



947004

LEGISLATIVE ACTION

| | | |
|------------|---|-------|
| Senate | . | House |
| Comm: RCS | . | |
| 04/02/2025 | . | |
| | . | |
| | . | |
| | . | |

The Committee on Health Policy (Trumbull) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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



947004

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

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

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

- 33 1. Vascularized human organs for transplantation.
- 34 2. Whole blood or blood components or blood derivative
35 products subject to regulation under part I of chapter 499.
- 36 3. Secreted or extracted human products, such as milk,
37 collagen, and cell factors; except that semen is considered a
38 human cell, tissue, or cellular or tissue-based product for
39 purposes of this paragraph.



947004

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

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

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

49 7. In vitro diagnostic products.

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

54 9. Fetal-derived stem cells.

55 10. Adipose-derived mesenchymal stem cells for
56 transplantation.

57 (b) "Minimally manipulated" means:

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

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

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

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



947004

69 The term does not include treatment or research using human
70 cells or tissues that were derived from a fetus or an embryo
71 after an abortion.

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

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

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

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

91 a. National Marrow Donor Program.

92 b. World Marrow Donor Association.

93 c. Association for the Advancement of Blood and
94 Biotherapies.

95 d. American Association of Tissue Banks.

96 (4) In the performance of any procedure using or purporting
97 to use stem cells or products containing stem cells, the



947004

98 physician shall adhere to the applicable current good
99 manufacturing practices for the collection, removal, processing,
100 implantation, and transfer of stem cells, or products containing
101 stem cells, pursuant to the Federal Food, Drug, and Cosmetic
102 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21
103 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-
104 Based Products.

105 (5) A physician who conducts stem cell therapy pursuant to
106 this section shall provide a patient who is being treated with
107 stem cell therapy with the following written notice before
108 performing the therapy:

109
110 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
111 This physician performs one or more stem cell
112 therapies that have not yet been approved by the
113 United States Food and Drug Administration. You are
114 encouraged to consult with your primary care provider
115 before undergoing any stem cell therapy.

116
117 (6) A physician who is required to provide the written
118 notice under subsection (5) shall:

119 (a) Provide the written notice to a patient on paper that
120 is at least 8.5 inches by 11 inches and printed in no less than
121 40-point type.

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

125 (c) Include the notice in any advertisement for the stem
126 cell therapy. In any form of advertisement, the notice must be



947004

127 clearly legible and in a font size no smaller than the largest
128 font size used in the advertisement.

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

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

137 1. The nature and character of the proposed treatment,
138 including the treatment's United States Food and Drug
139 Administration approval status.

140 2. The anticipated results of the proposed treatment.

141 3. The recognized possible alternative forms of treatment.

142 4. The recognized serious possible risks, complications,
143 and anticipated benefits involved in the treatment and in the
144 recognized possible alternative forms of treatment, including
145 nontreatment.

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

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

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

154 1. The Foundation for the Accreditation of Cellular
155 Therapy.



947004

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

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

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

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

163 (10) The Board of Medicine shall adopt rules in
164 consultation with the Board of Osteopathic Medicine to implement
165 this section.

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

168 459.0127 Stem cell therapy.-

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

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

183 (a) "Human cells, tissues, or cellular or tissue-based
184 products" means articles containing or consisting of human cells



947004

185 or tissues collected from cord blood donors who are residents of
186 the United States which are intended for implantation,
187 transplantation, infusion, or transfer into a human recipient,
188 including but not limited to, bones, ligaments, skin, dura
189 mater, heart valves, corneas, hematopoietic stem or progenitor
190 cells derived from peripheral and cord blood, manipulated
191 autologous chondrocytes, epithelial cells on a synthetic matrix,
192 and semen or other reproductive tissue. The term does not
193 include any of the following:

- 194 1. Vascularized human organs for transplantation.
- 195 2. Whole blood or blood components or blood derivative
196 products subject to regulation under part I of chapter 499.
- 197 3. Secreted or extracted human products, such as milk,
198 collagen, and cell factors; except that semen is considered a
199 human cell, tissue, or cellular or tissue-based product for
200 purposes of this paragraph.
- 201 4. Minimally manipulated bone marrow for homologous use and
202 not combined with another article, except for with water,
203 crystalloids, or a sterilizing, preserving, or storage agent, if
204 the addition of the agent does not raise new clinical safety
205 concerns with respect to the bone marrow.
- 206 5. Ancillary products used in the manufacture of human
207 cells, tissues, or cellular or tissue-based products.
- 208 6. Cells, tissues, and organs derived from animals other
209 than humans.
- 210 7. In vitro diagnostic products.
- 211 8. Blood vessels recovered with an organ, as defined in 42
212 C.F.R. s. 121.2, which are intended for use in organ
213 transplantation and labeled, "For use in organ transplantation



