

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
 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 | Business and Professional Regulation to adopt rules
 41 | regarding the distribution of prescription drugs by
 42 | blood establishments; providing 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.

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.

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
116 preceding calendar year;

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

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

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

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169 waive the civil penalty upon a showing of good cause by the
 170 blood establishment as to why the required disclosures were not
 171 made.

172 Section 2. Subsection (23) of section 499.003, Florida
 173 Statutes, is amended to read:

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

176 (23) "Health care entity" means a closed pharmacy or any
 177 person, organization, or business entity that provides
 178 diagnostic, medical, surgical, or dental treatment or care, or
 179 chronic or rehabilitative care, but does not include any
 180 wholesale distributor or retail pharmacy licensed under state
 181 law to deal in prescription drugs. However, a blood
 182 establishment is a health care entity that may engage in the
 183 wholesale distribution of prescription drugs under s.
 184 499.01(2)(g)1.c.

185 Section 3. Subsection (21) of section 499.005, Florida
 186 Statutes, is amended to read:

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

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

192 (a) Purchased by a public or private hospital or other
 193 health care entity; or

194 (b) Donated or supplied at a reduced price to a charitable
 195 organization,
 196

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

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

201 499.01 Permits.—

202 (2) The following permits are established:

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

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

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

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

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

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

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

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

235 c. A blood establishment located in this state which
 236 collects blood and blood components only from volunteer donors
 237 as defined in s. 381.06014 or pursuant to an authorized
 238 practitioner's order for medical treatment or therapy and
 239 engages in the wholesale distribution of a prescription drug not
 240 described in s. 499.003(54) (d) to a health care entity. The
 241 health care entity receiving a prescription drug distributed
 242 under this sub-subparagraph must be licensed as a closed
 243 pharmacy or provide health care services at that establishment.
 244 The blood establishment must operate in accordance with s.
 245 381.06014 and may distribute only:

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

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

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

252 (IV) Prescription drugs that are identified in rules

253 adopted by the department and that are essential to services
 254 performed or provided by blood establishments and authorized for
 255 distribution by blood establishments under federal law; or

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

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

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

279 3. A person who applies for a permit as a restricted
 280 prescription drug distributor, or for the renewal of such a

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281 permit, must provide to the department the information required
282 under s. 499.012.

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

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