BILL ANALYSIS

C.S.S.B. 1243
By: Burton
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

It has been reported that, in the United States, unused medications may account for as much as $1 billion each year in wasted drug costs. Interested parties assert that the majority of the medications are left unused, especially in the nursing home setting, as a result of a change in prescription, a death, or the transfer of a patient or resident and that many of these medications remain in the manufacturer's original, sealed, and tamper-evident bulk unit of dose packaging known as a blister pack. The parties, noting that many states have enacted laws and programs to recycle such unused medications, contend that these medications are wasted at the expense of taxpayers. C.S.S.B. 1243 seeks to establish a similar program in Texas.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

C.S.S.B. 1243 amends the Health and Safety Code to require the Department of State Health Services (DSHS) to establish a pilot program for the donation and redistribution of prescription drugs and conduct the pilot program in one or more municipalities with a population of more than 500,000 but less than one million. The bill authorizes a charitable drug donor to donate certain unused prescription drugs to DSHS for the pilot program. The bill defines "charitable drug donor" as a licensed convalescent or nursing facility or related institution, licensed hospice, hospital, physician, or pharmacy; a pharmaceutical seller or manufacturer that donates drugs under a qualified patient assistance program; or the licensed health care professional responsible for administration of drugs in a penal institution in Texas.

C.S.S.B. 1243 requires a charitable drug donor to use appropriate safeguards established by DSHS rule to ensure that the drugs are not compromised or illegally diverted while being stored or transported. The bill prohibits DSHS from accepting the donated drugs unless the charitable drug donor certifies that the drugs have been properly stored while in the possession of the donor or of the person for whom the drugs were originally dispensed, the charitable drug donor provides DSHS with a verifiable address and telephone number, and the person transferring possession of the drugs presents photographic identification.

C.S.S.B. 1243 authorizes DSHS to accept donated drugs only in accordance with the bill's provisions. The bill requires the donated drugs to be prescription drugs approved by the U.S. Food and Drug Administration (FDA) and to be sealed in unopened tamper-evident unit dose

packaging, be oral medication in sealed single-dose containers approved by the FDA, or be topical or inhalant drugs in sealed units-of-use containers approved by the FDA. The bill authorizes a drug packaged in single unit doses to be accepted and distributed if the outside packaging is opened but the single unit dose packaging is unopened. The bill prohibits the donated drugs from being the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer, being adulterated or misbranded, being a controlled substance under the Texas Controlled Substances Act, being a parenteral or injectable medication, requiring refrigeration, or expiring less than 60 days after the date of the donation. The bill authorizes DSHS to distribute the donated drugs only after a licensed pharmacist has determined that the drugs are of an acceptable integrity. The bill prohibits DSHS from charging a fee for the drugs donated under the pilot program other than a nominal handling fee to defray the costs incurred in implementing the pilot program and from reselling the drugs donated under the pilot program.

C.S.S.B. 1243 authorizes the donated drugs to be accepted and provided or administered to patients only by a charitable medical clinic as defined by the Texas Food, Drug, and Cosmetic Act, a physician's office using the drugs for patients who receive assistance from Medicaid or for other indigent health care, or a licensed health care professional responsible for administration of drugs in a penal institution in Texas. The bill requires a prescription drug provided or administered to a patient under the pilot program to be prescribed by a practitioner for use by that patient. The bill authorizes the clinic or physician providing or administering the drug to charge a nominal handling fee in an amount prescribed by DSHS rule. The bill prohibits a clinic, physician, or other licensed health care professional receiving donated drugs from reselling the drugs.

C.S.S.B. 1243 requires DSHS, not later than December 1, 2015, to establish a location to centrally store drugs donated under the pilot program for distribution to qualifying recipients and to establish and maintain an electronic database in which DSHS is required to list the name and quantity of each drug donated to DSHS under the pilot program and in which a charitable medical clinic, physician, or other licensed health care professional is authorized to search for and request donated drugs. The bill requires its provisions to be governed by DSHS rules that are designed to protect the public health and safety and that include information regarding a handling fee, database maintenance, and certain forms.

C.S.S.B. 1243 establishes that charitable drug donors, manufacturers and sellers of donated drugs, charitable medical clinics, physicians, penal institutions, and their employees acting in good faith in providing or administering prescription drugs under the pilot program are not civilly or criminally liable or subject to professional disciplinary action for harm caused by providing or administering drugs donated under the pilot program unless the harm is caused by wilful or wanton acts of negligence, conscious indifference or reckless disregard for the safety of others, or intentional conduct. This bill specifies that this limitation on liability does not apply if the harm results from the failure to comply with the bill's provisions and does not apply to a charitable medical clinic that fails to comply with the insurance provisions of the Charitable Immunity and Liability Act of 1987.

