

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

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

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

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

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

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

14 (b) A governmental entity or an officer, employee, or agent
15 of a governmental entity may not interfere with an eligible
16 patient's access to or use of an investigational [a] stem cell
17 treatment authorized under this subchapter unless the treatment
18 uses an adult stem cell product that is considered an adulterated or
19 misbranded drug under Chapter 431. For purposes of this subsection,
20 a governmental entity may not consider the adult stem cell product
21 to be an adulterated or misbranded drug solely on the basis that the
22 United States Food and Drug Administration has not approved the
23 adult stem cell product.

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

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

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

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

5 (B) commercially available; or

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

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

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

President of the Senate

Speaker of the House

I certify that H.B. No. 3148 was passed by the House on May 9, 2019, by the following vote: Yeas 141, Nays 0, 2 present, not voting; that the House refused to concur in Senate amendments to H.B. No. 3148 on May 23, 2019, and requested the appointment of a conference committee to consider the differences between the two houses; and that the House adopted the conference committee report on H.B. No. 3148 on May 26, 2019, by the following vote: Yeas 141, Nays 0, 3 present, not voting.

Chief Clerk of the House

H.B. No. 3148

I certify that H.B. No. 3148 was passed by the Senate, with amendments, on May 21, 2019, by the following vote: Yeas 31, Nays 0; at the request of the House, the Senate appointed a conference committee to consider the differences between the two houses; and that the Senate adopted the conference committee report on H.B. No. 3148 on May 26, 2019, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor