

By: Burton  
(Sheffield, Klick)

S.B. No. 1243

Substitute the following for S.B. No. 1243:

By: Crownover

C.S.S.B. No. 1243

A BILL TO BE ENTITLED

AN ACT

relating to a pilot program for donation and redistribution of certain unused prescription medications; authorizing a fee.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 431, Health and Safety Code, is amended by adding Subchapter O to read as follows:

SUBCHAPTER O. PRESCRIPTION DRUG DONATION PILOT PROGRAM

Sec. 431.451. DEFINITIONS. In this subchapter:

(1) "Charitable drug donor" means:

(A) a licensed convalescent or nursing facility or related institution, licensed hospice, hospital, physician, or pharmacy;

(B) a pharmaceutical seller or manufacturer that donates drugs under a qualified patient assistance program; or

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

(2) "Charitable medical clinic" has the meaning assigned by Section 431.321.

(3) "Manufacturer" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.

(4) "Patient assistance program" means a qualified program offered by a pharmaceutical manufacturer under which the

1 manufacturer provides drugs to financially disadvantaged persons  
2 at no charge or at a substantially reduced cost. The term does not  
3 include the provision of a drug as part of a clinical trial.

4 (5) "Pilot program" means the prescription drug  
5 donation pilot program under this subchapter.

6 (6) "Prescription drug" has the meaning assigned by  
7 Section 551.003, Occupations Code.

8 (7) "Seller" means a person, other than a charitable  
9 drug donor, as defined in Chapter 82, Civil Practice and Remedies  
10 Code.

11 Sec. 431.452. ESTABLISHMENT OF PILOT PROGRAM. (a) The  
12 department shall establish a pilot program for donation and  
13 redistribution of prescription drugs under this subchapter.

14 (b) The department shall conduct the pilot program in one or  
15 more municipalities with a population of more than 500,000 but less  
16 than one million.

17 Sec. 431.453. DONATION OF UNUSED DRUGS. (a) A charitable  
18 drug donor may donate certain unused prescription drugs to the  
19 department for the pilot program under this subchapter.

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

23 (c) A charitable drug donor shall use appropriate  
24 safeguards established by department rule to ensure that the drugs  
25 are not compromised or illegally diverted while being stored or  
26 transported.

27 (d) The department may not accept the donated drugs unless:

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

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

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

8           Sec. 431.454. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY  
9 BE ACCEPTED. (a) The department may accept donated drugs only in  
10 accordance with this subchapter.

11           (b) The donated drugs must be:

12                 (1) prescription drugs; and

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

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

17                         (B) be oral medication in sealed single-dose  
18 containers approved by the federal Food and Drug Administration; or

19                         (C) be topical or inhalant drugs in sealed  
20 units-of-use containers approved by the federal Food and Drug  
21 Administration.

22           (c) A drug packaged in single unit doses may be accepted and  
23 distributed if the outside packaging is opened but the single unit  
24 dose packaging is unopened.

25           (d) Donated drugs may not:

26                 (1) be the subject of a mandatory recall by a state or  
27 federal agency or a voluntary recall by a drug seller or

1 manufacturer;

2 (2) be adulterated or misbranded;

3 (3) be a controlled substance under Chapter 481;

4 (4) be a parenteral or injectable medication;

5 (5) require refrigeration; or

6 (6) expire less than 60 days after the date of the  
7 donation.

8 (e) The department may distribute the donated drugs only  
9 after a licensed pharmacist has determined that the drugs are of an  
10 acceptable integrity.

11 (f) The department may not charge a fee for the drugs  
12 donated under the pilot program other than a nominal handling fee to  
13 defray the costs incurred in implementing the pilot program under  
14 this subchapter.

15 (g) The department may not resell the drugs donated under  
16 the pilot program.

17 Sec. 431.455. PRESCRIPTION, PROVISION, AND ADMINISTRATION  
18 OF DONATED DRUGS. (a) The donated drugs may be accepted and  
19 provided or administered to patients only by:

20 (1) a charitable medical clinic;

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

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

1       (b) A prescription drug provided or administered to a  
2 patient under the pilot program must be prescribed by a  
3 practitioner for use by that patient.

