

SENATE AMENDMENTS

2nd Printing

By: Parker, Springer, Paul,
Anderson of McLennan, Burkett, et al.

H.B. No. 810

A BILL TO BE ENTITLED

1 AN ACT
2 relating to the provision of certain investigational stem cell
3 treatments to patients with certain severe chronic diseases or
4 terminal illnesses and regulating the possession, use, and transfer
5 of adult stem cells; creating a criminal offense.

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

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

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

11 SUBCHAPTER A. GENERAL PROVISIONS

12 SECTION 3. Chapter 1003, Health and Safety Code, is amended
13 by adding Subchapter B to read as follows:

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

16 Sec. 1003.051. DEFINITIONS. In this subchapter:

17 (1) "Investigational stem cell treatment" means an
18 adult stem cell treatment that:

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

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

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

1 (A) may be treated;
2 (B) is never cured or eliminated; and
3 (C) entails significant functional impairment or
4 severe pain.

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

9 Sec. 1003.052. RULES. The executive commissioner shall
10 adopt rules designating the medical conditions that constitute a
11 severe chronic disease or terminal illness for purposes of this
12 subchapter.

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

16 (1) the patient has a severe chronic disease or
17 terminal illness listed in the rules adopted under Section 1003.052
18 and attested to by the patient's treating physician; and

19 (2) the patient's physician:

20 (A) in consultation with the patient, has
21 considered all other treatment options currently approved by the
22 United States Food and Drug Administration and determined that
23 those treatment options are unavailable or unlikely to alleviate
24 the significant impairment or severe pain associated with the
25 severe chronic disease or terminal illness; and

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

1 treatment.

2 Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an
3 investigational stem cell treatment, an eligible patient must sign
4 a written informed consent.

5 (b) If the patient is a minor or lacks the mental capacity to
6 provide informed consent, a parent, guardian, or conservator may
7 provide informed consent on the patient's behalf.

8 (c) The executive commissioner by rule may adopt a form for
9 the informed consent under this section.

10 Sec. 1003.055. NO CAUSE OF ACTION CREATED. This subchapter
11 does not create a private or state cause of action against a
12 developer of an investigational stem cell treatment or against any
13 other person or entity involved in the care of an eligible patient
14 using the investigational stem cell treatment for any harm done to
15 the eligible patient resulting from the investigational stem cell
16 treatment.

17 Sec. 1003.056. EFFECT ON OTHER LAW. (a) This subchapter
18 does not affect the coverage of enrollees in clinical trials under
19 Chapter 1379, Insurance Code.

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

24 Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE
25 PROHIBITED. Notwithstanding any other law, the Texas Medical Board
26 may not revoke, fail to renew, suspend, or take any action against
27 a physician's license under Subchapter B, Chapter 164, Occupations

1 Code, based solely on the physician's recommendations to an
2 eligible patient regarding access to or use of an investigational
3 stem cell treatment, provided that the care provided or
4 recommendations made to the patient meet the standard of care and
5 the requirements of this subchapter.

6 Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a)
7 In this section, "governmental entity" means this state or an
8 agency or political subdivision of this state.

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

13 SECTION 4. Chapter 48, Penal Code, is amended by adding
14 Section 48.03 to read as follows:

15 Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM
16 CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a) In this
17 section:

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

20 (A) found in differentiated tissue; and
21 (B) able to renew itself and differentiate to
22 yield all or nearly all of the specialized cell types of the tissue
23 from which the cell originated.

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

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

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

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

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

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

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

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

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

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

22 SECTION 5. As soon as practicable after the effective date
23 of this Act, the executive commissioner of the Health and Human
24 Services Commission shall adopt rules necessary to implement
25 Subchapter B, Chapter 1003, Health and Safety Code, as added by this
26 Act.

27 SECTION 6. This Act takes effect September 1, 2017.

ADOPTED

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MAY 24 2017

FLOOR AMENDMENT NO. 1

Leta Spaw BY: *[Signature]*
Secretary of the Senate

1 Amend H.B. No. 810 (senate committee printing) in SECTION 3
2 of the bill, by striking added Section 1003.055, Health and
3 Safety Code (page 2, lines 17-23).

ADOPTED

MAY 24 2017

FLOOR AMENDMENT NO. 2

Leta Spaw
Secretary of the Senate

BY:

Van Taylor

1 Amend H.B. No. 810 (senate committee printing) as follows:

2 (1) In SECTION 3 of the bill, between added Sections
3 1003.054 and 1003.055, Health and Safety Code (page 2, between
4 lines 16 and 17), insert the following:

5 Sec. 1003.0545. TREATMENT REQUIREMENTS; COMPLIANCE WITH
6 TEXAS MEDICAL BOARD RULES. (a) Treatment provided under this
7 subchapter must be:

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

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

12 (3) provided at:

13 (A) a hospital licensed under Chapter 241;

14 (B) an ambulatory surgical center licensed under
15 Chapter 243; or

16 (C) a medical school, as defined by Section
17 61.501, Education Code.

18 (b) A physician administering an investigational stem cell
19 treatment under this subchapter shall comply with all applicable
20 Texas Medical Board rules.

