

By Senator Young

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1 A bill to be entitled
2 An act relating to the use of stem cells in a clinic
3 setting; creating ss. 458.352 and 459.027, F.S.;
4 defining the terms "clinic" and "stem cell"; requiring
5 a physician or osteopathic physician or a clinic owner
6 to register a clinic with the Department of Health if
7 the clinic meets certain criteria; specifying that
8 each clinic location must be registered separately and
9 must designate a physician to be responsible for
10 complying with certain requirements; requiring the
11 clinic to notify the department of a change of
12 designated physician within a specified timeframe;
13 providing that summary suspension of a clinic's
14 registration certificate may occur if a designated
15 physician or designated osteopathic physician is not
16 practicing at the clinic location; prohibiting a
17 physician from practicing medicine or an osteopathic
18 physician from practicing osteopathic medicine in a
19 certain clinic that is not registered with the
20 department; specifying certain disciplinary action for
21 violations; requiring a physician or osteopathic
22 physician to adhere to specified regulations in the
23 performance of any procedure using or purporting to
24 use stem cells or products containing stem cells;
25 requiring the department to adopt rules to administer
26 registration and an annual inspection of registered
27 clinics; specifying that a person or entity seeking to
28 register and operate a clinic must pay all costs of
29 registration and inspection; authorizing the

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30 department to impose fines on a physician or
 31 osteopathic physician or clinic that violates
 32 specified requirements; requiring the Board of
 33 Medicine and the Board of Osteopathic Medicine,
 34 respectively, to adopt certain rules and guidelines;
 35 authorizing the department to impose certain fines;
 36 requiring the department to consider certain factors
 37 in determining the imposition of such a fine;
 38 authorizing the department to impose a fine and revoke
 39 or deny a clinic registration in certain
 40 circumstances; requiring the imposition of certain
 41 fines for specified violations of clinic registration
 42 requirements; providing an effective date.

43

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

45

46 Section 1. Section 458.352, Florida Statutes, is created to
 47 read:

48 458.352 Use of stem cells in a clinic setting.-

49 (1) DEFINITIONS.-As used in this section, the term:

50 (a) "Clinic" means a publicly or privately owned facility
 51 or office that:

52 1. Advertises for any service that uses, or purports to
 53 use, stem cells or any product containing stem cells that is
 54 intended to diagnose, cure, mitigate, treat, provide therapy
 55 for, or prevent an injury or a disease; or

56 2. Performs any procedure that is intended to diagnose,
 57 cure, mitigate, treat, provide therapy for, or prevent an injury
 58 or a disease that uses, or purports to use, stem cells or any

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59 product containing stem cells which has not been approved by the
60 United States Food and Drug Administration or is not the subject
61 of a clinical trial approved by the United States Food and Drug
62 Administration.

63 (b) "Stem cell" means an allogenic or autologous cell that
64 is altered or processed to become undifferentiated, losing its
65 original structural function, so that it can become
66 differentiated into a specialized cell type. The term does not
67 include cells that are only rinsed, cleaned, or sized and remain
68 differentiated.

69 (2) REGISTRATION.—

70 (a) A physician or clinic owner who advertises, uses, or
71 purports to use stem cells or products containing stem cells in
72 a clinic must register the clinic with the department, unless
73 any of the following apply:

74 1. The clinic is a facility licensed under chapter 395;

75 2. The clinic is wholly owned and operated by one or more
76 physicians licensed under this chapter or chapter 459;

77 3. The clinic is affiliated with an accredited medical
78 school that provides training to medical students, residents, or
79 fellows; or

80 4. The clinic solely performs one or more of the following
81 procedures:

82 a. The collection of umbilical cord blood cells for blood
83 banking;

84 b. The collection, transfer, or insemination of oocytes; or

85 c. The injection or infusion of platelet-rich plasma.

86 (b) Each clinic location must be registered separately.

87 (c) As a part of registration, a clinic must designate a

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88 physician who is responsible for complying with all requirements
89 related to registration and operation of the clinic in
90 compliance with this section. Within 10 days after termination
91 of a designated physician, the clinic must notify the department
92 of the identity of another designated physician for that clinic.
93 A designated physician must have a full, active, and
94 unencumbered license issued under this chapter or chapter 459
95 and must practice at the clinic location for which he or she has
96 assumed responsibility. Failing to have a licensed designated
97 physician practicing at the location of the registered clinic
98 may be the basis for a summary suspension of the clinic
99 registration certificate as described in s. 456.073(8) for a
100 license or in s. 120.60(6).

