BILL ANALYSIS

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C.S.H.B. 21
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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) has a "compassionate use" exemption that allows terminally ill patients, with their doctors' approval and after meeting certain criteria, access to drugs that are in the clinical trial phase, but not approved. Currently, the process to get a compassionate use exemption for terminal patients is arduous and lengthy at a phase in their illness when patients simply do not have time.

This legislation would allow terminal patients to have quicker access to safe but experimental drugs that are often their last hope at saving their own lives.

An eligible patient must sign a written informed consent, which is designed to negate any legal action.

There is no mandate that the drug manufacturers have to provide the drug under the FDA policy.

Right to Try laws are already in place in Arizona, Arkansas, Colorado, Indiana, Louisiana, Michigan, Mississippi, Missouri, Montana, North Dakota, Oklahoma, South Dakota, Tennessee, Utah, Virginia, and Wyoming. Lawmakers in Florida have sent a similar bill to their governor for approval. This brings the total to 17 states.

C.S.H.B. 21 addresses the issue by spelling out a clear roadmap for terminally ill patients to receive access to experimental drugs when certain conditions are met.

C.S.H.B. 21 amends current law relating to authorizing patients with certain terminal illnesses to access certain investigation drugs, biological products, and devices that are in clinical trials.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 (Section 489.052, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. (a) Requires that this Act be known as the Right To Try Act.

(b) Provides that the legislature finds that:

(1) the process for the approval of investigational drugs, biological products, and devices in the United States takes many years;

(2) patients with a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration (FDA);

(3) the standards of FDA for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to patients with a terminal illness;

(4) patients with a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(5) the use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician to pursue the preservation of the patient's own life and is not a decision to be made by the government; and

(6) 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 the patient with a terminal illness and the patient's family.

(c) Provides that it is the intent of the legislature to allow for patients with a terminal illness to use potentially life-saving investigational drugs, biological products, and devices.

SECTION 2. Amends Subtitle C, Title 6, Health and Safety Code, by adding Chapter 489, as follows:

CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESSES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. DEFINITIONS. Defines "investigational drug, biological product, or device" and "terminal illness."

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

Sec. 489.051. 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 terminal illness, attested to by the patient's treating physician; and

(2) the patient's physician:

(A) in consultation with the patient, has considered all other treatment options currently approved by FDA and determined that those treatment options are unavailable or unlikely to prolong the patient's life; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

Sec. 489.052. INFORMED CONSENT. (a) Requires an eligible patient, before receiving an investigational drug, biological product, or device, to sign a written informed consent. Authorizes a parent or legal guardian 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 executive commissioner of the Health and Human Services Commission by rule to adopt a form for the informed consent under this section.

Sec. 489.053. 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 489.052.

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

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

Sec. 489.054. NO CAUSE OF ACTION 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 done to the eligible patient resulting from the investigational drug, biological product, or device.

Sec. 489.055. 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.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. 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. 489.151. 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 (Disciplinary Actions and Procedures), 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 made to the patient meet the medical standard of care.

SECTION 3. Effective date: upon passage or September 1, 2015.