016 would be required to submit a Premarket Tobacco Product Application (PMTA) by May 2020. A separate application was required for each flavor or product.[31] Due to the COVID-19 pandemic, the application date was pushed back September 9, 2020.

PMTAs are expected to be approved or denied by September 2021.[32] Products introduced for the first time after August 2016 are not permitted on the market.

In January 2020, the FDA announced it would begin enforcement to remove the following products that do not have premarket authorization:

- Any flavored, cartridge-based e-cigarette products (other than tobacco or menthol flavored products).

- All e-cigarette products for which the manufacturer has failed to take adequate measures to prevent minors' access; and
- Any e-cigarette product that is targeted to minors or likely to promote use of e-cigarettes by minors[33]

E-cigarette manufacturers are also federally required to include a list of ingredients on their packaging, along with a highly visible nicotine warning.

State activities and regulation of e-cigarettes

Texas's regulation of e-cigarettes center around the retail of these products. The Comptroller of Public Accounts (CPA) is the state entity charged with tobacco enforcement. The CPA's Tobacco Enforcement Program provides required signage, investigates sales to minors, inspects retail locations for signage and employee compliance, and provides training and education to peace officers, youth, and retailers. CPA's Criminal Investigations Division employs 24 peace officers to conduct investigations, and also partners frequently with local law enforcement to conduct investigations.[34]

Texas Health and Safety Code makes it a Class C misdemeanor for an employee to sell cigarettes, e-cigarettes, or tobacco products to a minor under 21.[35] Additionally, the Health and Safety Code outlines retailers' responsibilities surrounding required warning notices, employee notification requirements, tobacco vending machines, and limitations on outdoor advertising near a school or church.[36] Within a 12-month period, a violation of these chapters can yield the following penalties:

- First offense: up to $500 fine
- Second offence: Up to $750 fine
- Third offence: Up to $1,000 fine or 3-day permit suspension
- Four or more offences: permit revocation (can reapply after six months)[37]

Retailers who sell tobacco products are required to have a tobacco permit from the CPA, along with a sales tax permit. However, retailers who only sell e-cigarettes (and no other tobacco products) are not required to hold a permit.[38] In order to identify these unpermitted locations, CPA has run word searches of permit holders using key words ("vapor," "smoke," "e-cig"), but there are likely to be a large number of locations unknown to the CPA.[39]

About half of states centralize their tobacco and alcohol enforcement activities within the same agency. The other half, like Texas, house them separately.[40]

Taxation

Texas does not have a state e-cigarette tax. During the 86th Session, House Bill 4013 (Miller) and Senate Bill 1332 (Johnson) would have created a retail sales tax on e-cigarettes and vapor products. As filed, the bill imposed a tax of 5 cents/mL of vapor liquid. A later version of the bill would have taxed these products at 10% of retail price. As of February 2020, 21 states and

Washington D.C. have enacted some form of retail or wholesale tax applicable to e-cigarette products:

- A percentage of the price (10 states)
- Volume-based, with a flat tax per milliliter of e-liquid (8 states)
- Combination of these approaches (4 states)[41]

E-Cigarette, or Vaping, Product Use-Associated Lung Injury (EVALI)

In August 2019, the Centers for Disease Control (CDC) were alerted to a cluster of pulmonary illness among young adults, associated with the use of vaping products. Common symptoms include shortness of breath, nausea, vomiting, cough, chest pain, abdominal pain, diarrhea, fatigue, fever, and weight loss. EVALI can be severe and life-threatening, with 95% of patients being hospitalized.[42] The Texas Department of State Health Services (DSHS), in conjunction with the CDC and local health departments, has been investigating suspected cases of EVALI since the initial reports.

As of February 18, 2020, a total of 2,807 EVALI cases requiring hospitalization have been reported to the CDC from all 50 states. Sixty-eight deaths have been confirmed.[43]

In Texas, as of March 2, 2020, 251 confirmed or probable cases and four deaths have been reported. Of the confirmed or probable cases:

- About 25% of patients are under 18 years of age
- The median age is 22
- About 71% of patients are male
- About 88% of patients with available substance information reported vaping products with tetrahydrocannabinol (THC), the primary psychoactive ingredient in marijuana.[44]

