

BILL ANALYSIS

Senate Research Center

H.B. 810
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Health & Human Services
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

At this time, the United States Food and Drug Administration (FDA) has an exemption that allows terminally ill patients, with their doctors' approval and after meeting certain criteria, access to unapproved drugs that are in the clinical trial phase. H.B. 810 expands upon this exemption by granting certain terminally and chronically ill patients access to investigational stem cell treatments that are not currently approved by the FDA.

H.B. 810 allows patients with terminal illnesses or severe chronic diseases to safely access experimental treatments that often are their last hope of significantly improving their physical well-being or even saving their own lives. Terminal illnesses and severe chronic diseases that are qualified to receive treatment will be designated by the executive commissioner of the Texas Health and Human Services Commission, and to receive these treatments, an eligible patient must sign a written informed consent, which is designed to negate any legal action. If the patient is a minor, or lacks the mental capacity to provide consent, a parent, legal guardian, or conservator may provide informed consent on their behalf.

H.B. 810 amends current law relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses and regulating the possession, use, and transfer of adult stem cells and creates a criminal offense.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 3 (Sections 1003.052 and 1003.054, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Requires that this Act be known as Charlie's Law.

SECTION 2. Amends Chapter 1003, Health and Safety Code, by designating Sections 1003.001, 1003.002, and 1003.003 as Subchapter A and adding a subchapter heading to read as follows:

SUBCHAPTER A. GENERAL PROVISIONS

SECTION 3. Amends Chapter 1003, Health and Safety Code, by adding Subchapter B, as follows:

SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES

Sec. 1003.051. DEFINITIONS. Defines "investigational stem cell treatment," "severe chronic disease," and "terminal illness."

Sec. 1003.052. RULES. Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of this subchapter.

Sec. 1003.053. **PATIENT ELIGIBILITY.** Provides that a patient is eligible to access and use an investigational stem cell treatment under this subchapter if certain conditions are met.

Sec. 1003.054. **INFORMED CONSENT.** (a) Requires an eligible patient, before receiving an investigational stem cell treatment, to sign a written informed consent.

(b) 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.

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

Sec. 1003.055. **NO CAUSE OF ACTION CREATED.** Provides that this subchapter does 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.

Sec. 1003.056. **EFFECT ON OTHER LAW.** Provides that this subchapter 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.

(b) Provides that 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 (Prohibition of the Purchase and Sale of Human Organs) and 48.03, Penal Code.

Sec. 1003.057. **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 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 this subchapter.

Sec. 1003.058. **GOVERNMENTAL INTERFERENCE PROHIBITED.** (a) Defines "governmental entity."

(b) Prohibits a governmental entity or an officer, employee, or agent of a governmental entity from interfering with an eligible patient's access to or use of a stem cell treatment authorized under this subchapter.

SECTION 4. Amends Chapter 48, Penal Code, by adding Section 48.03, as follows:

Sec. 48.03. **PROHIBITION ON PURCHASE AND SALE OF ADULT STEM CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS.** (a) Defines "adult stem cell" and "investigational stem cell treatment."

(b) Provides that 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) Provides that it is an exception to the application of this section that the valuable consideration 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, reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the investigational stem cell treatment, or 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) Provides that it is an exception to the application of this section that the actor engaged in conduct authorized under Chapter 162 (Blood Banks and Donation of Blood), Health and Safety Code.

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

SECTION 5. Requires the executive commissioner, as soon as practicable after the effective date of this Act, to adopt rules necessary to implement Subchapter B, Chapter 1003, Health and Safety Code, as added by this Act.

SECTION 6. Effective date: September 1, 2017.