



Medicaid Drug Donation Program Feasibility Study

**As Required By
Section 2, S.B. 1243, 84th Texas Legislature, Regular Session, 2015**



**Department of State Health Services
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Executive Summary

Section 2 of [Senate Bill 1243](#), 84th Texas Legislature, Regular Session, 2015 requires the Department of State Health Services (DSHS) to conduct a study to determine the feasibility of creating a drug donation program for unused Medicaid-reimbursed drugs at hospitals, nursing homes, and other health facilities. In doing so, DSHS must determine the rules necessary for:

- The types of unused drugs that may be transferred
- The procedures for transferring unused drugs
- The procedures for allocating and distributing the unused drugs to public hospitals
- The qualifications for an entity to be designated by DSHS to receive and distribute unused drugs under the program, including demonstrated expertise in handling, storing, and assessing prescription and nonprescription drugs and coordinating with the state's public health system

In conducting this feasibility study, DSHS consulted with three drug donation programs in different states: the Iowa Prescription Drug Program, the Tulsa, Oklahoma Drug Donation Program, and the Wyoming Medication Donation Program. These programs do not deal exclusively with Medicaid-reimbursed drugs, but they were instrumental in aiding DSHS to determine the types of drugs to include in the program, disposal requirements, and memorandums of understanding between donors, recipients, and DSHS.

While DSHS has identified more than 2,000 facilities that could potentially serve as donors for the Medicaid drug donation program, facility operating procedures and Centers for Medicare and Medicaid Services (CMS) guidelines would likely preclude these entities from participating. Therefore, under current federal rules, regulations, and facility operations, a Medicaid drug donation program is not practical. If these legal barriers were addressed, the DSHS or a qualified designated entity would be able to operationalize the drug donation program with additional resources.

Introduction

Section 2 of [S.B. 1243, 84th Legislature, Regular Session, 2015](#) requires the Department of State Health Services (DSHS) to conduct a study to determine the feasibility of establishing a program under which a hospital, nursing facility, or other health facility may donate unused Medicaid drugs that will be redistributed to public hospitals. The provision specifies that the program could be operated by DSHS or an entity designated by DSHS.

In conducting this study, DSHS is required to consider the rules that may need to be adopted to implement the program, including rules that provide for:

- The types of unused drugs that may be transferred
- The procedures for transferring unused drugs
- The procedures for allocating and distributing the unused drugs to public hospitals
- The qualifications for an entity to be designated by DSHS to receive and distribute unused drugs under the program, including demonstrated expertise in handling, storing, and assessing prescription and nonprescription drugs and coordinating with the state's public health system

DSHS is required to submit a report to the Legislature containing the findings of the study. In preparing this report, DSHS coordinated with the Health and Human Services Commission, the state's Medicaid agency. DSHS also consulted with representatives from three drug donation programs in other states: the Iowa Prescription Drug Program, the Tulsa, Oklahoma Drug Donation Program, and the Wyoming Medication Donation Program. These programs do not deal exclusively with Medicaid-reimbursed drugs, but they were instrumental in aiding DSHS to determine the types of drugs to include in the program, disposal requirements, and memorandums of understanding between donors, recipients, and DSHS.

Potential Drug Donors

Section 2 of S.B. 1243 specifies that for the potential drug donation program contemplated in this report, the drugs will be donated by hospitals, nursing homes, and other health facilities. There are over 700 hospitals, more than 1,100 nursing homes, and nearly 720 other health facilities (including state-supported living centers, state hospitals, special care facilities, crisis stabilization units, substance abuse treatment facilities, and Intermediate Care Facilities for Individuals with Intellectual Disabilities) in Texas.

Medicaid covers a large range of drugs; as of July 18, 2016, there were 23,931 drugs included in the Medicaid Vendor Drug Program formulary (<http://www.txvendordrug.com/formulary/index.asp>). Drugs on this formulary that comply with the rules set forth by DSHS to ensure safety and quality could be donated under a potential drug donation program. However, as detailed below, facility operating procedures and Centers for Medicare and Medicaid Services (CMS) guidelines would likely preclude these entities from participating. Therefore, under current federal rules, regulations, and facility operations, a Medicaid drug donation program is not practical.

