Drug Donation Pilot Program Report

As Required By
Health and Safety Code, Section 431.460

Department of State Health Services
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Introduction

Senate Bill 1243, 84th Legislature, Regular Session, 2015 created the Prescription Drug Donation Pilot Program, codified in Health and Safety Code, Chapter 431, Subchapter O. The pilot program is intended to allow 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.

Section 431.460 of the Texas Health and Safety Code requires DSHS to report the results of the pilot program to the Legislature 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

SB 1243 amended statute to allow for the establishment of a drug donation pilot program; however, additional resources were not appropriated to implement the pilot. DSHS has concentrated its efforts over the biennium to exploring options for creating a drug donation pilot program using existing resources and within the current statutory framework. This work has included extensive research of current drug donation programs operating in other states and soliciting ideas for a program design through the formal Request for Information (RFI) process.

Pilot Program Criteria, Research, and Considerations

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 one 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

Research on Drug Donation Programs

In an effort to build on lessons learned from existing drug donation programs, DSHS staff consulted with representatives from programs across the country. Three drug donation programs were closely examined; two operated at the state level (Iowa and Wyoming), and one operated by a county (Tulsa County, Oklahoma). The three programs operate within parameters similar to the criteria required for the Texas pilot program. The table below provides information on each program.

Location	Population	Value of Drugs Distributed, 2014	Area of Program Work Space (Sq. Ft.)	# of FTEs
State of Wyoming	586,107	$1,765,112	1,000	2.75
Tulsa County, OK	603,403	$2,108,080	375	5
State of Iowa	3,123,899	$2,319,464	4,000	4.2

Considerations for a Pilot Program

As part of DSHS' analysis of potential implementation options, DSHS identified several logistical aspects that must be considered. In setting up a drug donation program, DSHS would need to establish rules, policies and/or procedures for shipment, receipt, inventory, storage, quality assessment, and allocation of the donated medications. It would also need to educate potential charitable drug donors about the pilot program and recruit new participants.

Transferring Drugs to DSHS

Eligible donors interested in participating in the program would need to apply and enter into a memorandum of understanding with DSHS. DSHS would maintain an up-to-date database of donors, as well as establish rules and policies for the shipment of drugs that ensure donated drugs have been stored properly, can be identified, and are not adulterated.

Appropriate methods would need to be established for transporting the drugs from the donor to DSHS. Existing drug donation programs use a variety of transportation methods, which could be used in a Texas program. Courier services that are authorized to send prescription medications could be utilized. Additionally, programs in other states have used a volunteer organization of retired physicians or paid drivers to transport drugs.

Storage and Inventory

A certified pharmacy technician would be needed for receiving, cataloging, warehousing, order processing, and shipping activities. Texas Health and Safety Code Section 431.457 requires DSHS to establish and maintain an electronic inventory system that allows recipients to search inventories and place orders. The current inventory system utilized by the DSHS Pharmacy Branch would not support the functionality required under current statute. DSHS would need to procure a new inventory system to comply with the requirements of the pilot program. DSHS

would also need to ensure that adequate warehouse space was available for drug storage. Some space is available in the current DSHS Pharmacy Branch warehouse; however, if large quantities were received, additional warehouse space would be needed.

Quality Control
A pharmacist would be needed to ensure all donated drugs received are of acceptable integrity and meet established guidelines for proper identification and quality assessment. Any drugs received that are not of acceptable integrity or do not meet pilot program requirements would need to be disposed of properly. Based on the experience of drug donation programs in other states, it is likely that a large volume of drugs that will require disposal in Texas. To do this, DSHS would need to enter into waste disposal agreements.

Distribution
After reviewing the inventory of available drugs, a recipient could place and order, which would be delivered using an acceptable transportation method. To support this work, DSHS could charge a handling fee, as allowed under Texas Health and Safety Code, Section 431.458.

Request for Information (RFI) Results

To gain additional insight into how a drug donation pilot program could be implemented in Texas using existing resources, DSHS posted a Request for Information (RFI) on the Texas Comptroller of Public Accounts website on June 27, 2016. The RFI, which was open to any public or private entity, asked for responses to specific questions about establishing a program to redistribute unused prescription drugs. After extending the deadline for responses twice, a non-profit entity with experience operating a drug donation program was the only RFI respondent.

The respondent provided feedback about how a drug donation pilot program could be implemented in Texas with a third party operator. Much of the respondent's feedback echoed the information from the drug donation programs in other states. The RFI response emphasized:

- Appropriate staff is necessary to examine and sort the donated medication.
- Adequate space and equipment is required to sort and store the donated medication, which is primarily in blister packs.
- Methods for transporting the donated drugs need to be developed that are capable of managing and tracking shipments and pick up of donations.
- Ample technical assistance and outreach is needed to recruit donors and recipients.

The respondent specified that it would require $750,000 for year one, $500,000 for year two, $300,000 for year three, and $150,000 for year four to operate a drug donation program in Texas. After the fourth year of operation, the respondent predicts that earned revenue could be used to sustain the program. The respondent suggested that costs could be significantly reduced if the drug donation program was established as a multistate centralized repository.

In the program structure suggested by the RFI respondent, ongoing funding to operate the program would come from three sources.

- Soliciting donations from local or regional foundations.

- Charging drug donors a fee to donate their unused drugs. These donors may have otherwise paid for the proper disposal of their surplus medicine and the respondent suggests that donors may be willing to pay a lower cost to donate their drugs.
- Charging patients without insurance, or those with high out-of-pocket expenses, an administrative fee for the donated medication. Providers such as clinics and hospital systems would pay an administrative fee on behalf of patients in need of donated medication.

To establish a repository within the state, the respondent estimated that a large warehouse of 2,500-3,000 square feet would be required. Initial staffing would require at least a pharmacist, 1-2 pharmacy technicians, and 1 staff member to manage donor and recipient partnerships. The respondent indicated that processes and online software for managing donations and providing supplies have been developed, which could potentially provide a publicly accessible, searchable inventory. The respondent suggested using a common carrier for the shipment of donations and delivery of medications. This structure could be built to scale so that staffing would be the only significant difference between operating a pilot program and rollout to a statewide system.

Some of the respondent's suggestions for a program structure would not be allowable under the current statutory framework governing the pilot program. The respondent proposed expanding the definition of "charitable drug donor" to broaden the pool of potential donors to any entity legally authorized to possess medicine, including but not limited to a manufacturer, third party logistic provider, wholesaler or distributor, repackager, clinic, prescriber, or assisted living facility, as well as allowing over the counter medications to be donated in addition to prescription drugs. The RFI response also advised that the provision requiring the individual transporting the drugs present photo identification be repealed.

Health and Safety Code Chapter 431 currently limits the operation of the drug donation program to a pilot, which would not allow for the establishment of a statewide program as was suggested by the respondent. As currently outlined in statute, the pilot would be operated by DSHS; the respondent suggested allowing the program to be operated by a third party. Additionally, the funding structure described in the RFI response includes donors paying a fee to donate unused drugs rather than paying for their disposal. Health and Safety Code Chapter 431 currently allows for the collection of a fee from drug recipients, but it does not specify that collecting a fee from a donor is allowable.

Conclusion

Although DSHS was unable to implement the drug donation pilot program, in-depth research on establishing a program was conducted through interviews with staff and tours of drug donation programs operating in other jurisdictions, as well as through the RFI process. If adequate resources were made available, DSHS would be well positioned to implement a drug donation program in Texas.