C.S.S.B. 1243 requires DSHS, not later than January 1 of each odd-numbered year, to report to the legislature on the results of the pilot program and prescribes the information to be included in the report. The bill requires DSHS, as soon as practicable after the bill's effective date, to conduct a study to determine the feasibility of establishing a program under which a hospital, a nursing facility, or another health facility may transfer to DSHS, or an entity designated by DSHS, for no payment, unused drugs the cost for which the hospital, nursing facility, or health facility received reimbursement under Medicaid and under which DSHS, or the entity designated by DSHS, distributes to public hospitals the unused drugs transferred to DSHS or the entity designated by DSHS. The bill requires DSHS, in conducting the study, to consider the rules the executive commissioner of the Health and Human Services Commission may need to adopt to implement the program described in the study, including rules that provide for certain

information as specified by the bill. The bill requires DSHS, not later than September 1, 2016, to submit a report to the legislature containing the findings of the study. The bill applies only to a drug that is donated, accepted, provided, or administered on or after January 1, 2016.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 1243 may differ from the engrossed in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the engrossed and committee substitute versions of the bill.

SENATE ENGROSSED	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:	No equivalent provision. *(But see SECTION 1 below.)*
CHAPTER 442. DONATION OF PRESCRIPTION DRUGS	
SUBCHAPTER A. GENERAL PROVISIONS	
Sec. 442.001. DEFINITIONS. In this chapter:	No equivalent provision.
(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.	
(5) "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.	
(6) "Participating provider" means a health care facility, pharmacy, or health care professional who elects to participate in the	

collection and redistribution of donated prescription drugs under this chapter.

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

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

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

(10) "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.

No equivalent provision.

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.

No equivalent provision.

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.

No equivalent provision.

(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:

No equivalent provision.

(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,

No equivalent provision.

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 the drug:

(1) is a controlled substance;

(2) is adulterated or misbranded; or

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

(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 a health care professional on behalf of 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.

No equivalent provision.

(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:

No equivalent provision.

(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.

No equivalent provision.

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 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. This subsection does not limit the liability of the manufacturer for a dangerous or defective drug.

No equivalent provision.

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, 2015, the executive commissioner of the Health and Human Services Commission shall adopt any necessary rules for the implementation of Chapter 442, Health and Safety Code, as added by this Act.	No equivalent provision.
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.	No equivalent provision.
No equivalent provision. *(But see SECTION 1 above.)*	SECTION 1. Chapter 431, Health and Safety Code, is amended by adding Subchapter O to read as follows: SUBCHAPTER O. PRESCRIPTION DRUG DONATION PILOT PROGRAM
No equivalent provision.	Sec. 431.451. DEFINITIONS. In this subchapter: (1) "Charitable drug donor" means: (A) a licensed convalescent or nursing facility or related institution, licensed hospice, hospital, physician, or pharmacy; (B) a pharmaceutical seller or manufacturer that donates drugs under a qualified patient assistance program; or (C) the licensed health care professional responsible for administration of drugs in a penal institution, as defined by Section 1.07, Penal Code, in this state. (2) "Charitable medical clinic" has the meaning assigned by Section 431.321. (3) "Manufacturer" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code. (4) "Patient assistance program" means a qualified program offered by a pharmaceutical manufacturer under which the manufacturer provides drugs to financially disadvantaged persons at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial. (5) "Pilot program" means the prescription drug donation pilot program under this subchapter. (6) "Prescription drug" has the meaning

	assigned by Section 551.003, Occupations Code. (7) "Seller" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.
No equivalent provision.	Sec. 431.452. ESTABLISHMENT OF PILOT PROGRAM. (a) The department shall establish a pilot program for donation and redistribution of prescription drugs under this subchapter. (b) The department shall conduct the pilot program in one or more municipalities with a population of more than 500,000 but less than one million.
No equivalent provision.	Sec. 431.453. DONATION OF UNUSED DRUGS. (a) A charitable drug donor may donate certain unused prescription drugs to the department for the pilot program under this subchapter. (b) A seller or manufacturer of a drug that donates drugs through a qualified patient assistance program is considered a charitable drug donor. (c) A charitable drug donor shall use appropriate safeguards established by department rule to ensure that the drugs are not compromised or illegally diverted while being stored or transported. (d) The department may not accept the donated drugs unless: (1) the charitable drug donor certifies that the drugs have been properly stored while in the possession of the donor or of the person for whom the drugs were originally dispensed; (2) the charitable drug donor provides the department with a verifiable address and telephone number; and (3) the person transferring possession of the drugs presents photographic identification.
No equivalent provision.	Sec. 431.454. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY BE ACCEPTED. (a) The department may accept donated drugs only in accordance with this subchapter. (b) The donated drugs must be: (1) prescription drugs; and (2) approved by the federal Food and Drug Administration and: (A) sealed in unopened tamper-evident unit dose packaging; (B) be oral medication in sealed single-dose containers approved by the federal Food and Drug Administration; or (C) be topical or inhalant drugs in sealed

