

BILL ANALYSIS

C.S.H.B. 638
By: Toth
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

In May 2018, the federal Right to Try Act was signed into law, creating a federal framework for patients to access new investigational drugs and biologics. In Texas, medical freedom advocates have made calls to provide more treatment options for those suffering from chronic disease. C.S.H.B. 638 seeks to address the issue of limited treatment options by permitting the use of investigational drugs, biological products, and devices for patients who, in consultation with their physician, have considered all other approved treatment options and determined they are unavailable or unlikely to provide relief.

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 rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 of this bill.

ANALYSIS

C.S.H.B. 638 amends the Health and Safety Code to make a patient eligible to access and use an investigational drug, biological product, or device under the following conditions:

- the patient has a severe chronic disease designated by the commissioner of state health services and that the patient's treating physician confirms in writing;
- use of the investigational drug, biological product, or device is consistent with the bill's provisions and the rules adopted thereunder; and
- the patient's physician has done the following:
 - in consultation with the patient, considers all other treatment options the FDA has currently approved and determines that those options are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and
 - recommends or prescribes in writing the patient's use of a specific class of investigational drug, biological product, or device.

The bill defines "investigational drug, biological product, or device" as such that has successfully completed phase one of a clinical trial but has not yet been approved for general use by FDA or its international equivalent and that remains under investigation in the clinical trial, but does not include low-THC cannabis or a product containing marijuana regardless of whether the cannabis or product successfully completed phase one of a clinical trial.

C.S.H.B. 638 authorizes a physician to recommend or prescribe an investigational drug, biological product, or device, only to an eligible patient who signs a written informed consent and authorizes a parent, guardian, or conservator to provide informed consent on the patient's

behalf if the patient is a minor or lacks the mental capacity to provide informed consent. The bill authorizes the commissioner of state health services to prescribe a form for the required informed consent and requires the commissioner, as soon as practicable after the bill's effective date, to designate the medical conditions considered to be severe chronic diseases, defined as a condition, injury, or illness that may be treated, may not be cured or eliminated, and entails significant functional impairment or severe pain, under the bill's provisions.

C.S.H.B. 638 expressly does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the drug, product, or device for any resulting harm to the patient. The bill expressly does not affect the coverage for routine patient care costs of enrollees in clinical trials as provided by applicable Insurance Code provisions.

C.S.H.B. 638 prohibits a state official, employee, or agent from preventing or attempting to prevent an eligible patient's access to an investigational drug, biological product, or device under the bill's provisions, unless the drug, biological product, or device is considered adulterated or misbranded under the Texas Food, Drug, and Cosmetic Act. The bill prohibits a governmental entity from considering the drug, biological product, or device to be adulterated or misbranded based solely on FDA not yet finally approving the drug, biological product, or device. The bill prohibits the Texas Medical Board from revoking, failing to renew, suspending, or taking any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with such a drug, product, or device, provided that the recommendations meet the requirements and rules adopted under the bill's provisions.

C.S.H.B. 638 requires the executive commissioner of the Health and Human Services Commission (HHSC), as soon as practicable after the bill's effective date, to adopt rules necessary to administer the bill's provisions. The bill authorizes the executive commissioner to adopt initial rules in the manner provided by law for emergency rules.

C.S.H.B. 638 includes legislative findings relating to the success of the Right To Try Act in saving the lives of many terminally ill patients; the long process for approving the use of investigational drugs, biological products, and devices by patients without a terminal illness; the urgency for final FDA approval for such among patients battling a severe chronic disease; restrictive FDA standards for using investigational drugs, biological products, and devices; and patients' rights to access and make decisions in consultation with their physician on the use of such drugs, products, and devices while being aware of the potential risks, benefits, and consequences of such. The bill establishes as legislative intent allowing patients with a severe chronic disease to use potentially life-altering investigational drugs, biological products, and devices.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2023.

COMPARISON OF INTRODUCED AND SUBSTITUTE

While C.S.H.B. 638 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.

The substitute includes a provision absent from the introduced excluding low-THC cannabis or a product containing marijuana regardless of whether the cannabis or product successfully completed phase one of a clinical trial from the definition of "investigational drug, biological product, or device." The substitute changes the definition of "severe chronic disease" from a condition, injury, or illness that requires medical attention and entails significant functional impairment or severe pain that limits a person's activities of daily life, as in the introduced, to a

condition, injury, or illness that may be treated, may not be cured or eliminated, and entails significant functional impairment or severe pain.

The substitute changes from the executive commissioner of HHSC, as in the introduced, to the commissioner of state health services the official who is required to designate the medical conditions that are considered severe chronic diseases. The substitute changes provisions in introduced relating to access to investigational drugs, biological products, and devices for patients with severe chronic diseases, as follows:

- includes a specification absent from the introduced that the confirmation by a patient's treating physician that the patient has a severe chronic disease is in writing;
- whereas the introduced required the patient to sign a written informed consent before receiving such a drug, product, or device, the substitute authorizes a physician to recommend or prescribe the drug, product, or device, only to an eligible patient who signs a written informed consent; and
- changes from the executive commissioner of HHSC, as in the introduced, to the commissioner of state health services the individual authorized to prescribe a form for the informed consent.

The substitute includes a requirement absent from the introduced for the executive commissioner of HHSC to adopt rules to implement the bill's provisions.

The substitute revises a prohibition in the introduced against a state official, employee, or agent preventing or attempting to prevent an eligible patient's access to an investigational drug, biological product, or device by including an exemption for a drug, biological product, or device that is considered adulterated or misbranded under the Texas Food, Drug, and Cosmetic Act. The substitute includes a prohibition absent from the introduced against a governmental entity considering the drug, biological product, or device to be adulterated or misbranded based solely on FDA not yet finally approving the drug, biological product, or device.

The substitute revises a prohibition in the introduced against the Texas Medical Board revoking, failing to renew, suspending, or taking any action against a physician based solely on the recommendations to an eligible patient regarding access to or treatment with an investigation drug, biological product or device by changing the condition triggering the prohibition from the recommendations made to the patient meeting the medical standard of care, as in the introduced, to the recommendations meeting the requirements of and rules adopted under the bill's provisions.

The substitute includes provisions absent from the introduced requiring the executive commissioner of HHSC to adopt rules as soon as practicable after the bill's effective date and authorizing the executive commissioner to adopt initial rules in the manner provided by law for emergency rules.