By the Committees on Rules; and Health Policy; and Senator Trumbull

595-03688-25 20251768c2

A bill to be entitled

An act relating to stem cell therapy; creating ss. 458.3245 and 459.0127, F.S.; providing legislative findings and intent; defining terms; authorizing physicians to perform stem cell therapy not approved by the United States Food and Drug Administration under certain circumstances; specifying requirements for the stem cells that may be used by such physicians; requiring such physicians to adhere to applicable current good manufacturing practices in the performance of such therapies; requiring physicians to include a specified notice in any form of advertisement; providing requirements for such notice; requiring physicians to obtain a signed consent form from the patient or his or her representative before performing the therapy; specifying requirements for the consent form; providing applicability; providing for disciplinary action; requiring the Board of Medicine and the Board of Osteopathic Medicine, respectively, to adopt rules in consultation with one another; providing an effective date.

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

Section 1. Section 458.3245, Florida Statutes, is created to read:

458.3245 Stem cell therapy.—

(1) The Legislature recognizes the significant potential of stem cell therapies in advancing medical treatments and

improving patient outcomes and further recognizes the need to ensure that such therapies are provided using stem cells obtained in an ethical manner that does not involve stem cells derived from aborted fetuses. It is the intent of the Legislature to foster medical innovation while upholding ethical standards that respect the sanctity of life. By encouraging the use of stem cell sources such as adult stem cells, umbilical cord blood, and other ethically obtained human cells, tissues, or cellular or tissue-based products, the state will advance regenerative medicine in a manner consistent with the values of this state.

(2) As used in this section, the term:

(a) "Human cells, tissues, or cellular or tissue-based products" means articles containing or consisting of human cells or tissues collected from cord blood donors who are residents of the United States which are intended for implantation, transplantation, infusion, or transfer into a human recipient, including, but not limited to, bones, ligaments, skin, dura mater, heart valves, corneas, hematopoietic stem or progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The term does not include any of the following:

1. Vascularized human organs for transplantation.

2. Whole blood or blood components or blood derivative products subject to regulation under part I of chapter 499.

3. Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered a human cell, tissue, or cellular or tissue-based product for

purposes of this paragraph.

4. Minimally manipulated bone marrow for homologous use and not combined with another article, except for with water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow.

5. Ancillary products used in the manufacture of human cells, tissues, or cellular or tissue-based products.

6. Cells, tissues, and organs derived from animals other than humans.

7. In vitro diagnostic products.

8. Blood vessels recovered with an organ, as defined in 42 C.F.R. s. 121.2, which are intended for use in organ transplantation and labeled, "For use in organ transplantation only."

9. Fetal-derived stem cells.

10. Adipose-derived mesenchymal stem cells for transplantation.

(b) "Minimally manipulated" means:

1. For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

2. For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(c) "Physician" means a physician licensed under this chapter or under chapter 459 acting in the course and scope of his or her employment.

(d) "Stem cell therapy" means a treatment involving the use

of human cells, tissues, or cellular or tissue-based products which complies with the regulatory and reporting requirements provided in this section. The term does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

(3)(a) A physician may perform stem cell therapy that is not approved by the United States Food and Drug Administration if such therapy is used for treatment or procedures that are within the scope of practice for such physician and the therapies are related to orthopedics, wound care, or pain management.

(b) To ensure that the retrieval, manufacture, storage, and use of stem cells used for therapies conducted under this section meet the highest standards, any stem cells used by a physician for therapy provided under this section must:

1. Be manufactured in a clean room space that has been certified by the United States Food and Drug Administration for using high-efficiency particulate air filtration or ultra-low penetration air filtration to minimize nonviable and viable particulate contamination;

2. Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States Food and Drug Administration and licensed or registered with one of the following entities:

a. National Marrow Donor Program.

b. World Marrow Donor Association.

c. Association for the Advancement of Blood and Biotherapies.

d. American Association of Tissue Banks; and

3. Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which will be sent to the physician before use with the physician's patient.

(4) In the performance of any procedure using or purporting to use stem cells or products containing stem cells, the physician shall adhere to the applicable current good manufacturing practices for the collection, removal, processing, implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

(5)(a) A physician who conducts stem cell therapy pursuant to this section shall include the following notice in any form of advertisement:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This physician 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 any stem cell therapy.

(b) The notice required by paragraph (a) must be clearly legible and in a type size no smaller than the largest type size used in the advertisement.

(6)(a) A physician who conducts stem cell therapy pursuant to this section shall obtain a signed consent form from the

patient before performing the stem cell therapy.

(b) The consent form must be signed by the patient or, if the patient is not legally competent, the patient's representative and must state all of the following in language the patient or his or her representative could reasonably be expected to understand:

1. The nature and character of the proposed treatment.

2. That the proposed stem cell therapy has not yet been approved by the United States Food and Drug Administration.

3. The anticipated results of the proposed treatment.

4. 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. That the patient is encouraged to consult with his or her primary care provider before undergoing any stem cell therapy.

(7) This section does not apply to either of the following:

(a) A physician 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.

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

1. The Foundation for the Accreditation of Cellular Therapy.

2. The Blood and Marrow Transplant Clinical Trials Network.

3. The Association for the Advancement of Blood and

Biotherapies.

