

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 facility that provides health care services to patients and maintains a pharmacy in the facility. The term includes the following facilities if a pharmacy is maintained in the facility:

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

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

(C) an institution licensed under Chapter 242.

(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 the ordinary course of business or professional practice. The term

1 does not include a health care facility.

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

7 (5) "Pharmacist" means a person licensed under Chapter  
8 558, Occupations Code.

9 (6) "Pharmacy" means an entity licensed under Chapter  
10 560, Occupations Code.

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

13 (8) "Recipient" means an individual who voluntarily  
14 receives donated prescription drugs under this chapter.

15 (9) "Tamper-evident" means packaging that allows for  
16 detection of unauthorized access to a prescription drug.

17 Sec. 442.002. RULEMAKING AUTHORITY. The executive  
18 commissioner may adopt rules to implement this chapter.

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

23 SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION

24 DRUGS

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

1 adopted under this chapter.

2 (b) A participating provider may dispense donated  
3 prescription drugs to a recipient in accordance with this chapter  
4 and rules adopted under this chapter.

5 Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION.

6 (a) The executive commissioner by rule shall adopt standards and  
7 procedures for:

8 (1) accepting, storing, labeling, and dispensing  
9 donated prescription drugs; and

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

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

17 Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS.

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

23 (b) A donated prescription drug may not be accepted or  
24 dispensed under this chapter if:

25 (1) the drug is a controlled substance;

26 (2) the drug is adulterated or misbranded;

27 (3) the drug is not stored in compliance with the

1 drug's product label; or

2 (4) the United States Food and Drug Administration  
3 requires the drug to have a risk evaluation or mitigation strategy.

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

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

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

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

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

1 to provide reimbursement for donated drugs dispensed to a recipient  
2 under this chapter.

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

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

8 (2) the donated prescription drug has been properly  
9 stored and the container has not been opened or tampered with;

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

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

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

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

20 (2) the recipient acknowledges that the donor is known  
21 to the participating provider and that there is no reason to believe  
22 that the prescription drug was improperly handled 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 that donates a  
12 drug under this chapter is not, in the absence of bad faith,  
13 criminally or civilly liable for bodily injury, death, or property  
14 damage arising from the donation, acceptance, or dispensing of the  
15 drug, including the manufacturer's failure to communicate to a  
16 donor or other person:

17           (1) product or consumer information about the donated  
18 prescription drug; or

19           (2) the expiration date of the donated prescription  
20 drug.

21       Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The  
22 department shall establish and maintain an electronic database that  
23 lists each participating provider. The department shall post the  
24 database on its Internet website.

25       SECTION 2. Not later than December 1, 2017, the executive  
26 commissioner of the Health and Human Services Commission shall  
27 adopt the rules necessary for the implementation of Chapter 442,

1 Health and Safety Code, as added by this Act.

2           SECTION 3. If before implementing any provision of this Act  
3 a state agency determines that a waiver or authorization from a  
4 federal agency is necessary for implementation of that provision,  
5 the agency affected by the provision shall request the waiver or  
6 authorization and may delay implementing that provision until the  
7 waiver or authorization is granted.

8           SECTION 4. This Act takes effect September 1, 2017.