Data from patient reports and product sample testing indicate that e-cigarette products containing THC are linked to most EVALI cases and play a major role in the outbreak, especially products that were obtained from informal sources such as family, friends, or dealers. Vitamin E acetate, an additive in some THC-containing e-cigarette products, is strongly linked to the outbreak.[45] Vitamin E does not usually cause harm when ingested, but research suggests that it may interfere with lung functioning if inhaled.[46]

The number of cases peaked nationally in September 2019, and the weekly number of hospitalized patients has since steadily declined, possibly due to increased awareness, the removal of vitamin E acetate from products, and/or law enforcement actions related to illicit products.[47]

Recommendations

1. **Study and consider the impacts of enacting a state retail sales tax on e-cigarette products at parity or a portion or parity with other tobacco products.**

2. **Require e-cigarette retailers to obtain a tobacco retailer permit.**
3. **Strengthen penalties for retailers who sell e-cigarette/tobacco products to minors or fail to properly authenticate age.**
4. **Strengthen penalties for adults that sell or provide e-cigarette products to minors.**
5. **Consider restricting advertisement and/or sale of e-cigarette/tobacco products near schools.**
6. **Consider directing the Comptroller of Public Accounts and the Texas Alcoholic Beverage Commission to collaborate or share jurisdiction on tobacco enforcement activities, or ensure the CPA has sufficient resources to enforce tobacco laws.**

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[1] Senate Committee on Health and Human Services, *Interim Hearing Witness List,* December 3, 2019.
[2] "Electronic Cigarettes," *Centers for Disease Control and Prevention.*
[3] Dr. Ernest Hawk, MD Anderson Cancer Center. *Testimony before the Senate Committee on Health and Human Services,* December 3, 2019.
[4] "Electronic Cigarettes," *Centers for Disease Control and Prevention.*
[5] Ibid.
[6] Ibid.
[7] "E-Cigarettes: Facts, stats, and regulations," *Truth Initiative.* December 2, 2020.
[8] "Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions," *U.S. Preventive Services Task Force.* September 21, 2015.
[9] "Public Health Consequences of E-Cigarettes," *The National Academies of Sciences.* 2018.
[10] "Electronic Cigarettes," *Centers for Disease Control and Prevention.*
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[13] "Cigarette Smoking Status Among Current Adult E-cigarettes Users, by Age Group--United States 2015." *Centers for Disease Control and Prevention.* October 28, 2016.
[14] Dr. Steven Kelder, UT School of Public Health. *Testimony before the Senate Committee on Health and Human Services,* December 3, 2019.
[15] National Youth Tobacco Survey, 2019
[16] National Youth Tobacco Survey, 2020
[17] National Youth Tobacco Survey, 2018
[18] "Regulating E-Cigarettes," *Campaign for Tobacco-Free Kids.* December 2019.
[19] "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization." *U.S. Food and Drug Administration.* January 2020.
[20] ibid.
[21] "FTC to Study E-cigarette Manufacturers' Sales, Advertising, and Promotional Methods," *Federal Trade Commission.* October 3, 2019.
[22] Information provided by JUUL Labs.
[23] "AG Paxton Announces Bipartisan, Multi-State Investigation into JUUL's Marketing Practices," *Attorney General of Texas.* February 25, 2020.
[24] "Electronic Cigarettes," Centers for Disease Control and Prevention.
[25] Information provided by JUUL Labs.
[26] "FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint," *U.S. Food and Drug Administration.* January 2, 2020.
[27] "Maryland Bans the Sale of Disposable E-Cigarettes," *Countertobacco.org.* February 28, 2020.
[28] National Youth Tobacco Survey, 2019 and 2020

[29] "FDA Notifies companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization," *U.S. Food and Drug Administration.* July 20, 2020.
[30] Dr. Norman "Ned" Sharpless, U.S. Food and Drug Administration. *Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.* September 25, 2019.
[31] Information provided by JUUL Labs.
[32] Ibid.
[33] "FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint," *U.S. Food and Drug Administration.* January 2, 2020.
[34] Joshua Thigpen, Comptroller of Public Accounts. *Testimony before the Senate Committee on Health and Human Services,* December 3, 2019.
[35] Texas Health and Safety Code, Sec. 161.081
[36] Texas Health and Safety Code, Sec. 161.081 and 161.122.
[37] Texas Tax Code, Sec. 155.0592
[38] Joshua Thigpen, Comptroller of Public Accounts. *Testimony before the Senate Committee on Health and Human Services,* December 3, 2019.
[39] Ibid.
[40] Information provide by the Texas Legislative Council. February 25, 2020.
[41] "E-Cigarette & Vaping Product Taxes," *National Conference of State Legislatures.* April 6, 2020.
[42] "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," *Centers for Disease Control and Prevention.*
[43] Ibid.
[44] "Department of State Health Services update on Investigations of Severe Pulmonary Illness among People who have Reported Vaping," *Texas Department of State Health Services.* March 2, 2020.
[45] "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," *Centers for Disease Control and Prevention.*
[46] Ibid.
[47] Ibid.