	units-of-use containers approved by the federal Food and Drug Administration. (c) A drug packaged in single unit doses may be accepted and distributed if the outside packaging is opened but the single unit dose packaging is unopened. (d) Donated drugs may not: (1) be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer; (2) be adulterated or misbranded; (3) be a controlled substance under Chapter 481; (4) be a parenteral or injectable medication; (5) require refrigeration; or (6) expire less than 60 days after the date of the donation. (e) The department may distribute the donated drugs only after a licensed pharmacist has determined that the drugs are of an acceptable integrity. (f) The department may not charge a fee for the drugs donated under the pilot program other than a nominal handling fee to defray the costs incurred in implementing the pilot program under this subchapter. (g) The department may not resell the drugs donated under the pilot program.
No equivalent provision.	Sec. 431.455. PRESCRIPTION, PROVISION, AND ADMINISTRATION OF DONATED DRUGS. (a) The donated drugs may be accepted and provided or administered to patients only by: (1) a charitable medical clinic; (2) a physician's office using the drugs for patients who receive assistance from the medical assistance program under Chapter 32, Human Resources Code, or for other indigent health care; or (3) a licensed health care professional responsible for administration of drugs in a penal institution, as defined by Section 1.07, Penal Code, in this state. (b) A prescription drug provided or administered to a patient under the pilot program must be prescribed by a practitioner for use by that patient. (c) The clinic or physician providing or administering the drug may charge a nominal handling fee in an amount prescribed by department rule. (d) A clinic, physician, or other licensed health care professional receiving donated drugs may not resell the drugs.
No equivalent provision.	Sec. 431.456. CENTRAL DRUG

	REPOSITORY. The department shall establish a location to centrally store drugs donated under this subchapter for distribution to qualifying recipients.
No equivalent provision.	Sec. 431.457. DATABASE OF DONATED DRUGS. The department shall establish and maintain an electronic database in which: (1) the department shall list the name and quantity of each drug donated to the department under the pilot program; and (2) a charitable medical clinic, physician, or other licensed health care professional may search for and request donated drugs.
No equivalent provision.	Sec. 431.458. RULES. This subchapter shall be governed by department rules that are designed to protect the public health and safety, including: (1) the maximum handling fee that may be imposed by a clinic or physician providing or administering a donated drug to a patient; (2) provisions for maintenance of the database of donated drugs; and (3) any necessary forms for the administration of the pilot program.
No equivalent provision.	Sec. 431.459. LIMITATION ON CIVIL AND CRIMINAL LIABILITY. (a) Charitable drug donors, manufacturers and sellers of donated drugs, charitable medical clinics, physicians, penal institutions, and their employees acting in good faith in providing or administering prescription drugs under the pilot program are not civilly or criminally liable or subject to professional disciplinary action for harm caused by providing or administering drugs donated under this subchapter unless the harm is caused by: (1) wilful or wanton acts of negligence; (2) conscious indifference or reckless disregard for the safety of others; or (3) intentional conduct. (b) This section does not apply if the harm results from the failure to comply with the requirements of this subchapter. (c) This section does not apply to a charitable medical clinic that fails to comply with the insurance provisions of Chapter 84, Civil Practice and Remedies Code.
No equivalent provision.	Sec. 431.460. REPORTS TO LEGISLATURE. Not later than January 1 of each odd-numbered year, the department shall report to the legislature on the results of the pilot program. The report must include:

(1) the pilot program's efficacy in expanding access to prescription medications;
(2) any cost savings to the state or local governments resulting from or projected to result from the pilot program;
(3) an evaluation of the pilot program's database and system of distribution;
(4) any health and safety issues posed by providing or administering donated drugs;
(5) recommendations on improvements to the pilot program; and
(6) an evaluation of potential expansion of the pilot program.

No equivalent provision.

SECTION 2. (a) As soon as practicable after the effective date of this Act, the Department of State Health Services shall conduct a study to determine the feasibility of establishing a program under which:
(1) a hospital, a nursing facility, or another health facility may transfer to the department, or an entity designated by the department, for no payment, unused drugs that the hospital, nursing facility, or health facility received reimbursement for the cost of under Medicaid; and
(2) the department, or the entity designated by the department, distributes to public hospitals the unused drugs transferred to the department or entity under Subdivision (1) of this subsection.
(b) In conducting the study under Subsection (a) of this section, the Department of State Health Services shall consider the rules the executive commissioner of the Health and Human Services Commission may need to adopt to implement the program described in Subsection (a) of this section, including rules that provide for:
(1) the types of unused drugs that may be transferred to the department or an entity designated by the department;
(2) the procedures for transferring unused drugs to the department or the entity designated by the department;
(3) the procedures for allocating and distributing the unused drugs to public hospitals; and
(4) the qualifications for an entity to be designated by the department to receive and distribute unused drugs under the program, including demonstrated expertise in handling, storing, and assessing prescription

	and nonprescription drugs and coordinating with the state's public hospital system. (c) Not later than September 1, 2016, the Department of State Health Services shall submit to the legislature a report containing the findings of the study conducted under Subsection (a) of this section.
No equivalent provision.	SECTION 3. Not later than December 1, 2015, the Department of State Health Services shall establish the central repository and database required by Subchapter O, Chapter 431, Health and Safety Code, as added by this Act.
No equivalent provision.	SECTION 4. The change in law made by this Act applies only to a drug that is donated, accepted, provided, or administered on or after January 1, 2016.
SECTION 4. This Act takes effect September 1, 2015.	SECTION 5. Same as engrossed version.