

Amendment No.

CHAMBER ACTION

SenateHouse

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Representative Buchanan offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

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 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

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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;

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39 6. Cells, tissues, and organs derived from animals other
40 than humans;

41 7. In vitro diagnostic products; or

42 8. Blood vessels recovered with an organ which are
43 intended for use in organ transplantation and labeled "For use
44 in organ transplantation only."

45 (b) "Minimally manipulated" means:

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

49 2. For cells or nonstructural tissues, processing that
50 does not alter the relevant biological characteristics of cells
51 or tissues.

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

54 (d) "Stem cell therapy" means a treatment involving the
55 use of afterbirth placental perinatal stem cells, or human
56 cells, tissues, or cellular or tissue-based products, which
57 complies with the regulatory requirements provided in this
58 section. The term does not include treatment or research using
59 human cells or tissues that were derived from a fetus or an
60 embryo after an abortion.

61 (3) (a) A physician may perform stem cell therapy that is
62 not approved by the United States Food and Drug Administration
63 if such therapy is used for treatment or procedures that are

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64 within the scope of practice for such physician and the
65 therapies are related to orthopedics, wound care, or pain
66 management.

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

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

74 2. Be retrieved, manufactured, and stored in a facility
75 that is certified or accredited by one of the following
76 entities:

77 a. National Marrow Donor Program.

78 b. World Marrow Donor Association.

79 c. Association for the Advancement of Blood and
80 Biotherapies.

81 d. American Association of Tissue Banks; and

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

86 (c) A physician performing stem cell therapy may not
87 obtain stem cells for therapies from a facility engaging in the
88 retrieval, manufacture, or storage of stem cells intended for

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89 human use under this section unless the facility maintains valid
90 certification or accreditation as required by this subsection.
91 Any contract or other agreement by which a physician obtains
92 stem cells for therapies from such a facility must include the
93 following:

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

96 a. The name and address of the facility.

97 b. The certifying or accrediting organization.

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

99 d. The effective and expiration dates of the certification
100 or accreditation.

101 e. Any limitations or conditions imposed by the certifying
102 or accrediting organization.

103 2. A requirement that the facility notify the physician
104 within 30 days after any change in certification or
105 accreditation status, including renewal, suspension, revocation,
106 or expiration.

107 (4) In the performance of any procedure using or
108 purporting to use stem cells or products containing stem cells,
109 the physician shall use stem cell therapy products obtained from
110 facilities that adhere to the applicable current good
111 manufacturing practices for the collection, removal, processing,
112 implantation, and transfer of stem cells, or products containing
113 stem cells, pursuant to the Federal Food, Drug, and Cosmetic

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114 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21
115 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-
116 Based Products.

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

120
121 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

122 This physician performs one or more stem cell
123 therapies that have not yet been approved by the
124 United States Food and Drug Administration. You are
125 encouraged to consult with your primary care provider
126 before undergoing any stem cell therapy.

127
128 (b) The notice required under paragraph (a) must be
129 clearly legible and in a type size no smaller than the largest
130 type size used in the advertisement.

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

134 (b) The consent form must be signed by the patient or, if
135 the patient is not legally competent, the patient's
136 representative and must state all of the following in language
137 the patient or his or her representative may reasonably be
138 expected to understand:

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

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

142 3. The anticipated results of the proposed treatment.

143 4. The recognized serious possible risks, complications,
144 and anticipated benefits involved in the treatment and in the
145 recognized possible alternative forms of treatment, including
146 nontreatment.

147 5. That the patient is encouraged to consult with his or
148 her primary care provider before undergoing any stem cell
149 therapy.

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

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

155 (b) A physician who performs stem cell therapy under an
156 employment or other contract on behalf of an institution
157 certified or accredited by any of the following:

158 1. The Foundation for the Accreditation of Cellular
159 Therapy.

160 2. The Blood and Marrow Transplant Clinical Trials
161 Network.

162 3. The Association for the Advancement of Blood and
163 Biotherapies.

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164 4. An entity with expertise in stem cell therapy as
165 determined by the department.

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

168 (9) A physician who willfully performs, or actively
169 participates in, the following commits a felony of the third
170 degree, punishable as provided in s. 775.082, s. 775.083, or s.
171 775.084, and is subject to disciplinary action under this
172 chapter and s. 456.072:

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

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

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

180 **Section 2. Section 459.0127, Florida Statutes, is created**
181 **to read:**

182 459.0127 Stem cell therapy.—

183 (1) The Legislature recognizes the significant potential
184 of stem cell therapies in advancing medical treatments and
185 improving patient outcomes and further recognizes the need to
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(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:

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243 and use of stem cells used for therapies conducted under this
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252 a. National Marrow Donor Program.

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255 Biotherapies.

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d. The effective and expiration dates of the certification
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,
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346 775.084, and is subject to disciplinary action under this
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350 (b) The sale, manufacture, or distribution of computer
351 products created using human cells, tissues, or cellular or
352 tissue-based products.

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

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

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357
358 **T I T L E A M E N D M E N T**

359 Remove lines 18-21 and insert:

360 for disciplinary action; providing criminal penalties;
361 authorizing the Board of Medicine to adopt rules;
362 providing an effective date.

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