



Drug Donation Pilot Program Report

**As Required by
Texas Health and Safety Code
Section 431.460**



TEXAS
**Health and Human
Services**

**Texas Department of
State Health Services**

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1. Introduction

[Senate Bill 1243, 84th Legislature, Regular Session, 2015](#) created the Prescription Drug Donation Pilot Program, codified in [Texas Health and Safety Code, Chapter 431, Subchapter O](#). The pilot program is intended to allow certain unused prescription medications approved by the U.S. Food and Drug Administration (FDA) to be donated to the Texas Department of State Health Services (DSHS) for distribution to charitable medical clinics, physicians caring for indigent or Medicaid-eligible patients, and penal institutions.

[Texas Health and Safety Code, Section 431.460](#) requires DSHS to report to the Legislature the results of the pilot program no later than January 1 of each odd-numbered year. The report must include:

- The pilot program's efficacy in expanding access to prescription medications
- Any cost savings to the state or local governments resulting from or projected to result from the pilot program
- An evaluation of the pilot program's database and system of distribution
- Any health and safety issues posed by providing or administering donated drugs
- Recommendations on improvements to the pilot program
- An evaluation of potential expansion of the pilot program

[House Bill 2561, 85th Legislature, Regular Session, 2017](#) created another prescription drug donation program, codified in [Texas Health and Safety Code, Chapter 442](#), allowing donors to donate unused prescription drugs in single unit-dose packaging¹ to participating providers, who distribute them

¹ Unit-dose packaging means each dose (or pill) is individually wrapped.

to eligible recipients. This program differs from the pilot program authorized by SB 1243 in that DSHS does not serve as the drug repository. Instead, participating providers serve as the repository and all activities take place locally. The program went into effect March 1, 2018.

2. Pilot Program Criteria and Research

Pilot Program Criteria

Texas Health and Safety Code requires the pilot program to be conducted in one or more municipalities with a population between 500,000 and 1 million. In Texas, three cities meet the criteria: Austin, Fort Worth, and El Paso.

The types of charitable drug donors that may participate include:

- Licensed convalescent or nursing facilities or related institutions
- Licensed hospices
- Hospitals
- Physicians
- Pharmacies
- Pharmaceutical sellers or manufacturers that donate drugs under a qualified patient assistance program
- Licensed health care professionals responsible for administering drugs in a penal institution

Donated drugs must be prescription drugs approved by the FDA that are:

- Sealed in unopened tamper-evident unit dose packaging
- Oral medication in sealed single-dose containers
- Topical or inhalant drugs in sealed units-of-use containers

Summary of 2016-17 Research Activities

As reported in 2017, DSHS consulted with drug donation programs in other states and examined considerations for establishing a program in Texas,

including logistical considerations for space and staffing needs, and establishing systems for receiving, cataloguing, warehousing, order processing, and shipping, as well as establishing rules through the Texas Administrative Code.

Additionally, DSHS posted a Request for Information on the Texas Comptroller of Public Accounts website to gain insight into how a drug donation pilot program could be implemented. One respondent provided feedback, which echoed the information from the drug donation programs in other states.

It was determined that it was not feasible to establish a drug donation program in Texas utilizing existing resources.

Full details of DSHS's research can be found in the [2017 Drug Donation Pilot Program Report](#).

3. Recent Texas Legislative Developments

[House Bill 2561, 85th Legislature, Regular Session, 2017](#) created another prescription drug donation program, codified in [Texas Health and Safety Code, Chapter 442](#), allowing donors to donate unused prescription drugs in single unit-dose packaging² to participating providers, who distribute them to eligible recipients. Participating providers may be a health care facility ([general or special hospital](#), [ambulatory surgical center](#), or [certain institution](#)), [pharmacy](#), or [pharmacist](#) who is the employee of a health care facility or pharmacy.

This program differs from the pilot program authorized by SB 1243 in that DSHS does not serve as the drug repository. Instead, participating providers serve as the repository and all activities take place locally. The DSHS Pharmacy Branch serves as the administrator of the program, but does not accept or dispense drugs from its warehouse.

[Texas Health and Safety Code, Chapter 442](#) grants the HHS Executive Commissioner rulemaking authority and requires that standards and procedures be adopted for:

- Accepting, storing, labeling, and dispensing donated prescription drugs
- Inspecting donated prescription drugs to determine whether the drugs are adulterated and whether the drugs are safe and suitable for redistribution

The chapter also requires that the Executive Commissioner ensure the donation and redistribution process is consistent with public health and safety standards.

DSHS began the rulemaking process related to the program in June 2017. On March 1, 2018, [Texas Health and Safety Code, Chapter 431, Subchapter O](#) went into effect.

² Unit-dose packaging means each dose (or pill) is individually wrapped.

DSHS is statutorily required to develop a form for donors and recipients participating in the program and establish and maintain an electronic database of participating providers. This database is currently posted on the [DSHS Pharmacy Branch's website](#), which also contains information regarding the requirements for donating drugs, frequently asked questions, and the donor and recipient forms. Though not mandated by statute, a participating provider form was created to streamline provider enrollment in the program.

4. Conclusion

DSHS was unable to fully implement the drug donation pilot program as described by SB 1243 (84R), due to lack of appropriations. However, the 85th Legislature passed HB 2561, which established a locally-driven drug donation program. This legislation has been implemented by the Department and is now in effect.