Interim Charge

Interim Charge Language*: Examine the state health and human services finance system including, but not limited to, the following programs and methods of finance: Local Provider Participation Funds, the Delivery System Reform Incentive Payment Program, Medicaid 1115 waivers and Section 1332 State Innovation waivers, Pay for Quality programs, the Quality Incentive Payment Program, and other state and local funding used to finance health care systems in Texas. Identify ways to streamline functions and reduce unnecessarily burdensome and costly requirements in the Texas Medicaid program. Provide recommendations to ensure the sustainability of the state's health and human services system and judicious use of taxpayer dollars.*

Hearing Information

The Senate Health and Human Services Committee held a hearing on December 3, 2019 to discuss a portion the interim charge. Specifically, the Committee received invited and public testimony on The Texas Healthcare Transformation and Quality Improvement Program Section 1115 Demonstration Waiver, the Delivery System Reform Incentive Payment Program (DSRIP) Transition Plan, and the Healthy Texas Women Section 1115 Demonstration Waiver.

Individuals representing the National Conference of State Legislatures, Eyman Associates, The National Association of Medicaid Directors, The Health and Human Services Commission (HHSC), Regional Healthcare Partnership 6, Texas Hospital Association, Houston Health Department, and UT Health McGovern Medical School provided invited testimony to the Committee.[1]

Introduction

The Texas Healthcare Transformation and Quality Improvement Program Section 1115 Demonstration Waiver

The 82nd Legislature directed The Health and Human Services Commission (HHSC) to pursue an 1115 Demonstration Waiver to transform publicly-funded healthcare in Texas. According to HHSC, the original waiver was designed to demonstrate the cost-effectiveness of Medicaid managed care, as well as, to improve the quality of healthcare services. The savings generated by the State from contracting with managed care organizations (MCOs) was repurposed into different pools of funds that were used to either cover uncompensated care costs for providers or incentivize improvements to healthcare quality and access.

Since the approval of the waiver by the Centers for Medicare and Medicaid (CMS) in 2011, Texas has achieved the following objectives under the waiver:

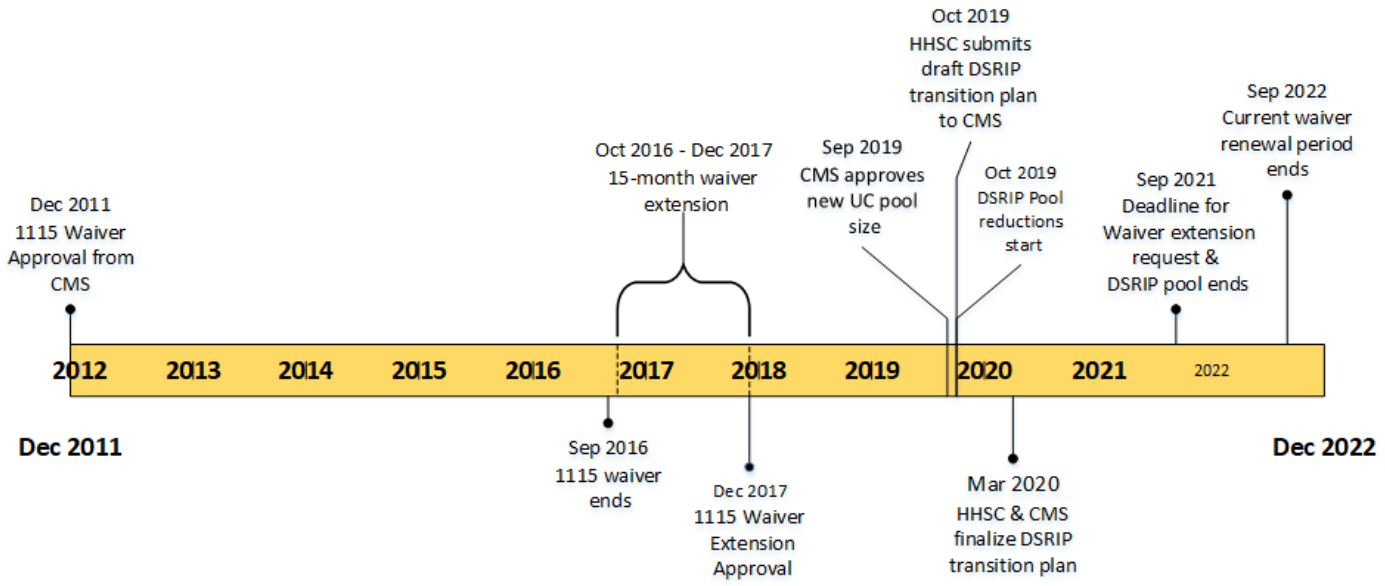
- Approximately 94% of Medicaid recipients have been enrolled into the managed care model and managed care has been rolled out statewide.[2]
- By 2021, HHSC managed care contract targets will require **50 percent** of total provider payments for medical and prescription expenses to be done through Alternative Payment Methodologies (APMs) and at **least 25 percent** of the total must be **risk-based**.[3]

