

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

595-03688-25

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1                                   A bill to be entitled  
2       An act relating to stem cell therapy; creating ss.  
3       458.3245 and 459.0127, F.S.; providing legislative  
4       findings and intent; defining terms; authorizing  
5       physicians to perform stem cell therapy not approved  
6       by the United States Food and Drug Administration  
7       under certain circumstances; specifying requirements  
8       for the stem cells that may be used by such  
9       physicians; requiring such physicians to adhere to  
10      applicable current good manufacturing practices in the  
11      performance of such therapies; requiring physicians to  
12      include a specified notice in any form of  
13      advertisement; providing requirements for such notice;  
14      requiring physicians to obtain a signed consent form  
15      from the patient or his or her representative before  
16      performing the therapy; specifying requirements for  
17      the consent form; providing applicability; providing  
18      for disciplinary action; requiring the Board of  
19      Medicine and the Board of Osteopathic Medicine,  
20      respectively, to adopt rules in consultation with one  
21      another; providing an effective date.

22  
23 Be It Enacted by the Legislature of the State of Florida:

24  
25       Section 1. Section 458.3245, Florida Statutes, is created  
26 to read:

27       458.3245 Stem cell therapy.-

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

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

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

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

53 1. Vascularized human organs for transplantation.

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

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

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59 purposes of this paragraph.

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

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

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

69 7. In vitro diagnostic products.

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

74 9. Fetal-derived stem cells.

75 10. Adipose-derived mesenchymal stem cells for  
76 transplantation.

77 (b) "Minimally manipulated" means:

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

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

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

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

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

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

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

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

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

112 a. National Marrow Donor Program.

113 b. World Marrow Donor Association.

114 c. Association for the Advancement of Blood and  
115 Biotherapies.

116 d. American Association of Tissue Banks; and

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

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

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

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

140  
141 (b) The notice required by paragraph (a) must be clearly  
142 legible and in a type size no smaller than the largest type size  
143 used in the advertisement.

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

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146 patient before performing the stem cell therapy.

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

152 1. The nature and character of the proposed treatment.

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

155 3. The anticipated results of the proposed treatment.

156 4. The recognized serious possible risks, complications,  
157 and anticipated benefits involved in the treatment and in the  
158 recognized possible alternative forms of treatment, including  
159 nontreatment.

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

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

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

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

171 1. The Foundation for the Accreditation of Cellular  
172 Therapy.

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

174 3. The Association for the Advancement of Blood and

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175 Biotherapies.

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

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

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

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

185 459.0127 Stem cell therapy.-

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

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

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

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- 204 transplantation, infusion, or transfer into a human recipient,  
205 including, but not limited to, bones, ligaments, skin, dura  
206 mater, heart valves, corneas, hematopoietic stem or progenitor  
207 cells derived from peripheral and cord blood, manipulated  
208 autologous chondrocytes, epithelial cells on a synthetic matrix,  
209 and semen or other reproductive tissue. The term does not  
210 include any of the following:
- 211 1. Vascularized human organs for transplantation.
  - 212 2. Whole blood or blood components or blood derivative  
213 products subject to regulation under part I of chapter 499.
  - 214 3. Secreted or extracted human products, such as milk,  
215 collagen, and cell factors; except that semen is considered a  
216 human cell, tissue, or cellular or tissue-based product for  
217 purposes of this paragraph.
  - 218 4. Minimally manipulated bone marrow for homologous use and  
219 not combined with another article, except for with water,  
220 crystalloids, or a sterilizing, preserving, or storage agent, if  
221 the addition of the agent does not raise new clinical safety  
222 concerns with respect to the bone marrow.
  - 223 5. Ancillary products used in the manufacture of human  
224 cells, tissues, or cellular or tissue-based products.
  - 225 6. Cells, tissues, and organs derived from animals other  
226 than humans.
  - 227 7. In vitro diagnostic products.
  - 228 8. Blood vessels recovered with an organ, as defined in 42  
229 C.F.R. s. 121.2, which are intended for use in organ  
230 transplantation and labeled, "For use in organ transplantation  
231 only."
  - 232 9. Fetal-derived stem cells.



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234 transplantation.

235 (b) "Minimally manipulated" means:

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

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

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

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

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

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

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

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

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

270 a. National Marrow Donor Program.

271 b. World Marrow Donor Association.

272 c. Association for the Advancement of Blood and  
273 Biotherapies.

274 d. American Association of Tissue Banks; and

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

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

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300 legible and in a type size no smaller than the largest type size  
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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

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320 investigational new drug or device from the United States Food  
321 and Drug Administration for the use of human cells, tissues, or  
322 cellular or tissue-based products.

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

326 1. The Foundation for the Accreditation of Cellular  
327 Therapy.

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

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

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

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

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

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