# CONFERENCE COMMITTEE REPORT FORM

Austin, Texas

5/24/2019
Date

Honorable Dan Patrick
President of the Senate

Honorable Dennis Bonnen
Speaker of the House of Representatives

Sirs:

We, Your Conference Committee, appointed to adjust the differences between the Senate and the House of Representatives on HB 3148 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.

Paul Bettencourt

Chuy Hinojosa

D. W. Kolkhorst

On the part of the Senate

Tan Parker

Ron Simmons

Jim Murphy

Lina Ortega

On the part of the House

**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.**

19D 7

**CORRECTED**

# CONFERENCE COMMITTEE REPORT

**3rd Printing**

H.B. No. 3148

A BILL TO BE ENTITLED

AN ACT

relating to the administration and oversight of investigational adult stem cell treatments administered to certain patients.

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

SECTION 1. Subchapter B, Chapter 1003, Health and Safety Code, is amended by adding Sections 1003.0525 and 1003.0526 to read as follows:

Sec. 1003.0525. ADMINISTRATION OF SUBCHAPTER. The department shall administer this subchapter.

Sec. 1003.0526. INVESTIGATIONAL STEM CELL REGISTRY. The department shall establish and maintain an investigational stem cell registry that lists each physician who administers an investigational stem cell treatment under this subchapter.

SECTION 2. Section 1003.054(c), Health and Safety Code, is amended to read as follows:

(c) The executive commissioner by rule shall [~~may~~] adopt a form for the informed consent under this section. The form must provide notice that the department administers this subchapter.

SECTION 3. Section 1003.055(d), Health and Safety Code, is amended to read as follows:

(d) An institutional review board that oversees investigational stem cell treatments administered under this subchapter must meet one of the following conditions [~~be affiliated with~~]:

(1) be affiliated with a medical school, as defined by Section 61.501, Education Code; [~~or~~]

(2) be affiliated with a hospital licensed under Chapter 241 that has at least 150 beds;

(3) be accredited by the Association for the Accreditation of Human Research Protection Programs;

(4) be registered by the United States Department of Health and Human Services, Office for Human Research Protections, in accordance with 21 C.F.R. Part 56; or

(5) be accredited by a national accreditation organization acceptable to the Texas Medical Board.

SECTION 4. Section 1003.058(b), Health and Safety Code, is amended to read as follows:

(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 an investigational [~~a~~] stem cell treatment authorized under this subchapter unless the treatment uses an adult stem cell product that is considered an adulterated or misbranded drug under Chapter 431. For purposes of this subsection, a governmental entity may not consider the adult stem cell product to be an adulterated or misbranded drug solely on the basis that the United States Food and Drug Administration has not approved the adult stem cell product.

SECTION 5. Subchapter B, Chapter 1003, Health and Safety Code, is amended by adding Section 1003.060 to read as follows:

Sec. 1003.060. CONSTRUCTION OF SUBCHAPTER. This subchapter may not be construed to:

(1) prohibit a physician from using adult stem cells for their intended homologous use if the stem cells are:

(A) produced by a manufacturer registered by the United States Food and Drug Administration; and

(B) commercially available; or

(2) require an institutional review board to oversee treatment using adult stem cells registered by the United States Food and Drug Administration for their intended homologous use.

SECTION 6. The Department of State Health Services may not establish the investigational stem cell registry described by Section 1003.0526, Health and Safety Code, as added by this Act, until September 1, 2027.

SECTION 7. This Act takes effect September 1, 2019.

