

By Senator Gaetz

4-00048-12

2012364

1 A bill to be entitled
2 An act relating to blood establishments; amending s.
3 381.06014, F.S.; redefining the term "blood
4 establishment" and defining the term "volunteer
5 donor"; prohibiting local governments from restricting
6 access to public facilities or infrastructure for
7 certain activities based on whether a blood
8 establishment is operating as a for-profit
9 organization or not-for-profit organization;
10 prohibiting a blood establishment from considering
11 whether certain customers are operating as for-profit
12 organizations or not-for-profit organizations when
13 determining service fees for selling blood or blood
14 components; requiring that certain blood
15 establishments disclose specified information on the
16 Internet; authorizing the Department of Legal Affairs
17 to assess a civil penalty against a blood
18 establishment that fails to disclose specified
19 information on the Internet; providing that the civil
20 penalty accrues to the state and requiring that it be
21 deposited as received into the General Revenue Fund;
22 amending s. 499.003, F.S.; redefining the term "health
23 care entity" to clarify that a blood establishment is
24 a health care entity that may engage in certain
25 activities; amending s. 499.005, F.S.; clarifying
26 provisions that prohibit the unauthorized wholesale
27 distribution of a prescription drug that was purchased
28 by a hospital or other health care entity or donated
29 or supplied at a reduced price to a charitable

4-00048-12

2012364

30 organization, to conform to changes made by the act;
31 amending s. 499.01, F.S.; exempting certain blood
32 establishments from the requirements to be permitted
33 as a prescription drug manufacturer and register
34 products; requiring that certain blood establishments
35 obtain a restricted prescription drug distributor
36 permit under specified conditions; limiting the
37 prescription drugs that a blood establishment may
38 distribute under a restricted prescription drug
39 distributor permit; authorizing the Department of
40 Health to adopt rules regarding the distribution of
41 prescription drugs by blood establishments; providing
42 an effective date.

43
44 Be It Enacted by the Legislature of the State of Florida:

45
46 Section 1. Section 381.06014, Florida Statutes, is amended
47 to read:

48 381.06014 Blood establishments.—

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

50 (a) "Blood establishment" means any person, entity, or
51 organization, operating within the state, which examines an
52 individual for the purpose of blood donation or which collects,
53 processes, stores, tests, or distributes blood or blood
54 components collected from the human body for the purpose of
55 transfusion, for any other medical purpose, or for the
56 production of any biological product. A person, entity, or
57 organization that uses a mobile unit to conduct such activities
58 within the state is also a blood establishment.

4-00048-12

2012364

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

64 (2) Any blood establishment operating in the state may not
65 conduct any activity defined in paragraph (1) (a) subsection (1)
66 unless that blood establishment is operated in a manner
67 consistent with the provisions of ~~Title 21 C.F.R. parts 211 and~~
68 ~~600-640, Code of Federal Regulations.~~

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

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

4-00048-12

2012364

88 (5) A local government may not restrict the access to or
89 use of any public facility or infrastructure for the collection
90 of blood or blood components from volunteer donors based on
91 whether the blood establishment is operating as a for-profit
92 organization or not-for-profit organization.

93 (6) In determining the service fee of blood or blood
94 components received from volunteer donors and sold to hospitals
95 or other health care providers, a blood establishment may not
96 base the service fee of the blood or blood component solely on
97 whether the purchasing entity is a for-profit organization or
98 not-for-profit organization.

99 (7) A blood establishment that collects blood or blood
100 components from volunteer donors must disclose on the Internet
101 the information required under this subsection to educate and
102 inform donors and the public about the blood establishment's
103 activities. A hospital that collects blood or blood components
104 to be used only by that hospital's licensed facilities or by a
105 health care provider that is a part of the hospital's business
106 entity is exempt from the disclosure requirements in this
107 subsection. The information required to be disclosed under this
108 subsection may be cumulative for all blood establishments within
109 a business entity. A blood establishment must disclose on its
110 website all of the following information:

111 (a) A description of the steps involved in collecting,
112 processing, and distributing volunteer donations.

113 (b) By March 1 of each year, the number of units of blood
114 components which were:

115 1. Produced by the blood establishment during the preceding
116 calendar year;

4-00048-12

2012364

117 2. Obtained from other sources during the preceding
118 calendar year;

119 3. Distributed during the preceding calendar year to health
120 care providers located outside this state. However, if the blood
121 establishment collects donations in a county outside this state,
122 distributions to health care providers in that county shall be
123 excluded. Such information shall be reported in the aggregate
124 for health care providers located within the United States and
125 its territories or outside the United States and its
126 territories; and

127 4. Distributed during the preceding calendar year to
128 entities that are not health care providers. Such information
129 shall be reported in the aggregate for purchasers located within
130 the United States and its territories or outside the United
131 States and its territories.