Hospitals

There are 715 public, non-profit, and for-profit hospitals across Texas. Each of these entities could be eligible to donate Medicaid-reimbursed drugs to DSHS or its designated entity. Typically, drugs are dispensed to patients in tamper-evident blister packs, which individually package each dose of medication. These blister packs are created by the hospital's in-house pharmacy, which pulls the exact number of pills a patient needs for one dose of medication from its bulk inventory and uses a machine to create the patient's custom blister pack. The patient is charged for the exact number of pills that they consume; thus, there is no medicinal waste, and the patient's payer source (in this case, Medicaid), is not charged for the medication unless it is taken by the patient.

If a patient does not take their prescription medication, and the blister pack is unopened, the hospital pharmacy ensures that the medications have not been tampered with or damaged and recycles them back into its inventory. The hospital disposes of medications that have been opened or otherwise adulterated. Therefore, hospitals would not be a likely source of unused Medicaid drugs to donate to a drug donation program.

Nursing Homes

There are 1,149 Medicaid-certified nursing homes in Texas. According to the May 2016 Department of Aging and Disability Services Statewide Occupancy report, there were 80,838 Medicaid-certified beds occupied in Texas' nursing homes. Each of these individuals could potentially have excess medications that could be donated if their prescription changed, they left the nursing home, or they passed away. However, because of the way drugs are dispensed to nursing homes, along with CMS requirements, it is also unlikely that nursing homes would serve as drug donor sources.

Nursing homes often work with contracted pharmacies to receive medications. These drugs are also typically dispensed via blister packs. However, unlike in hospitals, these blister packs come on sheets that contain multiple days' worth of medications, much like over-the-counter cold medications that can be purchased at retail pharmacies. If a nursing home resident has Medicaid prescription drug coverage, the entire lot of blister-packed medication on the sheet is paid for upfront when it is received from the contracting pharmacy.

If the resident no longer needs the medication, the remainder of the pills on the sheet are sent back to the originating pharmacy, and Medicaid receives notice of the number of pills that were unused on each sheet. If the entire sheet is unused, the pharmacy can reimburse Medicaid for the cost of the sheet and recycle the pills back into its inventory.

CMS does not allow a state to authorize donation of a Medicaid-reimbursed drug unless the federal amount paid for the drug is returned to CMS via the state Medicaid program. There is no process for a pharmacy to reimburse Medicaid for a portion of a blister-packed sheet. Therefore, if one or more pills have been dispensed to the resident, the remaining pills must be destroyed and cannot be donated. According to a letter sent from CMS to [State Medicaid Directors](#) on

March 22, 2006, "States must ensure that [nursing home pharmacies] are properly crediting the Medicaid program for the return of unused prescription medicines upon discontinuance of the prescription or transfer, discharge, or death of a Medicaid beneficiary." Because any unused drugs that have been dispensed to Medicaid patients have already been paid for by Medicaid, the pharmacy cannot donate these unused pills to a drug donation program without properly crediting the Medicaid program. Even if there were a method for pharmacies to reimburse Medicaid for a partially used blister-packed medication sheet, it would be unlikely that those drugs would be donated, as the pharmacy could resell the drugs for profit.

Other Health Facilities

There are 719 other inpatient health facilities in Texas, including 13 state-supported living centers, 11 state hospitals, 13 special care facilities, 5 crisis stabilization centers, and 677 substance abuse treatment facilities.¹ Alongside the 13 state-supported living centers, there are an additional 818 Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs); however the majority of these are assisted living facilities or group homes that do not oversee residents' medications. Medicaid-eligible individuals in these inpatient facilities receive medications much the same way residents in hospitals or nursing homes do, via blister-packed one dose medications that are created by an in-house pharmacy, or blister-packed multi-dose sheets purchased upfront by Medicaid from a contracting pharmacy. According to the Texas Medicaid program, the same CMS policies and procedures would prohibit these entities from donating drugs to DSHS or its designated entity.

Drug Donation Program Oversight and Administration

If the facility operating procedures and CMS guidelines mentioned above that would likely preclude hospitals, nursing homes, and other health facilities from donating drugs were to change, the DSHS Pharmacy Branch or a qualified designated entity would be able to operationalize the drug donation program with additional resources. Before implementing a program, DSHS would need to establish rules and guidelines necessary to ensure the safety and quality of drugs donated and distributed.

