SUBJECT: Creating a wholesale prescription drug importation program

COMMITTEE: Health Care Reform, Select — committee substitute recommended

VOTE: 7 ayes — Harless, Howard, Bonnen, Frank, Klick, Price, Walle

0 nays

4 absent — Bucy III, E. Morales, Oliverson, Rose

WITNESSES: For — Charles Cascio, AARP Texas; Emily Brizzolara-Dove, Texas 2036; Blake Hutson, Texas Association of Health Plans (*Registered, but did not testify*: Samuel Sheetz, Americans for Prosperity; Rebekah Chenelle, Dallas County Commissioners Court; Anne Dunkelberg, Every Texan; Alec Mendoza, Texans Care for Children; David Balat, Texas Public Policy Foundation; Cynthia Van Maanen, Travis County Democratic Party; and nine individuals)

Against — Sharon Lamberton, PhRMA; Wroe Jackson, Texas Association of Manufacturers; Duane Galligher, Texas Pharmacy Association (*Registered, but did not testify*: Victoria Ford, Texas Healthcare and Bioscience Institute; Mary Castle, Texas Values Action; Jackie Besinger)

On — Brandon Dyson, Texas Oncology (*Registered, but did not testify*: Timothy Stevenson, DSHS; JP Summers, Global Healthy Living Foundation; Keisha Rowe, Health and Human Services Commission)

DIGEST: CSHB 25 would create a wholesale prescription drug importation program to provide lower cost prescription drugs available outside of the United States to consumers in Texas. The Health and Human Services Commission (HHSC) would be required to implement the program by contracting with one or more prescription drug wholesalers and Canadian suppliers, as defined by the bill, to import prescription drugs and provide cost savings to consumers in Texas. HHSC also would be required to:

- develop a registration process for health benefit plan issuers, health care providers, and pharmacies to obtain and dispense imported drugs;
- develop and publish a list of prescription drugs, including their prices, that met certain safety requirements;
- establish an outreach and marketing plan to raise awareness of the program;
- administer a call center or electronic portal to provide information about the program;
- ensure that the program and prescription drug wholesalers under contract with the state comply with federal tracking, tracing, verification, and identification requirements;
- prohibit the distribution, dispensing, or sale of imported prescription drugs outside of the state; and
- perform any other duties HHSC's executive commissioner determines necessary.

HHSC would be required to ensure that the program meets federal requirements for the importation of prescription drugs. HHSC would be authorized to consult with interested parties to develop the program.

Prescription drugs could be imported into the state under the program only if the drug met the US Food and Drug Administration's standards related to prescription drug safety, effectiveness, misbranding, and adulteration, and the drug's importation did not violate any federal patent laws. Certain drugs could not be imported through the program, including controlled substances, biological products, infused drugs, intravenously injected drugs, drugs that are inhaled during surgery, or parenteral drugs. HHSC, in consultation with the attorney general, would be required to identify and monitor any potential anticompetitive activities in industries affected by the program.

HHSC would be allowed to impose a fee on each prescription drug sold under the program or establish another funding method to administer the program in addition to any funds that the Legislature appropriated. HHSC's executive commissioner would be required to develop

procedures by rule to audit prescription drug wholesalers participating in the program.

HHSC would be required to submit a report to the governor and the Legislature on the operation of the program by December 1 of each year. The report would include:

- which prescription drugs and Canadian suppliers were included in the program;
- the number of health benefit plan issuers, health care providers, and pharmacies participating in the program;
- the number of prescriptions dispensed through the program;
- the estimated cost savings since the establishment of the program and during the previous state fiscal year;
- information regarding the implementation of audit procedures; and
- any other information HHSC considers necessary or the governor or the Legislature requests.

HHSC's executive commissioner would be required to adopt any rules necessary to implement the program as soon as practicable after the effective date of the bill.

If a state agency determined that a waiver or authorization from a federal agency was necessary to implement a provision of the bill, the agency would be required to request the waiver and could delay implementation until the waiver or authorization was granted.

The bill would take effect September 1, 2023, and would be known as the Wholesale Prescription Drug Importation Act.

SUPPORTERS SAY:

CSHB 25 would save lives and improve health outcomes by allowing certain low-cost prescription drugs to be safely imported from Canada. Many people are unable to afford their prescription drugs, causing them to ration doses or to stop taking prescriptions entirely. Canadian prescription drugs are often cheaper, and Canada has a regulatory system comparable to the United States. The bill would require all imported prescription

drugs to meet FDA standards, including tracking and tracing requirements, and the FDA would have to approve the program, which would ensure safety. Many prescription drugs and prescription drug ingredients are already manufactured outside of the United States, so importing Canadian drugs would not create a large safety risk. Certain prescription drugs could not be imported, including controlled substances and biologics, which would further ensure that only safe prescription drugs were imported.

These drugs also would have to generate cost savings to be imported, ensuring that the drugs would be affordable. Importing prescription drugs from Canada could save money for state agencies without posing any risk to public health and would introduce more competition to the market, driving down prices for consumers.

CRITICS SAY:

CSHB 25 could harm patients by allowing unsafe prescription drugs to be imported from outside of the United States. Other countries do not have as strict of regulations regarding drug manufacturing, which could allow unsafe prescription drugs to enter the supply chain. The bill also is unlikely to generate cost savings because the cost of administering the program would outweigh potential savings. Though several states have pursued a wholesale prescription drug importation program, none have been approved by the FDA.

The United States' closed prescription drug system and high safety standards makes patients confident in prescription drug safety, and importing prescription drugs from outside of the country would undermine that confidence. Canada does not have a track-and-trace system for medical devices like the United States, which could increase the risk of unsafe medicines entering the state. Additionally, Canada is currently experiencing a prescription drug shortage, and Canada could be unwilling to export prescription drugs to the United States.
Instead of allowing for wholesale drug importation, lawmakers should focus on other policies that address the underlying cost drivers of prescription drugs and could lower prescription drug prices.

NOTES: The fiscal impact of the bill could not be determined because of uncertainty regarding the potential costs and revenues related to prescription drug importation.