BILL ANALYSIS

Senate Research Center
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H.B. 661
By: Parker et al. (Bettencourt)
Health & Human Services
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Interested parties note that while the United States Food and Drug Administration grants terminally ill patients, with doctor approval and after meeting certain criteria, access to unapproved drugs that are in the clinical trial phase, the process is arduous and lengthy and comes at a phase of illness when most patients simply do not have the time. H.B. 661 amends current law in order to allow patients with terminal illnesses or severe chronic diseases to safely and more quickly access experimental treatments.

H.B. 661 amends current law relating to access to certain investigational drugs, biological products, and devices that are 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 (Sections 490.002 and 490.052, 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) Sets forth legislative findings.

(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 "executive commissioner," "investigational drug, biological product, or device," and "severe chronic disease."

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) by rule to designate the medical conditions that are considered severe chronic diseases under 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 the patient

has a severe chronic disease designated by the executive commissioner under Section 490.002 and attested to by the patient's treating physician, the use of the investigational drug, biological product, or device is consistent with this chapter and rules adopted under this chapter, and the patient's physician meets certain criteria.

Sec. 490.052. 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, guardian, or conservator, if the patient is a minor or lacks the mental capacity to provide informed consent, to provide informed consent on the patient's behalf.

(b) Authorizes the executive commissioner by rule to adopt a form for the informed consent required under this section.

Sec. 490.053. 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. 490.054. 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. 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 (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. Requires the executive commissioner, as soon as practicable after the effective date of this Act, by rule to designate the medical conditions that are severe chronic diseases as required by Section 490.002, Health and Safety Code, as added by this Act.

SECTION 4. Effective date: upon passage or September 1, 2017.