DSHS Pharmacy Branch

The DSHS Pharmacy Branch has over 35 years of experience purchasing, storing, and distributing medications. It provides drugs, vaccines, and supplies to participating local health departments, DSHS Health Service Regions (HSR), clinics, private providers, and pharmacies to prevent, diagnose, and treat infectious diseases. It also ensures compliance with state and federal requirements related to the shipping, receiving, storage, and repackaging of medications, vaccines, and supplies. Its current inventory includes more than 340 drugs to treat HIV, tuberculosis, sexually transmitted diseases, and Hansen's disease, as well as medications utilized by the Refugee Health Program. The DSHS Pharmacy Branch is not a traditional pharmacy, but rather a re-packer and re-labeler regulated by the Food and Drug Administration (FDA).

¹ Not all substance abuse treatment facilities are inpatient; therefore, the number of locations that could participate in a drug donation program is fewer than 677.

In 2015, the DSHS Pharmacy Branch processed 86,748 drug orders sent to 889 unique locations. Alongside the provision of drugs, the DSHS Pharmacy Branch also provides oversight to approximately 80 Class D pharmacies in HSRs. This makes it well suited to oversee a drug donation program, which will require coordination with public health partners to receive and distribute unused drugs and to handle, store, and assess these medications.

In setting up the drug donation program, DSHS would need to establish rules, policies, and procedures for shipment, receipt, inventory, storage, quality assessment, and allocation of the medications. It would also need to determine the criteria for drugs that are eligible to be donated.

Types of Drugs Involved in the Program

Building upon the experience the DSHS Pharmacy Branch has with its current drug distribution program, along with insight garnered from other states' drug donation programs, DSHS has identified some recommendations related to the types of drugs that could be accepted in a potential Medicaid drug donation program.

Donated drugs must be:

- Prescription drugs
- Approved by the FDA
- Be sealed in unopened tamper-evident unit dose packaging
 - A drug packaged in single unit doses may be acceptable for distribution if the outside packaging is opened but the single unit dose packaging is unopened.

Donated drugs may not:

- Be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer
- Be adulterated or misbranded
- Be a controlled substance under Texas Health and Safety Code Chapter 481
- Require refrigeration
- Expire less than 60 days after the date of donation
- Be a drug that is prohibited from being dispensed to a patient other than a patient who is registered with the drug's manufacturer in accordance with FDA requirements²

Refrigerated drugs are not recommended to be part of the drug donation program because they must have their storage temperature strictly controlled to ensure efficacy. Controlled substances must be handled according to the rules set by the U.S. Drug Enforcement Administration (DEA), so they cannot be accepted for donation. Non-prescription drugs are not recommended to be a part of the drug donation program because other states with existing drug donation programs report that non-prescription drugs require a significant amount of labor and space to handle and disposal of donated over-the-counter drugs that cannot be redistributed is expensive. These requirements closely mirror those in other states' drug donation programs.

² There are some arrangements with drug companies that require a specific individual to receive a specific drug, which would prohibit the drug from being donated and redistributed to another person. For example, some drug companies have patient assistance programs that provide medications to patients at a discounted price if they meet certain eligibility criteria.

Quality Control

DSHS would need to develop additional guidelines for proper quality assessment of the donated drugs to ensure that they are safe for redistribution. Only a licensed pharmacist would be qualified to carry out this work. If DSHS were to implement a Medicaid drug donation program, the agency would need an additional pharmacist and pharmacy technician to carry out these quality assessments.

Any drugs received that do not meet these requirements would need to be disposed of properly. This is likely to be a significant quantity, as the Iowa Prescription Drug Program (IPDP) states that more than 50 percent of the drugs it receives do not fit its donation program requirements. The IPDP is classified as a small quantity generator of hazardous waste by Iowa's environmental regulating agency. According to the Texas Commission on Environmental Quality, DSHS would be similarly classified if it disposed of its own waste.

