

Chapter 1191

S.B. No. 1243

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

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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

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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;

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

8           (7) be a drug that is prohibited from being dispensed  
9 to a patient other than a patient who is registered with the drug's  
10 manufacturer in accordance with federal Food and Drug  
11 Administration requirements.

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

15           (f) The department may not charge a fee for the drugs  
16 donated under the pilot program other than a nominal handling fee to  
17 defray the costs incurred in implementing the pilot program under  
18 this subchapter.

19           (g) The department may not resell the drugs donated under  
20 the pilot program.

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

24           (1) a charitable medical clinic;

25           (2) a physician's office using the drugs for patients  
26 who receive assistance from the medical assistance program under  
27 Chapter 32, Human Resources Code, or for other indigent health

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1 care; or

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

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

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

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

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

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

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

20 (2) a charitable medical clinic, physician, or other  
21 licensed health care professional may search for and request  
22 donated drugs.

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

26 (1) the maximum handling fee that may be imposed by a  
27 clinic or physician providing or administering a donated drug to a

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1 patient;

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

4 (3) any necessary forms for the administration of the  
5 pilot program.

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

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

14 (1) wilful or wanton acts of negligence;

15 (2) conscious indifference or reckless disregard for  
16 the safety of others; or

17 (3) intentional conduct.

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

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

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

27 (1) the pilot program's efficacy in expanding access

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- 1 to prescription medications;  
2           (2) any cost savings to the state or local governments  
3 resulting from or projected to result from the pilot program;  
4           (3) an evaluation of the pilot program's database and  
5 system of distribution;  
6           (4) any health and safety issues posed by providing or  
7 administering donated drugs;  
8           (5) recommendations on improvements to the pilot  
9 program; and  
10           (6) an evaluation of potential expansion of the pilot  
11 program.

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

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

21           (2) the department, or the entity designated by the  
22 department, distributes to public hospitals the unused drugs  
23 transferred to the department or entity under Subdivision (1) of  
24 this subsection.

25           (b) In conducting the study under Subsection (a) of this  
26 section, the Department of State Health Services shall consider the  
27 rules the executive commissioner of the Health and Human Services

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1 Commission may need to adopt to implement the program described in  
2 Subsection (a) of this section, including rules that provide for:

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

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

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

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

14 (c) Not later than September 1, 2016, the Department of  
15 State Health Services shall submit to the legislature a report  
16 containing the findings of the study conducted under Subsection (a)  
17 of this section.

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

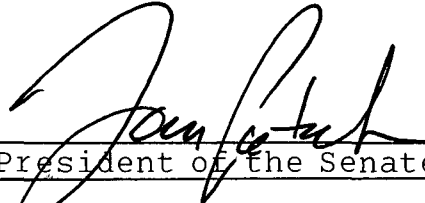
22 SECTION 4. The change in law made by this Act applies only  
23 to a drug that is donated, accepted, provided, or administered on or  
24 after January 1, 2016.

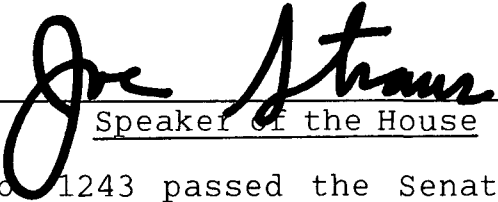
25 SECTION 5. This Act takes effect September 1, 2015.



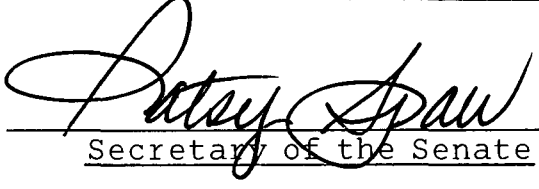
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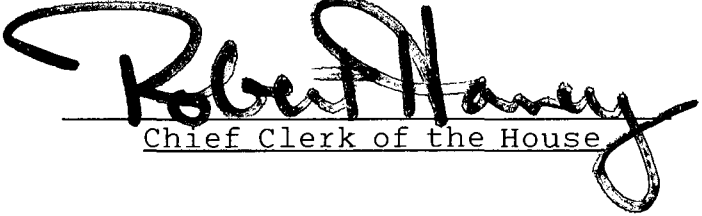
  
President of the Senate

  
Speaker of the House

I hereby certify that S.B. No. 1243 passed the Senate on April 29, 2015, by the following vote: Yeas 31, Nays 0; and that the Senate concurred in House amendments on May 29, 2015, by the following vote: Yeas 31, Nays 0.


  
Secretary of the Senate

I hereby certify that S.B. No. 1243 passed the House, with amendments, on May 26, 2015, by the following vote: Yeas 144, Nays 1, two present not voting.

