BILL ANALYSIS

Senate Research Center
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S.B. 1765
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Health & Human Services
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As Filed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

During the 85th legislative session, H.B. 810, also known as Charlie's Law, which allowed patients with certain severe chronic diseases or terminal illnesses to access adult stem cell treatments, was passed by the legislature and signed into law by the governor.

Interested parties have noted difficulty in accessibility as well as operational issues relative to this statute. S.B. 1765 seeks to address these problems by clarifying that the government cannot prohibit a qualifying individual from receiving adult stem cell treatments unless the adult stem cells to be administered have been deemed to be adulterated or misbranded.

It has also been observed that licensed physicians operating under the United States Food and Drug Administration's (FDA) rules regarding stem cell treatments were affected by the passage of H.B. 810.

S.B. 1765 seeks to clarify that there are no current laws or rules in existence that would prohibit a licensed physician from utilizing FDA registered, commercially available stem cells for their intended homologous use.

As proposed, S.B. 1765 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 Section 1003.0525, 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).

SECTION 2. Amends Section 1003.055(d), Health and Safety Code, as follows:

> (d) Requires an institutional review board that oversees investigational stem cell treatments administered under this subchapter to, rather than requiring an institutional review board that oversees investigational stem cell treatments administered under this subchapter (Provision of Investigational Stem Cell Treatments to Patients With Certain Severe Chronic Diseases or Terminal Illnesses) to be affiliated with:
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> > (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 (Hospitals) 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 DSHS.

SECTION 3. 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 a stem cell treatment authorized under this subchapter unless the treatment uses a drug that is considered adulterated or misbranded under Chapter 431 (Texas Food, Drug, and Cosmetic Act). Prohibits a governmental entity, for purposes of this subsection, from considering the drug to be adulterated or misbranded solely on the basis that the United States Food and Drug Administration has not approved the drug.

SECTION 4. 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 (General Provisions) from being construed to prohibit a physician from using adult stem cells for their intended homologous use if the stem cells are registered by the United States Food and Drug Administration and commercially available or construed to 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 5. Effective date: September 1, 2019.