21 (c) An institutional review board described by Subsection
22 (d) may certify a physician to provide an investigational stem
23 cell treatment under this subchapter.

24 (d) An institutional review board that oversees
25 investigational stem cell treatments administered under this
26 subchapter must:

27 (1) be affiliated with:

28 (A) a medical school, as defined by Section
29 61.501, Education Code; or

1 (B) a hospital licensed under Chapter 241 that
2 has a minimum of 150 beds; and

3 (2) comply with all applicable rules under 21 C.F.R.
4 Part 1271 related to human cells as of September 1, 2017.

5 (e) The Texas Medical Board may adopt rules as necessary
6 to implement this section for institutional review boards.

7 (2) In SECTION 3 of the bill, immediately following added
8 Section 1003.058, Health and Safety Code (page 2, between lines
9 46 and 47), insert the following:

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

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

24 (1) written;

25 (2) electronic; and

26 (3) made available to the public.

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 25, 2017

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB810 by Parker (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; creating a criminal offense.), **As Passed 2nd House**

No significant fiscal implication to the State is anticipated.

The bill would amend Health and Safety Code Chapter 1003 to require the Health and Human Services Commission to adopt rules designating medical conditions that are recognized to be a severe chronic disease or a terminal illness. The bill would allow patients with such medical conditions to access and use investigational stem cell treatment if certain requirements have been met. The bill also would amend Penal Code Chapter 48 to make it a Class A misdemeanor to sell or transfer adult stem cells, with exemptions under certain scenarios. The bill would take effect September 1, 2017.

According to the Health and Human Services Commission and the Texas Medical Board, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

A Class A misdemeanor is punishable by a fine of not more than \$4,000, confinement in jail for a term not to exceed one year, or both. Costs associated with enforcement, prosecution and confinement could likely be absorbed within existing resources. Revenue gain from fines imposed and collected is not anticipated to have a significant fiscal implication.

Source Agencies: 503 Texas Medical Board, 529 Health and Human Services Commission

LBB Staff: UP, KCA, EP, SSc

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 16, 2017

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB810 by Parker (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; creating a criminal offense.), **As Engrossed**

No significant fiscal implication to the State is anticipated.

The bill would amend Health and Safety Code Chapter 1003 to require the Health and Human Services Commission to adopt rules designating medical conditions that are recognized to be a severe chronic disease or a terminal illness. The bill would allow patients with such medical conditions to access and use investigational stem cell treatment if certain requirements have been met. The bill also would amend Penal Code Chapter 48 to make it a Class A misdemeanor to sell or transfer adult stem cells, with exemptions under certain scenarios. The bill would take effect September 1, 2017.

According to the Health and Human Services Commission and the Texas Medical Board, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

A Class A misdemeanor is punishable by a fine of not more than \$4,000, confinement in jail for a term not to exceed one year, or both. Costs associated with enforcement, prosecution and confinement could likely be absorbed within existing resources. Revenue gain from fines imposed and collected is not anticipated to have a significant fiscal implication.

Source Agencies: 503 Texas Medical Board, 529 Health and Human Services Commission

LBB Staff: UP, KCA, EP, SSc, JGA

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 30, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB810 by Parker (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; creating a criminal offense.), **Committee Report 1st House, Substituted**

<p>No significant fiscal implication to the State is anticipated.</p>
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The bill would amend Health and Safety Code Chapter 1003 to require the Health and Human Services Commission to adopt rules designating medical conditions that are recognized to be a severe chronic disease or a terminal illness. The bill would allow patients with such medical conditions to access and use investigational stem cell treatment if certain requirements have been met. The bill also would amend Penal Code Chapter 48 to make it a Class A misdemeanor to sell or transfer adult stem cells, with exemptions under certain scenarios. The bill would take effect September 1, 2017.

According to the Health and Human Services Commission and the Texas Medical Board, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

A Class A misdemeanor is punishable by a fine of not more than \$4,000, confinement in jail for a term not to exceed one year, or both. Costs associated with enforcement, prosecution and confinement could likely be absorbed within existing resources. Revenue gain from fines imposed and collected is not anticipated to have a significant fiscal implication.

Source Agencies: 503 Texas Medical Board, 529 Health and Human Services Commission

LBB Staff: UP, KCA, EP, SSc, JGA

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 13, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB810 by Parker (Relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses.), **As Introduced**

No significant fiscal implication to the State is anticipated.

The bill would amend Health and Safety Code Chapter 1003 to require the Health and Human Services Commission to adopt rules designating medical conditions that are recognized to be a severe chronic disease or a terminal illness. The bill would allow patients with such medical conditions to access and use investigational stem cell treatment if certain requirements have been met. The bill would take effect immediately upon receiving a two-thirds majority vote in each house. Otherwise, the bill would take effect September 1, 2017.

According to the Health and Human Services Commission and the Texas Medical Board, duties and responsibilities associated with implementing the provisions of the bill could be accomplished by utilizing existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 503 Texas Medical Board, 529 Health and Human Services Commission

LBB Staff: UP, KCA, EP, SSc, EK