BILL ANALYSIS

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C.S.S.B. 773
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The United States Food and Drug Administration (FDA) grants access to unapproved drugs that are in the clinical trial phase to both terminally and chronically ill patients (with doctor approval and after meeting certain criteria). However, interested parties have noted that the process is arduous, lengthy, and comes at a phase of illness when most patients simply do not have the time to wait.

The Right to Try Act of the 84th Session did excellent work expanding medical access for Texans suffering from terminal illnesses. S.B. 773 seeks to build on that foundation by doing the same for those with severe chronic illnesses.

S.B. 773 seeks to amends the Health and Safety Code to give the same level of medical freedom to the severely chronically ill as those suffering from terminal illness. "Severe chronic disease" is defined as "a condition, injury, or illness that (A) may be treated; (B) may not be cured or eliminated; (C) entails significant functional impairment or severe pain."

S.B. 773 amends current Texas law in order to allow patients with severe chronic diseases to safely and more quickly access experimental treatments that are not yet approved by the FDA.

(Original Author's/Sponsor's Statement of Intent)

C.S.S.B. 773 amends current law relating to access to certain investigational drugs, biological products, and devices used in clinical trials by patients with severe chronic diseases

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 (Section 490.003, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. (a) Requires that this Act be known as the "Medical Freedom Act."

(b) Provides that the legislature finds that:

(1) the Right To Try Act, as added by Chapter 502 (H.B. 21), Acts of the 84th Legislature, Regular Session, 2015, has had tremendous success in saving the lives of many patients with a terminal illness;

(2) the process for approving the use of investigational drugs, biological products, and devices by patients without a terminal illness who need access to the drugs, products, or devices continues to take many years in the United States;

(3) patients who are battling a severe chronic disease that is debilitating or causes severe pain do not have the luxury of waiting until the United States Food and Drug Administration gives final approval for an investigational drug, biological product, or device;

(4) the United States Food and Drug Administration standards for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-altering treatment to patients with a severe chronic disease;

(5) patients with a severe chronic disease have a fundamental right to attempt to pursue the preservation of their state of life by accessing available investigational drugs, biological products, and devices;

(6) the use of available investigational drugs, biological products, and devices is a decision that a patient with a severe chronic disease should make in consultation with the patient's physician and is not a decision the government should make; and

(7) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to a patient with a severe chronic disease and the patient's family.

(c) Provides that it is the intent of the legislature to allow patients with a severe chronic disease to use potentially life-altering investigational drugs, biological products, and devices.

SECTION 2. Amends Subtitle C, Title 6, Health and Safety Code, by adding Chapter 490, as follows:

CHAPTER 490. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 490.001. DEFINITIONS. Defines "commissioner," "executive commissioner," "investigational drug, biological product, or device," and "severe chronic disease."

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. Requires the commissioner of state health services (commissioner) to designate the medical conditions considered to be severe chronic diseases under this chapter.

Sec. 490.003. RULES. Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules necessary to administer this chapter.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH SEVERE CHRONIC DISEASES

Sec. 490.051. PATIENT ELIGIBILITY. Provides that a patient is eligible to access and use an investigational drug, biological product, or device under this chapter if:

(1) the patient has a severe chronic disease the commissioner designates under Section 490.002 that the patient's treating physician confirms in writing;

(2) the use of the investigational drug, biological product, or device is consistent with this chapter and rules adopted under this chapter; and

(3) the patient's physician:

(A) in consultation with the patient, considers all other treatment options the United States Food and Drug Administration has currently approved and determines those treatment options are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and

(B) recommends or prescribes in writing the patient's use of a specific class of investigational drug, biological product, or device.

Sec. 490.052. INFORMED CONSENT. (a) Requires an eligible patient to sign a written informed consent before receiving an investigational drug, biological product or device. 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.

(b) Authorizes the commissioner to prescribe a form for the informed consent required under this section.

Sec. 490.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) Authorizes a manufacturer of an investigational drug, biological product, or device to make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter if the patient provides to the manufacturer the informed consent required under Section 490.052.

(b) Provides that this chapter does not require a manufacturer to make available an investigational drug, biological product, or device to an eligible patient.

(c) Requires that the manufacturer provide the investigational drug, biological product, or device to the eligible patient without receiving compensation if a manufacturer makes available an investigational drug, biological product, or device to an eligible patient under this subchapter.

Sec. 490.054. CAUSE OF ACTION NOT CREATED. Provides that this chapter 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 investigational drug, biological product, or device for any harm to the patient resulting from the investigational drug, biological product, or device.

Sec. 490.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. Prohibits an official, employee, or agent of this state from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device under this chapter unless the drug, biological product, or device is considered adulterated or misbranded under Chapter 431 (Texas Food, Drug, and Cosmetic Act). Prohibits a governmental entity, for purposes of this section, from considering the drug, biological product, or device to be adulterated or misbranded based solely on the United States Food and Drug Administration not yet finally approving the drug, biological product, or device.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 490.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. Provides that this chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379 (Coverage for Routine Patient Care Costs for Enrollees Participating in Certain Clinical Trials), Insurance Code.

SUBCHAPTER D. PHYSICIANS

Sec. 490.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Prohibits the Texas Medical Board, notwithstanding any other law, from revoking, failing to renew, suspending, or taking any action against a physician's license under Subchapter B (License Denial and Disciplinary Actions), Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, provided that the recommendations meet the medical standard of care and the requirements of this chapter.

SECTION 3. (a) Requires the commissioner to designate the medical conditions considered to be severe chronic diseases as required by Section 490.002, Health and Safety Code, as added by this Act, as soon as practicable after the effective date of this Act.

(b) Requires the executive commissioner to adopt the rules required by Section 490.003, Health and Safety Code, as added by this Act, as soon as practicable after the effective date of this Act. Authorizes the executive commissioner to adopt initial rules in the manner provided by law for emergency rules.

SECTION 4. Effective date: upon passage or September 1, 2023.