

BILL ANALYSIS

C.S.H.B. 2271
By: Sheffield
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 contend that these medications are wasted at the expense of taxpayers, noting that many states have enacted laws and programs to recycle such unused medications. C.S.H.B. 2271 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.H.B. 2271 amends the Health and Safety Code to require the Department of State Health Services (DSHS) to establish a pilot program for donation and redistribution of prescription drugs. The bill requires DSHS to 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 and 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. The bill establishes that a seller or manufacturer of a drug that donates drugs through a qualified patient assistance program is considered a charitable drug donor and defines "patient assistance program" for this purpose. The bill requires a charitable drug donor to use appropriate safeguards established by department 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.H.B. 2271 authorizes DSHS to accept donated drugs only in accordance with the bill's provisions. The bill requires the donated drugs to be prescription drugs, and approved by the

U.S. Food and Drug Administration (FDA) and 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 donation of drugs that are the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer, that are adulterated or misbranded, that are a controlled substance under the Texas Controlled Substances Act, that are a parenteral or injectable medication, that require refrigeration, or that expire 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.H.B. 2271 authorizes the donated drugs to be accepted and provided or administered to patients only by a charitable medical clinic, a physician's office using the drugs for Medicaid patients or for other indigent health care, or a licensed health care professional responsible for administration of drugs in penal institutions 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 and authorizes the clinic or physician providing or administering the drug to charge a nominal handling fee in an amount prescribed by department rule. The bill prohibits a clinic, physician, or other licensed health care professional receiving donated drugs from reselling the drugs. The bill requires DSHS to establish a location to centrally store donated drugs for distribution to qualifying recipients. The bill requires DSHS to establish and maintain an electronic database in which DSHS shall 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 may search for and request donated drugs.

C.S.H.B. 2271 requires the pilot program to be governed by department rules that are designed to protect the public health and safety. The bill 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. The bill's provisions relating to immunity from liability do not apply if the harm results from the failure to comply with the requirements of the bill's provisions or to a charitable medical clinic that fails to comply with the insurance provisions of the Charitable Immunity and Liability Act of 1987.

C.S.H.B. 2271 requires DSHS, not later than January 1 of each odd-numbered year, to report to the legislature on the results of the pilot program, including the pilot program's efficacy in expanding access to prescription medications, any cost savings to the state or local governments resulting from or projected to result from the pilot program, an evaluation of the pilot program's database and system of distribution, any health and safety issues posed by providing or administering donated drugs, recommendations on improvements to the pilot program, and an evaluation of potential expansion of the pilot program.

C.S.H.B. 2271 requires DSHS, not later than December 1, 2015, to establish the central repository and database for donated drugs. The bill establishes that its provisions apply only to a drug that is donated, accepted, provided, or administered on or after January 1, 2016.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 2271 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED

SECTION 1. Subchapter M, Chapter 431, Health and Safety Code, is amended to read as follows:

SUBCHAPTER M. PRESCRIPTION DRUG DONATION PROGRAM

Sec. 431.321. DEFINITIONS. In this subchapter:

(1) "Charitable drug donor" means:

(A) a licensed convalescent or nursing home or related institution, licensed hospice, hospital, physician, or pharmacy;

or

(B) a pharmaceutical seller or manufacturer that donates drugs under a qualified patient assistance program.

(2) [(a)] "Charitable medical clinic" means a clinic, including a licensed pharmacy that is a community pharmaceutical access program provider, that provides medical care or drugs without charge or for a substantially reduced charge, complies with the insurance requirements of Chapter 84, Civil Practice and Remedies Code, and is exempt from federal income tax under Section 501(a) of the Internal Revenue Code of 1986 by being listed as an exempt organization in Section 501(c)(3) or 501(c)(4) of the code and is operated exclusively for the promotion of social welfare by being primarily engaged in promoting the common good and general welfare of the people in a community.

(3) "Community pharmaceutical access program" means a program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons by providing access to prescription drugs at no charge or at a substantially reduced charge.

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

HOUSE COMMITTEE SUBSTITUTE

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

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.

~~(5) [(b) "Seller" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.~~

~~[(e)] "Manufacturer" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.~~

~~(6) "Patient [(d) "Charitable drug donor" means a licensed convalescent or nursing home or related institution, licensed hospice, hospital, physician, pharmacy, or a pharmaceutical seller or manufacturer that donates drugs pursuant to a qualified patient assistance program, that donates drugs to a charitable medical clinic.~~

~~[(d-1) In this subchapter, "community pharmaceutical access program" means a program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons to access prescription drugs at no charge or at a substantially reduced charge.~~

~~[(e) In this subchapter, "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.~~

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

~~(8) "Program" means the prescription drug donation program under this subchapter.~~

~~(9) "Seller" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.~~

~~No equivalent provision.~~

Sec. 431.322. DONATION OF UNUSED DRUGS ~~[TO CHARITABLE MEDICAL CLINIC]~~. (a) A charitable drug donor may donate certain unused prescription drugs to

(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.

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

(5) "Pilot program" means the prescription drug donation pilot program under this subchapter.

(7) "Seller" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.

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.

Sec. 431.453. DONATION OF UNUSED DRUGS.