4       (c) The clinic or physician providing or administering the  
5 drug may charge a nominal handling fee in an amount prescribed by  
6 department rule.

7       (d) A clinic, physician, or other licensed health care  
8 professional receiving donated drugs may not resell the drugs.

9       Sec. 431.456. CENTRAL DRUG REPOSITORY. The department  
10 shall establish a location to centrally store drugs donated under  
11 this subchapter for distribution to qualifying recipients.

12       Sec. 431.457. DATABASE OF DONATED DRUGS. The department  
13 shall establish and maintain an electronic database in which:

14             (1) the department shall list the name and quantity of  
15 each drug donated to the department under the pilot program; and

16             (2) a charitable medical clinic, physician, or other  
17 licensed health care professional may search for and request  
18 donated drugs.

19       Sec. 431.458. RULES. This subchapter shall be governed by  
20 department rules that are designed to protect the public health and  
21 safety, including:

22             (1) the maximum handling fee that may be imposed by a  
23 clinic or physician providing or administering a donated drug to a  
24 patient;

25             (2) provisions for maintenance of the database of  
26 donated drugs; and

27             (3) any necessary forms for the administration of the

1 pilot program.

2 Sec. 431.459. LIMITATION ON CIVIL AND CRIMINAL LIABILITY.

3 (a) Charitable drug donors, manufacturers and sellers of donated  
4 drugs, charitable medical clinics, physicians, penal institutions,  
5 and their employees acting in good faith in providing or  
6 administering prescription drugs under the pilot program are not  
7 civilly or criminally liable or subject to professional  
8 disciplinary action for harm caused by providing or administering  
9 drugs donated under this subchapter unless the harm is caused by:

10 (1) wilful or wanton acts of negligence;

11 (2) conscious indifference or reckless disregard for  
12 the safety of others; or

13 (3) intentional conduct.

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

16 (c) This section does not apply to a charitable medical  
17 clinic that fails to comply with the insurance provisions of  
18 Chapter 84, Civil Practice and Remedies Code.

19 Sec. 431.460. REPORTS TO LEGISLATURE. Not later than  
20 January 1 of each odd-numbered year, the department shall report to  
21 the legislature on the results of the pilot program. The report  
22 must include:

23 (1) the pilot program's efficacy in expanding access  
24 to prescription medications;

25 (2) any cost savings to the state or local governments  
26 resulting from or projected to result from the pilot program;

27 (3) an evaluation of the pilot program's database and

1 system of distribution;

2 (4) any health and safety issues posed by providing or  
3 administering donated drugs;

4 (5) recommendations on improvements to the pilot  
5 program; and

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

8 SECTION 2. (a) As soon as practicable after the effective  
9 date of this Act, the Department of State Health Services shall  
10 conduct a study to determine the feasibility of establishing a  
11 program under which:

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

17 (2) the department, or the entity designated by the  
18 department, distributes to public hospitals the unused drugs  
19 transferred to the department or entity under Subdivision (1) of  
20 this subsection.

21 (b) In conducting the study under Subsection (a) of this  
22 section, the Department of State Health Services shall consider the  
23 rules the executive commissioner of the Health and Human Services  
24 Commission may need to adopt to implement the program described in  
25 Subsection (a) of this section, including rules that provide for:

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

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

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

5           (4) the qualifications for an entity to be designated  
6 by the department to receive and distribute unused drugs under the  
7 program, including demonstrated expertise in handling, storing,  
8 and assessing prescription and nonprescription drugs and  
9 coordinating with the state's public hospital system.

10          (c) Not later than September 1, 2016, the Department of  
11 State Health Services shall submit to the legislature a report  
12 containing the findings of the study conducted under Subsection (a)  
13 of this section.

14          SECTION 3. Not later than December 1, 2015, the Department  
15 of State Health Services shall establish the central repository and  
16 database required by Subchapter O, Chapter 431, Health and Safety  
17 Code, as added by this Act.

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

21          SECTION 5. This Act takes effect September 1, 2015.