

## **BILL ANALYSIS**

C.S.H.B. 661  
By: Parker  
Public Health  
Committee Report (Substituted)

### **BACKGROUND AND PURPOSE**

Interested parties contend that the process for a patient with a severe chronic disease to access an investigational drug, biological product, or device that is in the clinical trial phase is arduous and lengthy. C.S.H.B. 661 seeks to address this issue by providing for the Medical Freedom Act, which allows such a patient to safely and more quickly access experimental treatments.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 of this bill.

### **ANALYSIS**

C.S.H.B. 661 amends the Health and Safety Code to make a patient eligible to access and use an investigational drug, biological product, or device if the patient has a severe chronic disease designated by the executive commissioner of the Health and Human Services Commission and attested to by the patient's treating physician; the use of the investigational drug, biological product, or device is consistent with the bill's provisions and rules adopted under the bill's provisions; and the patient's physician has considered, in consultation with the patient, all other treatment options currently approved by the U.S. Food and Drug Administration (FDA) and determined that 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 has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device. The bill defines, among other terms, "investigational drug, biological product, or device" as a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the FDA or its international equivalent and remains under investigation in the clinical trial. The bill requires the executive commissioner by rule to designate the medical conditions that are considered severe chronic diseases under the bill's provisions.

C.S.H.B. 661 requires an eligible patient to sign a written informed consent before receiving an investigational drug, biological product, or device and 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. The bill authorizes the executive commissioner by rule to adopt a form for the informed consent. The bill expressly 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. The bill prohibits an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device under the bill's provisions.

C.S.H.B. 661 expressly does not affect the health coverage of enrollees in clinical trials under Insurance Code provisions relating to coverage for routine patient care costs for enrollees participating in certain clinical trials. The bill prohibits the Texas Medical Board from revoking, failing to renew, suspending, or taking any action against a physician's license to practice medicine 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.

### **EFFECTIVE DATE**

On passage, or, if the bill does not receive the necessary vote, September 1, 2017.

### **COMPARISON OF ORIGINAL AND SUBSTITUTE**

While C.S.H.B. 661 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

#### INTRODUCED

SECTION 1. Sets out legislative findings and intent.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 490 to read as follows:

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

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 490.001. DEFINITIONS. In this chapter:

(1) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that is being studied and administered to human participants in a clinical trial and that the United States Food and Drug Administration has not yet approved for general use.

(3) "Severe chronic disease" means a condition, injury, or illness that:

#### HOUSE COMMITTEE SUBSTITUTE

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(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration or its international equivalent and remains under investigation in the clinical trial.

(3) "Severe chronic disease" means a condition, injury, or illness that:

(A) lasts for at least one year;  
(B) requires ongoing medical attention; and  
(C) entails significant functional impairment or severe pain that limits a person's activities of daily life.

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES.

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

SUBCHAPTER C. HEALTH INSURANCE

SUBCHAPTER D. PHYSICIANS

SECTION 3. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission by rule shall 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. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2017.

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

SUBCHAPTER C. HEALTH INSURANCE

SUBCHAPTER D. PHYSICIANS

SECTION 3. Same as introduced version.

SECTION 4. Same as introduced version.