SENATE AMENDMENTS

2nd Printing

By: Parker, Springer, Zerwas, Lucio III, et al. 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 Section 1003.0525 to read as follows:

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

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. This Act takes effect September 1, 2019.

ADOPTED
MAY 21 2019
Secretary of the Senate

By: Parker/Bettencourt ___.B. No. _____

Substitute the following for ___.B. No. ____:

By: _____ C.S. H .B. No. 3146

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 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 7. This Act takes effect September 1, 2019.

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

May 21, 2019

TO: 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.), **As Passed 2nd House**

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 also require the Department of State Health Services (DSHS) to establish an investigational stem cell registry by 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

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

May 19, 2019

TO: Honorable Lois W. Kolkhorst, Chair, Senate Committee on Health & Human Services

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.), **Committee Report 2nd House, Substituted**

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 also require the Department of State Health Services (DSHS) to establish an investigational stem cell registry by 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, AKi, JQ, BH

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

May 13, 2019

TO: Honorable Lois W. Kolkhorst, Chair, Senate Committee on Health & Human Services

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.), **As Engrossed**

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 Department of State Health Services (DSHS).

The bill would also 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, the Health and Human Services Commission, and the Texas Medical Board 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: 503 Texas Medical Board, 529 Health and Human Services Commission, 537 State Health Services, Department of

LBB Staff: WP, AKi, JQ, BH

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

April 27, 2019

TO: Honorable Senfronia Thompson, Chair, House Committee on Public Health

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.), **Committee Report 1st House, Substituted**

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 Department of State Health Services (DSHS).

The bill would also 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, the Health and Human Services Commission, and the Texas Medical Board 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: 503 Texas Medical Board, 529 Health and Human Services Commission, 537 State Health Services, Department of

LBB Staff: WP, AKi, JQ, BH

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

April 8, 2019

TO: Honorable Senfronia Thompson, Chair, House Committee on Public Health

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.), **As Introduced**

No significant fiscal implication to the State is anticipated.

The bill would require that institutional review boards that oversee stem cell treatments either be accredited by the Association for the Accreditation of Human Research Protection programs, be registered by the United States Department of Health and Human Services, or be accredited by another national accreditation organization acceptable to the Department of State Health Services (DSHS). The bill would also prohibit a government entity from considering a drug adulterated or misbranded solely on the basis of the drug not being approved by United States Food and Drug Administration

DSHS, the Health and Human Services Commission, and the Texas Medical Board 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: 503 Texas Medical Board, 529 Health and Human Services Commission, 537 State Health Services, Department of

LBB Staff: WP, AKi, JQ, BH