101 (3) PHYSICIAN RESPONSIBILITIES.—

102 (a) A physician may not practice medicine in a clinic that
103 is not registered with the department as required by this
104 section or s. 459.027. A physician who violates this paragraph
105 is subject to disciplinary action by his or her appropriate
106 medical regulatory board.

107 (b) In the performance of any procedure using or purporting
108 to use stem cells or products containing stem cells, the
109 physician shall adhere to the applicable current good
110 manufacturing practices for the collection, removal, processing,
111 implantation, and transfer of stem cells, or products containing
112 stem cells, pursuant to the Federal Food, Drug, and Cosmetic
113 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21
114 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-Based
115 Products.

116 (4) RULEMAKING.—

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117 (a) The department shall adopt rules necessary to
118 administer registration and an annual inspection of registered
119 clinics. The person or entity seeking to register and operate
120 the clinic must pay all costs of registration and inspection.

121 (b) The board shall adopt rules regarding advertising,
122 adverse incident reporting, and informed consent guidelines for
123 the use or purported use of stem cells or products containing
124 stem cells in a clinic required to register under this section.

125 (5) PENALTIES; ENFORCEMENT.—

126 (a) The department may impose an administrative fine on a
127 physician or a clinic of up to \$5,000 per violation for
128 violating the requirements of this section; chapter 499, the
129 Florida Drug and Cosmetic Act; the Federal Food, Drug, and
130 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.;
131 21 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-
132 Based Products; or the rules of the department. In determining
133 whether a penalty is to be imposed, and in fixing the amount of
134 the fine, the department shall consider the following factors:

135 1. The gravity of the violation, including the probability
136 that patient deception, or serious physical or emotional harm,
137 has resulted or could have resulted; the severity of the
138 deception, harm, or potential harm; and the extent to which the
139 provisions of the applicable laws or rules were violated.

140 2. What actions, if any, the physician, clinic owner, or
141 designated physician took to correct the violations.

142 3. Whether there were any previous violations at the
143 clinic.

144 4. The financial benefits that the physician, clinic, or
145 designated physician derived from committing or continuing to

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146 commit the violation.

147 (b) Each day a violation continues after the date fixed for
148 termination of the violation as ordered by the department
149 constitutes an additional, separate, and distinct violation.

150 (c) The department may impose a fine and, in the case of an
151 owner-operated clinic, revoke or deny a clinic registration if
152 the clinic's designated physician knowingly misrepresents
153 actions taken to correct a violation.

154 (d) A physician, clinic, or designated physician that
155 concurrently operates an unregistered clinic is subject to an
156 administrative fine of \$5,000 per day for each clinic location.

157 (e) If the physician or owner of a clinic that is required
158 to register fails to apply to register upon a change of
159 ownership and operates the clinic under the new ownership, the
160 new owner is also subject to a fine of \$5,000 per day for each
161 location.

162 Section 2. Section 459.027, Florida Statutes, is created to
163 read:

164 459.027 Use of stem cells in clinic setting.-

165 (1) DEFINITIONS.-As used in this section, the term:

166 (a) "Clinic" means a publicly or privately owned facility
167 or office that:

168 1. Advertises for any service that uses, or purports to
169 use, stem cells or any product containing stem cells that is
170 intended to diagnose, cure, mitigate, treat, provide therapy
171 for, or prevent an injury or a disease; or

172 2. Performs any procedure that is intended to diagnose,
173 cure, mitigate, treat, provide therapy for, or prevent an injury
174 or a disease that uses, or purports to use, stem cells or any

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175 product containing stem cells which has not been approved by the
176 United States Food and Drug Administration or is not the subject
177 of a clinical trial approved by the United States Food and Drug
178 Administration.

179 (b) "Stem cell" means an allogenic or autologous cell that
180 is altered or processed to become undifferentiated, losing its
181 original structural function, so that it can become
182 differentiated into a specialized cell type. The term does not
183 include cells that are only rinsed, cleaned, or sized and remain
184 differentiated.

