By: Parker H.B. No. 810

A BILL TO BE ENTITLED

AN ACT

relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. 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 2. 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 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.

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. 1003.056. 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. 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.

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.