

By Senator Gaetz

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1 A bill to be entitled
2 An act relating to blood establishments; amending s.
3 381.06014, F.S.; defining the term "volunteer donor";
4 prohibiting local governments from restricting access
5 to public facilities or infrastructure for certain
6 activities based on whether a blood establishment is
7 operating as a for-profit organization or not-for-
8 profit organization; prohibiting a blood establishment
9 from considering whether certain customers are
10 operating as for-profit organizations or not-for-
11 profit organizations when determining service fees for
12 selling blood or blood components; requiring that
13 certain blood establishments disclose specified
14 information on the Internet; amending s. 483.201,
15 F.S.; providing for disciplinary action against
16 clinical laboratories that fail to disclose specified
17 information on the Internet; providing a maximum
18 annual administrative fine that may be imposed
19 annually against certain clinical laboratories for
20 failure to comply with such disclosure requirement;
21 amending s. 499.003, F.S.; redefining the term "health
22 care entity" to clarify that a blood establishment may
23 be a health care entity and engage in certain
24 activities; amending s. 499.005, F.S.; clarifying
25 provisions prohibiting the unauthorized wholesale
26 distribution of a prescription drug that was purchased
27 by a hospital or other health care entity, to conform
28 to changes made by the act; amending s. 499.01, F.S.;
29 exempting certain blood establishments from the

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30 requirements to be permitted as a prescription drug
31 manufacturer and register products; requiring that
32 certain blood establishments obtain a restricted
33 prescription drug distributor permit under specified
34 conditions; limiting the prescription drugs that a
35 blood establishment may distribute under a restricted
36 prescription drug distributor permit; authorizing the
37 Department of Health to adopt rules; providing an
38 effective date.

39
40 Be It Enacted by the Legislature of the State of Florida:

41
42 Section 1. Section 381.06014, Florida Statutes, is amended
43 to read:

44 381.06014 Blood establishments.—

45 (1) As used in this section, the term:

46 (a) "Blood establishment" means any person, entity, or
47 organization, operating within the state, which examines an
48 individual for the purpose of blood donation or which collects,
49 processes, stores, tests, or distributes blood or blood
50 components collected from the human body for the purpose of
51 transfusion, for any other medical purpose, or for the
52 production of any biological product.

53 (b) "Volunteer donor" means a person who does not receive
54 remuneration, other than an incentive, for a blood donation
55 intended for transfusion, and the product container of the
56 donation from the person qualifies for labeling with the
57 statement "volunteer donor" under 21 C.F.R. s. 606.121.

58 (2) Any blood establishment operating in the state may not

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59 conduct any activity defined in paragraph (1) (a) ~~subsection (1)~~
60 unless that blood establishment is operated in a manner
61 consistent with the provisions of Title 21 C.F.R. parts 211 and
62 600-640, ~~Code of Federal Regulations~~.

63 (3) Any blood establishment determined to be operating in
64 the state in a manner not consistent with the provisions of
65 Title 21 C.F.R. parts 211 and 600-640, ~~Code of Federal~~
66 ~~Regulations~~, and in a manner that constitutes a danger to the
67 health or well-being of donors or recipients as evidenced by the
68 federal Food and Drug Administration's inspection reports and
69 the revocation of the blood establishment's license or
70 registration is ~~shall be~~ in violation of this chapter and shall
71 immediately cease all operations in the state.

72 (4) The operation of a blood establishment in a manner not
73 consistent with the provisions of Title 21 C.F.R. parts 211 and
74 600-640, ~~Code of Federal Regulations~~, and in a manner that
75 constitutes a danger to the health or well-being of blood donors
76 or recipients as evidenced by the federal Food and Drug
77 Administration's inspection process is declared a nuisance and
78 inimical to the public health, welfare, and safety. The Agency
79 for Health Care Administration or any state attorney may bring
80 an action for an injunction to restrain such operations or
81 enjoin the future operation of the blood establishment.

82 (5) A local government may not restrict the access to or
83 use of any public facility or infrastructure for the collection
84 of blood or blood components from volunteer donors based on
85 whether the blood establishment is operating as a for-profit
86 organization or not-for-profit organization.

87 (6) In determining the service fee of blood or blood

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88 components received from volunteer donors and sold to hospitals
89 or other health care providers, a blood establishment may not
90 base the service fee of the blood or blood component solely on
91 whether the purchasing entity is a for-profit organization or
92 not-for-profit organization.