(a) A charitable drug donor may donate certain unused prescription drugs to the

~~the department for the program under [a charitable medical clinic, and a charitable clinic may accept, dispense, or administer the donated drugs in accordance with] this subchapter.~~

(b) A seller or manufacturer of a drug may not donate drugs to the department ~~[a charitable medical clinic]~~ except under [pursuant to] a qualified patient assistance program. A seller or manufacturer of a drug that donates drugs through a qualified patient assistance program is ~~[shall be]~~ considered a charitable drug donor.

(c) A ~~[The]~~ charitable drug donor shall use appropriate safeguards established by the department ~~[board]~~ to ensure that the drugs are not compromised or illegally diverted while being stored or transported ~~[to the charitable medical clinic]~~.

(d) The department ~~[charitable medical clinic]~~ 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 ~~[clinic]~~ with a verifiable address and telephone number; and

(3) the person transferring possession of the drugs presents ~~[the charitable medical clinic with]~~ photographic identification.

Sec. 431.323. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY BE ACCEPTED ~~[AND DISPENSED]~~. (a) The department ~~[A charitable medical clinic]~~ may accept ~~[and dispense or administer]~~ donated drugs only in accordance with this subchapter.

(b) The donated drugs must be:

(1) ~~[drugs that require a]~~ prescription drugs;

(2) ~~[. A donated drug may not be a controlled substance under Chapter 481.~~

~~[(e) The donated drugs must be]~~ approved by the federal Food and Drug Administration and:

(A) ~~[(1) be]~~ sealed in the manufacturer's unopened original tamper-evident packaging and either:

(i) ~~[(A)]~~ individually packaged; or

(ii) ~~[(B)]~~ packaged in unit-dose packaging;

(B) ~~[(2)]~~ be oral ~~[or parenteral]~~ medication in sealed single-dose containers approved

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.

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

by the federal Food and Drug Administration; or

~~(C) [(3)]~~ be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration.

~~(c)~~ Donated drugs may ~~[-or~~

~~[(4) be parenteral medication in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn; and~~

~~[(5) must]~~ 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.~~

~~(d) The department [charitable medical clinic] may distribute [dispense or administer] the donated drugs only[-~~

~~[(1) before the expiration date or within the recommended shelf life of the donated drugs, as applicable; and~~

~~[(2)] after a licensed pharmacist has determined that the drugs are of an acceptable integrity.~~

~~(e) The department may not charge a fee for the drugs donated under the program other than a nominal handling fee to defray the costs incurred in implementing the program under this subchapter.~~

~~(f) The department may not resell the drugs donated under the program.~~

Sec. 431.3231. DISPENSATION OF DONATED DRUGS.

~~(a) [(e)]~~ The donated drugs may be accepted and ~~dispensed~~ or administered ~~only~~ by:

~~(1) a [the] charitable medical clinic; or~~

~~(2) a physician's office using the drugs for patients who receive assistance from the medical assistance program under Chapter 32, Human Resources Code [only in accordance with rules adopted by the department].~~

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.

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,

(b) A prescription drug dispensed or administered to a patient under the program must be prescribed by a practitioner for use by that patient.

(c) The clinic or physician dispensing or administering the drug may charge a nominal handling fee in an amount prescribed by department rule.

(d) A clinic or physician receiving donated drugs may not resell the drugs.

Sec. 431.3232. CENTRAL DRUG REPOSITORY. The department shall establish a location to centrally store drugs donated under this subchapter for disbursement to qualifying recipients.

Sec. 431.3233. 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 program; and

(2) a charitable medical clinic or physician may search for and request donated drugs.

Sec. 431.324. RULES. The executive commissioner of the Health and Human Services Commission [department] shall adopt rules to implement this subchapter 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 dispensing or administering a donated drug;

(2) provisions for maintenance of the database of donated drugs; and

(3) any necessary forms for the administration of the program.

Sec. 431.325. LIMITATION ON CIVIL AND CRIMINAL LIABILITY. (a) Charitable drug donors, charitable medical clinics, physicians, and their employees are not civilly or criminally liable or subject to professional disciplinary action for harm caused by the [accepting,] dispensing[-] or administering of drugs donated under [strict compliance with] this subchapter unless the harm is caused by:

(1) wilful [(i) willful] or wanton acts of negligence;

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.

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.

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.

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.

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) ~~(ii)~~ conscious indifference or reckless disregard for the safety of others; or
(3) ~~(iii)~~ intentional conduct.

(b) This section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer under ~~[pursuant to]~~ Chapter 82, Civil Practice and Remedies Code.

(c) This section does ~~shall~~ not apply if the ~~where~~ harm results from the failure to ~~fully and completely~~ comply with the requirements of this subchapter.

(d) This section does ~~shall~~ 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.

SECTION 2. Not later than December 1, 2015:

(1) the executive commissioner of the Health and Human Services Commission shall adopt any rules necessary to implement Subchapter M, Chapter 431, Health and Safety Code, as amended by this Act; and

(2) the Department of State Health Services shall establish the central repository and database required by Subchapter M, Chapter 431, Health and Safety Code, as amended by this Act.

- (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.

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.

SECTION 2. 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.

SECTION 3. (a) The change in law made by this Act applies only to a drug that is donated, accepted, dispensed, or administered on or after January 1, 2016.

(b) Notwithstanding Subsection (a) of this section, a charitable medical clinic that, on January 1, 2016, possesses drugs donated under Subchapter M, Chapter 431, Health and Safety Code, as it existed immediately before the effective date of this Act, may dispense those remaining drugs in accordance with the former law.

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

SECTION 3. 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. Same as introduced version.