

# CONFERENCE COMMITTEE REPORT FORM

Austin, Texas

May 26, 2017

Date

Honorable Dan Patrick  
President of the Senate

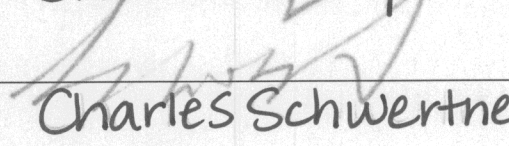
Honorable Joe Straus  
Speaker of the House of Representatives

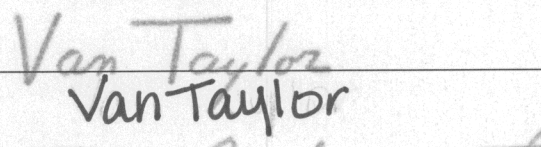
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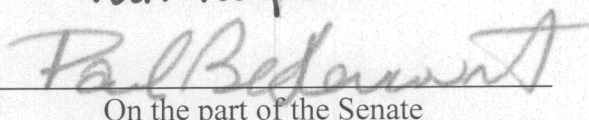
We, Your Conference Committee, appointed to adjust the differences between the Senate and the House of Representatives on House Bill 810 have had the same under consideration, and beg to report it back with the recommendation that it do pass in the form and text hereto attached.


  
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José Menéndez

  
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Charles Perry

  
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Charles Schwertner

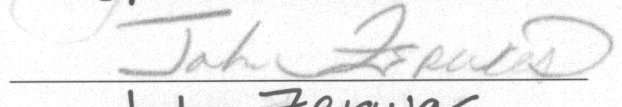
  
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Van Taylor

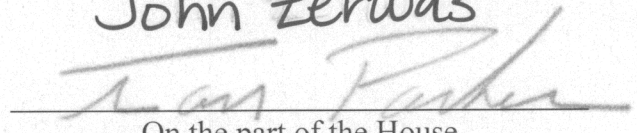
  
\_\_\_\_\_  
On the part of the Senate  
Paul Bettencourt

  
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Drew Springer

  
\_\_\_\_\_  
Charlie Geren

  
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Garnet Coleman

  
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John Zerwas

  
\_\_\_\_\_  
On the part of the House  
Tan Parker

## Note to Conference Committee Clerk:

Please type the names of the members of the Conference Committee under the lines provided for signature. Those members desiring to sign the report should sign each of the six copies. Attach a copy of the Conference Committee Report and a Section by Section side by side comparison to each of the six reporting forms. The original and two copies are filed in house of origin of the bill, and three copies in the other house.



# CONFERENCE COMMITTEE REPORT

3<sup>rd</sup> Printing

H.B. No. 810

A BILL TO BE ENTITLED

AN ACT

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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.

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

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:

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. TREATMENT REQUIREMENTS; TEXAS MEDICAL BOARD  
11 RULES. (a) Treatment provided under this subchapter must be:

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

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

16 (3) provided at:

17 (A) a hospital licensed under Chapter 241;

18 (B) an ambulatory surgical center licensed under  
19 Chapter 243; or

20 (C) a medical school, as defined by Section  
21 61.501, Education Code.

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

25 (c) An institutional review board described by Subsection

26 (d) may certify a physician to provide an investigational stem cell  
27 treatment under this subchapter.

1       (d) An institutional review board that oversees  
2 investigational stem cell treatments administered under this  
3 subchapter must be affiliated with:

4               (1) a medical school, as defined by Section 61.501,  
5 Education Code; or

6               (2) a hospital licensed under Chapter 241 that has at  
7 least 150 beds.

8       (e) The Texas Medical Board may adopt rules regarding  
9 institutional review boards as necessary to implement this section.

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

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

17       Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE  
18 PROHIBITED. Notwithstanding any other law, the Texas Medical Board  
19 may not revoke, fail to renew, suspend, or take any action against  
20 a physician's license under Subchapter B, Chapter 164, Occupations  
21 Code, based solely on the physician's recommendations to an  
22 eligible patient regarding access to or use of an investigational  
23 stem cell treatment, provided that the care provided or  
24 recommendations made to the patient meet the standard of care and  
25 the requirements of this subchapter.

26       Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a)  
27 In this section, "governmental entity" means this state or an

1 agency or political subdivision of this state.

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

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

13 (b) Each institutional review board overseeing an  
14 investigational stem cell treatment under this subchapter shall  
15 submit an annual report to the Texas Medical Board on the review  
16 board's findings based on records kept under Subsection (a). The  
17 report may not include any patient identifying information and must  
18 be made available to the public in both written and electronic form.

