

BILL ANALYSIS

C.S.H.B. 25
By: Talarico
Health Care Reform, Select
Committee Report (Substituted)

BACKGROUND AND PURPOSE

According to the Kaiser Family Foundation, per capita prescription drug spending is astronomically higher in the United States every year than in all of its peer nations. The Brookings Institute found that Americans pay twice as much as Canadians for their prescription drugs, despite the fact that the United States and Canada share equivalent regulatory systems for these medicines. In 2020, the Trump Administration established a pathway for states to import prescription drugs from Canada after finding that it would result in significant cost savings for patients and could be done safely, and the Biden Administration later ordered the FDA to help states implement related programs.

In order to import prescription drugs from Canada, states must pass laws to allow for importation and then submit an application to the FDA for approval of their programs. Six states—Florida, Colorado, New Mexico, Maine, Vermont, and New Hampshire—have begun this process. The Colorado Department of Health Care Policy and Financing predicts that its program will generate cost savings of 65 percent for patients and employers. Drug importation can also generate significant cost savings for states. For example, the Florida Agency for Health Care Administration predicts that its program will save state agencies over \$150 million annually.

C.S.H.B. 25 would require the Health and Human Services Commission to design a wholesale prescription drug importation program for the purpose of providing lower cost prescription drugs available outside of the United States to Texas consumers at a lower cost.

CRIMINAL JUSTICE IMPACT

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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

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It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTIONS 2 and 3 of this bill.

ANALYSIS

C.S.H.B. 25 amends the Health and Safety Code to require the Health and Human Services Commission (HHSC) to establish the wholesale prescription drug importation program to provide lower cost prescription drugs available outside of the United States to Texas consumers at the lower cost. The bill authorizes HHSC to consult with interested parties in developing the program and requires HHSC to implement the program by doing the following:

- contracting with one or more prescription drug wholesalers licensed by the state as a wholesale distributor and Canadian suppliers appropriately licensed or permitted under Canadian laws and rules to manufacture, distribute, or dispense prescription drugs for the purpose of importing prescription drugs and providing prescription drug cost savings to

- prohibiting the distribution, dispensing, or sale of prescription drugs imported under the program outside Texas' boundaries;
- performing any other duties the executive commissioner of HHSC determines necessary to implement the program; and
- ensuring that the program meets requirements under federal law relating to the importation of prescription drugs.

C.S.H.B. 25 makes eligible for the importation program a drug that is expected to generate cost savings for consumers, does not violate any federal patent laws through its importation, and meets the FDA's standards related to prescription drug safety, effectiveness, misbranding, and adulteration. The bill excludes from program eligibility any drug that is listed as a controlled substance under state or federal law, a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug.

C.S.H.B. 25 authorizes HHSC to impose a fee on each prescription drug sold under the program or establish another funding method to administer the program in addition to money appropriated by the legislature. The bill requires HHSC, in consultation with the attorney general, to identify and monitor any potential anticompetitive activities in industries affected by the program and requires HHSC, not later than December 1 of each year, to submit a report to the governor and the legislature that includes specified information regarding the program's operation during the preceding state fiscal year. The bill requires the executive commissioner of HHSC to adopt any rules necessary to implement the bill's provisions and requires the executive commissioner by rule to develop procedures to effectively audit a prescription drug wholesaler participating in the program. The bill provides for the delayed implementation of any provision for which an applicable state agency determines a federal waiver or authorization is necessary for implementation until the waiver or authorization is requested and granted.

EFFECTIVE DATE

September 1, 2023.

COMPARISON OF INTRODUCED AND SUBSTITUTE

While C.S.H.B. 25 may differ from the introduced in minor or nonsubstantive ways, the following summarizes the substantial differences between the introduced and committee substitute versions of the bill.

Whereas the introduced required HHSC to submit a formal request to the secretary of the U.S. Department of Health and Human Services for certification of the state's program and, upon that certification of approval, begin implementing the program and begin operating the program within six months, the substitute provides for the delayed implementation of any provision for which an applicable state agency determines a federal waiver or authorization is necessary for implementation until the waiver or authorization is requested and granted.

While both the introduced and substitute versions exclude the importation of a controlled substance under the program, the substitute further excludes any drug that is a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug.

While the introduced authorized its provisions to be extended to any other country allowed by federal law to import prescription drugs into the United States at the discretion of HHSC, the substitute does not.

While both the introduced and the substitute require HHSC to annually submit a report to the governor and the legislature, the substitute specifies that the deadline for this submission is not later than December 1 of each year.

develop procedures to effectively audit a prescription drug wholesaler participating in the program.

The substitute replaces a requirement included in the introduced for HHSC to consult with interested stakeholders, including the committee, the legislature, health insurance plans, employers, pharmacies, health care providers and consumers with an authorization for HHSC to consult with interested parties in developing the program.

The substitute does not include a provision included in the introduced requiring any other state agency designated by the executive commissioner of HHSC to adopt rules necessary to implement the bill's provisions.

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