HEALTH AND SAFETY CODE

TITLE 12. HEALTH AND MENTAL HEALTH

CHAPTER 1003. ADULT STEM CELLS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 1003.001. ESTABLISHMENT OF ADULT STEM CELL BANK. (a) If the executive commissioner of the Health and Human Services Commission determines that it will be cost-effective and increase the efficiency or quality of health care, health and human services, and health benefits programs in this state, the executive commissioner by rule shall establish eligibility criteria for the creation and operation of an autologous adult stem cell bank.

(b) In adopting the rules under Subsection (a), the executive commissioner shall consider:

(1) the ability of the applicant to establish, operate, and maintain an autologous adult stem cell bank and to provide related services; and

(2) the demonstrated experience of the applicant in operating similar facilities in this state.

(c) This section does not affect the application of or apply to Chapter 162.

Added by Acts 2011, 82nd Leg., 1st C.S., Ch. 7 (S.B. 7), Sec. 14.01, eff. September 28, 2011.

Sec. 1003.002. GENERAL REQUIREMENTS FOR ADULT STEM CELL USE IN HEALTH CARE. A person using adult stem cells in the provision of health care:

(1) must use adult stem cells that are properly manufactured and stored; and

(2) may only use adult stem cells in a clinical trial approved by the United States Food and Drug Administration.

Added by Acts 2015, 84th Leg., R.S., Ch. 992 (H.B. 177), Sec. 5, eff. September 1, 2015.

Sec. 1003.003. ADDITIONAL REQUIREMENTS FOR ADULT STEM CELL USE IN HOSPITALS. A hospital may use adult stem cells in a

procedure if:

(1) a physician providing services at the hospital determines that the use of adult stem cells in the procedure is appropriate;

(2) the patient consents in writing to the use;

(3) the requirements for stem cell use under Section 1003.002 are met;

(4) the manufacturing processes for the adult stem cells satisfy current good manufacturing practices adopted by the United States Food and Drug Administration; and

(5) appropriate state and federal guidelines on the use of adult stem cells are followed.

Added by Acts 2015, 84th Leg., R.S., Ch. 992 (H.B. 177), Sec. 5, eff. September 1, 2015.

SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES

Sec. 1003.051. DEFINITIONS. In this subchapter:

(1) "Investigational stem cell treatment" means an adult stem cell treatment that:

(A) is under investigation in a clinical trial and being administered to human participants in that trial; and

(B) has not yet been approved for general use by the United States Food and Drug Administration.

(2) "Severe chronic disease" means a condition, injury, or illness that:

(A) may be treated;

(B) is never cured or eliminated; and

(C) entails significant functional impairment or severe pain.

(3) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Sec. 1003.052. RULES. The executive commissioner shall adopt rules designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of this subchapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

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

Added by Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 1, eff. September 1, 2019.

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.

Added by Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 1, eff. September 1, 2019.

Sec. 1003.053. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational stem cell treatment under this subchapter if:

(1) the patient has a severe chronic disease or terminal illness listed in the rules adopted under Section 1003.052 and attested to by the patient's treating physician; and

(2) the patient's physician:

(A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3,

eff. September 1, 2017.

Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an investigational stem cell treatment, an eligible patient must sign a written informed consent.

(b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(c) The executive commissioner by rule shall adopt a form for the informed consent under this section. The form must provide notice that the department administers this subchapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 2, eff. September 1, 2019.

Sec. 1003.055. TREATMENT REQUIREMENTS; TEXAS MEDICAL BOARD RULES. (a) Treatment provided under this subchapter must be:

(1) administered directly by a physician certified under Subsection (c);

(2) overseen by an institutional review board described by Subsection (d); and

(3) provided at:

(A) a hospital licensed under Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243; or

(C) a medical school, as defined by Section 61.501, Education Code.

(b) A physician administering an investigational stem cell treatment under this subchapter shall comply with all applicable Texas Medical Board rules.

(c) An institutional review board described by Subsection (d) may certify a physician to provide an investigational stem cell treatment under this subchapter.

(d) An institutional review board that oversees investigational stem cell treatments administered under this

subchapter must meet one of the following conditions:

(1) be affiliated with a medical school, as defined by Section 61.501, 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.

(e) The Texas Medical Board may adopt rules regarding institutional review boards as necessary to implement this section.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 3, eff. September 1, 2019.

Sec. 1003.056. EFFECT ON OTHER LAW. (a) This subchapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

(b) This subchapter does not affect or authorize a person to violate any law regulating the possession, use, or transfer of fetal tissue, fetal stem cells, adult stem cells, or human organs, including Sections 48.02 and 48.04, Penal Code.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 467 (H.B. 4170), Sec. 21.002(13), eff. September 1, 2019.

Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164,

Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or use of an investigational stem cell treatment, provided that the care provided or recommendations made to the patient meet the standard of care and the requirements of this subchapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a) In this section, "governmental entity" means this state or an agency or political subdivision of this state.

(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 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.

Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 4, eff. September 1, 2019.

Sec. 1003.059. INSTITUTIONAL REVIEW BOARD DOCUMENTATION; REPORT. (a) An institutional review board overseeing an investigational stem cell treatment under this subchapter shall keep a record on each person to whom a physician administers the treatment and document in the record the provision of each treatment and the effects of the treatment on the person throughout the period the treatment is administered to the person.

(b) Each institutional review board overseeing an investigational stem cell treatment under this subchapter shall submit an annual report to the Texas Medical Board on the review

board's findings based on records kept under Subsection (a). The report may not include any patient identifying information and must be made available to the public in both written and electronic form. Added by Acts 2017, 85th Leg., R.S., Ch. 697 (H.B. 810), Sec. 3, eff. September 1, 2017.

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. Added by Acts 2019, 86th Leg., R.S., Ch. 1158 (H.B. 3148), Sec. 5, eff. September 1, 2019.