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

21 Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM  
22 CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a) In this  
23 section:

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

26 (A) found in differentiated tissue; and

27 (B) able to renew itself and differentiate to

1 yield all or nearly all of the specialized cell types of the tissue  
2 from which the cell originated.

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

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

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

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

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

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

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

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

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

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



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

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

**House Bill 810**  
Conference Committee Report  
Section-by-Section Analysis

HOUSE VERSION

SENATE VERSION (IE)

CONFERENCE

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

SECTION 1. Same as House version.

SECTION 1. Same as House version.

SECTION 2. Chapter 1003, Health and Safety Code, is amended.

SECTION 2. Same as House version.

SECTION 2. Same as House version.

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

SECTION 3. Same as House version except as follows:

SECTION 3. Same as House version except as follows:

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

SUBCHAPTER B. Same as House version.

SUBCHAPTER B. Same as House version.

Sections 1003.051, 1003.052, 1003.053, and 1003.054.

Sections 1003.051, 1003.052, 1003.053, and 1003.054. Same as House version.

Sections 1003.051, 1003.052, 1003.053, and 1003.054. Same as House version.

*No equivalent provision.*

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  
(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.

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  
(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.

**House Bill 810**  
Conference Committee Report  
Section-by-Section Analysis

HOUSE VERSION

SENATE VERSION (IE)

CONFERENCE

(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. [Deleted by FA1]

Sections 1003.056, 1003.057, and 1003.058. Same as House version.

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

(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 be affiliated with:

(1) a medical school, as defined by Section 61.501, Education Code; or

(2) a hospital licensed under Chapter 241 that has at least 150 beds.

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

Same as Senate version.

Sections 1003.056, 1003.057, and 1003.058. Same as House version.

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

**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.**

Sections 1003.056, 1003.057, and 1003.058.

*No equivalent provision.*

**House Bill 810**  
Conference Committee Report  
Section-by-Section Analysis

HOUSE VERSION

SENATE VERSION (IE)

CONFERENCE

record the provision of each treatment and the effects of the treatment on the person throughout the period the treatment is 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. Chapter 48, Penal Code, is amended.

SECTION 4. Same as House version.

SECTION 5. Procedural provision.

SECTION 5. Same as House version.

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

SECTION 6. Same as House version.

record the provision of each treatment and the effects of the treatment on the person throughout the period the treatment is 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 *review* board's findings based on records kept under Subsection (a). The report may not include any patient identifying information and must be made available to the public *in both* written and electronic *form*.

SECTION 4. Same as House version.

SECTION 5. Same as House version.

SECTION 6. Same as House version.

LEGISLATIVE BUDGET BOARD  
Austin, Texas

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 27, 2017

**TO:** Honorable Dan Patrick, Lieutenant Governor, Senate  
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. ),  
**Conference Committee Report**

**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.

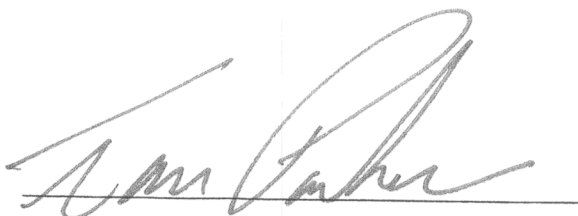
**Source Agencies:** 503 Texas Medical Board, 529 Health and Human Services Commission

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

**Certification of Compliance with  
Rule 13, Section 6(b), House Rules of Procedure**

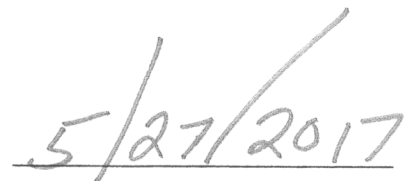
Rule 13, Section 6(b), House Rules of Procedure, requires a copy of a conference committee report signed by a majority of each committee of the conference to be furnished to each member of the committee in person or, if unable to deliver in person, by placing a copy in the member's newspaper mailbox at least one hour before the report is furnished to each member of the house under Rule 13, Section 10(a). The paper copies of the report submitted to the chief clerk under Rule 13, Section 10(b), must contain a certificate that the requirement of Rule 13, Section 6(b), has been satisfied, and that certificate must be attached to the copy of the report furnished to each member under Rule 13, Section 10(d). Failure to comply with this requirement is not a sustainable point of order under Rule 13.

I certify that a copy of the conference committee report on HB 810 was furnished to each member of the conference committee in compliance with Rule 13, Section 6(b), House Rules of Procedure, before submission of the paper copies of the report to the chief clerk under Rule 13, Section 10(b), House Rules of Procedure.



(name)

17R337(3)



(date)