The DSHS Pharmacy Branch currently disposes of a small amount of medications each year that expire before they are shipped out to their recipients or are returned by local and regional health clinics; however, with the anticipated volume of unacceptable drugs it would receive from the drug donation program, it would need to enter into additional waste disposal agreements. The Tulsa County drug donation program developed an initiative with the Oklahoma Department of Narcotics and Dangerous Drugs to collect unusable drugs and destroy them. The drugs are packaged by the Oklahoma State Bureau of Investigation's Narcotics Division and taken to a private company that incinerates the waste to generate energy, at no cost to the program.

Storage and Inventory

If DSHS were to operate the program, donated drugs would be stored in the same facility as the DSHS Pharmacy Branch's current inventory, in a secure warehouse location that is climate controlled to ensure the medications do not deteriorate over time. Because the inventory for a drug donation program would constantly change, new storage procedures would need to be developed to ensure the best use of warehouse space. If the drug donation program was heavily utilized and the DSHS Pharmacy Branch received a very large quantity of donated drugs, it may need to identify additional space beyond its current warehouse to store the medications, or modify the parameters of the program to reduce the volume of drugs being received.

In order to catalogue and distribute the drugs donated under the program, a database of the current drug inventory searchable by public hospital recipients would also be needed. While DSHS's Inventory Tracking Electronic Asset Management System (ITEAMS) is used to keep track of the Pharmacy Branch warehouse's current inventory, a new inventory system would likely need to be procured to handle the large formulary of Medicaid-reimbursed drugs that could be donated to DSHS. The Medicaid Vendor Drug Program currently includes 23,931 distinct medications. This far exceeds the 349 medications currently handled by the DSHS Pharmacy Branch. Furthermore, ITEAMS also lacks industry-standard pharmacist verification and validation tools needed to support the large formulary of the drug donation program, as well as adhere to the stringent FDA and Texas State Board of Pharmacy (TSBP) regulations for this type

of operation. ITEAMS also does not allow DSHS to generate reports, keep track of lot numbers in accordance with FDA requirements, or utilize the national Drug Fact and Comparison daily updated National Drug Code database. These functionalities would allow the program to expediently report drug volume and utilization, comply with FDA requirements, and cross-reference drugs to ensure they are labeled appropriately. Additionally, ITEAMS currently is not capable of allowing public hospitals to search current inventory online.

Designated Entities

As specified in S.B. 1243, in order for DSHS to designate an entity to oversee a drug donation program, the designated entity would need to demonstrate its expertise in handling, storing, and assessing prescription and nonprescription drugs and coordinating with the state's public health system. This would require proper quality control, storage space, and electronic inventory systems as described above for DSHS; on-site licensed pharmacists and certified pharmacy technicians available to assess that drugs are safe and within program guidelines; along with a proven track record of safe handling, storage, and shipment of drugs to and from the designated entity, with no violations of the law and up-to-date licensing requirements.

Unless otherwise directed by the Legislature, DSHS would initiate a request for proposal (RFP) process to identify potential entities and select an entity that is best suited to serve the needs of the program.

Procedures for Transferring Drugs to DSHS

If the practical and legal obstacles to implementing a Medicaid drug donation program were addressed, a hospital, nursing home, or other health facility wanting to participate would need to enter into an agreement with DSHS in order to ensure drugs are accounted for and are kept in an environment that is within the guidelines of the drug manufacturer to maintain efficacy. These entities will also need to affirm that the drugs have been paid for by Medicaid and are eligible to be included in the drug donation program. DSHS would need to develop a donor application and memorandum of understanding for each entity that would like to participate. This information could be used to maintain an up-to-date database of donors. Policies and procedures will also need to be established for the shipment of drugs from the originating facility to DSHS, such as the required documentation and shipping procedures.

Potential Drug Recipients

Public Hospitals

Section 2 of S.B. 1243 specifies that for the potential drug donation program contemplated in this report, the drugs will be donated to public hospitals. There are 116 licensed public hospitals in Texas (see Appendix A for a map of their locations). These entities would be eligible to receive drugs donated under the program.

Procedures for Allocating and Distributing Donated Drugs to Public Hospitals

Public hospitals that would like to participate in the Medicaid drug donation program would need to enter into agreements with DSHS to ensure that the drugs are being used in the appropriate manner, are being handled and stored safely, and are dispensed to the appropriate recipients. Public hospitals would need to comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of such drugs and inspect all donated drugs prior to dispensing to determine if they appear to be adulterated or misbranded.

