

BILL ANALYSIS

Senate Research Center

S.B. 1243
By: Burton
Health & Human Services
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Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Current Texas statute requires that unused prescription drugs be disposed of. Pills can go unused when a patient recovers from an illness sooner than expected, or switches to other medications. Nursing facilities and hospitals can throw away numerous pills each year. Providing a means to donate those unused drugs can provide an alternate means of obtaining treatment for individuals who may not be able to afford the hundreds or thousands of dollars needed for some medications.

S.B. 1537 establishes an expanded charitable pharmaceutical donation program in Texas under the purview of the Department of State Health Services. The program is designed to allow participating health care facilities to donate unused prescription drugs to other providers, subject to inspection of the drugs for safety.

This bill is modeled after a New Mexico law that was codified in 2011. Conversations with New Mexico House of Representatives staff have not identified any problems with their program implementation.

Prominent provisions of the bill include:

- A method for the patient drug "donor" to donate their unused drugs to a qualified "participating drug provider."
- A requirement that the executive commissioner of the Health and Human Services Commission adopt regulatory standards for the acceptance, storage, labeling and dispensing of the donated drugs. Additionally, the statutory procedures require that all regulatory procedures comply with public health and safety standards.
- A requirement that only unused, unopened drug containers can be accepted for donation.
- A prohibition that no controlled substances can be donated nor can a drug that is adulterated/misbranded or a drug that has not been properly stored.
- A codified donation process with a donor form.
- A codified recipient process with a recipient form with a waiver of liability.
- A statutory limitation of liability for the manufacturer, participating drug provider, and donor.
- A requirement to be in compliance with all applicable laws including federal law.

Several questions need to be answered in the regulatory codification of this bill including: Although many parts of the program are spelled out in the bill, the implementation of the bill will take very careful consideration of the executive commissioner of the Health and Human Services Commission.

S.B. 1243 amends current law relating to a pilot program for donation and redistribution of certain unused prescription medications and authorizes a fee.

[**Note:** While the statutory reference in this bill is to the Texas Department of Health (TDH), the following amendments affect the Department of State Health Services, as the successor agency to TDH.]

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas Department of Health in SECTION 1 (Sections 431.453, 431.455, and 431.458, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 431, Health and Safety Code, by adding Subchapter O, as follows:

SUBCHAPTER O. PRESCRIPTION DRUG DONATION PILOT PROGRAM

Sec. 431.451. DEFINITIONS. Defines "charitable drug donor," "charitable medical clinic," "manufacturer," "patient assistance program," "pilot program," "prescription drug," and "seller" in this subchapter.

Sec. 431.452. ESTABLISHMENT OF PILOT PROGRAM. (a) Requires the Texas Department of Health (TDH) to establish a pilot program for donation and redistribution of prescription drugs under this subchapter.

(b) Requires TDH to conduct the pilot program in one or more municipalities with a population of more than 500,000 but less than one million.

Sec. 431.453. DONATION OF UNUSED DRUGS. (a) Authorizes a charitable drug donor to donate certain unused prescription drugs to TDH for the pilot program under this subchapter.

(b) Provides that a seller or manufacturer of a drug that donates drugs through a qualified patient assistance program is considered a charitable drug donor.

(c) Requires a charitable drug donor to use appropriate safeguards established by TDH rule to ensure that the drugs are not compromised or illegally diverted while being stored or transported.

(d) Prohibits TDH from accepting the donated drugs unless:

(1) the charitable drug donor certifies that the drugs have been properly stored while in the possession of the donor or of the person for whom the drugs were originally dispensed;

(2) the charitable drug donor provides TDH with a verifiable address and telephone number; and

(3) the person transferring possession of the drugs presents photographic identification.

Sec. 431.454. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY BE ACCEPTED. (a) Authorizes TDH to accept donated drugs only in accordance with this subchapter.

(b) Requires that the donated drugs be:

(1) prescription drugs; and

(2) approved by the federal Food and Drug Administration (FDA) and:

(A) sealed in unopened tamper-evident unit dose packaging;

(B) be oral medication in sealed single-dose containers approved by the FDA; or

(C) be topical or inhalant drugs in sealed units-of-use containers approved by the FDA.

(c) Authorizes a drug packaged in single unit doses to be accepted and distributed if the outside packaging is opened but the single unit dose packaging is unopened.

(d) Prohibits donated drugs from:

(1) being the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer;

(2) being adulterated or misbranded;

(3) being a controlled substance under Chapter 481 (Texas Controlled Substances Act);

(4) being a parenteral or injectable medication;

(5) requiring refrigeration;

(6) expiring less than 60 days after the date of the donation; or

(7) being 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 requirements.

(e) Authorizes TDH to distribute the donated drugs only after a licensed pharmacist has determined that the drugs are of an acceptable integrity.

