

Amend **HB 810** (senate committee printing) as follows:

(1) In SECTION 3 of the bill, between added Sections 1003.054 and 1003.055, Health and Safety Code (page 2, between lines 16 and 17), insert the following:

Sec. 1003.0545. TREATMENT REQUIREMENTS; COMPLIANCE WITH 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:

(1) be affiliated with:

(A) a medical school, as defined by Section 61.501, Education Code; or

(B) a hospital licensed under Chapter 241 that has a minimum of 150 beds; and

(2) comply with all applicable rules under 21 C.F.R. Part 1271 related to human cells as of September 1, 2017.

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

(2) In SECTION 3 of the bill, immediately following added Section 1003.058, Health and Safety Code (page 2, between lines 46

and 47), insert the following:

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 board's findings based on records kept under Subsection (a). The report may not include any patient identifying information and must be:

- (1) written;
- (2) electronic; and
- (3) made available to the public.