20251768er 1 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 performance of such therapies; requiring physicians to 11 12 include a specified notice in any form of 13 advertisement; providing requirements for such notice; requiring physicians to obtain a signed consent form 14 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; providing criminal penalties; authorizing the Board of Medicine to adopt rules; 19 20 providing an effective date. 21 22 Be It Enacted by the Legislature of the State of Florida: 23 24 Section 1. Section 458.3245, Florida Statutes, is created 25 to read: 26 458.3245 Stem cell therapy.-27 (1) The Legislature recognizes the significant potential of 28 stem cell therapies in advancing medical treatments and 29 improving patient outcomes and further recognizes the need to

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30	ensure that such therapies are provided using stem cells
31	obtained in an ethical manner that does not involve stem cells
32	derived from aborted fetuses. It is the intent of the
33	Legislature to foster medical innovation while upholding ethical
34	standards that respect the sanctity of life. By encouraging the
35	use of stem cell sources such as adult stem cells, umbilical
36	cord blood, and other ethically obtained human cells, tissues,
37	or cellular or tissue-based products, the state will advance
38	regenerative medicine in a manner consistent with the values of
39	this state.
40	(2) As used in this section, the term:
41	(a) "Human cells, tissues, or cellular or tissue-based
42	products" means articles containing or consisting of human cells
43	or tissues that are intended for implantation, transplantation,
44	infusion, or transfer into a human recipient. The term does not
45	include:
46	1. Vascularized human organs for transplantation;
47	2. Whole blood or blood components or blood derivative
48	products;
49	3. Secreted or extracted human products, such as milk,
50	collagen, and cell factors, other than semen;
51	4. Minimally manipulated bone marrow for homologous use and
52	not combined with another article other than water,
53	crystalloids, or a sterilizing, preserving, or storage agent, if
54	the addition of the agent does not raise new clinical safety
55	concerns with respect to the bone marrow;
56	5. Ancillary products used in the manufacture of human
57	cells, tissues, or cellular or tissue-based products;
58	6. Cells, tissues, and organs derived from animals other

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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

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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.

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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.		20251768er
or accreditation. e. Any limitations or conditions imposed by the certifying or accrediting organization. 2. A requirement that the facility notify the physician within 30 days after any change in certification or accreditation status, including renewal, suspension, revocation or expiration. (4) In the performance of any procedure using or purporting to use stem cells or products containing stem cells, the physician shall use stem cell therapy products obtained from facilities that adhere to the applicable current good manufacturing practices for the collection, removal, processing implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products. (5) (a) A physician who conducts stem cell therapy pursuant to this section shall include the following in any form of 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 <	117	c. The type and scope of certification or accreditation.
120e. Any limitations or conditions imposed by the certifying or accrediting organization.1212. A requirement that the facility notify the physician within 30 days after any change in certification or accreditation status, including renewal, suspension, revocation or expiration.126(4) In the performance of any procedure using or purportin to use stem cells or products containing stem cells, the physician shall use stem cell therapy products obtained from facilities that adhere to the applicable current good131implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products.137Chi section shall include the following in any form of advertisement:139THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This physician performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider	118	d. The effective and expiration dates of the certification
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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: 139 140 140 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	133	Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21
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143United States Food and Drug Administration. You are144encouraged to consult with your primary care provider		This physician performs one or more stem cell
144 encouraged to consult with your primary care provider		therapies that have not yet been approved by the
145 before undergoing any stem cell therapy.		
	145	before undergoing any stem cell therapy.

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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

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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

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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

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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

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262	section meet the highest standards, any stem cells used by a
263	physician for therapy provided under this section must:
264	1. Be retrieved, manufactured, and stored in a facility
265	that is registered and regulated by the United States Food and
266	Drug Administration;
267	2. Be retrieved, manufactured, and stored in a facility
268	that is certified or accredited by one of the following
269	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	(c) A physician performing stem cell therapy may not obtain
280	stem cells for therapies from a facility engaging in the
281	retrieval, manufacture, or storage of stem cells intended for
282	human use under this section unless the facility maintains valid
283	certification or accreditation as required by this subsection.
284	Any contract or other agreement by which a physician obtains
285	stem cells for therapies from such a facility must include the
286	following:
287	1. A requirement that the facility provide all of the
288	following information to the physician:
289	a. The name and address of the facility.
290	b. The certifying or accrediting organization.

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20251768er 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. (5) (a) A physician who conducts stem cell therapy pursuant 310 311 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.

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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

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349	employment or other contract on behalf of an institution
350	certified or accredited 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 Network.
354	3. The Association for the Advancement of Blood and
355	Biotherapies.
356	4. An entity with expertise in stem cell therapy as
357	determined by the department.
358	(8) A violation of this section may subject the physician
359	to disciplinary action by the board.
360	(9) A physician who willfully performs, or actively
361	participates in, the following commits a felony of the third
362	degree, punishable as provided in s. 775.082, s. 775.083, or s.
363	775.084, and is subject to disciplinary action under this
364	chapter and s. 456.072:
365	(a) Treatment or research using human cells or tissues
366	derived from a fetus or an embryo after an abortion; or
367	(b) The sale, manufacture, or distribution of computer
368	products created using human cells, tissues, or cellular or
369	tissue-based products.
370	(10) The board may adopt rules necessary to implement this
371	section.
372	Section 3. This act shall take effect July 1, 2025.

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