- Texas requires MCOs "to share data and performance reports with APM providers and dedicate resources to evaluate the impact of APMs on utilization, quality and cost, as well as return on investment".[4]

- HHSC has reported to CMS that the waiver has achieved the anticipated cost savings, as well as improved access and quality of care.[5]

On November 30, 2020, HHSC submitted a "Fast Track" application for a five-year extension of the Texas 1115 Waiver Demonstration. CMS accepted the application on December 15, 2020 and is currently reviewing Texas' request to extend the waiver's authorization until 2027.

Texas Section 1115 Demonstration Waiver Timeline [6]



Delivery System Reform Incentive Payment Program (DSRIP)

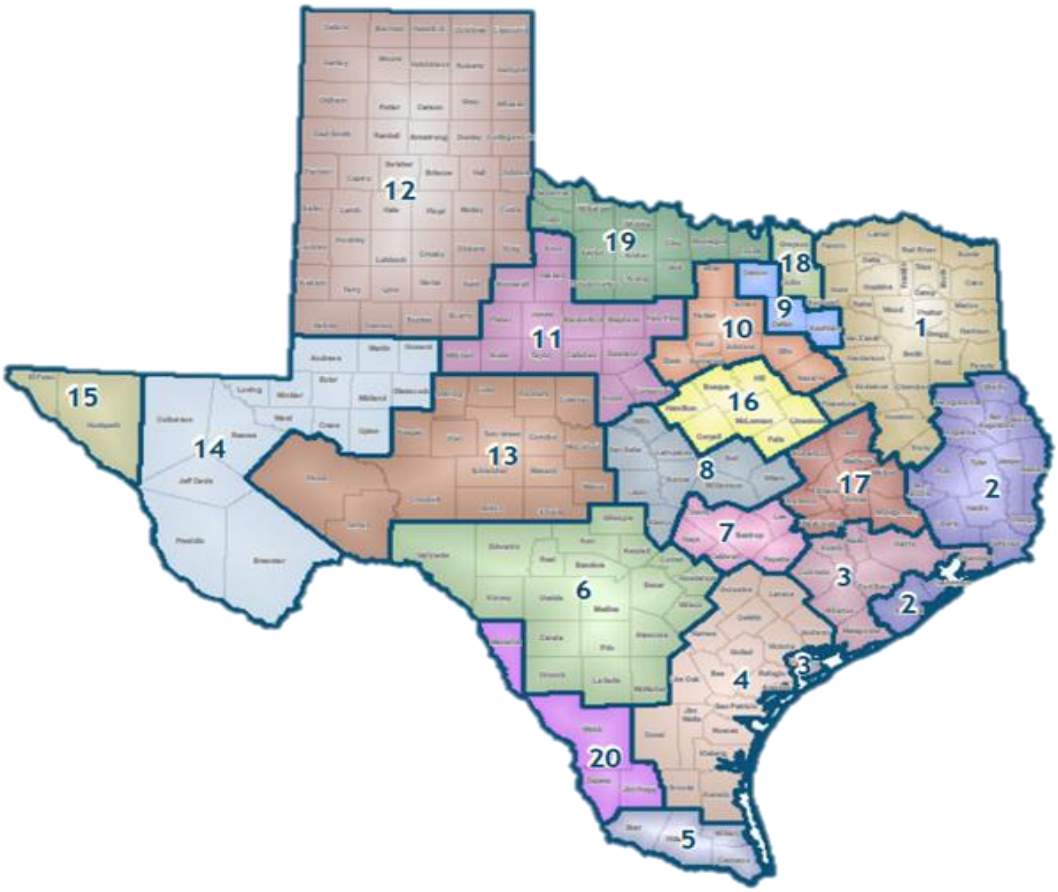
The DSRIP program is authorized under the 1115 Texas Healthcare Transformation and Quality Improvement Program waiver. It provides incentive payments to providers to support an array of projects to enhance access to healthcare, quality of care, and/or better serve specific populations.

