

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  
 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.

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

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

85 or

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

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

88 (c) As a part of registration, a clinic must designate a  
89 physician who is responsible for complying with all requirements  
90 related to registration and operation of the clinic in  
91 compliance with this section. Within 10 days after termination  
92 of a designated physician, the clinic must notify the department  
93 of the identity of another designated physician for that clinic.

94 A designated physician must have a full, active, and  
95 unencumbered license issued under this chapter or chapter 459  
96 and must practice at the clinic location for which he or she has  
97 assumed responsibility. Failing to have a licensed designated  
98 physician practicing at the location of the registered clinic  
99 may be the basis for a summary suspension of the clinic  
100 registration certificate as described in s. 456.073(8) for a

101 license or in s. 120.60(6).

102 (3) PHYSICIAN RESPONSIBILITIES.—

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

108 (b) In the performance of any procedure using or  
 109 purporting to use stem cells or products containing stem cells,  
 110 the physician shall 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  
 114 Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21  
 115 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-Based  
 116 Products.

117 (4) RULEMAKING.—

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

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

126 (5) PENALTIES; ENFORCEMENT.—

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

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

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

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

145 4. The financial benefits that the physician, clinic, or  
146 designated physician derived from committing or continuing to  
147 commit the violation.

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

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

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

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

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

165 459.027 Use of stem cells in clinic setting.—

166 (1) DEFINITIONS.—As used in this section, the term:

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

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

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

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

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

186 (2) REGISTRATION.—

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

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

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

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

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

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



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

202 or

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

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

205 (c) As a part of registration, a clinic must designate a  
206 physician who is responsible for complying with all requirements  
207 related to registration and operation of the clinic in  
208 compliance with this section. Within 10 days after termination  
209 of a designated physician, the clinic must notify the department  
210 of the identity of another designated physician for that clinic.

211 A designated physician must have a full, active, and  
212 unencumbered license issued under this chapter or chapter 458  
213 and must practice at the clinic location for which he or she has  
214 assumed responsibility. Failing to have a licensed designated  
215 physician practicing at the location of the registered clinic  
216 may be the basis for a summary suspension of the clinic  
217 registration certificate as described in s. 456.073(8) for a  
218 license or in s. 120.60(6).

219 (3) PHYSICIAN RESPONSIBILITIES.—

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

225 (b) In the performance of any procedure using or

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

234 (4) RULEMAKING.—

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

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

243 (5) PENALTIES; ENFORCEMENT.—

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

251 a penalty is to be imposed, and in fixing the amount of the  
252 fine, the department shall consider the following factors:

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

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

260 3. Whether there were any previous violations at the  
261 clinic.

262 4. The financial benefits that the osteopathic physician,  
263 clinic, or designated physician derived from committing or  
264 continuing to commit the violation.

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

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

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

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

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