**House Bill 3148**
Conference Committee Report
Section-by-Section Analysis

| HOUSE VERSION | SENATE VERSION (CS) | CONFERENCE |
|---|---|---|
| SECTION 1. Subchapter B, Chapter 1003, Health and Safety Code, is amended by adding Section 1003.0525 to read as follows:<br>Sec. 1003.0525. ADMINISTRATION OF SUBCHAPTER. The department shall administer this subchapter. | SECTION 1. Subchapter B, Chapter 1003, Health and Safety Code, is amended by adding Sections 1003.0525 and 1003.0526 to read as follows:<br>Sec. 1003.0525. ADMINISTRATION OF SUBCHAPTER. The department shall administer this subchapter. | SECTION 1. Same as Senate version. |
| ***No equivalent provision.*** | Sec. 1003.0526. INVESTIGATIONAL STEM CELL REGISTRY. The department shall establish and maintain an investigational stem cell registry that lists each physician who administers an investigational stem cell treatment under this subchapter. | |
| SECTION 2. Section 1003.054(c), Health and Safety Code, is amended. | SECTION 2. Same as House version. | SECTION 2. Same as House version. |
| SECTION 3. Section 1003.055(d), Health and Safety Code, is amended to read as follows:<br>(d) An institutional review board that oversees investigational stem cell treatments administered under this subchapter must meet one of the following conditions [~~be affiliated with~~]:<br>(1) be affiliated with a medical school, as defined by Section 61.501, Education Code; [~~or~~]<br>(2) be affiliated with a hospital licensed under Chapter 241 that has at least 150 beds;<br>(3) be accredited by the Association for the Accreditation of Human Research Protection Programs;<br>(4) be registered by the United States Department of Health and Human Services, Office for Human Research Protections, in accordance with 21 C.F.R. Part 56; or<br>(5) be accredited by a national accreditation organization acceptable to the ***department***. | SECTION 3. Section 1003.055(d), Health and Safety Code, is amended to read as follows:<br>(d) An institutional review board that oversees investigational stem cell treatments administered under this subchapter must meet one of the following conditions [~~be affiliated with~~]:<br>(1) be affiliated with a medical school, as defined by Section 61.501, Education Code; [~~or~~]<br>(2) be affiliated with a hospital licensed under Chapter 241 that has at least 150 beds;<br>(3) be accredited by the Association for the Accreditation of Human Research Protection Programs;<br>(4) be registered by the United States Department of Health and Human Services, Office for Human Research Protections, in accordance with 21 C.F.R. Part 56; or<br>(5) be accredited by a national accreditation organization acceptable to the ***Texas Medical Board***. | SECTION 3. Same as Senate version. |

| HOUSE VERSION | SENATE VERSION (CS) | CONFERENCE |
|---|---|---|
| SECTION 4. Section 1003.058(b), Health and Safety Code, is amended. | SECTION 4. Same as House version. | SECTION 4. Same as House version. |
| SECTION 5. Subchapter B, Chapter 1003, Health and Safety Code, is amended by adding Section 1003.060. | SECTION 5. Same as House version. | SECTION 5. Same as House version. |
| ***No equivalent provision.*** | SECTION 6. The Department of State Health Services ***is not required to*** establish the investigational stem cell registry described by Section 1003.0526, Health and Safety Code, as added by this Act, until September 1, 2027. | SECTION 6. The Department of State Health Services ***may not*** establish the investigational stem cell registry described by Section 1003.0526, Health and Safety Code, as added by this Act, until September 1, 2027. |
| SECTION 6. Effective date. | SECTION 7. Same as House version. | SECTION 7. Same as House version. |

**LEGISLATIVE BUDGET BOARD**
**Austin, Texas**

**FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION**

**May 25, 2019**

**TO:** Honorable Dan Patrick, Lieutenant Governor, Senate
Honorable Dennis Bonnen, Speaker of the House, House of Representatives

**FROM:** John McGeady, Assistant Director Sarah Keyton, Assistant Director
Legislative Budget Board

**IN RE:** **HB3148** by Parker (Relating to the administration and oversight of investigational adult stem cell treatments administered to certain patients.), **Conference Committee Report**

**No significant fiscal implication to the State is anticipated.**

The bill would require that institutional review boards that oversee investigational stem cell treatments either be affiliated with a medical school, affiliated with a hospital, accredited by the Association for the Accreditation of Human Research Protection programs, registered by the United States Department of Health and Human Services, or accredited by another national accreditation organization acceptable to the Texas Medical Board (TMB).

The bill would require the Department of State Health Services (DSHS) to establish and maintain an investigational stem cell registry. Under the provisions of the bill, DSHS may not establish an investigational stem cell registry until September 1, 2027.

The bill would prohibit a government entity from considering an adult stem cell product to be an adulterated or misbranded drug solely on the basis of the drug not being approved by United States Food and Drug Administration.

DSHS and TMB indicate that the provisions of the bill could be absorbed using existing resources.

**Local Government Impact**

No significant fiscal implication to units of local government is anticipated.

**Source Agencies:** 537 State Health Services, Department of, 503 Texas Medical Board, 529 Health and Human Services Commission

**LBB Staff:** WP, SD, AKi, JQ, BH

# 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 House 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 subject to a point of order under Rule 13.

I certify that a copy of the conference committee report on HB 3148 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.

Tom Parker
(name)

5/24/2019
(date)