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

138 (d) Except for a hospital that collects blood or blood
139 components from volunteer donors:

140 1. The most recent 3 years of the Return of Organization
141 Exempt from Income Tax, Internal Revenue Service Form 990, if
142 the business entity for the blood establishment is eligible to
143 file such return. The Form 990 must be available on the blood
144 establishment's website within 60 calendar days after it is
145 filed with the Internal Revenue Service; or

4-00048-12

2012364

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

155 (8) A blood establishment is liable for a civil penalty for
156 failing to make the disclosures required under subsection (7).
157 The Department of Legal Affairs may assess the civil penalty
158 against the blood establishment for each day that it fails to
159 make such required disclosures, but the penalty may not exceed
160 \$10,000 per year. If multiple blood establishments operated by a
161 single business entity fail to meet such disclosure
162 requirements, the civil penalty may be assessed against only one
163 of the business entity's blood establishments. The Department of
164 Legal Affairs may terminate an action if the blood establishment
165 agrees to pay a stipulated civil penalty. A civil penalty so
166 collected accrues to the state and shall be deposited as
167 received into the General Revenue Fund unallocated. The
168 Department of Legal Affairs may terminate the action and waive
169 the civil penalty upon a showing of good cause by the blood
170 establishment as to why the required disclosures were not made.

171 Section 2. 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:

4-00048-12

2012364

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 is a health care entity that may engage in the
182 wholesale distribution of prescription drugs under s.
183 499.01(2)(g)1.c.

184 Section 3. 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; or

193 (b) Donated or supplied at a reduced price to a charitable
194 organization,

195
196 unless the wholesale distribution of the prescription drug is
197 authorized in s. 499.01(2)(g)1.c.

198 Section 4. Paragraphs (a) and (g) of subsection (2) of
199 section 499.01, Florida Statutes, are amended to read:

200 499.01 Permits.—

201 (2) The following permits are established:

202 (a) *Prescription drug manufacturer permit.*—A prescription
203 drug manufacturer permit is required for any person that is a

4-00048-12

2012364

204 manufacturer of a prescription drug and that manufactures or
205 distributes such prescription drugs in this state.

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

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

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

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

222 1. A restricted prescription drug distributor permit is
223 required for:

224 a. Any person located in this state who ~~that~~ engages in the
225 distribution of a prescription drug, which distribution is not
226 considered "wholesale distribution" under s. 499.003(54)(a).

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

4-00048-12

2012364

233 the return, or the manufacturer of the drug.

234 c. A blood establishment located in this state which
235 collects blood and blood components only from volunteer donors
236 as defined in s. 381.06014 or pursuant to an authorized
237 practitioner's order for medical treatment or therapy and
238 engages in the wholesale distribution of a prescription drug not
239 described in s. 499.003(54) (d) to a health care entity. The
240 health care entity receiving a prescription drug distributed
241 under this sub-subparagraph must be licensed as a closed
242 pharmacy or provide health care services at that establishment.
243 The blood establishment must operate in accordance with s.
244 381.06014 and may distribute only:

245 (I) Prescription drugs indicated for a bleeding or clotting
246 disorder or anemia;

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

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

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

255 (V) To the extent authorized by federal law, drugs
256 necessary to collect blood or blood components from volunteer
257 blood donors; for blood establishment personnel to perform
258 therapeutic procedures under the direction and supervision of a
259 licensed physician; and to diagnose, treat, manage, and prevent
260 any reaction of a volunteer blood donor or a patient undergoing
261 a therapeutic procedure performed under the direction and

4-00048-12

2012364

262 supervision of a licensed physician,
263
264 as long as all of the health care services provided by the blood
265 establishment are related to its activities as a registered
266 blood establishment or the health care services consist of
267 collecting, processing, storing, or administering human
268 hematopoietic stem cells or progenitor cells or performing
269 diagnostic testing of specimens if such specimens are tested
270 together with specimens undergoing routine donor testing.

271 2. Storage, handling, and recordkeeping of these
272 distributions by a person required to be permitted as a
273 restricted prescription drug distributor must be in accordance
274 ~~comply~~ with the requirements for wholesale distributors under s.
275 499.0121, but not those set forth in s. 499.01212 if the
276 distribution occurs pursuant to sub-subparagraph 1.a. or sub-
277 subparagraph 1.b.

278 3. A person who applies for a permit as a restricted
279 prescription drug distributor, or for the renewal of such a
280 permit, must provide to the department the information required
281 under s. 499.012.

282 4. The department may adopt rules regarding the
283 distribution of prescription drugs by hospitals, health care
284 entities, charitable organizations, ~~or~~ other persons not
285 involved in wholesale distribution, and blood establishments,
286 which rules are necessary for the protection of the public
287 health, safety, and welfare.

288 Section 5. This act shall take effect July 1, 2012.