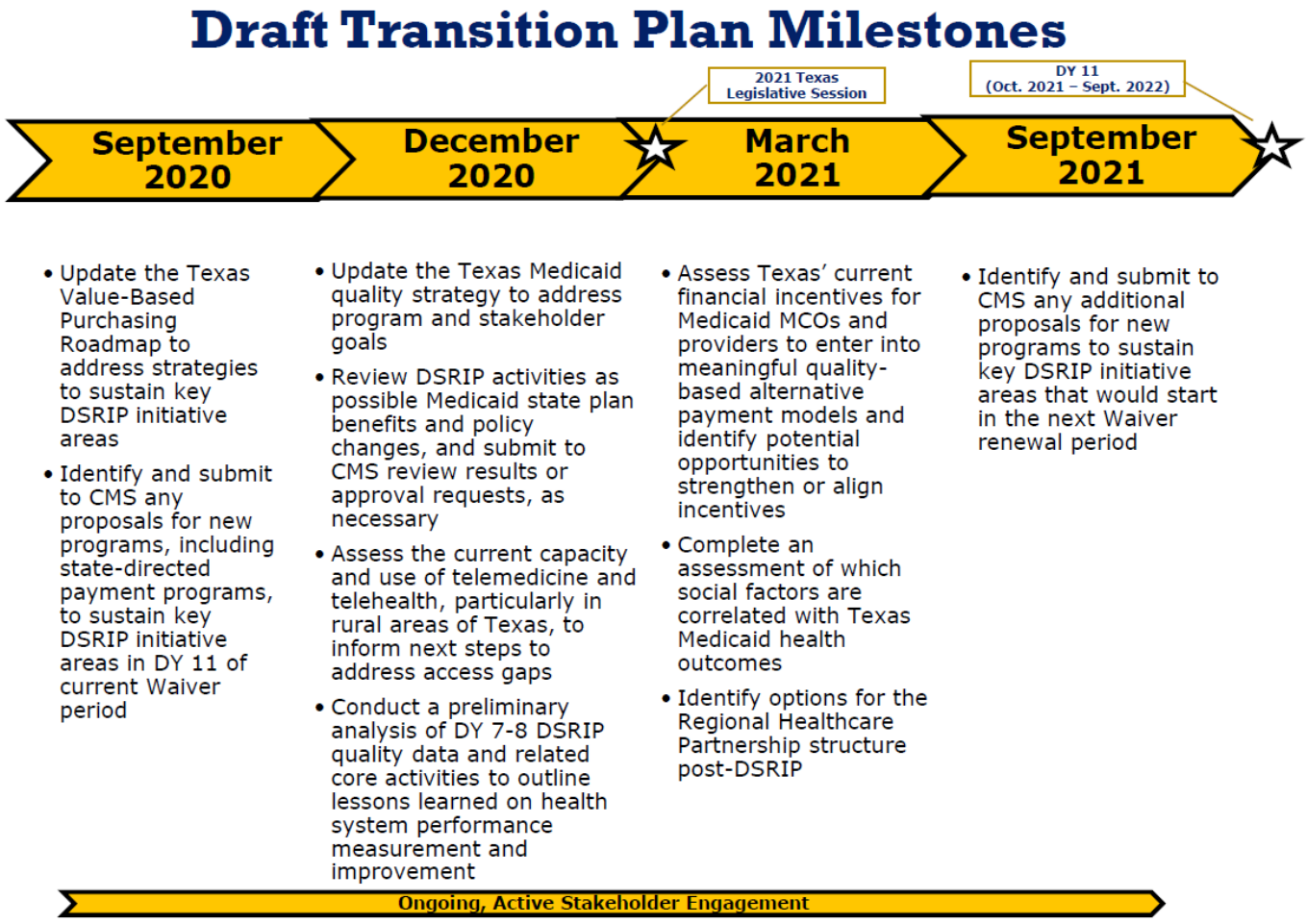
The DSRIP program is organized and measured annually, also known as demonstration years (DYs). According to the Medicaid and CHIP Payment and Access Commission (MACPAC), **$26 billion** has been allocated to over 300 medical and behavioral health providers statewide, if those providers met predetermined metrics throughout the waiver demonstration. [7]