(f) Prohibits TDH from charging a fee for the drugs donated under the pilot program other than a nominal handling fee to defray the costs incurred in implementing the pilot program under this subchapter.

(g) Prohibits TDH from reselling the drugs donated under the pilot program.

Sec. 431.455. PRESCRIPTION, PROVISION, AND ADMINISTRATION OF DONATED DRUGS. (a) Authorizes the donated drugs to be accepted and provided or administered to patients only by:

(1) a charitable medical clinic;

(2) a physician's office using the drugs for patients who receive assistance from the medical assistance program under Chapter 32 (Medical Assistance Program), Human Resources Code, or for other indigent health care; or

(3) a licensed health care professional responsible for administration of drugs in a penal institution, as defined by Section 1.07 (Definitions), Penal Code, in this state.

(b) Requires that a prescription drug provided or administered to a patient under the pilot program be prescribed by a practitioner for use by that patient.

(c) Authorizes the clinic or physician providing or administering the drug to charge a nominal handling fee in an amount prescribed by TDH rule.

(d) Prohibits a clinic, physician, or other licensed health care professional receiving donated drugs from reselling the drugs.

Sec. 431.456. CENTRAL DRUG REPOSITORY. Requires TDH to establish a location to centrally store drugs donated under this subchapter for distribution to qualifying recipients.

Sec. 431.457. DATABASE OF DONATED DRUGS. Requires TDH to establish and maintain an electronic database in which:

- (1) TDH is required to list the name and quantity of each drug donated to TDH under the pilot program; and
- (2) a charitable medical clinic, physician, or other licensed health care professional may search for and request donated drugs.

Sec. 431.458. RULES. Requires that this subchapter be governed by TDH rules that are designed to protect the public health and safety, including:

- (1) the maximum handling fee that may be imposed by a clinic or physician providing or administering a donated drug to a patient;
- (2) provisions for maintenance of the database of donated drugs; and
- (3) any necessary forms for the administration of the pilot program.

Sec. 431.459. LIMITATION ON CIVIL AND CRIMINAL LIABILITY. (a) Provides that charitable drug donors, manufacturers and sellers of donated drugs, charitable medical clinics, physicians, penal institutions, and their employees acting in good faith in providing or administering prescription drugs under the pilot program are not civilly or criminally liable or subject to professional disciplinary action for harm caused by providing or administering drugs donated under this subchapter unless the harm is caused by:

- (1) wilful or wanton acts of negligence;
- (2) conscious indifference or reckless disregard for the safety of others; or
- (3) intentional conduct.

(b) Provides that this section does not apply if the harm results from the failure to comply with the requirements of this subchapter.

(c) Provides that this section does not apply to a charitable medical clinic that fails to comply with the insurance provisions of Chapter 84 (Charitable Immunity and Liability), Civil Practice and Remedies Code.

Sec. 431.460. REPORTS TO LEGISLATURE. Requires TDH, not later than January 1 of each odd-numbered year, to report to the legislature on the results of the pilot program. Requires that the report include:

- (1) the pilot program's efficacy in expanding access to prescription medications;
- (2) any cost savings to the state or local governments resulting from or projected to result from the pilot program;
- (3) an evaluation of the pilot program's database and system of distribution;
- (4) any health and safety issues posed by providing or administering donated drugs;
- (5) recommendations on improvements to the pilot program; and

(6) an evaluation of potential expansion of the pilot program.

SECTION 2. (a) Requires the Department of State Health Services (DSHS), as soon as practicable after the effective date of this Act, to conduct a study to determine the feasibility of establishing a program under which:

(1) a hospital, a nursing facility, or another health facility may transfer to DSHS, or an entity designated by DSHS, for no payment, unused drugs that the hospital, nursing facility, or health facility received reimbursement for the cost of under Medicaid; and

(2) DSHS, or the entity designated by DSHS, distributes to public hospitals the unused drugs transferred to DSHS or entity under Subdivision (1) of this subsection.

(b) Requires DSHS, in conducting the study under Subsection (a) of this section, to consider the rules the executive commissioner of the Health and Human Services Commission may need to adopt to implement the program described in Subsection (a) of this section, including rules that provide for:

(1) the types of unused drugs that may be transferred to DSHS or an entity designated by DSHS;

(2) the procedures for transferring unused drugs to DSHS or the entity designated by DSHS;

(3) the procedures for allocating and distributing the unused drugs to public hospitals; and

(4) 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 hospital system.

(c) Requires DSHS, not later than September 1, 2016, to submit to the legislature a report containing the findings of the study conducted under Subsection (a) of this section.

SECTION 3. Requires DSHS, not later than December 1, 2015, to establish the central repository and database required by Subchapter O, Chapter 431, Health and Safety Code, as added by this Act.

SECTION 4. Provides that the change in law made by this Act applies only to a drug that is donated, accepted, provided, or administered on or after January 1, 2016.

SECTION 5. Effective date: September 1, 2015.