

1                   A bill to be entitled  
 2           An act relating to blood establishments; providing  
 3           legislative findings and intent; amending s. 381.06014,  
 4           F.S.; revising the definition of the term "blood  
 5           establishment"; requiring a blood establishment to report  
 6           certain financial information to the Agency for Health  
 7           Care Administration; requiring a blood establishment to  
 8           identify suppliers, sources, costs, destinations, and  
 9           pricing structure of its inventory of blood products;  
 10          providing for a fee; authorizing the agency to adopt  
 11          rules; providing an effective date.

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

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 15           Section 1. Legislative findings and intent.—The  
 16 Legislature finds that blood establishments in the state have  
 17 historically not been subject to financial disclosure or to  
 18 public disclosure of their basic operations despite the fact  
 19 that they are responsible for providing blood products on a vast  
 20 scale for use in transfusions and other vital and necessary  
 21 services to the citizens of the state. The Legislature intends  
 22 that blood establishments in the state be subject to financial  
 23 reporting requirements and transparency concerning the supply,  
 24 sources, cost, pricing, and destinations of blood products.

25           Section 2. Section 381.06014, Florida Statutes, is amended  
 26 to read:

27           381.06014 Blood establishments.—

28           (1) As used in this section, the term "blood

29 establishment" means any person, entity, or organization,  
30 operating within the state, which examines an individual for the  
31 purpose of blood donation or which collects, processes, stores,  
32 tests, or distributes blood or blood components collected from  
33 the human body for the purpose of transfusion, for any other  
34 medical purpose, or for the production of any biological  
35 product. The term does not include a hospital licensed under  
36 chapter 395.

37 (2) Any blood establishment operating in the state may not  
38 conduct any activity defined in subsection (1) unless that blood  
39 establishment is operated in a manner consistent with the  
40 provisions of Title 21 parts 211 and 600-640, Code of Federal  
41 Regulations. In addition, any blood establishment operating in  
42 the state shall file an annual report with the Agency for Health  
43 Care Administration disclosing the following information:

44 (a) The blood establishment's audited financial  
45 statements, prepared according to generally accepted accounting  
46 principles, disclosing all assets, liabilities, operating and  
47 nonoperating revenues, operating and nonoperating expenses, net  
48 income, cash flow, and accountants' notes.

49 (b) The quantity of blood products, by type, that are  
50 within the blood establishment's inventory at the beginning and  
51 at the end of the reporting period.

52 (c) The source of blood products collected during the  
53 reporting period. This component of the report shall indicate  
54 the extent to which blood was collected by the blood  
55 establishment from individual donors within the state and the  
56 extent to which blood was obtained by the blood establishment

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57 from blood service providers within or outside of the state. The  
58 identity of any individual donor shall not be disclosed. The  
59 name, business address, and quantity of blood product received  
60 from any other blood establishment within or outside of the  
61 state shall be disclosed.

62 (d) The blood establishment's general administrative and  
63 overhead costs, including salaries, associated with collecting,  
64 processing, testing, storing, and distributing blood products,  
65 itemized separately and with specificity.

66 (e) The destination of all blood products disseminated by  
67 the blood establishment during the reporting period, indicating  
68 the quantity, type of blood product, and name and business  
69 address of the recipient. The sale or delivery of blood products  
70 outside of the state and outside of the United States must be  
71 separately designated in this report.

72 (f) The blood establishment net pricing, which is the list  
73 price minus all applicable discounts, rebates, and any other  
74 contractual or policy deductions, for the blood establishment's  
75 25 largest providers or recipients of the following blood  
76 products: leukocyte-reduced red blood cells, non-leukocyte-  
77 reduced red blood cells, leukocyte-reduced platelet pheresis,  
78 leukocyte-reduced platelets, fresh frozen plasma, and  
79 cryoprecipitate.

80 (3) Any blood establishment determined to be operating in  
81 the state in a manner not consistent with the provisions of  
82 Title 21 parts 211 and 600-640, Code of Federal Regulations, and  
83 in a manner that constitutes a danger to the health or well-  
84 being of donors or recipients as evidenced by the federal Food

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85 and Drug Administration's inspection reports and the revocation  
86 of the blood establishment's license or registration shall be in  
87 violation of this chapter and shall immediately cease all  
88 operations in the state.

89 (4) The operation of a blood establishment in a manner not  
90 consistent with the provisions of Title 21 parts 211 and 600-  
91 640, Code of Federal Regulations, and in a manner that  
92 constitutes a danger to the health or well-being of blood donors  
93 or recipients as evidenced by the federal Food and Drug  
94 Administration's inspection process is declared a nuisance and  
95 inimical to the public health, welfare, and safety. The Agency  
96 for Health Care Administration or any state attorney may bring  
97 an action for an injunction to restrain such operations or  
98 enjoin the future operation of the blood establishment.

99 (5) The Agency for Health Care Administration shall assess  
100 each blood establishment an annual fee of \$10,000 for the cost  
101 of collecting and maintaining the information required by  
102 subsection (2).

103 (6) The Agency for Health Care Administration may adopt  
104 rules to implement the provisions of this section.

105 Section 3. This act shall take effect upon becoming a law.