DSRIP payments to providers are funded by federal funds matched with intergovernmental transfers (IGTs) from providers. HHSC organized the DSRIP providers into 20 Regional Healthcare Partnerships (RHPs). The RHPs are based on distinct geographic boundaries and community/regional health dynamics and collaborative relationships.

DSRIP was a temporary funding source with a set timeline for project development and implementation. CMS required Texas to develop a transition plan to sustain the projects developed under the program. CMS approved HHSC's transition plan in August 2020.

DSRIP Regional Healthcare Partnerships (RHPs)[8]





(Source: HHSC: DSRIP Transition Plan)[9]

The Healthy Texas Women Section 1115 Demonstration Waiver

The Healthy Texas Women (HTW) Program is a Section 1115 Demonstration Waiver approved by CMS in January 2020. The federal government will provide $350 million dollars for the five year period of the waiver demonstration project. The program provides a set benefit package to non-pregnant, uninsured women, ages 15-44 years old, at or below 200% of Federal Poverty Level (FPL).

The goal of the program according to HHSC is to *"increase access to women's health and family planning services to avert unintended pregnancies, positively affect the outcome of future pregnancies, and positively impact the health and well-being of women and their families"*[10]

HHSC reported that the HTW program resulted in cost savings to the State in 2019. The program served 191,278 unduplicated clients and has 3,057 providers currently billing.[11]

The 86th Legislature passed Senate Bill 750 to enhance the services provided to women in the program. These new benefits were designed to address the top causes of maternal mortality and

severe morbidity. The new benefits became effective on September 1, 2020. HHSC is currently seeking a plan amendment from CMS to gain federal approval of these new benefits.

Discussion

The Committee received invited and public testimony on the current status and future direction of the three waiver programs from national experts, HHSC staff, and key provider stakeholders participating in the DSRIP program.

HHSC provided an update on the current status of the three waiver programs. HHSC also provided testimony on the future plans and strategies for sustaining the programs and initiatives currently funded by the DSRIP program. Specifically, HHSC detailed ten *"milestones"* that the State has agreed to achieve to transition from the DSRIP program.

A panel of national experts, including representatives from the National Conference of State Legislatures (NCSL) and the National Association of Medicaid Directors provided the committee with information on national trends in Medicaid and the various financing and policy options adopted by other states. Barbara Eyman, provided suggestions for integrating current DSRIP projects and financing into the State's managed care model and behavioral health systems. DSRIP providers and stakeholders provided testimony highlighting the critical importance of DSRIP supplemental funding, especially in the areas of mental health and access to primary/preventative care.

The Committee also received testimony on a proposed rule by CMS called the Medicaid Fiscal Accountability Regulation (MFAR) published on November 12, 2019. The rule would have changed and limited how States could receive and use supplemental payments under the Medicaid program. Texas submitted written comments supporting the transparency requirements of the rule, but highlighted the extensive negative impact the rule would have on the State's public healthcare finance system. CMS withdrew the MFAR rule in September 2020.

Conclusion

Due to the COVID-19 pandemic, the Committee was only able to hold a public hearing on one section of the multi-part interim charge. Due to this limitation and given the State's decision to seek an 1115 waiver extension, the Committee defers recommendations at this time and provides this report section for informational purposes.

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[1] Senate Committee on Health and Human Services, Interim Hearing Witness List, December 3, 2019.
[2] *Report on Medicaid Managed Care Provider Network Adequacy,* Senate Bill 760, 84th Legislature, HHSC, December 2020.
[3] *Texas Value-Based Payment and Quality Improvement Advisory Committee Opportunities to Advance Value-Based Payment in Texas,* HHSC, December 2020.

