PLACENTAL TISSUE AMENDMENTS

2024 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Curtis S. Bramble

House Sponsor: Katy Hall

LONG TITLE

General Description:

This bill requires certain health care providers to provide certain disclosures when administering a treatment using placental stem cells.

Highlighted Provisions:

This bill:

- defines terms;
- requires certain health care providers to provide certain disclosures to a patient when administering a treatment using placental stem cells; and
- creates a penalty for failing to provide the disclosures.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

ENACTS:

58-1-512, as Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-1-512** is enacted to read:

58-1-512 . Stem cell disclosure.

(1) As used in this section:

(a) "Health care provider" means the same as that term is defined in Section 78B-3-403.

(b) "Human cells, tissues, or cellular or tissue-based products" has the same meaning as in 21 C.F.R. Sec. 1271.3 as it exists on May 1, 2024.

(c) (i) "Stem cell therapy" means a treatment involving the use of afterbirth placental

perinatal stem cells or human cells, tissues, or cellular or tissue-based products.

(ii) "Stem cell therapy" does not include treatment or research using human cells or tissues that were derived from a fetus or embryo after an abortion.

(2) A health care provider whose scope of practice includes the use of stem cell therapy may perform a stem cell therapy that is not approved by the United States Food and Drug Administration, if the health care provider provides the patient with the following written notice before performing the therapy:

"THIS NOTICE MUST BE PROVIDED TO YOU UNDER UTAH LAW. This health care practitioner performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing a stem cell therapy."

(3) (a) The written notice described in Subsection (2) shall be:

(i) on paper that is at least eight and one-half inches by eleven inches; and

(ii) written in no less than forty point type.

(b) The health care provider shall prominently display the written notice in the entrance and in an area visible to patients in the health care provider's office.

(4) (a) A health care provider who is required to provide written notice under Subsection (2) shall obtain a signed consent form before performing the therapy.

(b) The consent form shall:

(i) be signed by the patient, or, if the patient is legally not competent, the patient's representative; and

(ii) state, in language the patient could reasonably be expected to understand:

(A) the nature and character of the proposed treatment, including the treatment's United States Food and Drug Administration approval status;

(B) the anticipated results of the proposed treatment;

(C) the recognized possible alternative forms of treatment; and

(D) the recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.

(5) (a) A health care provider described in Subsection (2) shall include the notice described in Subsection (2) in any advertisement for the stem cell therapy.

(b) In a print advertisement, the notice shall be clearly legible, in a font size no smaller than the largest font size used in the advertisement.

(c) In any other advertisement, the notice shall be:

(i) clearly legible in a font size no smaller than the largest font size used in the advertisement; or

(ii) clearly spoken.

(6) This section does not apply to:

(a) a health care provider who has obtained approval for an investigational new drug or device from the United States Food and Drug Administration for the use of human cells, tissues, or cellular or tissue-based products; or

(b) a health care provider who performs a stem cell therapy under an employment or other contract on behalf of an institution certified by any of the following:

(i) the Foundation for the Accreditation of Cellular Therapy;

(ii) the Blood and Marrow Transplant Clinical Trials Network;

(iii) the Association for the Advancement of Blood and Biotherapies; or

(iv) an entity with expertise regarding stem cell therapy as determined by the division.

(7) A violation of this section is unprofessional conduct.

Section 2. **Effective date.**

This bill takes effect on May 1, 2024.