

SUBJECT: Creating a pilot program to donate and redistribute certain unused drugs

COMMITTEE: Public Health — committee substitute recommended

VOTE: 8 ayes — Crownover, Naishtat, Collier, S. Davis, Guerra, R. Miller,  
Sheffield, Zerwas

0 nays

3 absent — Blanco, Coleman, Zedler

SENATE VOTE: On final passage, April 29 — 31-0

WITNESSES: No public hearing

DIGEST: CSSB 1243 would require the Department of State Health Services (DSHS) to establish a pilot program for the donation and redistribution of certain prescription drugs. The program would be conducted in one or more municipalities with a population of more than 500,000 but less than 1 million.

**Donations.** Under the program, a charitable drug donor could donate certain unused prescription drugs to DSHS. The department would not accept the drugs unless the drugs were properly stored while in the donor's possession, the department was provided with a verifiable address and phone number of the donor, and the person transferring the drugs presented photo identification.

Donated drugs would be required to be prescription drugs that had been approved by the U.S. Food and Drug Administration and were sealed in unopened, tamper-evident, unit dose packaging. Drugs packaged in single-unit doses would be acceptable if the outside packaging was opened but the single unit dose packaging was unopened.

The drugs could not be subject to a mandatory or voluntary recall, adulterated or misbranded, a controlled substance, a parenteral or

injectable medication, require refrigeration, or expire less than 60 days after the date of donation.

DSHS would not be permitted to distribute the drugs without inspection by a licensed pharmacist. It also would not be permitted to charge a fee for the drugs other than a nominal handling fee, or resell the drugs.

DSHS would be required to establish a location to centrally store drugs for distribution to qualifying patients. The department also would be required to establish and maintain an electronic database in which the name and quantity of each drug was listed and a charitable medical clinic, physician, or other licensed health care professional could search for and request drugs donated under the pilot program.

**Administration of donated drugs.** Drugs would be administered to patients only by a charitable medical clinic, a licensed health care professional in a Texas penal institution, or a physician's office using the drugs for indigent health care or for patients who receive Medicaid assistance.

A drug would be required to be prescribed for the patient. The clinic or physician administering the drug could not charge a fee for the drugs, other than a nominal handling fee, or resell the drugs.

Qualified individuals acting in good faith in administering drugs under the pilot program would not be civilly or criminally liable or subject to professional disciplinary action for harm caused by administering drugs unless the harm was caused by negligence, recklessness or indifference, or intentional conduct.

DSHS would be required to establish rules governing the program. The department would be required to establish the central repository and database for the donated drugs by December 1, 2015.

**Reports.** On or before January 1 of each odd-numbered year, DSHS would be required to report to the Legislature on the results of the pilot

program. The report would be required to include:

- the program's efficacy in expanding access to prescription medications;
- any cost savings to the state or local government;
- an evaluation of the program's database and system of distribution;
- any health and safety issues;
- recommended improvements; and
- an evaluation of potential expansion of the program.

The bill also would require DSHS to conduct a feasibility study on establishing a program under which hospitals, nursing facilities, or other health facilities could transfer unused drugs to the department or another entity designated by the department for distribution to public hospitals. The study would consider which rules would need to be adopted to implement such a program, including rules related to the types of drugs which might be transferred, the procedures for transferring and allocation the drugs and qualification for an entity designated to transfer and distribute drugs. DSHS would submit its findings to the Legislature no later than September 1, 2016.

The bill would take effect September 1, 2015, and would apply only to a drug donated, accepted, provided or administered on or after January 1, 2016.

**SUPPORTERS  
SAY:**

CSSB 1243 would establish a pilot program and feasibility study that could identify new ways to help people in Texas receive necessary and expensive medicines they might otherwise not be able to receive.

Currently, health care facilities dispose of large quantities of medication that is still safely packaged and could benefit others. Patients for whom the medication was originally prescribed may not need the drugs for a variety of reasons, leaving the drugs untouched and still within their expiration dates. Some of these medicines — such as cancer treatment drugs — are very expensive and may be inaccessible to those without adequate insurance. This pilot program would provide the opportunity to

address this issue on a small scale and allow for refinements going forward. Similar programs have been successful in other states.

The bill would provide adequate protections for patients and providers who would participate — both in terms of the program requirements it would create and the liability language in the bill. Donated drugs would be subject to strict standards regarding what could and could not be used. The liability standards established by the bill would be appropriate because stricter standards could discourage manufacturers from donating, which would hurt a program that relied on voluntary donations.

The program also would help keep unused medicines out of the wastewater system and therefore the water supply, which is important for public health and the environment. It also could save the state money — for example by helping to reduce the health care costs of individuals being treated at penal institutions.

**OPPONENTS  
SAY:**

CSSB 1243 would establish a drug donation pilot program that could make it easier for certain medicines to fall into the wrong hands. It would be difficult to ensure that the requirements were always followed, such as drugs being kept at certain temperatures or ensuring against tampering. The bill should include language holding donors and others to a standard of reasonable care. Current provisions in the bill state that involved individuals would not be civilly or criminally liable or subject to professional disciplinary action for harm caused by providing or administering the drugs donated as long as they acted in good faith. This may not provide adequate protection for patients. The term “good faith” is not well defined and could be difficult for courts to interpret.