By: Burton S.B. No. 382

(In the Senate - Filed December 20, 2016; February 1, 2017, read first time and referred to Committee on Health & Human Services; April 26, 2017, reported adversely, with favorable Committee Substitute by the following vote: Yeas 9, Nays 0; April 26, 2017, sent to printer.)

COMMITTEE VOTE

	Yea	Nay	Absent	PNV
Schwertner	X			
Uresti	X			
Buckingham	X			
Burton	X			
Kolkhorst	X			
Miles	X			
Perry	X			
Taylor of Collin	X			
Watson	X			

COMMITTEE SUBSTITUTE FOR S.B. No. 382 By: Burton

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 does not include a health care facility.

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

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

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

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

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

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

Sec. 442.002. RULEMAKING AUTHORITY. The executive

commissioner may adopt rules to implement this chapter.

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

SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS

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

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

Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION. (a) The executive commissioner by rule shall adopt standards and procedures for:

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

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

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

Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS. (a) A donated prescription drug may be accepted or dispensed under this chapter only if the drug is in its original, unopened, sealed, and tamper-evident unit-dose packaging. A drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single unit-dose packaging is unopened.

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

(1) the drug is a controlled substance;

(2) the drug is adulterated or misbranded;

(3) the drug is not stored in compliance with the drug's product label; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) A manufacturer of a prescription drug that donates a drug under this chapter is not, in the absence of bad faith, criminally or civilly liable for bodily injury, death, or property damage arising from the donation, acceptance, or dispensing of the drug, including the manufacturer's failure to communicate to a donor or other person:

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

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

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

SECTION 2. Not later than December 1, 2017, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary for the implementation of Chapter 442, Health and Safety Code, as added by this Act.

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

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

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