

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 intent; defining terms; authorizing allopathic
5 physicians and osteopathic physicians to perform stem
6 cell therapy not approved by the United States Food
7 and Drug Administration under certain circumstances;
8 specifying requirements for the stem cells that may be
9 used by allopathic physicians and osteopathic
10 physicians; requiring allopathic physicians and
11 osteopathic physicians to adhere to applicable current
12 good manufacturing practices in the performance of
13 such therapies; prohibiting allopathic physicians and
14 osteopathic physicians from obtaining stem cells for
15 therapies from facilities failing to meet certain
16 requirements; requiring allopathic physicians and
17 osteopathic physicians to include certain terms in
18 contracts or agreements with facilities producing stem
19 cells for therapies; requiring allopathic physicians
20 and osteopathic physicians to include a specified
21 notice in any form of advertisement; providing
22 requirements for such notice; requiring allopathic
23 physicians and osteopathic physicians to obtain a
24 signed consent form from the patient or his or her
25 representative before performing the therapy;

26 specifying requirements for the consent form;
 27 providing applicability; providing for disciplinary
 28 action; requiring the Board of Medicine and the Board
 29 of Osteopathic Medicine to adopt rules, respectively;
 30 providing an effective date.

31
 32 Be It Enacted by the Legislature of the State of Florida:

33
 34 **Section 1. Section 458.3245, Florida Statutes, is created**
 35 **to read:**

36 458.3245 Stem cell therapy.—

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

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

51 (a) "Human cells, tissues, or cellular or tissue-based
52 products" means articles containing or consisting of human cells
53 or tissues obtained from umbilical cord or cord blood, donated
54 by residents of the United States, which are intended for
55 implantation, transplantation, infusion, or transfer into a
56 human recipient. The term does not include any of the following:

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

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

62 3. Vascularized human organs for transplantation.

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

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

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

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

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

78 9. In vitro diagnostic products.

79 10. Blood vessels recovered with an organ, as defined in
80 42 C.F.R. s. 121.2, which are intended for use in organ
81 transplantation and labeled, "For use in organ transplantation
82 only."

83 11. Fetal-derived stem cells.

84 12. Adipose-derived mesenchymal stem cells for
85 transplantation.

86 (b) "Minimally manipulated" means:

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

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

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

95 (d) "Stem cell therapy" means a treatment involving the
96 use of afterbirth placental perinatal stem cells, or human
97 cells, tissues, or cellular or tissue-based products, which
98 complies with the regulatory requirements provided in this
99 section. The term does not include treatment or research using
100 human cells or tissues that were derived from a fetus or an

101 embryo after an abortion.

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

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

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

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

121 a. National Marrow Donor Program.

122 b. World Marrow Donor Association.

123 c. Association for the Advancement of Blood and
124 Biotherapies.

125 d. American Association of Tissue Banks; and

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

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

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

140 a. The name and address of the facility.

141 b. The certifying organization.

142 c. The type and scope of certification.

143 d. The effective and expiration dates of the
144 certification.

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

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

150 (4) In the performance of any procedure using or

151 purporting to use stem cells or products containing stem cells,
152 the physician shall adhere to the applicable current good
153 manufacturing practices for the collection, removal, processing,
154 implantation, and transfer of stem cells, or products containing
155 stem cells, pursuant to the Federal Food, Drug, and Cosmetic
156 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21
157 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-
158 Based Products.

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

162
163 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
164 This physician performs one or more stem cell
165 therapies that have not yet been approved by the
166 United States Food and Drug Administration. You are
167 encouraged to consult with your primary care provider
168 before undergoing any stem cell therapy.

169
170 (b) The notice required under paragraph (a) must be
171 clearly legible and in a type size no smaller than the largest
172 type size used in the advertisement.

173 (6) (a) A physician who conducts stem cell therapy pursuant
174 to this section shall obtain a signed consent form from the
175 patient before performing the stem cell therapy.

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

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

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

184 3. The anticipated results of the proposed treatment.

185 4. The recognized serious possible risks, complications,
 186 and anticipated benefits involved in the treatment and in the
 187 recognized possible alternative forms of treatment, including
 188 nontreatment.

