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1
2 An act relating to podiatric medicine; amending s.
3 461.007, F.S.; requiring certain podiatric physicians,
4 instead of all podiatric physicians, to complete
5 specified continuing education; creating s. 461.011,
6 F.S.; providing legislative findings and intent;
7 defining terms; authorizing podiatric physicians to
8 perform procedures using cellular or tissue-based
9 products not approved by the United States Food and
10 Drug Administration under certain circumstances;
11 specifying requirements for the cellular or tissue-
12 based products that may be used by such podiatric
13 physicians; requiring such podiatric physicians to
14 include a specified notice in any form of
15 advertisement; specifying requirements for such
16 notice; requiring podiatric physicians to obtain a
17 signed consent form from the patient or his or her
18 representative before performing procedures using
19 cellular or tissue-based products; specifying
20 requirements for the consent form; providing
21 applicability; providing for disciplinary action;
22 providing criminal penalties; authorizing the Board of
23 Podiatric Medicine to adopt rules; providing an
24 effective date.

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26 Be It Enacted by the Legislature of the State of Florida:

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28 Section 1. Subsection (3) of section 461.007, Florida
29 Statutes, is amended to read:

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30 461.007 Renewal of license.—

31 (3) The board may by rule prescribe continuing education,
32 not to exceed 40 hours biennially, as a condition for renewal of
33 a license, with a minimum of 2 hours of continuing education
34 related to the safe and effective prescribing of controlled
35 substances for licensees who are registered with the United
36 States Drug Enforcement Administration and authorized to
37 prescribe controlled substance pursuant to 21 U.S.C. s. 822. The
38 criteria for such programs or courses shall be approved by the
39 board.

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

42 461.011 Cellular and tissue-based products.—

43 (1) The Legislature recognizes the significant potential of
44 cellular and tissue-based products in advancing medical
45 treatments and improving patient outcomes and further recognizes
46 the need to ensure that such treatments are provided using
47 cellular or tissue-based products obtained in an ethical manner
48 that does not involve cells derived from aborted fetuses. It is
49 the intent of the Legislature to foster medical innovation while
50 upholding ethical standards that respect the sanctity of life.
51 By encouraging the use of cellular or tissue-based products, the
52 state will advance regenerative medicine in a manner consistent
53 with the values of the state.

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

55 (a) "Cellular or tissue-based products" means products
56 containing or consisting of human cells or tissues which are
57 intended for implantation, transplantation, infusion, or
58 transfer into a human recipient. The term does not include:

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- 59 1. Vascularized human organs for transplantation;
60 2. Whole blood or blood components or blood derivative
61 products;
62 3. Secreted or extracted human products, such as milk,
63 collagen, and cell factors, other than semen;
64 4. Minimally manipulated bone marrow for homologous use and
65 not combined with another article other than water,
66 crystalloids, or a sterilizing, preserving, or storage agent, if
67 the addition of the agent does not raise new clinical safety
68 concerns with respect to the bone marrow;
69 5. Ancillary products used in the manufacture of human
70 cells, tissues, or cellular or tissue-based products;
71 6. Cells, tissues, and organs derived from animals;
72 7. In vitro diagnostic products;
73 8. Blood vessels recovered with an organ which are intended
74 for use in organ transplantation and labeled "For use in organ
75 transplantation only"; or
76 9. Harvesting and reimplantation of autologous tissue.
77 (b) "Minimally manipulated" means:
78 1. For structural tissue, processing that does not alter
79 the original relevant characteristics of the tissue relating to
80 the tissue's utility for reconstruction, repair, or replacement.
81 2. For cells or nonstructural tissues, processing that does
82 not alter the relevant biological characteristics of cells or
83 tissues.
84 (c) "Procedure using cellular or tissue-based products"
85 means a treatment involving the use of human cells, tissues, or
86 cellular or tissue-based products which complies with the
87 regulatory requirements provided in this section. The term does

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88 not include treatment or research using human cells or tissues
89 derived from a fetus or an embryo after an abortion.

90 (3) (a) A podiatric physician may perform a procedure using
91 cellular or tissue-based products that are not approved by the
92 United States Food and Drug Administration if such products are
93 used for treatment or procedures within the scope of practice
94 for such podiatric physician and the treatment or procedures are
95 related to connective tissue, ligament, and tendon repair; wound
96 care; or pain management.

97 (b) To ensure that the retrieval, manufacture, storage, and
98 use of any cellular or tissue-based products pursuant to this
99 section meet the highest standards, any cellular or tissue-based
100 products used by a podiatric physician for a procedure provided
101 under this section must meet all of the following conditions:

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

105 2. Be retrieved, manufactured, and stored in a facility
106 that is certified or accredited by one of the following
107 entities:

108 a. The National Marrow Donor Program.

109 b. The World Marrow Donor Association.

110 c. The Association for the Advancement of Blood and
111 Biotherapies.

112 d. The American Association of Tissue Banks.

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

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117 (4) (a) A podiatric physician who performs a procedure using
118 cellular or tissue-based products pursuant to this section shall
119 include the following in any form of advertisement:

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121 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
122 This podiatric physician performs procedures using
123 cellular or tissue-based products that have not yet
124 been approved by the United States Food and Drug
125 Administration. You are encouraged to consult with
126 your primary care provider before undergoing any
127 procedure using these products.

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

132 (5) (a) A podiatric physician who performs a procedure using
133 cellular or tissue-based products pursuant to this section shall
134 obtain a signed consent form from the patient before performing
135 the procedure.

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

- 141 1. The nature and character of the proposed treatment.
142 2. That the proposed procedure uses cellular or tissue-
143 based products that have not yet been approved by the United
144 States Food and Drug Administration.
145 3. The anticipated results of the proposed treatment.

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146 4. The recognized serious possible risks, complications,
147 and anticipated benefits involved in the treatment and in the
148 recognized possible alternative forms of treatment, including
149 nontreatment.

150 5. That the patient is encouraged to consult with his or
151 her primary care provider before undergoing the procedure.

152 (6) This section does not apply to the following:

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

157 (b) A podiatric physician who performs procedures using
158 cellular or tissue-based products under an employment or other
159 contract on behalf of an institution certified or accredited by
160 any of the following:

161 1. The Foundation for the Accreditation of Cellular
162 Therapy.

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

164 3. The Association for the Advancement of Blood and
165 Biotherapies.

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

168 (8) A podiatric physician who willfully performs, or
169 actively participates in, the following commits a felony of the
170 third degree, punishable as provided in s. 775.082, s. 775.083,
171 or s. 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

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

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

180 Section 3. This act shall take effect upon becoming a law.