

By: Sheffield

H.B. No. 2271

A BILL TO BE ENTITLED

AN ACT

relating to the prescription drug donation program; authorizing fees.

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

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

SUBCHAPTER M. PRESCRIPTION DRUG DONATION PROGRAM

Sec. 431.321. DEFINITIONS. In this subchapter:

(1) "Charitable drug donor" means:

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

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

(2) [~~a~~] "Charitable medical clinic" means a clinic, including a licensed pharmacy that is a community pharmaceutical access program provider, that provides medical care or drugs without charge or for a substantially reduced charge, complies with the insurance requirements of Chapter 84, Civil Practice and Remedies Code, and is exempt from federal income tax under Section 501(a) of the Internal Revenue Code of 1986 by being listed as an exempt organization in Section 501(c)(3) or 501(c)(4) of the code and is operated exclusively for the promotion of social welfare by being primarily engaged in promoting the common good and general

1 welfare of the people in a community.

2 (3) "Community pharmaceutical access program" means a
3 program offered by a licensed pharmacy under which the pharmacy
4 assists financially disadvantaged persons by providing access to
5 prescription drugs at no charge or at a substantially reduced
6 charge.

7 (4) "Department" means the Department of State Health
8 Services.

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

12 [(c)] "Manufacturer" means a person, other than a
13 charitable drug donor, as defined in Chapter 82, Civil Practice and
14 Remedies Code.

15 (6) "Patient [(d) "Charitable drug donor" means a
16 licensed convalescent or nursing home or related institution,
17 licensed hospice, hospital, physician, pharmacy, or a
18 pharmaceutical seller or manufacturer that donates drugs pursuant
19 to a qualified patient assistance program, that donates drugs to a
20 charitable medical clinic.

21 [(d-1) In this subchapter, "community pharmaceutical access
22 program" means a program offered by a licensed pharmacy under which
23 the pharmacy assists financially disadvantaged persons to access
24 prescription drugs at no charge or at a substantially reduced
25 charge.

26 [(e) In this subchapter, "patient] assistance program"
27 means a qualified program offered by a pharmaceutical manufacturer

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

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

7 (8) "Program" means the prescription drug donation
8 program under this subchapter.

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

12 Sec. 431.322. DONATION OF UNUSED DRUGS [~~TO CHARITABLE~~
13 ~~MEDICAL CLINIC~~]. (a) A charitable drug donor may donate certain
14 unused prescription drugs to the department for the program under
15 ~~[a charitable medical clinic, and a charitable clinic may accept,~~
16 ~~dispense, or administer the donated drugs in accordance with]~~ this
17 subchapter.

18 (b) A seller or manufacturer of a drug may not donate drugs
19 to the department ~~[a charitable medical clinic]~~ except under
20 ~~[pursuant to]~~ a qualified patient assistance program. A seller or
21 manufacturer of a drug that donates drugs through a qualified
22 patient assistance program is ~~[shall be]~~ considered a charitable
23 drug donor.

24 (c) A ~~[The]~~ charitable drug donor shall use appropriate
25 safeguards established by the department ~~[board]~~ to ensure that the
26 drugs are not compromised or illegally diverted while being stored
27 or transported ~~[to the charitable medical clinic]~~.

1 (d) The department [~~charitable medical clinic~~] may not
2 accept the donated drugs unless:

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

6 (2) the charitable drug donor provides the department
7 [~~clinic~~] with a verifiable address and telephone number; and

8 (3) the person transferring possession of the drugs
9 presents [~~the charitable medical clinic with~~] photographic
10 identification.

11 Sec. 431.323. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY
12 BE ACCEPTED [~~AND DISPENSED~~]. (a) The department [~~A charitable~~
13 ~~medical clinic~~] may accept [~~and dispense or administer~~] donated
14 drugs only in accordance with this subchapter.

15 (b) The donated drugs must be:

16 (1) [~~drugs that require a~~] prescription drugs;

17 (2) [~~. A donated drug may not be a controlled substance~~
18 ~~under Chapter 481.~~

19 [~~(c) The donated drugs must be~~] approved by the federal Food
20 and Drug Administration and:

21 (A) [~~(1) be~~] sealed in the manufacturer's
22 unopened original tamper-evident packaging and either:

23 (i) [~~(A)~~] individually packaged; or

24 (ii) [~~(B)~~] packaged in unit-dose packaging;

25 (B) [~~(2)~~] be oral [~~or parenteral~~] medication in
26 sealed single-dose containers approved by the federal Food and Drug
27 Administration; or

1 (C) [~~3~~] be topical or inhalant drugs in sealed
2 units-of-use containers approved by the federal Food and Drug
3 Administration.

