BILL ANALYSIS

Senate Research Center
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C.S.S.B. 694
By: Bettencourt et al.
Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The United States Food and Drug Administration 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 "compassionate use" exception for terminal patients is arduous and lengthy.

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

The committee substitute defines patient eligibility the same way as the bill as filed. The committee substitute requires an eligible patient to sign a written informed consent the same way as the bill as filed, which is designed to negate any legal action. The committee substitute does not require drug manufacturers to make their drug or product available, but does require that they provide it at no cost if they opt in. The bill as filed would have allowed them choose whether to provide at no cost or to charge for the drug or product. The committee substitute prohibits a physician from charging a fee or cost for administering an investigational drug. The bill as filed has no such provision. The committee substitute and the bill as filed both include language to declare that no state or private cause of action is created, and that the state may not block an eligible patient's access to an investigational drug, product or device. The committee substitute states that this act does not affect the coverage of enrollees in clinical trials. The bill as filed states the same, but also states that insurance is not required to cover the cost of an investigational drug, product or device. This provision was no longer needed, since the use of investigational drugs will not involve any financial transaction under the committee substitute. The committee substitute prohibits the Texas Medical Board from taking action against a physician who issues an investigational drug or product, based solely on their participation in this program, provided that the recommendations made to the patient meet the medical standard of care. The bill as filed does not address the medical standard of care in this section.

C.S.S.B. 694 amends current law relating to authorizing patients with certain terminal illnesses to access certain investigational 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) Sets forth legislative findings.

(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 the patient has a terminal illness, attested to by the patient's treating physician; and the patient's physician in consultation with the patient, has considered all other treatment options currently approved by the FDA and determined that those treatment options are unavailable or unlikely to prolong the patient's life; and 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 to sign a written informed consent before receiving an investigational drug, biological product, or device. 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 (executive commissioner) 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 investigational drug, biological product, or device to the eligible patient without receiving compensation.

Sec. 489.054. CERTAIN FEES BY PHYSICIAN PROHIBITED. Prohibits a physician from charging a fee or any related cost for administering an investigational drug under this chapter.

Sec. 489.055. 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 such a drug, product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device.

Sec. 489.056. 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.