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

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

193 (a) A physician who has obtained approval for an
 194 investigational new drug or device from the United States Food
 195 and Drug Administration for the use of human cells, tissues, or
 196 cellular or tissue-based products; or

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

200 1. The Foundation for the Accreditation of Cellular

201 Therapy.

202 2. The Blood and Marrow Transplant Clinical Trials
 203 Network.

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

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

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

210 (10) The board may adopt rules to implement this section.

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

213 459.0127 Stem cell therapy.-

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

226 this state.

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

228 (a) "Human cells, tissues, or cellular or tissue-based
229 products" means articles containing or consisting of human cells
230 or tissues obtained from umbilical cord or cord blood, donated
231 by residents of the United States, which are intended for
232 implantation, transplantation, infusion, or transfer into a
233 human recipient. The term does not include any of the following:

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

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

239 3. Vascularized human organs for transplantation.

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

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

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

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

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

255 9. In vitro diagnostic products.

256 10. Blood vessels recovered with an organ, as defined in
257 42 C.F.R. s. 121.2, which are intended for use in organ
258 transplantation and labeled, "For use in organ transplantation
259 only."

260 11. Fetal-derived stem cells.

261 12. Adipose-derived mesenchymal stem cells for
262 transplantation.

263 (b) "Minimally manipulated" means:

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

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

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

272 (d) "Stem cell therapy" means a treatment involving the
273 use of afterbirth placental perinatal stem cells, or human
274 cells, tissues, or cellular or tissue-based products, which
275 complies with the regulatory requirements provided in this

276 section. The term does not include treatment or research using
277 human cells or tissues that were derived from a fetus or an
278 embryo after an abortion.

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

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

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

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

298 a. National Marrow Donor Program.

299 b. World Marrow Donor Association.

300 c. Association for the Advancement of Blood and

301 Biotherapies.

302 d. American Association of Tissue Banks; and

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

307 (c) A physician performing stem cell therapy may not
308 obtain stem cells for therapies from a facility engaging in the
309 retrieval, manufacture, or storage of stem cells intended for
310 human use under this section unless the facility maintains valid
311 accreditation or certification as required by this subsection.

312 Any contract or other agreement by which a physician obtains
313 stem cells for therapies from such a facility must include:

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

316 a. The name and address of the facility.

317 b. The certifying organization.

318 c. The type and scope of certification.

319 d. The effective and expiration dates of the
320 certification.

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

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

326 (4) In the performance of any stem cell therapy procedure,
327 the physician shall use stem cells or products containing stem
328 cells produced by a facility which adheres to the applicable
329 current good manufacturing practices for the collection,
330 removal, processing, implantation, and transfer of stem cells,
331 or products containing stem cells, pursuant to the Federal Food,
332 Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040
333 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and
334 Cellular and Tissue-Based Products.

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

338
339 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
340 This physician performs one or more stem cell
341 therapies that have not yet been approved by the
342 United States Food and Drug Administration. You are
343 encouraged to consult with your primary care provider
344 before undergoing any stem cell therapy.

345
346 (b) The notice required by paragraph (a) must be clearly
347 legible and in a type size no smaller than the largest type size
348 used in the advertisement.

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

351 patient before performing the stem cell therapy.

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

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

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

360 3. The anticipated results of the proposed treatment.

361 4. The recognized serious possible risks, complications,
362 and anticipated benefits involved in the treatment and in the
363 recognized possible alternative forms of treatment, including
364 nontreatment.

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

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

369 (a) A physician who has obtained approval for an
370 investigational new drug or device from the United States Food
371 and Drug Administration for the use of human cells, tissues, or
372 cellular or tissue-based products; or

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

376 | 1. The Foundation for the Accreditation of Cellular
 377 | Therapy.

378 | 2. The Blood and Marrow Transplant Clinical Trials
 379 | Network.

380 | 3. The Association for the Advancement of Blood and
 381 | Biotherapies.

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

384 | (8) A violation of this section may subject the physician
 385 | to disciplinary action by the board.

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

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