

BILL ANALYSIS

Senate Research Center
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S.B. 382
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Health & Human Services
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The 84th Texas Legislature passed S.B. 1243, establishing a pilot program in certain cities allowing for the donation of certain unused prescription drugs. Under the current statutory design of the program, hospitals, drug manufacturers, healthcare facilities, physicians, and pharmacists can donate certain unused prescription drugs to the Department of State Health Services (DSHS). DSHS then inspects the drugs to certify their integrity and quality and must log the drugs in an electronic database and store them in a central depository until they are dispensed. The donated drugs are then distributed and administered to certain limited patient populations; these populations include patients in a charitable medical clinic, patients who receive treatment under Medicaid, indigent patients, and patients in a penal institution.

Although the program passed into law, it was never implemented. The agency cited a five-year fiscal implication of nearly \$2,000,000 that was not anticipated or reported when the legislation was passed. Also, the program was limited to operate in cities with a population of between 500,000 and one million persons. This currently relegates the program to operate in Fort Worth, El Paso, and Austin. As originally filed, S.B. 1243 allowed for statewide peer-to-peer drug donation supervised by a professional healthcare provider with a limitation on donor and provider liability.

S.B. 382 replaces the drug donation pilot program created under S.B. 1243 (Subchapter O, Chapter 431, Health and Safety Code) with a new, decentralized, statewide drug donation model. Under this new model, an individual can donate unused, sealed prescription drugs to a healthcare facility, pharmacy, or doctor who participates in the drug donation program as a participating provider. Upon receipt of a donated drug, a participating provider inspects the drugs to ensure their integrity. A participating provider may then dispense the donated drugs to patients with a prescription. DSHS must create an online database of participating providers and must establish rules for the donation, inspection, and redistribution of donated drugs. The legislation also contains a general release of liability for drug donors, participating providers, and drug manufacturers that must be agreed to by recipients of donated drugs.

Supporters of this legislation contend that donated drugs can benefit individuals who cannot afford certain medications that would otherwise go to waste.

Opponents fear that donated drugs would be adulterated, misbranded, or otherwise less effective than newly purchased drugs.

As proposed, S.B. 382 amends current law relating to donation of unused prescription drugs and authorizes a fee.

RULEMAKING AUTHORITY

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

Rulemaking authority previously granted to the Department of State Health Services is rescinded in SECTION 2 (Section 431.458, 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 "donor," "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 Texas 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.

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.

(b) Authorizes a participating provider to dispense donated prescription drugs to a recipient.

Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION. (a) Requires the executive commissioner by rule to adopt standards and procedures for accepting, storing, labeling, and dispensing donated prescription drugs; and 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, 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) Authorizes a donated prescription drug to be accepted or dispensed 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 drug from being accepted or dispensed if the drug is a controlled substance under Chapter 481 (Texas Controlled Substances Act), is a drug required by the United States Food and Drug Administration to have a risk evaluation or mitigation strategy, is adulterated or misbranded, or 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 donated prescription drug, before being dispensed to a recipient, be inspected by a health care professional on behalf of the participating provider in accordance with federal and state laws 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 a recipient to 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 provider from reselling a donated prescription drug. Prohibits a donor from selling a prescription drug to a 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. Provides that a public or private third-party payor is not required to provide reimbursement for donated drugs dispensed to a recipient.

Sec. 442.055. DONOR FORM. Requires a donor, before donating a prescription drug, to sign a form prescribed by DSHS stating that the donor is the owner of the donated drug, the donated drug has been properly stored in an unopened, tamper-evident package, the donated drug has not been adulterated or misbranded, and the donor is voluntarily donating the drug.

Sec. 442.056. RECIPIENT FORM. Requires a recipient, before accepting a donated prescription drug, to sign a form prescribed by DSHS stating certain acknowledgements relating to the donation and storage of the drug and release of liability for the donor.

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 is not criminally liable and is not subject to professional disciplinary action for those activities, and is not civilly liable for damages for bodily injury, death, or property damage unless the injury, death, or damage arises from the participating provider's recklessness or intentional conduct.

(b) Provides that a manufacturer of a donated prescription drug is not liable for bodily injury, death, or property damage arising from a donor or 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, and requires DSHS to post the database on its Internet website.

SECTION 2. Repealer: Subchapter O, (Prescription Drug Donation Pilot Program), Chapter 431, Health and Safety Code.

SECTION 3. Requires the executive commissioner to adopt the rules necessary for the implementation of Chapter 442, Health and Safety Code, as added by this Act, not later than December 1, 2017.

SECTION 4. 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, 2017.