BILL ANALYSIS

C.S.H.B. 21
By: Kacal
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Certain patients, through "compassionate use" programs, are able to access treatment options that are under investigation in a clinical trial and not yet approved by the U.S. Food and Drug Administration. Interested parties contend that the current process for accessing compassionate use programs for terminal patients is arduous and lengthy at a time when a patient cannot afford to wait. C.S.H.B. 21 seeks to facilitate the ability of certain patients to access an investigational drug, biological product, or device.

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. 21 amends the Health and Safety Code to make a patient eligible to access and use an investigational 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 U.S. Food and Drug Administration (FDA) and remains under investigation in the clinical trial 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 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. 21 requires an eligible patient, before receiving an investigational drug, biological product, or device, to sign a written informed consent and authorizes a parent or legal guardian to provide informed consent on the behalf of a patient who is a minor or who lacks the mental capacity to provide informed consent. The bill authorizes the executive commissioner of the Health and Human Services Commission, in collaboration with the Texas Medical Board, by rule to adopt a form for the informed consent.

C.S.H.B. 21 authorizes, but expressly 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 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 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 a state official, employee, or agent from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device.

C.S.H.B. 21 establishes that a person covered by the state's correctional managed health care plan is an eligible patient for the bill's purposes only to the extent that the correctional managed health care Offender Health Services Plan and federal law governing offender participation in biomedical research permit the offender's access to and use of the investigational drug, biological product, or device. The bill authorizes, but expressly 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 coverage of enrollees in clinical trials under specified 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 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 standard of care and the requirements established by the bill.

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. 21 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 "Right To Try Act." (b) The legislature finds that: (1) the process for approval of investigational drugs, biological products, and devices in the United States takes many years; (2) patients with a terminal illness 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 benefits of potentially life-saving treatment to patients with a terminal illness; (4) patients with a terminal illness have a fundamental right to attempt to pursue the	SECTION 1. (a) This Act shall be known as the Right To Try 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 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 benefits of potentially life-saving treatments to terminally ill patients; (4) patients with a terminal illness 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 in consultation with the patient's physician and the patient's family 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 and the patient's family.

(c) 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. 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

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 a clinical trial.

(2) "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.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

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(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 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 and the patient's family.

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SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

Sec. 489.051. PATIENT ELIGIBILITY.

Sec. 489.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent described by this section that is attested to by the patient's physician and a witness.

(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 required under this section.

Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER.

Sec. 489.054. NO CAUSE OF ACTION CREATED.

Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. HEALTH BENEFIT PLANS.

Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES.

Sec. 489.051. PATIENT ELIGIBILITY.

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If the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian may provide informed consent on the patient's behalf.

(b) The executive commissioner of the Health and Human Services Commission, in collaboration with the Texas Medical Board, by rule may adopt a form for the informed consent under this section.

Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER.

Sec. 489.054. NO CAUSE OF ACTION CREATED.

Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

Sec. 489.056. CORRECTIONAL MANAGED CARE. A person covered by the correctional managed health care plan under Subchapter E, Chapter 501, Government Code, is an eligible patient for purposes of this chapter only to the extent that the correctional managed health care Offender Health Services Plan and federal law governing offender participation in biomedical research permit the offender's access to and use of the investigational drug, biological product, or device.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. HEALTH BENEFIT PLANS.

Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES.

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 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.	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 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.