

By: Burton

S.B. No. 1243

A BILL TO BE ENTITLED

AN ACT

relating to donation of unused prescription drugs.

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) "Department" means the Department of State Health Services.

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

(3) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(4) "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.



1 participating provider in accordance with this chapter and rules  
2 adopted under this chapter.

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

6 Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION.

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

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

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

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

18 Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS.

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

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

26 (1) is a controlled substance;

27 (2) is a drug required by the United States Food and

1 Drug Administration to have a risk evaluation or mitigation  
2 strategy;

3 (3) is adulterated or misbranded; or

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

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

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

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

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

26 (d) A participating provider may not submit a claim or  
27 otherwise seek reimbursement from any public or private third-party

1 payor for donated prescription drugs dispensed to a recipient under  
2 this chapter. A public or private third-party payor is not required  
3 to provide reimbursement for donated drugs dispensed to a recipient  
4 under this chapter.

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

8 (1) the donor is the owner of the donated prescription  
9 drug;

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

12 (3) the donated prescription drug has not been  
13 adulterated or misbranded; and

14 (4) the donor is voluntarily donating the prescription  
15 drug.

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

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

22 (2) the recipient acknowledges that the donor is known  
23 to the participating provider and that there is no reason to believe  
24 that the prescription drug was improperly handled or stored;

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

27 (4) the recipient releases the donor, participating

1 provider, and manufacturer of the drug from liability related to  
2 the prescription drug.

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

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

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

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

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

23 SECTION 2. Not later than December 1, 2015, the executive  
24 commissioner of the Health and Human Services Commission shall  
25 adopt any necessary rules for the implementation of Chapter 442,  
26 Health and Safety Code, as added by this Act.

27 SECTION 3. 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 4. This Act takes effect September 1, 2015.