BILL ANALYSIS

C.S.H.B. 2908
By: Parker
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Interested parties note that while the U.S. 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 time. C.S.H.B. 2908 amends current law in order to allow patients with terminal illnesses or severe chronic diseases 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. 2908 amends the Health and Safety Code to make a patient eligible to access and use an investigational drug, biological product, or device that is being studied and administered to human participants in a clinical trial but has not yet been approved for general use by the U.S. Food and Drug Administration (FDA), which may include a treatment using stem cells other than embryonic stem cells, if the patient has a terminal illness or severe chronic disease, attested to by the patient's treating physician; if the use of the investigational drug, biological product, or device is consistent with the rules adopted by the executive commissioner of the Health and Human Services Commission under the bill's provisions; if 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 if the patient's physician has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

C.S.H.B. 2908 authorizes the executive commissioner by rule to designate a condition as a terminal illness or a severe chronic disease and requires the executive commissioner to adopt rules specifying which treatments may be accessed by patients under the bill's provisions and the manner in which those treatments may be accessed. The bill authorizes the executive commissioner to approve for treatment an investigational drug, biological product, or device that has completed or is in the appropriate phase of a clinical trial in another country, provided that the executive commissioner determines that the benefit of authorizing the treatment outweighs the potential risk. The bill requires the executive commissioner, for any approved treatment, to specify the safety parameters and protocols the executive commissioner considers necessary for patient use of the drug, product, or device. The bill expressly does not authorize the use of cannabis to treat patients with terminal illnesses or severe chronic diseases.

C.S.H.B. 2908 requires an eligible patient, before receiving an investigational drug, biological product, or device, to sign a written informed consent and authorizes a parent, guardian, or conservator to provide informed consent on the behalf of a patient who is a minor or lacks the mental capacity to provide informed consent. The bill requires the executive commissioner, in collaboration with the Texas Medical Board, by rule to adopt a form for the informed consent.

C.S.H.B. 2908 authorizes but does not require 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 the bill's provisions if the patient provides to the manufacturer the required informed consent. The bill authorizes a manufacturer to provide an investigational drug, biological product, or device to an eligible patient without receiving compensation or to require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device. 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.

C.S.H.B. 2908 authorizes but does not require a health benefit plan to provide coverage for the cost of an investigational drug, biological product, or device. The bill does not affect the insurance coverage of enrollees 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 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 care provided or recommendations made to the patient meet the standard of care and the requirements of the bill's provisions.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 2908 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	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. (a) This Act shall be known as the "Medical Freedom Act." (b) 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 or severe chronic disease 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; (3) the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the	SECTION 1. Substantially the same as introduced version.

benefits of potentially life-saving treatment to patients with a terminal illness or severe chronic disease;

(4) patients with a terminal illness or severe chronic disease 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 or severe chronic disease in consultation with the patient's physician 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 or severe chronic disease and the patient's family.

(c) It is the intent of the legislature to allow for patients with a terminal illness or severe chronic disease to use potentially life-saving investigational drugs, biological products, and devices.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 489 to read as follows:

CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESSES OR SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. DEFINITIONS. In this chapter:

(1) "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 and remains under investigation in the clinical trial.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 489 to read as follows:

CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESSES OR SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. 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 but has not yet been approved for general use by the United States Food and Drug Administration. The term may include a treatment using stem cells other than

	embryonic stem cells.
(2) "Severe chronic disease" means a condition, injury, or illness that:	(3) "Severe chronic disease" means a condition, injury, or illness that:
(A) may be treated;	(A) may be treated;
(B) is never cured or eliminated; and	(B) is never cured or eliminated; and
(C) entails significant functional impairment or severe pain.	(C) entails significant functional impairment or severe pain.
(3) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis and that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.	(4) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis and that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.
Sec. 489.002. RULES. The executive commissioner of the Health and Human Services Commission by rule may designate a condition as a terminal illness or a severe chronic disease.	Sec. 489.002. RULES. (a) The executive commissioner by rule may designate a condition as a terminal illness or a severe chronic disease.
	(b) The executive commissioner shall adopt rules specifying which treatments may be accessed by patients under this chapter and the manner in which those treatments may be accessed.
	(c) The executive commissioner may approve for treatment an investigational drug, biological product, or device that has completed or is in the appropriate phase of a clinical trial in another country, provided that the executive commissioner determines that the benefit of authorizing the treatment outweighs the potential risk.
	(d) For any treatment approved under this section, the executive commissioner shall specify the safety parameters and protocols the executive commissioner considers necessary for patient use of the drug, product, or device.
Sec. 489.003. EXCLUSION OF TREATMENTS. This chapter does not allow the use of cannabis as an investigational drug, biological product or device to treat patients with terminal illnesses or severe chronic diseases.	Sec. 489.003. EXCLUSION OF CERTAIN TREATMENTS. This chapter does not authorize the use of cannabis to treat patients with terminal illnesses or severe chronic diseases.
SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES OR SEVERE CHRONIC DISEASES	SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES OR SEVERE CHRONIC DISEASES
Sec. 489.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational drug,	Sec. 489.051. PATIENT ELIGIBILITY. 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 or severe chronic disease, attested to by the patient's treating physician; and	biological product, or device under this chapter if: (1) the patient has a terminal illness or severe chronic disease, attested to by the patient's treating physician; (2) the use of the investigational drug, biological product, or device is consistent with rules adopted under Section 489.002; and
(2) the patient's physician: (A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration 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.	(3) the patient's physician: (A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration 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) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent. (b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf. (c) The executive commissioner of the Health and Human Services Commission by rule shall adopt a form for the informed consent under this section.	Sec. 489.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent. (b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf. (c) The executive commissioner, in collaboration with the Texas Medical Board, by rule shall adopt a form for the informed consent under this section.
Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER.	Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER.
Sec. 489.054. NO CAUSE OF ACTION CREATED.	Sec. 489.054. NO CAUSE OF ACTION CREATED.
Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device under this section.	No equivalent provision.

SUBCHAPTER C. HEALTH INSURANCE	SUBCHAPTER C. HEALTH INSURANCE
Sec. 489.101. HEALTH BENEFIT PLANS.	Sec. 489.101. HEALTH BENEFIT PLANS.
Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES.	Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES.
SUBCHAPTER D. PHYSICIANS	SUBCHAPTER D. PHYSICIANS
Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license issued under Subchapter B, Chapter 164, 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.	Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, 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 care provided or recommendations made to the patient meet the standard of care and the requirements of this chapter.
SECTION 3. The executive commissioner of the Health and Human Services Commission by rule shall adopt the form for informed consent as required by Section 489.052(c), Health and Safety Code, as added by this Act, not later than the 30th day after the effective date of this Act.	No equivalent provision.
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, 2015.	SECTION 3. Same as introduced version.