

By: Burton

S.B. No. 382

A BILL TO BE ENTITLED

AN ACT

relating to donation of unused prescription drugs; authorizing a fee.

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

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:

CHAPTER 442. DONATION OF PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Donor" means an individual who donates unused prescription drugs under this chapter to a participating provider.

(2) "Health care facility" means:

(A) a general or special hospital as defined by Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243;

(C) an institution licensed under Chapter 242; or

(D) any other facility that provides health care services to patients and is authorized to maintain an inventory of prescription drugs for dispensing to the facility's patients or residents.

(3) "Health care professional" means an individual licensed, certified, or otherwise authorized to administer health care and prescribe prescription drugs, for profit or otherwise, in

1 the ordinary course of business or professional practice. The term
2 does not include a health care facility.

3 (4) "Participating provider" means a health care
4 facility, pharmacy, or health care professional who elects to
5 participate in the collection and redistribution of donated
6 prescription drugs under this chapter.

7 (5) "Pharmacy" means an entity licensed under Chapter
8 560, Occupations Code.

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

11 (7) "Recipient" means an individual who voluntarily
12 receives donated prescription drugs under this chapter.

13 (8) "Tamper-evident" means packaging that allows for
14 detection of unauthorized access to a prescription drug.

15 Sec. 442.002. RULEMAKING AUTHORITY. The executive
16 commissioner may adopt rules to implement this chapter.

17 Sec. 442.003. CONSTRUCTION WITH OTHER LAW. This chapter
18 does not limit the authority of this state or a political
19 subdivision of this state to regulate or prohibit a prescription
20 drug.

21 SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION
22 DRUGS

23 Sec. 442.051. DONATION AND REDISTRIBUTION OF PRESCRIPTION
24 DRUGS. (a) A donor may donate unused prescription drugs to a
25 participating provider in accordance with this chapter and rules
26 adopted under this chapter.

27 (b) A participating provider may dispense donated

1 prescription drugs to a recipient in accordance with this chapter
2 and rules adopted under this chapter.

3 Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION.

4 (a) The executive commissioner by rule shall adopt standards and
5 procedures for:

6 (1) accepting, storing, labeling, and dispensing
7 donated prescription drugs; and

8 (2) inspecting donated prescription drugs to
9 determine whether the drugs are adulterated and whether the drugs
10 are safe and suitable for redistribution.

11 (b) In adopting standards and procedures under this
12 section, the executive commissioner shall ensure that the donation
13 and redistribution process is consistent with public health and
14 safety standards.

15 Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS.

16 (a) A donated prescription drug may be accepted or dispensed under
17 this chapter only if the drug is in its original, unopened, sealed,
18 and tamper-evident unit-dose packaging. A drug packaged in single
19 unit doses may be accepted and dispensed if the outside packaging is
20 opened but the single unit-dose packaging is unopened.

21 (b) A donated prescription drug may not be accepted or
22 dispensed under this chapter if the drug:

23 (1) is a controlled substance under Chapter 481;

24 (2) is a drug required by the United States Food and
25 Drug Administration to have a risk evaluation or mitigation
26 strategy;

27 (3) is adulterated or misbranded; or

1 (4) is not stored in compliance with the drug's product
2 label.

3 (c) A participating provider shall comply with all
4 applicable provisions of state and federal law relating to the
5 inspection, storage, labeling, and dispensing of prescription
6 drugs.

7 Sec. 442.054. DONATION PROCESS. (a) Before being
8 dispensed to a recipient, a prescription drug donated under this
9 chapter must be inspected by a health care professional on behalf of
10 the participating provider in accordance with federal law, laws of
11 this state, and department rule to determine whether the drug is
12 adulterated or misbranded and whether the drug has been stored in
13 compliance with the requirements of the product label.

14 (b) A donated prescription drug dispensed to a recipient
15 under this chapter must be prescribed by a health care professional
16 for use by the recipient.

17 (c) A participating provider may charge a handling fee not
18 to exceed \$20 to a recipient to cover the costs of inspecting,
19 storing, labeling, and dispensing the donated prescription drug. A
20 participating provider may not resell a prescription drug donated
21 under this chapter. A donor may not sell a prescription drug to a
22 participating provider.

23 (d) A participating provider may not submit a claim or
24 otherwise seek reimbursement from any public or private third-party
25 payor for donated prescription drugs dispensed to a recipient under
26 this chapter. A public or private third-party payor is not required
27 to provide reimbursement for donated drugs dispensed to a recipient

1 under this chapter.

2 Sec. 442.055. DONOR FORM. Before donating a prescription
3 drug under this chapter, a donor shall sign a form prescribed by the
4 department stating that:

5 (1) the donor is the owner of the donated prescription
6 drug;

7 (2) the donated prescription drug has been properly
8 stored in an unopened, tamper-evident package;

9 (3) the donated prescription drug has not been
10 adulterated or misbranded; and

11 (4) the donor is voluntarily donating the prescription
12 drug.

13 Sec. 442.056. RECIPIENT FORM. Before accepting a donated
14 prescription drug under this chapter, a recipient shall sign a form
15 prescribed by the department stating that:

16 (1) the recipient acknowledges that the donor is not a
17 pharmacist and the donor took ordinary care of the prescription
18 drug;

19 (2) the recipient acknowledges that the donor is known
20 to the participating provider and that the recipient is unaware of
21 any reason to believe the prescription drug was improperly handled
22 or stored;

23 (3) by accepting the prescription drug, the recipient
24 accepts any risk that an accidental mishandling could create; and

25 (4) the recipient releases the donor, participating
26 provider, and manufacturer of the drug from liability related to
27 the prescription drug.

1 Sec. 442.057. LIMITATION OF LIABILITY. (a) A donor or
2 participating provider who acts in good faith in donating,
3 accepting, storing, labeling, distributing, or dispensing
4 prescription drugs under this chapter:

5 (1) is not criminally liable and is not subject to
6 professional disciplinary action for those activities; and

7 (2) is not civilly liable for damages for bodily
8 injury, death, or property damage that arises from those activities
9 unless the injury, death, or damage arises from the donor or
10 participating provider's recklessness or intentional conduct.

11 (b) A manufacturer of a prescription drug donated under this
12 chapter is not liable for bodily injury, death, or property damage
13 arising from a donor or participating provider's failure to
14 properly handle or store the drug. This subsection does not limit
15 the liability of the manufacturer for a dangerous or defective
16 drug.

17 Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The
18 department shall establish and maintain an electronic database that
19 lists each participating provider. The department shall post the
20 database on its Internet website.

21 SECTION 2. Subchapter O, Chapter 431, Health and Safety
22 Code, is repealed.

23 SECTION 3. Not later than December 1, 2017, the executive
24 commissioner of the Health and Human Services Commission shall
25 adopt the rules necessary for the implementation of Chapter 442,
26 Health and Safety Code, as added by this Act.

27 SECTION 4. If before implementing any provision of this Act

1 a state agency determines that a waiver or authorization from a
2 federal agency is necessary for implementation of that provision,
3 the agency affected by the provision shall request the waiver or
4 authorization and may delay implementing that provision until the
5 waiver or authorization is granted.

6 SECTION 5. This Act takes effect September 1, 2017.