By Senator Berman

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A bill to be entitled

An act relating to stem cells; creating s. 385.301, F.S.; defining terms; requiring the Department of Health to adopt rules by a specified date; providing patient eligibility; requiring eligible patients to sign a written informed consent prior to receiving an investigational stem cell treatment; authorizing the department to adopt a form by rule for the informed consent; requiring an investigational stem cell treatment to be administered directly by a licensed and certified physician, overseen by an institutional review board, and provided at a certain facility; providing construction; prohibiting a licensing board from taking action against a physician's license under certain circumstances; prohibiting a state entity responsible for Medicare certification from taking action against a physician's Medicare certification under certain circumstances; prohibiting a state entity from interfering with an eligible patient's access to or use of a stem cell treatment; requiring institutional review boards to keep records on the treatment of each patient; requiring each institutional review board to submit an annual report analyzing patient records to the Board of Medicine and the Board of Osteopathic Medicine; requiring that the report exclude the personal identifying information of patients and that it be made available to the public in both written and electronic form; amending s. 873.01, F.S.; clarifying that the purchase or sale of

stem cells is a felony; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 385.301, Florida Statutes, is created to read:

385.301 Investigational stem cell treatments.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Adult stem cell" means a living cell produced by or normally present within the body of a human being which functions to repair or to replace other cells and tissues within the human body and which is not obtained from a human embryo or fetus. The term also includes cells contained in an umbilical cord and placenta after the delivery of a newborn.

(b) "Department" means the Department of Health.

(c) "Institutional review board" means a board that:

1. Is affiliated with a hospital licensed under chapter 395 which has at least 150 beds or an accredited medical school; and

2. Has been approved by the department to certify the physician administration of and to oversee an investigational stem cell treatment in compliance with this section.

(d) "Investigational stem cell treatment" means treatment using adult stem cells which:

1. Is under an investigation in a clinical trial approved by the United States Food and Drug Administration;

2. Is being administered to human participants in the clinical trial; and

3. Has not been approved for general use by the United States Food and Drug Administration.

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

1. May be treated;

2. Is never cured or eliminated; and

3. Entails significant functional impairment or severe pain.

(f) "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.

(2) RULEMAKING.—No later than January 1, 2020, the department shall adopt rules designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of this section, rules regarding institutional review boards, and any other rules necessary to administer this section.

(3) PATIENT ELIGIBILITY.—A patient is eligible to access and use an investigational stem cell treatment under this section if:

(a) The patient has been diagnosed by his or her treating physician with a severe chronic disease or terminal illness;

(b) The physician, 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

(c) The physician has recommended or prescribed in writing that the patient use a specific class of investigational stem

cell treatment.

(4) INFORMED CONSENT.—

(a) An eligible patient must sign a written informed consent before receiving an investigational stem cell treatment.

(b) If the eligible 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 department may adopt a form by rule for the informed consent required under this section.

(5) TREATMENT REQUIREMENTS.—

(a) Treatment provided under this section must be:

1. Administered directly by a physician licensed under chapter 458 or chapter 459 who is certified by an institutional review board to provide such treatment;

2. Overseen by an institutional review board; and

3. Provided at a hospital or ambulatory surgical center licensed under chapter 395 or an accredited medical school.

(b) A physician administering an investigational stem cell treatment under this section shall comply with all applicable Board of Medicine or Board of Osteopathic Medicine rules.

(6) EFFECT ON OTHER LAW.—

(a) This section does not expand the coverage that an insurer must provide under the Florida Insurance Code and does not affect mandatory health coverage for participation in clinical trials.

(b) This section does not authorize a person to sell a human organ or tissue in violation of s. 873.01.

(7) ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED;

MEDICARE.—A licensing board may not revoke, fail to renew, suspend, or take any action against a physician's license issued under chapter 458 or chapter 459 based solely on the physician's recommendations to an eligible patient regarding access to or use of an investigational stem cell treatment. A state entity responsible for Medicare certification may not take action against a physician's Medicare certification based solely on the physician's recommendation that an eligible patient access or use an investigational stem cell treatment.

(8) GOVERNMENTAL INTERFERENCE PROHIBITED.—A state 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 section.

(9) INSTITUTIONAL REVIEW BOARD RECORDS; REPORT.—

(a) An institutional review board overseeing an investigational stem cell treatment under this section shall keep a record on each patient 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 patient throughout the period the treatment is administered to the patient.

(b) Each institutional review board overseeing an investigational stem cell treatment under this section shall submit an annual report to the Board of Medicine and the Board of Osteopathic Medicine which analyzes the patient records described in paragraph (a). A report may not include the personal identifying information of any patient and must be made available to the public in both written and electronic form.

Section 2. Subsection (3) of section 873.01, Florida Statutes, is amended, and subsections (1), (2), and (4) of that section are republished, to read:

873.01 Purchase or sale of human organs and tissue prohibited.—

(1) No person shall knowingly offer to purchase or sell, or purchase, sell, or otherwise transfer, any human organ or tissue for valuable consideration.

(2) No for-profit corporation or any employee thereof shall transfer or arrange for the transfer of any human body part for valuable consideration.

(3)(a) The human organs and tissues subject to the provisions of this section are the eye, cornea, kidney, liver, heart, lung, pancreas, bone, stem cells, and skin or any other organ or tissue adopted by rule by the Agency for Health Care Administration for this purpose.

(b) As used in this section, the term "valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human organ or tissue.

(4) A person who violates the provisions of this section is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 3. This act shall take effect July 1, 2019.