4 (c) Donated drugs may [~~or~~
5 [~~4~~] ~~be parenteral medication in sealed multiple-dose~~
6 ~~containers approved by the federal Food and Drug Administration~~
7 ~~from which no doses have been withdrawn; and~~

8 [~~5~~] ~~must~~] not:

9 (1) be the subject of a mandatory recall by a state or
10 federal agency or a voluntary recall by a drug seller or
11 manufacturer;

12 (2) be adulterated or misbranded;

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

14 (4) be a parenteral or injectable medication;

15 (5) require refrigeration; or

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

18 (d) The department [~~charitable medical clinic~~] may
19 distribute [~~dispense or administer~~] the donated drugs only[~~+~~

20 [~~1~~] ~~before the expiration date or within the~~
21 ~~recommended shelf life of the donated drugs, as applicable; and~~

22 [~~2~~] after a licensed pharmacist has determined that
23 the drugs are of an acceptable integrity.

24 (e) The department may not charge a fee for the drugs
25 donated under the program other than a nominal handling fee to
26 defray the costs incurred in implementing the program under this
27 subchapter.

1 (f) The department may not resell the drugs donated under
2 the program.

3 Sec. 431.3231. DISPENSATION OF DONATED DRUGS. (a)

4 ~~[(e)]~~ The donated drugs may be accepted and dispensed or
5 administered only by:

6 (1) a ~~the~~ charitable medical clinic; or

7 (2) a physician's office using the drugs for patients
8 who receive assistance from the medical assistance program under
9 Chapter 32, Human Resources Code ~~[only in accordance with rules~~
10 ~~adopted by the department]~~.

11 (b) A prescription drug dispensed or administered to a
12 patient under the program must be prescribed by a practitioner for
13 use by that patient.

14 (c) The clinic or physician dispensing or administering the
15 drug may charge a nominal handling fee in an amount prescribed by
16 department rule.

17 (d) A clinic or physician receiving donated drugs may not
18 resell the drugs.

19 Sec. 431.3232. CENTRAL DRUG REPOSITORY. The department
20 shall establish a location to centrally store drugs donated under
21 this subchapter for disbursement to qualifying recipients.

22 Sec. 431.3233. DATABASE OF DONATED DRUGS. The department
23 shall establish and maintain an electronic database in which:

24 (1) the department shall list the name and quantity of
25 each drug donated to the department under the program; and

26 (2) a charitable medical clinic or physician may
27 search for and request donated drugs.

1 Sec. 431.324. RULES. The executive commissioner of the
2 Health and Human Services Commission [~~department~~] shall adopt rules
3 to implement this subchapter that are designed to protect the
4 public health and safety, including:

5 (1) the maximum handling fee that may be imposed by a
6 clinic or physician dispensing or administering a donated drug;

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

9 (3) any necessary forms for the administration of the
10 program.

11 Sec. 431.325. LIMITATION ON CIVIL AND CRIMINAL LIABILITY.

12 (a) Charitable drug donors, charitable medical clinics,
13 physicians, and their employees are not civilly or criminally
14 liable or subject to professional disciplinary action for harm
15 caused by the [~~accepting,~~] dispensing[~~,~~] or administering of drugs
16 donated under [~~in strict compliance with~~] this subchapter unless
17 the harm is caused by:

18 (1) wilful [~~(i) willful~~] or wanton acts of
19 negligence;

20 (2) [~~(ii)~~] conscious indifference or reckless
21 disregard for the safety of others; or

22 (3) [~~(iii)~~] intentional conduct.

23 (b) This section does not limit, or in any way affect or
24 diminish, the liability of a drug seller or manufacturer under
25 [~~pursuant to~~] Chapter 82, Civil Practice and Remedies Code.

26 (c) This section does [~~shall~~] not apply if the [~~where~~] harm
27 results from the failure to [~~fully and completely~~] comply with the

1 requirements of this subchapter.

2 (d) This section does [~~shall~~] not apply to a charitable
3 medical clinic that fails to comply with the insurance provisions
4 of Chapter 84, Civil Practice and Remedies Code.

5 SECTION 2. Not later than December 1, 2015:

6 (1) the executive commissioner of the Health and Human
7 Services Commission shall adopt any rules necessary to implement
8 Subchapter M, Chapter 431, Health and Safety Code, as amended by
9 this Act; and

10 (2) the Department of State Health Services shall
11 establish the central repository and database required by
12 Subchapter M, Chapter 431, Health and Safety Code, as amended by
13 this Act.

14 SECTION 3. (a) The change in law made by this Act applies
15 only to a drug that is donated, accepted, dispensed, or
16 administered on or after January 1, 2016.

17 (b) Notwithstanding Subsection (a) of this section, a
18 charitable medical clinic that, on January 1, 2016, possesses drugs
19 donated under Subchapter M, Chapter 431, Health and Safety Code, as
20 it existed immediately before the effective date of this Act, may
21 dispense those remaining drugs in accordance with the former law.

22 SECTION 4. This Act takes effect September 1, 2015.