DSHS recommends that drugs be allocated to public hospitals on a first come, first served basis, based on the order in which public hospitals requested a specific drug from inventory of donated drugs. Drugs could be requested via email, fax, or if DSHS obtains a successor to ITEAMS, they could also be requested in real-time via an online inventory. Requested drugs would be shipped via common carrier using all appropriate packaging requirements.

The circumstances under which patients would qualify for the donated drugs would need to be established. Factors such as income and insurance status could be used to determine who may receive donated drugs. In Wyoming, for example, drug donation recipients must meet all of the following eligibility requirements:

- Have a current prescription
- Wyoming resident
- Low-income (200% Federal Poverty Level or below)
- Either be enrolled in Wyoming Medicaid or not have prescription insurance

Liability

In order to alleviate civil and criminal liability concerns for the drug donor, manufacturer and seller of donated drugs, DSHS or its designated entity, and public hospitals, a release form would need to be developed that drug recipients would be required to sign stating that they understand the immunity provisions of the program and acknowledge that the medication was originally dispensed to another patient and has been donated to the Medicaid Donation Program for re-dispensing. Wyoming's Medication Donation Program has a very similar liability waiver for its drug donation recipients.

DSHS would also need to develop rules that would follow liability provisions currently in law for the charitable drug donation program under Texas Health and Safety Code Chapter 431, Subchapter M, and the pilot drug donation pilot program under Texas Health and Safety Code Chapter 431, Subchapter O. The charitable drug donation program under Subchapter M was enacted during the 77th Legislature in 2001 to allow charitable drug donors to donate drugs to charitable medical clinics under certain conditions. The pilot drug donation program under Subchapter O was enacted during the 84th Legislature in 2015 to allow charitable drug donors to donate drugs to DSHS under certain conditions, and DSHS then distributes these drugs to certain specified healthcare providers. Both subchapters have very similar liability clauses that limit the civil and criminal liability of donors, recipient organizations, and their employees unless harm is caused by willful or wanton acts of negligence, conscious indifference or reckless disregard for the safety of others, or intentional conduct.

