

By the Committee on Health Policy; and Senator Trumbull

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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 provide a specified written notice to patients before performing any stem cell therapy; specifying requirements for the written notice; providing advertisement requirements; requiring physicians to obtain written consent 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.-

588-03144-25

20251768c1

(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,

588-03144-25

20251768c1

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

588-03144-25

20251768c1

his or her employment.

(d) "Stem cell therapy" means a treatment involving the use of human cells, tissues, or cellular or tissue-based products. 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 be:

1. 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; and

2. 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.

588-03144-25

20251768c1

117 d. American Association of Tissue Banks.

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

127 (5) A physician who conducts stem cell therapy pursuant to
128 this section shall provide a patient who is being treated with
129 stem cell therapy with the following written notice before
130 performing the therapy:

131
132 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
133 This physician performs one or more stem cell
134 therapies that have not yet been approved by the
135 United States Food and Drug Administration. You are
136 encouraged to consult with your primary care provider
137 before undergoing any stem cell therapy.

138
139 (6) A physician who is required to provide the written
140 notice under subsection (5) shall:

141 (a) Provide the written notice to a patient on paper that
142 is at least 8.5 inches by 11 inches and printed in no less than
143 40-point type.

144 (b) Prominently display the written notice at the entrance
145 to the physician's office and in an area visible to patients

588-03144-25

20251768c1

146 inside such office.

147 (c) Include the notice in any advertisement for the stem
148 cell therapy. In any form of advertisement, the notice must be
149 clearly legible and in a font size no smaller than the largest
150 font size used in the advertisement.

151 (7) (a) A physician required to provide the written notice
152 under subsection (5) must obtain a signed consent form from the
153 patient before performing the stem cell therapy.

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

159 1. The nature and character of the proposed treatment,
160 including the treatment's United States Food and Drug
161 Administration approval status.

162 2. The anticipated results of the proposed treatment.

163 3. The recognized possible alternative forms of treatment.

164 4. The recognized serious possible risks, complications,
165 and anticipated benefits involved in the treatment and in the
166 recognized possible alternative forms of treatment, including
167 nontreatment.

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

169 (a) A physician who has obtained approval for an
170 investigational new drug or device from the United States Food
171 and Drug Administration for the use of human cells, tissues, or
172 cellular or tissue-based products.

173 (b) A physician who performs a stem cell therapy under an
174 employment or other contract on behalf of an institution

588-03144-25

20251768c1

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.

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

(10) 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.

588-03144-25

20251768c1

(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.

588-03144-25

20251768c1

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

237 9. Fetal-derived stem cells.

238 10. Adipose-derived mesenchymal stem cells for
239 transplantation.

240 (b) "Minimally manipulated" means:

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

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

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

250 (d) "Stem cell therapy" means a treatment involving the use
251 of human cells, tissues, or cellular or tissue-based products.
252 The term does not include treatment or research using human
253 cells or tissues that were derived from a fetus or an embryo
254 after an abortion.

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

261 (b) To ensure that the retrieval, manufacture, storage, and

588-03144-25

20251768c1

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 be:

1. 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; and

2. 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.

(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 physician who conducts stem cell therapy pursuant to this section shall provide a patient who is being treated with stem cell therapy with the following written notice before

588-03144-25

20251768c1

291 performing the therapy:

292
293 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

294 This physician performs one or more stem cell
295 therapies that have not yet been approved by the
296 United States Food and Drug Administration. You are
297 encouraged to consult with your primary care provider
298 before undergoing any stem cell therapy.

299
300 (6) A physician who is required to provide the written
301 notice under subsection (5) shall:

302 (a) Provide the written notice to a patient on paper that
303 is at least 8.5 inches by 11 inches and printed in no less than
304 40-point type.

305 (b) Prominently display the written notice at the entrance
306 to the physician's office and in an area visible to patients
307 inside such office.

308 (c) Include the notice in any advertisement for the stem
309 cell therapy. In any form of advertisement, the notice must be
310 clearly legible and in a font size no smaller than the largest
311 font size used in the advertisement.

312 (7) (a) A physician required to provide the written notice
313 under subsection (5) must obtain a signed consent form from the
314 patient before performing the stem cell therapy.

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

588-03144-25

20251768c1

320 1. The nature and character of the proposed treatment,
321 including the treatment's United States Food and Drug
322 Administration approval status.

323 2. The anticipated results of the proposed treatment.

324 3. The recognized possible alternative forms of treatment.

325 4. The recognized serious possible risks, complications,
326 and anticipated benefits involved in the treatment and in the
327 recognized possible alternative forms of treatment, including
328 nontreatment.

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

330 (a) A physician who has obtained approval for an
331 investigational new drug or device from the United States Food
332 and Drug Administration for the use of human cells, tissues, or
333 cellular or tissue-based products.

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

337 1. The Foundation for the Accreditation of Cellular
338 Therapy.

339 2. The Blood and Marrow Transplant Clinical Trials Network.

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

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

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

347 (10) The Board of Osteopathic Medicine shall adopt rules in
348 consultation with the Board of Medicine to implement this

588-03144-25

20251768c1

349 section.

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