A bill to be entitled

An act relating to stem cell therapy; creating ss. 458.3245 and 459.0127, F.S.; providing legislative intent; defining terms; authorizing allopathic physicians and osteopathic 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 allopathic physicians and osteopathic physicians; requiring allopathic physicians and osteopathic physicians to adhere to applicable current good manufacturing practices in the performance of such therapies; prohibiting allopathic physicians and osteopathic physicians from obtaining stem cells for therapies from facilities failing to meet certain requirements; requiring allopathic physicians and osteopathic physicians to include certain terms in contracts or agreements with facilities producing stem cells for therapies; requiring allopathic physicians and osteopathic physicians to include a specified notice in any form of advertisement; providing requirements for such notice; requiring allopathic physicians and osteopathic 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 to adopt rules, respectively; 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 obtained from umbilical cord or cord blood, donated by residents of the United States, which are intended for implantation, transplantation, infusion, or transfer into a human recipient. The term does not include any of the following:

1. Treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

2. The sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products.

3. Vascularized human organs for transplantation.

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

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

6. 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.

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

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

9. In vitro diagnostic products.

10. 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."

11. Fetal-derived stem cells.

12. 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 acting in the course and scope of his or her employment.

(d) "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, which complies with the regulatory 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.

(c) A physician performing stem cell therapy may not obtain stem cells for therapies from a facility engaging in the retrieval, manufacture, or storage of stem cells intended for human use under this section unless the facility maintains valid accreditation or certification as required by this subsection. Any contract or other agreement by which a physician obtains stem cells for therapies from such a facility must include the following:

1. A requirement that the facility provide all of the following information to the physician:

a. The name and address of the facility.

b. The certifying organization.

c. The type and scope of certification.

d. The effective and expiration dates of the certification.

e. Any limitations or conditions imposed by the certifying organization.

2. A requirement that the facility notify the physician within 30 days of any change in certification status, including renewal, suspension, revocation, or expiration.

(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 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 under 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 may 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 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; or

(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.

(10) The board may adopt rules 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 obtained from umbilical cord or cord blood, donated by residents of the United States, which are intended for implantation, transplantation, infusion, or transfer into a human recipient. The term does not include any of the following:

1. Treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

2. The sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products.

3. Vascularized human organs for transplantation.

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

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

6. 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.

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

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

9. In vitro diagnostic products.

10. 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."

11. Fetal-derived stem cells.

12. 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 acting in the course and scope of his or her employment.

(d) "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, which complies with the regulatory 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.

(c) A physician performing stem cell therapy may not obtain stem cells for therapies from a facility engaging in the retrieval, manufacture, or storage of stem cells intended for human use under this section unless the facility maintains valid accreditation or certification as required by this subsection. Any contract or other agreement by which a physician obtains stem cells for therapies from such a facility must include:

1. A requirement that the facility provide the all of the following information to the physician:

a. The name and address of the facility.

b. The certifying organization.

c. The type and scope of certification.

d. The effective and expiration dates of the certification.

e. Any limitations or conditions imposed by the certifying organization.

2. A requirement that the facility notify the physician within 30 days of any change in certification status, including renewal, suspension, revocation, or expiration.

(4) In the performance of any stem cell therapy procedure, the physician shall use stem cells or products containing stem cells produced by a facility which adheres 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 may 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 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; or

(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 by the board.

(9) The board may adopt rules necessary to implement this section.

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