93 (7) A blood establishment that collects blood or blood
94 components from volunteer donors must disclose on the Internet
95 information to educate and inform donors and the public about
96 the blood establishment's activities. A hospital that collects
97 blood or blood components from volunteer donors for its own use
98 or for health care providers that are part of its business
99 entity is exempt from the disclosure requirements in this
100 subsection. The information required to be disclosed under this
101 subsection may be cumulative for all blood establishments within
102 a business entity. Disciplinary action against the blood
103 establishment's clinical laboratory license may be taken as
104 provided in s. 483.201 for a blood establishment that is
105 required to disclose but fails to disclose on its website all of
106 the following information:

107 (a) A description of the steps involved in collecting,
108 processing, and distributing volunteer donations, presented in a
109 manner appropriate for the donating public.

110 (b) By March 1 of each year, the number of units of blood
111 components, identified by component, which were:

112 1. Produced by the blood establishment during the preceding
113 calendar year;

114 2. Obtained from other sources during the preceding
115 calendar year;

116 3. Distributed during the preceding year to health care

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117 providers located outside this state. However, if the blood
118 establishment collects donations in a county outside this state,
119 distributions to health care providers in that county shall be
120 excluded. Such information shall be aggregated by health care
121 providers located within the United States and its territories
122 or outside the United States and its territories; and

123 4. Distributed during the preceding year to entities that
124 are not health care providers. Such information shall be
125 aggregated by purchasers located within the United States and
126 its territories or outside the United States and its
127 territories.

128
129 For purposes of this paragraph, the components that must be
130 reported include whole blood, red blood cells, leukoreduced red
131 blood cells, fresh frozen plasma or the equivalent, recovered
132 plasma, platelets, and cryoprecipitated antihemophilic factor.

133 (c) The blood establishment's conflict-of-interest policy,
134 policy concerning related-party transactions, whistleblower
135 policy, and policy for determining executive compensation. If a
136 change to any of these documents occurs, the revised document
137 must be available on the blood establishment's website by the
138 following March 1.

139 (d)1. The most recent 3 years of the Return of Organization
140 Exempt from Income Tax, Internal Revenue Service Form 990, if
141 the business entity for the blood establishment is eligible to
142 file such return. The Form 990 must be available on the blood
143 establishment's website within 30 calendar days after it is
144 filed with the Internal Revenue Service; or

145 2. If the business entity for the blood establishment is

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146 not eligible to file the Form 990 return, a balance sheet,
147 income statement, and statement of changes in cash flow, along
148 with the expression of an opinion thereon by an independent
149 certified public accountant who audited or reviewed such
150 financial statements. Such documents must be available on the
151 blood establishment's website within 120 days after the end of
152 the blood establishment's fiscal year and must remain on the
153 blood establishment's website for at least 36 months.

154 Section 2. Subsection (11) is added to section 483.201,
155 Florida Statutes, to read:

156 483.201 Grounds for disciplinary action against clinical
157 laboratories.—In addition to the requirements of part II of
158 chapter 408, the following acts constitute grounds for which a
159 disciplinary action specified in s. 483.221 may be taken against
160 a clinical laboratory:

161 (11) For a blood establishment that collects blood or blood
162 components from volunteer donors, failing to disclose
163 information concerning its activities as required by s.
164 381.06014. Each day of violation constitutes a separate
165 violation and each separate violation is subject to a separate
166 fine. If multiple licensed establishments operated by a single
167 business entity fail to meet such disclosure requirements, the
168 agency may assess fines against only one of the business
169 entity's clinical laboratory licenses. The total administrative
170 fine may not exceed \$10,000 for each annual reporting period.

171 Section 3. Subsection (23) of section 499.003, Florida
172 Statutes, is amended to read

173 499.003 Definitions of terms used in this part.—As used in
174 this part, the term:

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175 (23) "Health care entity" means a closed pharmacy or any
176 person, organization, or business entity that provides
177 diagnostic, medical, surgical, or dental treatment or care, or
178 chronic or rehabilitative care, but does not include any
179 wholesale distributor or retail pharmacy licensed under state
180 law to deal in prescription drugs. However, a blood
181 establishment may be a health care entity and engage in the
182 wholesale distribution of prescription drugs under s.
183 499.01(2)(g)1.c.

184 Section 4. Subsection (21) of section 499.005, Florida
185 Statutes, is amended to read:

186 499.005 Prohibited acts.—It is unlawful for a person to
187 perform or cause the performance of any of the following acts in
188 this state:

189 (21) The wholesale distribution of any prescription drug
190 that was:

191 (a) Purchased by a public or private hospital or other
192 health care entity, except as authorized in s. 499.01(2)(g)1.c.;
193 or

194 (b) Donated or supplied at a reduced price to a charitable
195 organization.

