

BILL ANALYSIS

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S.B. 1243
By: Burton
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Current Texas statute requires that unused prescription drugs be disposed of. Pills can go unused when a patient recovers from an illness sooner than expected, or switches to other medications. Nursing facilities and hospitals can throw away numerous pills each year. Providing a means to donate those unused drugs can provide an alternate means of obtaining treatment for individuals who may not be able to afford the hundreds or thousands of dollars needed for some medications.

S.B. 1537 establishes an expanded charitable pharmaceutical donation program in Texas under the purview of the Department of State Health Services. The program is designed to allow participating health care facilities to donate unused prescription drugs to other providers, subject to inspection of the drugs for safety.

This bill is modeled after a New Mexico law that was codified in 2011. Conversations with New Mexico House of Representative staff have not identified any problems with their program implementation.

Prominent provisions of the bill include:

- A method for the patient drug "donor" to donate their unused drugs to a qualified "participating drug provider."
- A requirement that the executive commissioner of the Health and Human Services Commission adopt regulatory standards for the acceptance, storage, labeling and dispensing of the donated drugs. Additionally, the statutory procedures require that all regulatory procedures comply with public health and safety standards.
- A requirement that only unused, unopened drug containers can be accepted for donation.
- A prohibition that no controlled substances can be donated nor can a drug that has been identified as a drug that has a high risk evaluation, a drug that is adulterated/misbranded or a drug that has not been properly stored.
- A codified donation process with a donor form.
- A codified recipient process with a recipient form with a waiver of liability.
- A statutory limitation of liability for the manufacturer, participating drug provider, and donor.
- A requirement to be in compliance with all applicable laws including federal law.

Several questions need to be answered in the regulatory codification of this bill including:

- Although many parts of the program are spelled out in the bill, the implementation of the bill will take very careful consideration of the executive commissioner of the Health and Human Services Commission.

As proposed, S.B. 1243 amends current law relating to donation of unused prescription drugs.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 442.002 and 442.052, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle A, Title 6, Health and Safety Code, by adding Chapter 442, as follows:

CHAPTER 442. DONATION OF PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442.001. DEFINITIONS. Defines "department," "donor," "executive commissioner," "health care facility," "health care professional," "participating provider," "pharmacy," "prescription drug," "recipient," and "tamper-evident."

Sec. 442.002. RULEMAKING AUTHORITY. Authorizes the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules to implement this chapter.

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

[Reserves Sections 442.004-442.050 for expansion.]

SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS

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

(b) Authorizes a participating provider to 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) Requires the executive commissioner by rule to 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) Requires the executive commissioner, in adopting standards and procedures under this section, to ensure that the donation and redistribution process is consistent with public health and safety standards.

Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS. (a) Provides that 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. Authorizes a drug packaged in single unit doses to be accepted and dispensed if the outside packaging is opened but the single unit-dose packaging is unopened.

(b) Prohibits a donated prescription from being accepted or dispensed under this chapter if the drug:

(1) is a controlled substance;

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

(3) is adulterated or misbranded; or

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

(c) Requires a participating provider to 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) Requires that a prescription drug donated under this chapter, before being dispensed to a recipient, be inspected by a health care professional on behalf of the participating provider in accordance with federal law, laws of this state, and Department of State Health Services (DSHS) 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) Requires that a donated prescription drug dispensed to a recipient under this chapter be prescribed by a health care professional for use by the recipient.

(c) Authorizes a participating provider to 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. Prohibits a participating provider from reselling a prescription drug donated under this chapter. Prohibits a donor from selling a prescription drug to a participating provider.

(d) Prohibits a participating provider from submitting a claim or otherwise seeking reimbursement from any public or private third-party payor for donated prescription drugs dispensed to a recipient under this chapter. Provides that 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. Requires a donor, before donating a prescription drug under this chapter, to sign a form prescribed by DSHS 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. Requires a recipient, before accepting a donated prescription drug under this chapter, to sign a form prescribed by DSHS 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) Provides that 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) Provides that a manufacturer of a prescription drug donated under this chapter is not liable for bodily injury, death, or property damage arising from a donor or participating provider's failure to properly handle or store the drug. Provides that this subsection does not limit the liability of the manufacturer for a dangerous or defective drug.

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

SECTION 2. Requires the executive commissioner, not later than December 1, 2015, to adopt any necessary rules for the implementation of Chapter 442, Health and Safety Code, as added by this Act.

SECTION 3. Requires a state agency, if necessary for implementation of a provision of this Act, to request a waiver or authorization from a federal agency, and authorizes a delay of implementation until such a waiver or authorization is granted.

SECTION 5. Effective date: September 1, 2015.