185 (2) REGISTRATION.—

186 (a) An osteopathic physician or clinic owner who
187 advertises, uses, or purports to use stem cells or products
188 containing stem cells in a clinic must register the clinic with
189 the department, unless any of the following apply:

190 1. The clinic is a facility licensed under chapter 395;

191 2. The clinic is wholly owned and operated by one or more
192 physicians licensed under this chapter or chapter 458;

193 3. The clinic is affiliated with an accredited medical
194 school that provides training to medical students, residents, or
195 fellows; or

196 4. The clinic solely performs one or more of the following
197 procedures:

198 a. The collection of umbilical cord blood cells for blood
199 banking;

200 b. The collection, transfer, or insemination of oocytes; or

201 c. The injection or infusion of platelet-rich plasma.

202 (b) Each clinic location must be registered separately.

203 (c) As a part of registration, a clinic must designate a

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204 physician who is responsible for complying with all requirements
205 related to registration and operation of the clinic in
206 compliance with this section. Within 10 days after termination
207 of a designated physician, the clinic must notify the department
208 of the identity of another designated physician for that clinic.
209 A designated physician must have a full, active, and
210 unencumbered license issued under this chapter or chapter 458
211 and must practice at the clinic location for which he or she has
212 assumed responsibility. Failing to have a licensed designated
213 physician practicing at the location of the registered clinic
214 may be the basis for a summary suspension of the clinic
215 registration certificate as described in s. 456.073(8) for a
216 license or in s. 120.60(6).

217 (3) PHYSICIAN RESPONSIBILITIES.—

218 (a) An osteopathic physician may not practice osteopathic
219 medicine in a clinic that is not registered with the department
220 as required by this section or s. 458.352. An osteopathic
221 physician who violates this paragraph is subject to disciplinary
222 action by his or her appropriate medical regulatory board.

223 (b) In the performance of any procedure using or purporting
224 to use stem cells or products containing stem cells, the
225 osteopathic physician shall adhere to the applicable current
226 good manufacturing practices for the collection, removal,
227 processing, implantation, and transfer of stem cells, or
228 products containing stem cells, pursuant to the Federal Food,
229 Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040
230 et seq.; and 21 C.F.R. 1271, Human Cells, Tissues, and Cellular
231 and Tissue-Based Products.

232 (4) RULEMAKING.—

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233 (a) The department shall adopt rules necessary to
234 administer registration and an annual inspection of registered
235 clinics. The person or entity seeking to register and operate
236 the clinic must pay all costs of registration and inspection.

237 (b) The board shall adopt rules regarding advertising,
238 adverse incident reporting, and informed consent guidelines for
239 the use or purported use of stem cells or products containing
240 stem cells in a clinic required to register under this section.

241 (5) PENALTIES; ENFORCEMENT.—

242 (a) The department may impose an administrative fine on an
243 osteopathic physician or a clinic of up to \$5,000 per violation
244 for violating the requirements of this section; chapter 499, the
245 Florida Drug and Cosmetic Act; the Federal Food, Drug, and
246 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.;
247 21 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-
248 Based Products; or the rules of the department. In determining
249 whether a penalty is to be imposed, and in fixing the amount of
250 the fine, the department shall consider the following factors:

251 1. The gravity of the violation, including the probability
252 that patient deception, or serious physical or emotional harm,
253 has resulted or could have resulted; the severity of the
254 deception, harm, or potential harm; and the extent to which the
255 provisions of the applicable laws or rules were violated.

256 2. What actions, if any, the osteopathic physician, clinic
257 owner, or designated physician took to correct the violations.

258 3. Whether there were any previous violations at the
259 clinic.

260 4. The financial benefits that the osteopathic physician,
261 clinic, or designated physician derived from committing or

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262 continuing to commit the violation.

263 (b) Each day a violation continues after the date fixed for
264 termination of the violation as ordered by the department
265 constitutes an additional, separate, and distinct violation.

266 (c) The department may impose a fine and, in the case of an
267 owner-operated clinic, revoke or deny a clinic registration if
268 the clinic's designated physician knowingly misrepresents
269 actions taken to correct a violation.

270 (d) An osteopathic physician, clinic, or designated
271 physician that concurrently operates an unregistered clinic is
272 subject to an administrative fine of \$5,000 per day for each
273 clinic location.

274 (e) If the osteopathic physician or owner of a clinic that
275 is required to register fails to apply to register upon a change
276 of ownership and operates the clinic under the new ownership,
277 the new owner is also subject to a fine of \$5,000 per day for
278 each location.

279 Section 3. This act shall take effect July 1, 2018.