4. An entity with expertise in stem cell therapy as determined by the department.

(8) A violation of this section may subject the physician to disciplinary action by the board or the department.

(9) The Board of Medicine shall adopt rules in consultation with the Board of Osteopathic Medicine to implement this section.

Section 2. Section 459.0127, Florida Statutes, is created to read:

459.0127 Stem cell therapy.—

(1) The Legislature recognizes the significant potential of stem cell therapies in advancing medical treatments and improving patient outcomes and further recognizes the need to ensure that such therapies are provided using stem cells obtained in an ethical manner that does not involve stem cells derived from aborted fetuses. It is the intent of the Legislature to foster medical innovation while upholding ethical standards that respect the sanctity of life. By encouraging the use of stem cell sources such as adult stem cells, umbilical cord blood, and other ethically obtained human cells, tissues, or cellular or tissue-based products, the state will advance regenerative medicine in a manner consistent with the values of this state.

(2) As used in this section, the term:

(a) "Human cells, tissues, or cellular or tissue-based products" means articles containing or consisting of human cells or tissues collected from cord blood donors who are residents of the United States which are intended for implantation,

transplantation, infusion, or transfer into a human recipient, including, but not limited to, bones, ligaments, skin, dura mater, heart valves, corneas, hematopoietic stem or progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The term does not include any of the following:

1. Vascularized human organs for transplantation.

2. Whole blood or blood components or blood derivative products subject to regulation under part I of chapter 499.

3. Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered a human cell, tissue, or cellular or tissue-based product for purposes of this paragraph.

4. Minimally manipulated bone marrow for homologous use and not combined with another article, except for with water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow.

5. Ancillary products used in the manufacture of human cells, tissues, or cellular or tissue-based products.

6. Cells, tissues, and organs derived from animals other than humans.

7. In vitro diagnostic products.

8. Blood vessels recovered with an organ, as defined in 42 C.F.R. s. 121.2, which are intended for use in organ transplantation and labeled, "For use in organ transplantation only."

9. Fetal-derived stem cells.

10. Adipose-derived mesenchymal stem cells for transplantation.

(b) "Minimally manipulated" means:

1. For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

2. For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(c) "Physician" means a physician licensed under this chapter or under chapter 458 acting in the course and scope of his or her employment.

(d) "Stem cell therapy" means a treatment involving the use of human cells, tissues, or cellular or tissue-based products which complies with the regulatory and reporting requirements provided in this section. The term does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

(3)(a) A physician may perform stem cell therapy that is not approved by the United States Food and Drug Administration if such therapy is used for treatment or procedures that are within the scope of practice for such physician and the therapies are related to orthopedics, wound care, or pain management.

(b) To ensure that the retrieval, manufacture, storage, and use of stem cells used for therapies conducted under this section meet the highest standards, any stem cells used by a physician for therapy provided under this section must:

1. Be manufactured in a clean room space that has been

certified by the United States Food and Drug Administration for using high-efficiency particulate air filtration or ultra-low penetration air filtration to minimize nonviable and viable particulate contamination;

2. Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States Food and Drug Administration and licensed or registered with one of the following entities:

a. National Marrow Donor Program.

b. World Marrow Donor Association.

c. Association for the Advancement of Blood and Biotherapies.

d. American Association of Tissue Banks; and

3. Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which will be sent to the physician before use with the physician's patient.

(4) In the performance of any procedure using or purporting to use stem cells or products containing stem cells, the physician shall adhere to the applicable current good manufacturing practices for the collection, removal, processing, implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

(5)(a) A physician who conducts stem cell therapy pursuant to this section shall include the following notice in any form of advertisement:

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292 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
293 This physician performs one or more stem cell
294 therapies that have not yet been approved by the
295 United States Food and Drug Administration. You are
296 encouraged to consult with your primary care provider
297 before undergoing any stem cell therapy.
298
299 (b) The notice required by paragraph (a) must be clearly
300 legible and in a type size no smaller than the largest type size
301 used in the advertisement.
302 (6)(a) A physician who conducts stem cell therapy pursuant
303 to this section shall obtain a signed consent form from the
304 patient before performing the stem cell therapy.
305 (b) The consent form must be signed by the patient or, if
306 the patient is not legally competent, the patient's
307 representative and must state all of the following in language
308 the patient or his or her representative could reasonably be
309 expected to understand:
310 1. The nature and character of the proposed treatment.
311 2. That the proposed stem cell therapy has not yet been
312 approved by the United States Food and Drug Administration.
313 3. The anticipated results of the proposed treatment.
314 4. The recognized serious possible risks, complications,
315 and anticipated benefits involved in the treatment and in the
316 recognized possible alternative forms of treatment, including
317 nontreatment.
318 (7) This section does not apply to either of the following:
319 (a) A physician 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.

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

1. The Foundation for the Accreditation of Cellular Therapy.

2. The Blood and Marrow Transplant Clinical Trials Network.

3. The Association for the Advancement of Blood and Biotherapies.

4. An entity with expertise in stem cell therapy as determined by the department.

(8) A violation of this section may subject the physician to disciplinary action under the rules that have been developed by the board or the department as applicable.

(9) The Board of Osteopathic Medicine shall adopt rules in consultation with the Board of Medicine to implement this section.

Section 3. This act shall take effect July 1, 2025.