

20251768e1

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
include a specified notice in any form of
advertisement; providing requirements for such notice;
requiring physicians to obtain a signed consent form
from the patient or his or her representative before
performing the therapy; specifying requirements for
the consent form; providing applicability; providing
for disciplinary action; providing criminal penalties;
authorizing the Board of Medicine to adopt rules;
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.—

(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

20251768e1

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 that are intended for implantation, transplantation, infusion, or transfer into a human recipient. The term does not include:

1. Vascularized human organs for transplantation;
2. Whole blood or blood components or blood derivative products;
3. Secreted or extracted human products, such as milk, collagen, and cell factors, other than semen;
4. Minimally manipulated bone marrow for homologous use and not combined with another article other than 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

20251768e1

59 than humans;

60 7. In vitro diagnostic products; or

61 8. Blood vessels recovered with an organ which are intended
62 for use in organ transplantation and labeled "For use in organ
63 transplantation only."

64 (b) "Minimally manipulated" means:

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

68 2. For cells or nonstructural tissues, processing that does
69 not alter the relevant biological characteristics of cells or
70 tissues.

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

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

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

86 (b) To ensure that the retrieval, manufacture, storage, and
87 use of stem cells used for therapies conducted under this

20251768e1

88 section meet the highest standards, any stem cells used by a
89 physician for therapy provided under this section must:

90 1. Be retrieved, manufactured, and stored in a facility
91 that is registered and regulated by the United States Food and
92 Drug Administration;

93 2. Be retrieved, manufactured, and stored in a facility
94 that is certified or accredited by one of the following
95 entities:

96 a. National Marrow Donor Program.

97 b. World Marrow Donor Association.

98 c. Association for the Advancement of Blood and
99 Biotherapies.

100 d. American Association of Tissue Banks; and

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

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

113 1. A requirement that the facility provide all of the
114 following information to the physician:

115 a. The name and address of the facility.

116 b. The certifying or accrediting organization.

20251768e1

117 c. The type and scope of certification or accreditation.

118 d. The effective and expiration dates of the certification
119 or accreditation.

120 e. Any limitations or conditions imposed by the certifying
121 or accrediting organization.

122 2. A requirement that the facility notify the physician
123 within 30 days after any change in certification or
124 accreditation status, including renewal, suspension, revocation,
125 or expiration.

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

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

139
140 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

141 This physician performs one or more stem cell
142 therapies that have not yet been approved by the
143 United States Food and Drug Administration. You are
144 encouraged to consult with your primary care provider
145 before undergoing any stem cell therapy.

20251768e1

146
147 (b) The notice required under paragraph (a) must be clearly
148 legible and in a type size no smaller than the largest type size
149 used in the advertisement.

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

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

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

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

161 3. The anticipated results of the proposed treatment.

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

166 5. That the patient is encouraged to consult with his or
167 her primary care provider before undergoing any stem cell
168 therapy.

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

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

174 (b) A physician who performs stem cell therapy under an

20251768e1

175 employment or other contract on behalf of an institution
176 certified or accredited by any of the following:

177 1. The Foundation for the Accreditation of Cellular
178 Therapy.

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

180 3. The Association for the Advancement of Blood and
181 Biotherapies.

182 4. An entity with expertise in stem cell therapy as
183 determined by the department.

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

186 (9) A physician who willfully performs, or actively
187 participates in, the following commits a felony of the third
188 degree, punishable as provided in s. 775.082, s. 775.083, or s.
189 775.084, and is subject to disciplinary action under this
190 chapter and s. 456.072:

191 (a) Treatment or research using human cells or tissues
192 derived from a fetus or an embryo after an abortion; or

193 (b) The sale, manufacture, or distribution of computer
194 products created using human cells, tissues, or cellular or
195 tissue-based products.

196 (10) The board may adopt rules necessary to implement this
197 section.

198 Section 2. Section 459.0127, Florida Statutes, is created
199 to read:

200 459.0127 Stem cell therapy.—

201 (1) The Legislature recognizes the significant potential of
202 stem cell therapies in advancing medical treatments and
203 improving patient outcomes and further recognizes the need to

20251768e1

204 ensure that such therapies are provided using stem cells
205 obtained in an ethical manner that does not involve stem cells
206 derived from aborted fetuses. It is the intent of the
207 Legislature to foster medical innovation while upholding ethical
208 standards that respect the sanctity of life. By encouraging the
209 use of stem cell sources such as adult stem cells, umbilical
210 cord blood, and other ethically obtained human cells, tissues,
211 or cellular or tissue-based products, the state will advance
212 regenerative medicine in a manner consistent with the values of
213 this state.

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

215 (a) "Human cells, tissues, or cellular or tissue-based
216 products" means articles containing or consisting of human cells
217 or tissues that are intended for implantation, transplantation,
218 infusion, or transfer into a human recipient. The term does not
219 include:

- 220 1. Vascularized human organs for transplantation;
- 221 2. Whole blood or blood components or blood derivative
222 products;
- 223 3. Secreted or extracted human products, such as milk,
224 collagen, and cell factors, other than semen;
- 225 4. Minimally manipulated bone marrow for homologous use and
226 not combined with another article other than water,
227 crystalloids, or a sterilizing, preserving, or storage agent, if
228 the addition of the agent does not raise new clinical safety
229 concerns with respect to the bone marrow;
- 230 5. Ancillary products used in the manufacture of human
231 cells, tissues, or cellular or tissue-based products;
- 232 6. Cells, tissues, and organs derived from animals other

20251768e1

233 than humans;

234 7. In vitro diagnostic products; or

235 8. Blood vessels recovered with an organ which are intended
236 for use in organ transplantation and labeled "For use in organ
237 transplantation only."

238 (b) "Minimally manipulated" means:

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

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

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

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

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

260 (b) To ensure that the retrieval, manufacture, storage, and
261 use of stem cells used for therapies conducted under this

20251768e1

section meet the highest standards, any stem cells used by a physician for therapy provided under this section must:

1. Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States Food and Drug Administration;

2. Be retrieved, manufactured, and stored in a facility that is certified or accredited by 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; and

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

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

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

a. The name and address of the facility.

b. The certifying or accrediting organization.

20251768e1

291 c. The type and scope of certification or accreditation.

292 d. The effective and expiration dates of the certification
293 or accreditation.

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

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

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

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

313
314 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

315 This physician performs one or more stem cell
316 therapies that have not yet been approved by the
317 United States Food and Drug Administration. You are
318 encouraged to consult with your primary care provider
319 before undergoing any stem cell therapy.

20251768e1

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

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

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

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

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

335 3. The anticipated results of the proposed treatment.

336 4. The recognized serious possible risks, complications,
337 and anticipated benefits involved in the treatment and in the
338 recognized possible alternative forms of treatment, including
339 nontreatment.

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

343 (7) This section does not apply to the 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; or

348 (b) A physician who performs stem cell therapy under an

20251768e1

employment or other contract on behalf of an institution
certified or accredited 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.

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

(9) A physician who willfully performs, or actively
participates in, the following commits a felony of the third
degree, punishable as provided in s. 775.082, s. 775.083, or s.
775.084, and is subject to disciplinary action under this
chapter and s. 456.072:

(a) Treatment or research using human cells or tissues
derived from a fetus or an embryo after an abortion; or

(b) The sale, manufacture, or distribution of computer
products created using human cells, tissues, or cellular or
tissue-based products.

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

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