

AN ACT

relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses and regulating the possession, use, and transfer of adult stem cells; creating a criminal offense.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. This Act shall be known as Charlie's Law.

SECTION 2. Chapter 1003, Health and Safety Code, is amended by designating Sections 1003.001, 1003.002, and 1003.003 as Subchapter A and adding a subchapter heading to read as follows:

SUBCHAPTER A. GENERAL PROVISIONS

SECTION 3. Chapter 1003, Health and Safety Code, is amended by adding Subchapter B to read as follows:

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:

1 treatment.

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

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

8 (c) The executive commissioner by rule may adopt a form for
9 the informed consent under this section.

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

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

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

16 (3) provided at:

17 (A) a hospital licensed under Chapter 241;

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

20 (C) a medical school, as defined by Section
21 61.501, Education Code.

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

25 (c) An institutional review board described by Subsection

26 (d) may certify a physician to provide an investigational stem cell
27 treatment under this subchapter.