BILL ANALYSIS

Senate Research Center

S.B. 694
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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 "compassionate use" exception for terminal patients is arduous and lengthy at a phase in their illness when patients simply do not have time.

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.

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 must provide the drug under the FDA policy.

Five states—Colorado, Arizona, Louisiana, Michigan, and Missouri—have passed right to try laws, and they are all very similar to this bill.

S.B. 694 spells out a clear roadmap for terminally ill patients to receive access to experimental drugs when certain conditions are met.

As proposed, 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) Authorizes a manufacturer to provide an investigational drug, biological product, or device to an eligible patient without receiving compensation, or require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

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

Sec. 489.055. 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. HEALTH BENEFIT PLANS. Provides that a health benefit plan may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device.

Sec. 489.102. 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.

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