196 Section 5. Paragraphs (a) and (g) of subsection (2) of
197 section 499.01, Florida Statutes, are amended to read:

198 499.01 Permits.—

199 (2) The following permits are established:

200 (a) *Prescription drug manufacturer permit.*—A prescription
201 drug manufacturer permit is required for any person that is a
202 manufacturer of a prescription drug and that manufactures or
203 distributes such prescription drugs in this state.

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204 1. A person that operates an establishment permitted as a
205 prescription drug manufacturer may engage in wholesale
206 distribution of prescription drugs manufactured at that
207 establishment and must comply with all of the provisions of this
208 part, except s. 499.01212, and the rules adopted under this
209 part, except s. 499.01212, which ~~that~~ apply to a wholesale
210 distributor.

211 2. A prescription drug manufacturer must comply with all
212 appropriate state and federal good manufacturing practices.

213 3. A blood establishment, as defined in s. 381.06014,
214 operating in a manner consistent with the provisions of Title 21
215 C.F.R. parts 211 and 600-640, and manufacturing only the
216 prescription drugs described in s. 499.003(54)(d) is not
217 required to be permitted as a prescription drug manufacturer
218 under this paragraph or to register products under s. 499.015.

219 (g) *Restricted prescription drug distributor permit.*—

220 1. A restricted prescription drug distributor permit is
221 required for:

222 a. Any person that engages in the distribution of a
223 prescription drug, which distribution is not considered
224 “wholesale distribution” under s. 499.003(54)(a).

225 ~~b.1.~~ Any ~~A~~ person who engages in the receipt or
226 distribution of a prescription drug in this state for the
227 purpose of processing its return or its destruction ~~must obtain~~
228 ~~a permit as a restricted prescription drug distributor~~ if such
229 person is not the person initiating the return, the prescription
230 drug wholesale supplier of the person initiating the return, or
231 the manufacturer of the drug.

232 c. A blood establishment located in this state which

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233 collects blood and blood components only from volunteer donors
234 as defined in s. 381.06014 or pursuant to an authorized
235 practitioner's order for medical treatment or therapy and
236 engages in the wholesale distribution of a prescription drug not
237 described in s. 499.003(54) (d) to a health care entity. The
238 health care entity receiving a prescription drug distributed
239 under this sub-subparagraph must be licensed as a closed
240 pharmacy or provide health care services at that establishment.
241 The blood establishment must operate in accordance with s.
242 381.06014 and may distribute only:

243 (I) Prescription drugs indicated for a bleeding or clotting
244 disorder or anemia;

245 (II) Blood-collection containers approved under s. 505 of
246 the federal act;

247 (III) Drugs that are blood derivatives, or a recombinant or
248 synthetic form of a blood derivative; or

249 (IV) Prescription drugs that are identified in rules
250 adopted by the department and that are essential to services
251 performed or provided by blood establishments and authorized for
252 distribution by blood establishments under federal law,

253
254 as long as all of the health care services provided by the blood
255 establishment are related to its activities as a registered
256 blood establishment or the health care services consist of
257 collecting, processing, storing, or administering human
258 hematopoietic stem cells or progenitor cells or performing
259 diagnostic testing of specimens if such specimens are tested
260 together with specimens undergoing routine donor testing.

261 2. Storage, handling, and recordkeeping of these

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262 distributions by a person permitted as a restricted prescription
263 drug distributor must comply with the requirements for wholesale
264 distributors under s. 499.0121, but not those set forth in s.
265 499.01212 if the distribution occurs pursuant to sub-
266 subparagraph 1.a. or sub-subparagraph 1.b.

267 3. A person who applies for a permit as a restricted
268 prescription drug distributor, or for the renewal of such a
269 permit, must provide to the department the information required
270 under s. 499.012.

271 4. The department may adopt rules regarding the
272 distribution of prescription drugs by hospitals, health care
273 entities, charitable organizations, or other persons not
274 involved in wholesale distribution, and blood establishments;
275 which rules are necessary for the protection of the public
276 health, safety, and welfare. The department may adopt rules
277 related to the transportation, storage, and recordkeeping of
278 prescription drugs that are essential to services performed or
279 provided by a blood establishment, including requirements for
280 the use of prescription drugs in mobile blood-collection
281 vehicles.

282 Section 6. This act shall take effect July 1, 2011.