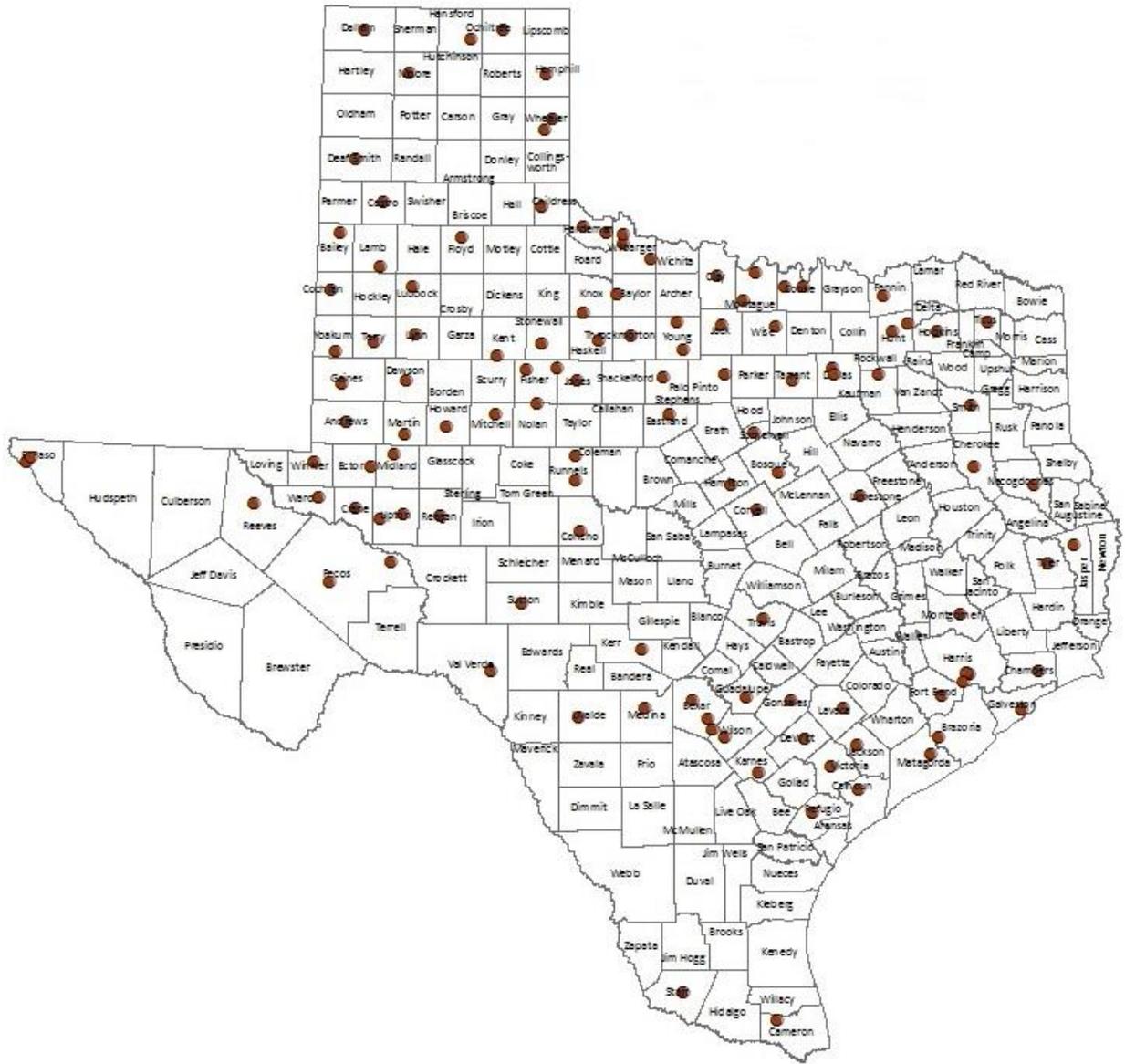
Conclusions

While there are more than 2,000 hospitals, nursing homes, and other health facilities that receive Medicaid drug reimbursements, facility operating procedures and CMS guidelines would likely preclude entities from donating drugs to a potential Texas Medicaid drug donation program unless the state were to reimburse the federal portion of the amount reimbursed by Medicaid. Even if there were a method for pharmacies to reimburse Medicaid for partially used blister-packed medication sheets, it would be unlikely that those drugs would be donated to DSHS, as the pharmacy could resell the drugs for profit. Therefore, the Medicaid drug donation program is unfeasible under current rules, regulations, and facility operating procedures.

If these practical and legal barriers were addressed, DSHS or a qualified designated entity, would be able to operationalize the drug donation program with additional resources. Before implementing a program, DSHS would need to establish rules and guidelines necessary to ensure the safety and quality of drugs donated and distributed.

Appendix A: Public Hospital Locations in Texas

Figure 1. Public Hospital Locations in Texas



Map showing locations of public hospitals in Texas. See Table 1 below for details.

Table 1. Public Hospital Locations in Texas

Public Hospital	Location
Anson General Hospital	Anson
Austin State Hospital	Austin
Ballinger Memorial Hospital District	Ballinger
Bayside Community Hospital	Anahuac
Big Spring State Hospital	Big Spring
Bowie Memorial Hospital	Bowie
Brownfield Regional Medical Center	Brownfield
Childress Regional Medical Center	Childress
Chillicothe Hospital	Chillicothe
CHRISTUS Southeast Texas - Jasper Memorial	Jasper
Citizens Medical Center	Victoria
Clay County Memorial Hospital	Henrietta
Cochran Memorial Hospital	Morton
Cogdell Memorial Hospital	Snyder
Concho County Hospital	Eden
Connally Memorial Medical Center	Floresville
Coon Memorial Hospital and Home	Dalhart
Coryell Memorial Hospital	Gatesville
Crane Memorial Hospital	Crane
Cuero Community Hospital	Cuero
Eastland Memorial Hospital	Eastland
El Paso Psychiatric Center	El Paso
Electra Memorial Hospital	Electra
Faith Community Hospital	Jacksboro
Fisher County Hospital District	Rotan
Glen Rose Medical Center	Glen Rose
Goodall-Witcher Hospital	Clifton
Graham Regional Medical Center	Graham
Medical Center Hospital	Odessa
Medina Regional Hospital	Hondo
Memorial Hospital	Seminole
Memorial Hospital	Gonzales
Memorial Hospital	Dumas
Memorial Medical Center	Port Lavaca
Midland Memorial Hospital	Midland
Mitchell County Hospital	Colorado City
Montgomery County Mental Health Treatment Facility	Conroe
Muenster Memorial Hospital	Muenster
Muleshoe Area Medical Center	Muleshoe
Nacogdoches Memorial Hospital	Nacogdoches

