SUBCHAPTER B. INVESTIGATIONAL STEM CELL TREATMENTS FOR PATIENTS WITH CERTAIN SEVERE CHRONIC DIAGNOSES OR TERMINAL ILLNESSES

22 TAC §198.5, §198.6

The new rules are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine in this state; enforce this subtitle; and establish rules related to licensure.

No other statutes, articles or codes are affected by this proposal.

§198.5.Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses.

(a) The Legislature recognizes the need for patient access to innovative medical treatments. At the same time, the health and welfare of Texas citizens must be protected. These goals must be carefully balanced.

(b) The purpose of this subchapter is to set out the requirements for a patient to be eligible for consideration of receiving investigational stem cell treatment and under what circumstances a certified physician may administer or provide investigational stem cell treatments. The implementation of this rule is contingent upon qualifying chronic diseases or terminal illness being defined, as set out in §1003.052 of the Texas Health and Safety Code.

(c) This rule does not require an eligible patient receive such treatment, but rather the statute sets the eligibility standards and the parameters under which treatment may be provided to an individual with a qualifying severe chronic disease or terminal illness.

(d) Stem cell treatments which are under investigation in a clinical trial and being administered to human participants:

(1) may be administered or provided to eligible patients with qualifying terminal illnesses or severe chronic diseases as defined by the executive commissioner of the Health and Human Services Commission; and

(2) must be done in compliance with applicable law.

(e) In order for a patient to be eligible to receive treatment with investigational stem cells, the eligible patient must:

(1) be enrolled in a clinical trial investigating the use of adult stem cells in humans;

(2) sign a written informed consent before receiving treatment, include documentation in the medical record of compliance with §1003.053(2)(a) of the Texas Health and Safety Code;

(3) receive treatment from a physician certified under §1003.055 of the Texas Health and Safety Code by:

(A) a qualifying IRB;

(B) a medical school as defined by §61.501 of the Education Code; or

(C) a hospital licensed under Chapter 241 of the Texas Health and Safety Code; and

(4) receive treatment in a qualifying facility under §1003.055 of the Texas Health and Safety Code.

§198.6.Process and Procedures for IRBs Engaged in the Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses.

(a) In accordance with Chapter 1003 of the Texas Health and Safety Code, each IRB overseeing clinical trials of investigational stem cell treatments shall submit an annual report to the Board that:

(1) sets forth the study's current findings;

(2) specifies the number of patients participating in the stem cell clinical trial(s);

(3) includes the treatment results of all patients treated with investigational stem cell treatments;

(4) generally describes the effects of the treatments and study's findings to date, including all adverse events;

(5) includes the medical school or hospital the IRB is affiliated with in accordance with §1003.055 of the Texas Health and Safety Code;

(6) includes the location where the patients' treatments were provided in accordance with §1003.055 of the Texas Health and Safety Code;

(7) includes the names of all physicians certified by the IRB or the affiliated entity to administer or provide investigational stem cell treatments and the time-period of that certification; and

(8) shall not include any patient identifying information, as the report will be made available to the public upon request.

(b) Each IRB overseeing clinical trials must be current with required reporting to the TMB. The annual report shall cover the time-period beginning September 1 and ending on August 31. The report must be submitted to the Medical Board before the end of the calendar year in which the reporting time-period ends.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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