

BILL ANALYSIS

Senate Research Center

C.S.H.B. 3148
By: Parker et al. (Bettencourt)
Health & Human Services
5/19/2019
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

C.S.H.B. 3148 amends current law relating to the administration and oversight of investigational adult stem cell treatments administered to certain patients.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

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

Sec. 1003.0525. ADMINISTRATION OF SUBCHAPTER. Requires the Department of State Health Services (DSHS) to administer this subchapter (Provision of Investigational Stem Cell Treatments to Patients With Certain Severe Chronic Diseases or Terminal Illnesses).

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

SECTION 2. Amends Section 1003.054(c), Health and Safety Code, as follows:

(c) Requires, rather than authorizes, the executive commissioner of the Health and Human Services Commission (executive commissioner) by rule to adopt a form for the informed consent under this section (Informed Consent). Requires the form to provide notice that DSHS administers this subchapter.

SECTION 3. Amends Section 1003.055(d), Health and Safety Code, as follows:

(d) Makes nonsubstantive changes to Subdivisions (1)–(2). Requires an institutional review board that oversees investigational stem cell treatments administered under this subchapter to meet one of the following conditions:

(1) be affiliated with a medical school, as defined by Section 61.501 (Definitions), Education Code;

(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. Amends Section 1003.058(b), Health and Safety Code, as follows:

(b) Prohibits a governmental entity or an officer, employee, or agent of a governmental entity from interfering with an eligible patient's access to or use of an investigational 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 (Texas Food, Drug, and Cosmetic Act). Prohibits a governmental entity, for purposes of this subsection, from considering the adult stem cell product to be an adulterated or misbranded drug solely on the basis that the United States Food and Drug Administration (FDA) has not approved the adult stem cell product.

SECTION 5. Amends Subchapter B, Chapter 1003, Health and Safety Code, by adding Section 1003.060, as follows:

Sec. 1003.060. CONSTRUCTION OF SUBCHAPTER. Prohibits this subchapter from being 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 FDA; and

(B) commercially available; or

(2) require an institutional review board to oversee treatment using adult stem cells registered by FDA for their intended homologous use.

SECTION 6. Provides that DSHS 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. Effective date: September 1, 2019.