

By the Committee on Health Regulation

588-02042A-10

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1 A bill to be entitled
2 An act relating to blood establishments; amending s.
3 381.06014, F.S.; prohibiting local governments from
4 restricting access to public facilities or
5 infrastructure for certain activities based on whether
6 a blood establishment is operating as a for-profit
7 organization or not-for-profit organization;
8 prohibiting a blood establishment from considering
9 whether certain customers are operating as a for-
10 profit organization or not-for-profit organization
11 when determining prices for selling blood or blood
12 components; amending s. 499.005, F.S.; clarifying
13 provisions prohibiting the unauthorized wholesale
14 distribution of a prescription drug that was purchased
15 by a hospital or other health care entity, to conform
16 to changes made by the act; amending s. 499.01, F.S.;
17 requiring certain blood establishments to obtain a
18 restricted prescription drug distributor permit under
19 specified conditions; providing an effective date.

20
21 Be It Enacted by the Legislature of the State of Florida:

22
23 Section 1. Subsections (5) and (6) are added to section
24 381.06014, Florida Statutes, to read:

25 381.06014 Blood establishments.—

26 (5) A local government may not restrict the access to or
27 use of any public facility or infrastructure for the collection
28 of blood or blood components from volunteer donors based on
29 whether the blood establishment is operating as a for-profit

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30 organization or not-for-profit organization.

31 (6) In determining the price of blood or blood components
32 that are received from volunteer donors and sold to hospitals or
33 other health care providers, a blood establishment may not base
34 the price of the blood or blood component solely on whether the
35 purchasing entity is a for-profit organization or not-for-profit
36 organization.

37 Section 2. Subsection (21) of section 499.005, Florida
38 Statutes, is amended to read:

39 499.005 Prohibited acts.—It is unlawful for a person to
40 perform or cause the performance of any of the following acts in
41 this state:

42 (21) The wholesale distribution of any prescription drug
43 that was:

44 (a) Purchased by a public or private hospital or other
45 health care entity, except as authorized in s. 499.01(2)(g); or

46 (b) Donated or supplied at a reduced price to a charitable
47 organization.

48 Section 3. Paragraph (g) of subsection (2) of section
49 499.01, Florida Statutes, is amended to read:

50 499.01 Permits.—

51 (2) The following permits are established:

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

53 1. A restricted prescription drug distributor permit is
54 required for:

55 a. Any person that engages in the distribution of a
56 prescription drug, which distribution is not considered
57 “wholesale distribution” under s. 499.003(53)(a).

58 b.1. ~~Any~~ A person who engages in the receipt or

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59 distribution of a prescription drug in this state for the
60 purpose of processing its return or its destruction ~~must obtain~~
61 ~~a permit as a restricted prescription drug distributor~~ if such
62 person is not the person initiating the return, the prescription
63 drug wholesale supplier of the person initiating the return, or
64 the manufacturer of the drug.

65 c. A blood establishment located in this state which
66 collects blood and blood components only from volunteer donors
67 and which engages in the wholesale distribution of a
68 prescription drug to a health care entity. The blood
69 establishment must operate in accordance with s. 381.06014. The
70 blood establishment shall distribute only:

71 (I) Prescription drugs indicated for a bleeding or clotting
72 disorder or anemia;

73 (II) Blood-collection containers approved under s. 505 of
74 the federal act; or

75 (III) Drugs that are blood derivatives, or a recombinant or
76 synthetic form of a blood derivative,

77
78 as long as all of the health care services that the blood
79 establishment provides are related to its activities as a
80 registered blood establishment or the health care services
81 consist of collecting, processing, storing, or administering
82 human hematopoietic stem cells or progenitor cells or performing
83 diagnostic testing of specimens if these specimens are tested
84 together with specimens undergoing routine donor testing.

85 2. Storage, handling, and recordkeeping of these
86 distributions by a person permitted as a restricted prescription
87 drug distributor must comply with the requirements for wholesale

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88 distributors under s. 499.0121, but not those set forth in s.
89 499.01212 if the distribution occurs pursuant to sub-
90 subparagraph 1.a. or sub-subparagraph 1.b.

91 3. A person who applies for a permit as a restricted
92 prescription drug distributor, or for the renewal of such a
93 permit, must provide to the department the information required
94 under s. 499.012.

95 4. The department may adopt rules regarding the
96 distribution of prescription drugs by hospitals, health care
97 entities, charitable organizations, or other persons not
98 involved in wholesale distribution, which rules are necessary
99 for the protection of the public health, safety, and welfare.

100 Section 4. This act shall take effect July 1, 2010.