

BILL ANALYSIS

C.S.H.B. 810
By: Parker
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Interested parties contend that the process enabling certain patients to access an unapproved drug that is in a clinical trial is arduous and lengthy. C.S.H.B. 810 seeks to address this issue by granting certain patients with a severe chronic disease or terminal illness access to investigational stem cell treatments.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill expressly does one or more of the following: creates a criminal offense, increases the punishment for an existing criminal offense or category of offenses, or changes 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. 810 amends the Health and Safety Code to make a patient eligible to access and use an investigational stem cell treatment if the patient has a severe chronic disease or terminal illness listed in rules adopted by the executive commissioner of the Health and Human Services Commission and attested to by the patient's treating physician and if the patient's physician, in consultation with the patient, has considered 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 alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness and has recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment. The bill defines, among other terms, "investigational stem cell treatment" as an adult stem cell treatment that is under investigation in a clinical trial and being administered to human participants in that trial and that has not yet been approved for general use by the FDA. The bill requires the executive commissioner to adopt rules designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of the bill's Health and Safety Code provisions.

C.S.H.B. 810 requires an eligible patient to sign a written informed consent before receiving an investigational stem cell treatment 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 to adopt by rule a form for such informed consent. The bill's Health and Safety Code provisions expressly do not create a private or state cause of action against a developer of an investigational stem cell treatment or against any other person or entity involved in the care of an eligible patient using the investigational stem cell treatment for any harm done to the eligible patient resulting from the investigational stem cell treatment, affect the healthcare coverage of enrollees in certain clinical

trials, or affect or authorize a person to violate any law regulating the possession, use, or transfer of fetal tissue, fetal stem cells, adult stem cells, or human organs.

C.S.H.B. 810 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 use of an investigational stem cell treatment, provided that the care provided or recommendations made to the patient meet the standard of care and the requirements of the bill's Health and Safety Code provisions. The bill prohibits the state or an agency or political subdivision of the state or an officer, employee, or agent of such a governmental entity from interfering with an eligible patient's access to or use of a stem cell treatment authorized by the bill. The bill requires the executive commissioner to adopt rules necessary to implement the bill's Health and Safety Code provisions as soon as practicable after the bill's effective date.

C.S.H.B. 810 amends the Penal Code to create a Class A misdemeanor offense for a person who knowingly offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any adult stem cells for valuable consideration for use in an investigational stem cell treatment. The bill excepts from the application of the offense an actor who engaged in conduct authorized by statutory provisions relating to blood banks and the donation of blood and any valuable consideration that is a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services, that is reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the investigational stem cell treatment, or that is reimbursement of expenses of travel, housing, and lost wages incurred by the donor of adult stem cells in connection with the donation of the adult stem cells.

EFFECTIVE DATE

September 1, 2017.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 810 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. Chapter 1003, Health and Safety Code, is amended.	SECTION 1. Same as introduced version.
SECTION 2. Chapter 1003, Health and Safety Code, is amended by adding Subchapter B to read as follows: <u>SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES</u>	SECTION 2. Chapter 1003, Health and Safety Code, is amended by adding Subchapter B to read as follows: <u>SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES</u>
<u>Sec. 1003.051. DEFINITIONS.</u>	<u>Sec. 1003.051. DEFINITIONS.</u>
<u>Sec. 1003.052. RULES.</u>	<u>Sec. 1003.052. RULES.</u>
<u>Sec. 1003.053. PATIENT ELIGIBILITY.</u>	<u>Sec. 1003.053. PATIENT ELIGIBILITY.</u>

Sec. 1003.054. INFORMED CONSENT.

Sec. 1003.055. NO CAUSE OF ACTION CREATED.

Sec. 1003.056. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES.

This subchapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED.

Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED.

No equivalent provision.

Sec. 1003.054. INFORMED CONSENT.

Sec. 1003.055. NO CAUSE OF ACTION CREATED.

Sec. 1003.056. EFFECT ON OTHER LAW.

(a) This subchapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

(b) This subchapter does not affect or authorize a person to violate any law regulating the possession, use, or transfer of fetal tissue, fetal stem cells, adult stem cells, or human organs, including Sections 48.02 and 48.03, Penal Code.

Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED.

Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED.

SECTION 3. Chapter 48, Penal Code, is amended by adding Section 48.03 to read as follows:

Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a)

In this section:

(1) "Adult stem cell" means an undifferentiated cell that is:

(A) found in differentiated tissue; and

(B) able to renew itself and differentiate to yield all or nearly all of the specialized cell types of the tissue from which the cell originated.

(2) "Investigational stem cell treatment" means an adult stem cell treatment that:

(A) is under investigation in a clinical trial and being administered to human participants in that trial; and

(B) has not yet been approved for general use by the United States Food and Drug Administration.

(b) A person commits an offense if the person knowingly offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any adult stem cells for valuable consideration for use in an investigational

stem cell treatment.

(c) It is an exception to the application of this section that the valuable consideration is:

(1) a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services;

(2) reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the investigational stem cell treatment; or

(3) reimbursement of expenses of travel, housing, and lost wages incurred by the donor of adult stem cells in connection with the donation of the adult stem cells.

(d) It is an exception to the application of this section that the actor engaged in conduct authorized under Chapter 162, Health and Safety Code.

(e) A violation of this section is a Class A misdemeanor.

SECTION 3. As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission shall adopt rules necessary to implement Subchapter B, Chapter 1003, 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.

SECTION 4. Same as introduced version.

SECTION 5. This Act takes effect September 1, 2017.