

Amendment No.1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED (Y/N)
ADOPTED AS AMENDED (Y/N)
ADOPTED W/O OBJECTION (Y/N)
FAILED TO ADOPT (Y/N)
WITHDRAWN (Y/N)
OTHER

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee

3 Representative Buchanan offered the following:

4
5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 **Section 1. Section 458.3245, Florida Statutes, is created**
8 **to read:**

9 458.3245 Stem cell therapy.-

10 (1) The Legislature recognizes the significant potential
11 of stem cell therapies in advancing medical treatments and
12 improving patient outcomes and further recognizes the need to
13 ensure that such therapies are provided using stem cells
14 obtained in an ethical manner that does not involve stem cells
15 derived from aborted fetuses. It is the intent of the
16 Legislature to foster medical innovation while upholding ethical

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17 standards that respect the sanctity of life. By encouraging the
18 use of stem cell sources such as adult stem cells, umbilical
19 cord blood, and other ethically obtained human cells, tissues,
20 or cellular or tissue-based products, the state will advance
21 regenerative medicine in a manner consistent with the values of
22 this state.

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

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

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

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

35 3. Vascularized human organs for transplantation.

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

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

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

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

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

51 9. In vitro diagnostic products.

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

56 11. Fetal-derived stem cells.

57 12. Adipose-derived mesenchymal stem cells for
58 transplantation.

59 (b) "Minimally manipulated" means:

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

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

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

68 (d) "Stem cell therapy" means a treatment involving the
69 use of afterbirth placental perinatal stem cells, or human
70 cells, tissues, or cellular or tissue-based products, which
71 complies with the regulatory requirements provided in this
72 section. The term does not include treatment or research using
73 human cells or tissues that were derived from a fetus or an
74 embryo after an abortion.

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

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

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

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90 2. Be retrieved, manufactured, and stored in a facility
91 that is registered and regulated by the United States Food and
92 Drug Administration and licensed or registered with one of the
93 following entities:

94 a. National Marrow Donor Program.

95 b. World Marrow Donor Association.

96 c. Association for the Advancement of Blood and
97 Biotherapies.

98 d. American Association of Tissue Banks; and

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

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

110 1. A requirement that the facility provide the following
111 information to the physician:

112 a. The name and address of the facility;

113 b. The certifying organization;

114 c. The type and scope of certification;

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115 d. The effective and expiration dates of the
116 certification; and

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

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

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

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

134
135 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

136 This physician performs one or more stem cell
137 therapies that have not yet been approved by the
138 United States Food and Drug Administration. You are

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139 encouraged to consult with your primary care provider
140 before undergoing any stem cell therapy.

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

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

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

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

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

156 3. The anticipated results of the proposed treatment.

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

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

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

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

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

173 1. The Foundation for the Accreditation of Cellular
174 Therapy.

175 2. The Blood and Marrow Transplant Clinical Trials
176 Network.

177 3. The Association for the Advancement of Blood and
178 Biotherapies.

179 4. An entity with expertise in stem cell therapy as
180 determined by the department.

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

183 (9) The Board of Medicine may adopt rules necessary to
184 implement this section.

185 **Section 2. Section 459.0127, Florida Statutes, is created**
186 **to read:**

187 459.0127 Stem cell therapy.-

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

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

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

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

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

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- 213 3. Vascularized human organs for transplantation.
- 214 4. Whole blood or blood components or blood derivative
215 products subject to regulation under part I of chapter 499.
- 216 5. Secreted or extracted human products, such as milk,
217 collagen, and cell factors; except that semen is considered a
218 human cell, tissue, or cellular or tissue-based product for
219 purposes of this paragraph.
- 220 6. Minimally manipulated bone marrow for homologous use
221 and not combined with another article, except for with water,
222 crystalloids, or a sterilizing, preserving, or storage agent, if
223 the addition of the agent does not raise new clinical safety
224 concerns with respect to the bone marrow.
- 225 7. Ancillary products used in the manufacture of human
226 cells, tissues, or cellular or tissue-based products.
- 227 8. Cells, tissues, and organs derived from animals other
228 than humans.
- 229 9. In vitro diagnostic products.
- 230 10. Blood vessels recovered with an organ, as defined in
231 42 C.F.R. s. 121.2, which are intended for use in organ
232 transplantation and labeled, "For use in organ transplantation
233 only."
- 234 11. Fetal-derived stem cells.
- 235 12. Adipose-derived mesenchymal stem cells for
236 transplantation.
- 237 (b) "Minimally manipulated" means:

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

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

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

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

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

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

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263 1. Be manufactured in a clean room space that has been
264 certified by the United States Food and Drug Administration for
265 using high-efficiency particulate air filtration or ultra-low
266 penetration air filtration to minimize nonviable and viable
267 particulate contamination;

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

272 a. National Marrow Donor Program.

