By: Parker, Springer, Zerwas, Lucio III H.B. No. 3148

Substitute the following for H.B. No. 3148:

By: Zedler C.S.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.