

1 A bill to be entitled
2 An act relating to podiatric medicine; amending s.
3 461.007, F.S.; revising certain continuing education
4 requirements to apply to certain persons; creating s.
5 461.011, F.S.; providing legislative findings and
6 intent; providing definitions; authorizing podiatric
7 physicians to perform stem cell therapy under certain
8 circumstances; providing requirements for the stem
9 cells obtained and used by the physician; providing
10 advertising requirements for stem cell therapies;
11 requiring a physician to obtain a signed consent form
12 before performing stem cell therapy; providing
13 requirements for the consent form; providing
14 applicability; providing criminal penalties; providing
15 for rulemaking; providing an effective date.

16
17 Be It Enacted by the Legislature of the State of Florida:
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19 **Section 1. Subsection (3) of section 461.007, Florida**
20 **Statutes, is amended to read:**

21 461.007 Renewal of license.—

22 (3) The board may by rule prescribe continuing education,
23 not to exceed 40 hours biennially, as a condition for renewal of
24 a license, with a minimum of 2 hours of continuing education
25 related to the safe and effective prescribing of controlled

substances for each person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances pursuant to 21 U.S.C. s. 822. The criteria for such programs or courses shall be approved by the board.

Section 2. Section 461.011, Florida Statutes, is created to read:

461.011 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 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

51 include:

- 52 1. Vascularized human organs for transplantation;
53 2. Whole blood or blood components or blood derivative
54 products;
55 3. Secreted or extracted human products, such as milk,
56 collagen, and cell factors, other than semen;
57 4. Minimally manipulated bone marrow for homologous use
58 and not combined with another article other than water,
59 crystalloids, or a sterilizing, preserving, or storage agent, if
60 the addition of the agent does not raise new clinical safety
61 concerns with respect to the bone marrow;
62 5. Ancillary products used in the manufacture of human
63 cells, tissues, or cellular or tissue-based products;
64 6. Cells, tissues, and organs derived from animals other
65 than humans;
66 7. In vitro diagnostic products; or
67 8. Blood vessels recovered with an organ which are
68 intended for use in organ transplantation and labeled, "For use
69 in organ transplantation only."

70 (b) "Minimally manipulated" means:

- 71 1. For structural tissue, processing that does not alter
72 the original relevant characteristics of the tissue relating to
73 the tissue's use for reconstruction, repair, or replacement.
74 2. For cells or nonstructural tissues, processing that
75 does not alter the relevant biological characteristics of cells

76 or tissues.

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

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

90 (b) To ensure that the retrieval, manufacture, storage,
91 and use of stem cells used for therapies conducted pursuant to
92 this section meet the highest standards, any stem cells used by
93 a physician for therapy provided must:

94 1. Be retrieved, manufactured, and stored in a facility
95 that is:

96 a. Registered and regulated by the United States Food and
97 Drug Administration; or

98 b. Certified or accredited by one of the following
99 entities:

100 (I) National Marrow Donor Program.

101 (II) World Marrow Donor Association.

102 (III) Association for the Advancement of Blood and
103 Biotherapies.

104 (IV) American Association of Tissue Banks; and

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

109 (c) A podiatric physician performing stem cell therapy may
110 only obtain stem cells for therapies from a facility engaging in
111 the retrieval, manufacture, or storage of stem cells intended
112 for human use if the facility maintains valid certification or
113 accreditation as required by this subsection. Any contract or
114 other agreement by which a physician obtains stem cells for
115 therapies from such a facility must include the following:

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

118 a. The name and address of the facility.

119 b. The certifying or accrediting organization.

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

121 d. The effective and expiration dates of the certification
122 or accreditation.

123 e. Any limitations or conditions imposed by the certifying
124 or accrediting organization.

125 2. A requirement that the facility notify the podiatric

126 physician within 30 days after any change in certification or
127 accreditation status, including renewal, suspension, revocation,
128 or expiration.

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

139 (5) (a) A podiatric physician who conducts stem cell
140 therapy pursuant to this section shall include the following
141 notice in any form of advertisement:

142
143 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

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

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150 (b) The notice required under paragraph (a) must be

151 clearly legible and in a type size no smaller than the largest
152 type size used in the advertisement.

153 (6) (a) A podiatric physician who provides stem cell
154 therapy pursuant to this section shall obtain a signed consent
155 form from the patient before performing stem cell therapy.

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

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

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

164 3. The anticipated results of the proposed treatment.

165 4. The recognized serious possible risks, complications,
166 and anticipated benefits involved in the treatment and in the
167 recognized possible alternative forms of treatment, including
168 nontreatment.

169 5. That the patient is encouraged to consult with his or
170 her primary care provider before undergoing any stem cell
171 therapy.

172 (7) This section does not apply to:

173 (a) A podiatric physician who has obtained approval for an
174 investigational new drug or device from the United States Food
175 and Drug Administration for the use of human cells, tissues, or

176 cellular or tissue-based products; or

177 (b) A podiatric physician who performs stem cell therapy
178 under an employment or other contract on behalf of an
179 institution certified or accredited by any of the following:

180 1. The Foundation for the Accreditation of Cellular
181 Therapy.

182 2. The Blood and Marrow Transplant Clinical Trials
183 Network.

184 3. The Association for the Advancement of Blood and
185 Biotherapies.

186 4. An entity with expertise in stem cell therapy as
187 determined by the department.

188 (8) A violation of this section shall subject the
189 podiatric physician to disciplinary action by the board.

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

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

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

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

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201 | section.

202 | **Section 3.** This act shall take effect July 1, 2026.