273 b. World Marrow Donor Association.

274 c. Association for the Advancement of Blood and
275 Biotherapies.

276 d. American Association of Tissue Banks; and

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

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

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288 1. A requirement that the facility provide the following
289 information to the physician:

290 a. The name and address of the facility;

291 b. The certifying organization;

292 c. The type and scope of certification;

293 d. The effective and expiration dates of the
294 certification; and

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

297 2. A requirement that the facility notify the physician within
298 30 days of any change in certification status, including
299 renewal, suspension, revocation, or expiration.

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

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

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313 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
314 This physician performs one or more stem cell
315 therapies that have not yet been approved by the
316 United States Food and Drug Administration. You are
317 encouraged to consult with your primary care provider
318 before undergoing any stem cell therapy.

319
320 (b) The notice required by paragraph (a) must be clearly
321 legible and in a type size no smaller than the largest type size
322 used in the advertisement.

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

326 (b) The consent form must be signed by the patient or, if
327 the patient is not legally competent, the patient's
328 representative and must state all of the following in language
329 the patient or his or her representative could reasonably be
330 expected to understand:

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

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

334 3. The anticipated results of the proposed treatment.

335 4. The recognized serious possible risks, complications,
336 and anticipated benefits involved in the treatment and in the

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337 recognized possible alternative forms of treatment, including
338 nontreatment.

339 5. That the patient is encouraged to consult with his or
340 her primary care provider before undergoing any stem cell
341 therapy.

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

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

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

351 1. The Foundation for the Accreditation of Cellular
352 Therapy.

353 2. The Blood and Marrow Transplant Clinical Trials
354 Network.

355 3. The Association for the Advancement of Blood and
356 Biotherapies.

357 4. An entity with expertise in stem cell therapy as
358 determined by the department.

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

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361 (9) The Board of Osteopathic Medicine may adopt rules
362 necessary to implement this section.

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

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366 **T I T L E A M E N D M E N T**

367 Remove everything before the enacting clause and insert:
368 An act relating to stem cell therapy; creating s.
369 458.3245, F.S.; providing legislative intent; defining
370 terms; authorizing allopathic physicians to perform
371 stem cell therapy not approved by the United States
372 Food and Drug Administration under certain
373 circumstances; specifying requirements for the stem
374 cells that may be used by allopathic physicians;
375 requiring allopathic physicians to adhere to
376 applicable current good manufacturing practices in the
377 performance of such therapies; prohibiting allopathic
378 physicians from obtaining stem cells for therapies
379 from facilities failing to meet certain requirements;
380 requiring allopathic physicians to include certain
381 terms in contracts or agreements with facilities
382 producing stem cells for therapies; requiring
383 allopathic physicians to include a specified notice in
384 any form of advertisement; providing requirements for
385 such notice; requiring allopathic physicians to obtain

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386 a signed consent form from the patient or his or her
387 representative before performing the therapy;
388 specifying requirements for the consent form;
389 providing applicability; providing for disciplinary
390 action; requiring the Board of Medicine to adopt
391 rules; creating s. 459.0127, F.S.; providing
392 legislative intent; defining terms; authorizing
393 osteopathic physicians to perform stem cell therapy
394 not approved by the United States Food and Drug
395 Administration under certain circumstances; specifying
396 requirements for the stem cells that may be used by
397 osteopathic physicians; requiring osteopathic
398 physicians to adhere to applicable current good
399 manufacturing practices in the performance of such
400 therapies; prohibiting osteopathic physicians from
401 obtaining stem cells for therapies from facilities
402 failing to meet certain requirements; requiring
403 osteopathic physicians to include certain terms in
404 contracts or agreements with facilities producing stem
405 cells for therapies; requiring osteopathic physicians
406 to include a specified notice in any form of
407 advertisement; providing requirements for such notice;
408 requiring osteopathic physicians to obtain a signed
409 consent form from the patient or his or her
410 representative before performing the therapy;

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Published On: 4/21/2025 8:25:39 PM

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411 specifying requirements for the consent form;
412 providing applicability; providing for disciplinary
413 action; requiring the Board of Osteopathic Medicine to
414 adopt rules; providing an effective date.