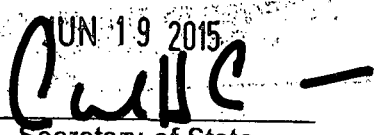
  
Chief Clerk of the House

Approved:

6-17-2015  
Date

  
Governor

FILED IN THE OFFICE OF THE  
SECRETARY OF STATE  
6:30 pm O'CLOCK

  
Secretary of State

**LEGISLATIVE BUDGET BOARD**  
**Austin, Texas**

**FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION**

**May 26, 2015**

**TO:** Honorable Dan Patrick, Lieutenant Governor, Senate

**FROM:** Ursula Parks, Director, Legislative Budget Board

**IN RE:** SB1243 by Burton (Relating to a pilot program for donation and redistribution of certain unused prescription medications; authorizing a fee. ), **As Passed 2nd House**

<b>No significant fiscal implication to the State is anticipated.</b>
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The bill would amend Chapter 431 of the Health and Safety Code to require the Department of State Health Services (DSHS) to establish a pilot program for the donation and redistribution of prescription drugs and adopt rules to administer the program. The pilot program would be limited to one or more municipalities with a population between 500,000 and 1 million. The bill would require DSHS to accept, store, and distribute donated drugs as well as establish and maintain a searchable, electronic database of donated drugs. In addition, the bill would require DSHS to conduct a study determining the feasibility of establishing a program under which DSHS accepts and distributes certain unused drugs to public hospitals. The bill would require DSHS to report the results of the pilot program and feasibility study to the legislature.

DSHS indicates there would be a cost to operate the pilot program in a single municipality, some of which would be offset by the collection of handling fees as authorized by the bill. It is assumed that any remaining costs could be absorbed within available resources.

It is not anticipated that the bill would have a significant fiscal impact on the Medicaid program. According to HHSC, physicians who distribute prescription donated drugs to Medicaid recipients may bill the Medicaid program for costs associated with the administration of the prescription donated drug or the related office visit. It is assumed these costs would be offset by savings associated with less prescription drug costs billed to the Medicaid program. However, if the costs associated with the administration of the prescription donated drug or the related office visit are greater than the costs of the prescription drug, there could be a cost to the Medicaid program.

**Local Government Impact**

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 529 Health and Human Services Commission, 537 State Health Services, Department of

**LBB Staff:** UP, ADe, NB, WP, VJC

**LEGISLATIVE BUDGET BOARD**  
**Austin, Texas**

**FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION**

**May 20, 2015**

**TO:** Honorable Myra Crownover, Chair, House Committee on Public Health

**FROM:** Ursula Parks, Director, Legislative Budget Board

**IN RE: SB1243** by Burton (Relating to a pilot program for donation and redistribution of certain unused prescription medications; authorizing a fee. ), **Committee Report 2nd House, Substituted**

<b>No significant fiscal implication to the State is anticipated.</b>
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**Local Government Impact**

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 529 Health and Human Services Commission, 537 State Health Services, Department of

**LBB Staff:** UP, NB, WP, ADe, VJC

**LEGISLATIVE BUDGET BOARD  
Austin, Texas**

**FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION**

**May 5, 2015**

**TO:** Honorable Myra Crownover, Chair, House Committee on Public Health

**FROM:** Ursula Parks, Director, Legislative Budget Board

**IN RE:** SB1243 by Burton (Relating to donation of unused prescription drugs.), **As Engrossed**

**No significant fiscal implication to the State is anticipated.**

The bill would amend the Health and Safety Code relating to a program for the donation of unused prescription drugs. The bill would require the Department of State Health Services (DSHS) to develop a form for donors and recipients participating in the program and establish and maintain an electronic database of participating providers. Additionally the bill would require the Health and Human Services Commission (HHSC) to adopt rules to implement the program. Based on the analysis provided by DSHS and HHSC, it is assumed the provisions of the bill can be implemented within existing resources.

**Local Government Impact**

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 529 Health and Human Services Commission, 537 State Health Services,  
Department of

**LBB Staff:** UP, NB, CH, LR

**LEGISLATIVE BUDGET BOARD**  
**Austin, Texas**

**FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION**

**April 15, 2015**

**TO:** Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

**FROM:** Ursula Parks, Director, Legislative Budget Board

**IN RE: SB1243** by Burton (Relating to the donation of unused prescription drugs.), **Committee Report 1st House, Substituted**

**No significant fiscal implication to the State is anticipated.**

The bill would amend the Health and Safety Code relating to a program for the donation of unused prescription drugs. The bill would require the Department of State Health Services (DSHS) to develop a form for donors and recipients participating in the program and establish and maintain an electronic database of participating providers. Additionally the bill would require the Health and Human Services Commission (HHSC) to adopt rules to implement the program. Based on the analysis provided by DSHS and HHSC, it is assumed the provisions of the bill can be implemented within existing resources.

**Local Government Impact**

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 529 Health and Human Services Commission, 537 State Health Services, Department of

**LBB Staff:** UP, NB, CH, LR

**LEGISLATIVE BUDGET BOARD  
Austin, Texas**

**FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION**

**April 3, 2015**

**TO:** Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

**FROM:** Ursula Parks, Director, Legislative Budget Board

**IN RE:** SB1243 by Burton (Relating to donation of unused prescription drugs.), **As Introduced**

**No significant fiscal implication to the State is anticipated.**

The bill would amend the Health and Safety Code relating to a program for the donation of unused prescription drugs. The bill would require the Department of State Health Services (DSHS) to develop a form for donors and recipients participating in the program and establish and maintain an electronic database of participating providers. Additionally the bill would require the Health and Human Services Commission (HHSC) to adopt rules to implement the program. Based on the analysis provided by DSHS and HHSC, it is assumed the provisions of the bill can be implemented within existing resources.

**Local Government Impact**

No fiscal implication to units of local government is anticipated.

**Source Agencies:** 529 Health and Human Services Commission, 537 State Health Services, Department of

**LBB Staff:** UP, NB, CH, LR