947004

214 only.”
215 9. Fetal-derived stem cells.
216 10. Adipose-derived mesenchymal stem cells for
217 transplantation.
218 (b) “Minimally manipulated” means:
219 1. For structural tissue, processing that does not alter
220 the original relevant characteristics of the tissue relating to
221 the tissue’s utility for reconstruction, repair, or replacement.
222 2. For cells or nonstructural tissues, processing that does
223 not alter the relevant biological characteristics of cells or
224 tissues.
225 (c) “Physician” means a physician licensed under this
226 chapter or under chapter 458 acting in the course and scope of
227 his or her employment.
228 (d) “Stem cell therapy” means a treatment involving the use
229 of human cells, tissues, or cellular or tissue-based products.
230 The term does not include treatment or research using human
231 cells or tissues that were derived from a fetus or an embryo
232 after an abortion.
233 (3) (a) A physician may perform stem cell therapy that is
234 not approved by the United States Food and Drug Administration
235 if such therapy is used for treatment or procedures that are
236 within the scope of practice for such physician and the
237 therapies are related to orthopedics, wound care, or pain
238 management.
239 (b) To ensure that the retrieval, manufacture, storage, and
240 use of stem cells used for therapies conducted under this
241 section meet the highest standards, any stem cells used by a
242 physician for therapy provided under this section must be:



947004

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

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

252 a. National Marrow Donor Program.

253 b. World Marrow Donor Association.

254 c. Association for the Advancement of Blood and
255 Biotherapies.

256 d. American Association of Tissue Banks.

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

266 (5) A physician who conducts stem cell therapy pursuant to
267 this section shall provide a patient who is being treated with
268 stem cell therapy with the following written notice before
269 performing the therapy:

270
271 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.



947004

272 This physician performs one or more stem cell
273 therapies that have not yet been approved by the
274 United States Food and Drug Administration. You are
275 encouraged to consult with your primary care provider
276 before undergoing any stem cell therapy.

277
278 (6) A physician who is required to provide the written
279 notice under subsection (5) shall:

280 (a) Provide the written notice to a patient on paper that
281 is at least 8.5 inches by 11 inches and printed in no less than
282 40-point type.

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

286 (c) Include the notice in any advertisement for the stem
287 cell therapy. In any form of advertisement, the notice must be
288 clearly legible and in a font size no smaller than the largest
289 font size used in the advertisement.

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

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

298 1. The nature and character of the proposed treatment,
299 including the treatment's United States Food and Drug
300 Administration approval status.



947004

301 2. The anticipated results of the proposed treatment.

302 3. The recognized possible alternative forms of treatment.

303 4. The recognized serious possible risks, complications,
304 and anticipated benefits involved in the treatment and in the
305 recognized possible alternative forms of treatment, including
306 nontreatment.

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

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

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

315 1. The Foundation for the Accreditation of Cellular
316 Therapy.

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

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

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

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

325 (10) The Board of Osteopathic Medicine shall adopt rules in
326 consultation with the Board of Medicine to implement this
327 section.

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



947004

330 ===== T I T L E A M E N D M E N T =====

331 And the title is amended as follows:

332 Delete everything before the enacting clause

333 and insert:

334 A bill to be entitled

335 An act relating to stem cell therapy; creating ss.
336 458.3245 and 459.0127, F.S.; providing legislative
337 findings and intent; defining terms; authorizing
338 physicians to perform stem cell therapy not approved
339 by the United States Food and Drug Administration
340 under certain circumstances; specifying requirements
341 for the stem cells that may be used by such
342 physicians; requiring such physicians to adhere to
343 applicable current good manufacturing practices in the
344 performance of such therapies; requiring physicians to
345 provide a specified written notice to patients before
346 performing any stem cell therapy; specifying
347 requirements for the written notice; providing
348 advertisement requirements; requiring physicians to
349 obtain written consent from the patient or his or her
350 representative before performing the therapy;
351 specifying requirements for the consent form;
352 providing applicability; providing for disciplinary
353 action; requiring the Board of Medicine and the Board
354 of Osteopathic Medicine, respectively, to adopt rules
355 in consultation with one another; providing an
356 effective date.