Public Hospital	Location
Nocona General Hospital	Nocona
North Runnels Hospital	Winters
North Texas Medical Center	Gainesville
North Texas State Hospital	Vernon
OakBend Medical Center	Richmond
Ochiltree General Hospital	Perryton
Otto Kaiser Memorial Hospital	Kenedy
Palo Pinto General Hospital	Mineral Wells
Parkland Memorial Hospital	Dallas
Parkview Hospital	Wheeler
Pecos County Memorial Hospital	Fort Stockton
Permian Regional Medical Center	Andrews
Plains Memorial Hospital	Dimmitt
Rankin County Hospital District	Rankin
Reagan Memorial Hospital	Big Lake
Reeves County Hospital	Pecos
Refugio County Memorial Hospital District	Refugio
Rio Grande State Center	Harlingen
Guadalupe Regional Medical Center	Seguin
Hamilton General Hospital	Hamilton
Hamilton Hospital	Olney
Hamlin Memorial Hospital	Hamlin
Hansford County Hospital	Spearman
Hardeman County Memorial Hospital	Quanah
Harris County Psychiatric Center	Houston
Harris Health System Ben Taub Hospital	Houston
Haskell Memorial Hospital	Haskell
Hemphill County Hospital	Canadian
Hereford Regional Medical Center	Hereford
Hopkins County Memorial Hospital	Sulphur Springs
Hunt Regional Community Hospital	Commerce
Hunt Regional Medical Center Greenville	Greenville
Iraan General Hospital	Iraan
Jackson County Hospital	Edna
John Peter Smith Hospital	Fort Worth
Kerrville State Hospital	Kerrville
Knox County Hospital	Knox City
Lamb Healthcare Center	Littlefield
Lavaca Medical Center	Hallettsville
Lillian M. Hudspeth Memorial Hospital	Sonora
Limestone Medical Center	Groesbeck
Lynn County Hospital District	Tahoka

Public Hospital	Location
Martin County Hospital District	Stanton
Matagorda Regional Medical Center	Bay City
McCamey Hospital	McCamey
Medical Arts Hospital	Lamesa
Rolling Plains Memorial Hospital	Sweetwater
Rusk State Hospital	Rusk
San Antonio State Hospital	San Antonio
Seymour Hospital	Seymour
Shamrock General Hospital	Shamrock
Starr County Memorial Hospital	Rio Grande City
Stephens Memorial Hospital	Breckenridge
Stonewall Memorial Hospital	Aspermont
Sweeny Community Hospital	Sweeny
Terrell State Hospital	Terrell
Texas Center for Infectious Disease	San Antonio
Throckmorton County Memorial Hospital	Throckmorton
Titus Regional Medical Center	Mount Pleasant
TMC Bonham Hospital	Bonham
Tyler County Hospital	Woodville
University Hospital	San Antonio
University Medical Center	Lubbock
University Medical Center of El Paso	El Paso
University of Texas M.D. Anderson Cancer Center	Houston
University of Texas Medical Branch Hospital	Galveston
University of Texas Southwestern Medical Center	Dallas
UT Health Northeast	Tyler
Uvalde Memorial Hospital	Uvalde
Val Verde Regional Medical Center	Del Rio
W.J. Mangold Memorial Hospital	Lockney
Ward Memorial Hospital	Monahans
Wilbarger General Hospital	Vernon
Winkler County Memorial Hospital	Kermit
Wise Regional Health System	Decatur
Yoakum County Hospital	Denver City