

House Bill 810
Senate Amendments
Section-by-Section Analysis

HOUSE VERSION

SECTION 1. This Act shall be known as Charlie's Law.

SECTION 2. Chapter 1003, Health and Safety Code, is amended 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. Chapter 1003, Health and Safety Code, is amended by adding Subchapter B to read as follows:

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

Sec. 1003.051. DEFINITIONS. In this subchapter:

(1) "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.

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

(A) may be treated;

(B) is never cured or eliminated; and

(C) entails significant functional impairment or severe pain.

(3) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

Sec. 1003.052. RULES. The executive commissioner shall adopt rules designating the medical conditions that constitute

SENATE VERSION (IE)

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a severe chronic disease or terminal illness for purposes of this subchapter.

Sec. 1003.053. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational stem cell treatment under this subchapter if:

(1) the patient has a severe chronic disease or terminal illness listed in the rules adopted under Section 1003.052 and attested to by the patient's treating physician; 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 alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment.

Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an investigational stem cell treatment, 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 by rule may adopt a form for the informed consent under this section.

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Sec. 1003.0545. TREATMENT REQUIREMENTS: COMPLIANCE WITH TEXAS MEDICAL BOARD RULES.

(a) Treatment provided under this subchapter must be:

(1) administered directly by a physician certified under Subsection (c);

(2) overseen by an institutional review board described by Subsection (d); and

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(3) provided at:
(A) a hospital licensed under Chapter 241;
(B) an ambulatory surgical center licensed under Chapter 243; or
(C) a medical school, as defined by Section 61.501, Education Code.
(b) A physician administering an investigational stem cell treatment under this subchapter shall comply with all applicable Texas Medical Board rules.
(c) An institutional review board described by Subsection (d) may certify a physician to provide an investigational stem cell treatment under this subchapter.
(d) An institutional review board that oversees investigational stem cell treatments administered under this subchapter must:
(1) be affiliated with:
(A) a medical school, as defined by Section 61.501, Education Code; or
(B) a hospital licensed under Chapter 241 that has a minimum of 150 beds; and
(2) comply with all applicable rules under 21 C.F.R. Part 1271 related to human cells as of September 1, 2017.
(e) The Texas Medical Board may adopt rules as necessary to implement this section for institutional review boards.
[FA2(1)]

Sec. 1003.055. NO CAUSE OF ACTION CREATED. 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. 1003.055. [Deleted by FA1]

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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. 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 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) In this section, "governmental entity" means this state or an agency or political subdivision of this state.

(b) A governmental entity or an officer, employee, or agent of a governmental entity may not interfere with an eligible patient's access to or use of a stem cell treatment authorized under this subchapter.

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Sec. 1003.059. INSTITUTIONAL REVIEW BOARD DOCUMENTATION; REPORT. (a) An institutional review board overseeing an investigational stem cell treatment under this subchapter shall keep a record on each person to whom a physician administers the treatment and document in the record the provision of each treatment and the effects of the treatment on the person throughout the period the treatment is

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SECTION 4. 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

administered to the person.

(b) Each institutional review board overseeing an investigational stem cell treatment under this subchapter shall submit an annual report to the Texas Medical Board on the board's findings based on records kept under Subsection (a). The report may not include any patient identifying information and must be:

(1) written;

(2) electronic; and

(3) made available to the public. [FA2(2)]

SECTION 4. Same as House version.

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

SECTION 5. Same as House version.

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