[4] *Alternative Payment Models and Progress Toward Value Based Purchasing in Texas Medicaid,* The University of Texas at Austin, Dell Medical School. December 2018.
[5] Centers for Medicare & Medicaid Services, Section 1115 Demonstration FAST TRACK Extension Template for Program Changes, December 2020.
[6] HHSC, Presentation to the Senate Health and Human Services Committee, Dec. 3, 2019.
[7] Delivery System Reform Incentive Payment Programs, Issue Brief, The Medicaid and CHIP Payment and Access Commission, April 2020.
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[9] HHSC, Presentation to the Senate Health and Human Services Committee, Dec. 3, 2019
[10] Texas Women's Health Programs Report Fiscal Year 2019, Article II, Health and Human Services Commission, Rider 74, May 2020.
[11] Ibid.

NATHAN JOHNSON
STATE SENATOR • DISTRICT 16

January 11, 2021

The Honorable Lois Kolkhorst
Chair, Senate Committee on Health and Human Services
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Thank you for your leadership as the Chair of the Senate Committee on Health and Human Services, and to your staff for their diligent and unflagging efforts in the difficult circumstances of the COVID-19 pandemic. I have added my signature to the report. In addition to my general concurrence and appreciation, however, I submit these comments and recommendations.

The strain of the revenue shortfall we face this session, as well as the huge number of people who have lost or will lose employer-sponsored health insurance as a result of the pandemic's crushing blow to the state economy, make all the more regrettable that the Committee was unable to fulfill our interim charge to "[p]rovide recommendations to ensure the sustainability of the state's health and human services system and judicious use of taxpayer dollars." It is urgent that we fulfill this charge now, as the legislative session begins.

Even before the pandemic, the state was facing the impending loss of almost $3 billion annually, due to the expiration of our DSRIP waiver. While HHSC has requested that CMS grant a one-year extension of the DSRIP waiver, funding would in any event expire in 2022.[1] This session presents our last chance to find a mechanism to offset the DSRIP funding loss.

With Texas having the highest uninsured rate in the nation, and suffering almost the consequent tolls upon public health, business productivity, social equity, and the overall strength of our economy now and in the future, circumstances compel this Committee and the 87th Texas Legislature as a whole to avail of all funding options. In particular, the Legislature must examine whether drawing down federal Medicaid dollars under the Affordable Care Act[2] offers the most comprehensive, powerful, and economically

[1] In addition, the federal commitment has not committed to provide, beyond next year (2022), funding for the cost of uncompensated care imposed by the unsustainably high number of uninsured Texans.
[2] Options include a direct ACA Medicaid expansion or, alternatively, an 1115 expansion waiver whereby Texas retains a maximum of control and flexibility over how Medicaid dollars are spent, how we incentivize cost-effectiveness and quality of care, and how we administer health delivery systems.

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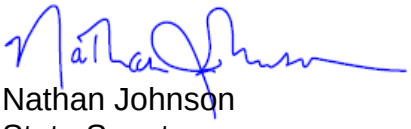
advantageous option. Experts estimate that an ACA expansion funded with a 90-10 federal match would result in insuring approximately a million Texans while generating net positive state revenue without the imposition of new taxes.[3]

There exist other mechanisms for drawing down federal Medicaid dollars, although they reach only a small fraction of those who could be insured under an ACA expansion. As for judicious use of taxpayer dollars, only an ACA expansion provides funding at a 90-10 match rate, whereas narrower alternatives typically draw dollars at a less-favorable FMAP rate (typically 60-40) and rely on local property taxes for funding.

Given the dire conditions of public health, fiscal pressures, and economic opportunities associated with improved public health, I urge the Committee to immediately undertake to not only meet the interim charge to provide recommendations, but also act upon them during this 87th Legislative Session.



Nathan Johnson
State Senator
Senate District 16

[3] See, among other sources, An Open Letter to Elected Officials, November 9, 2020 by Ray Perryman, Laura Dague, Randy Fritz, and Vivian Ho published on the Episcopal Health Foundation website: ***"[T]he probable net static fiscal impact of implementing a federally funded expansion in Texas would be positive and in the range of $75 million to $125 million during the 2022-2023 Biennium."***