$\mathbf{B}\mathbf{y}$ the Committee on Health, Aging, and Long-Term Care; and Senator Saunders

317-2248-03

31 Federal Regulations.

1	A bill to be entitled
2	An act relating to blood establishments;
3	defining the term "blood establishment";
4	providing standards for the operation of a
5	blood establishment; declaring a blood
6	establishment that does not meet those
7	standards to be nuisance; authorizing the
8	Agency for Health Care Administration or any
9	state attorney to bring an action for
10	injunction to cease operations or enjoin future
11	operations of any blood establishment that does
12	not meet the standards and that endangers
13	donors or recipients; providing an effective
14	date.
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16	Be It Enacted by the Legislature of the State of Florida:
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18	Section 1. Blood establishments
19	(1) As used in this section, the term "blood
20	establishment" means any person, entity, or organization,
21	operating within the state, which examines an individual for
22	the purpose of blood donation or which collects, processes,
23	stores, tests, or distributes blood or blood components
24	collected from the human body for the purpose of transfusion,
25	for any other medical purpose, or for the production of any
26	biological product.
27	(2) Any blood establishment operating in the state may
28	not conduct any activity defined in subsection (1) unless that
29	blood establishment is operated in a manner consistent with
30	the provisions of parts 211 and 600-640 of Title 21, Code of

1	(3) Any blood establishment determined to be operating
2	in the state in a manner not consistent with the provisions of
3	parts 211 and 600-640 of Title 21, Code of Federal Regulations
4	and in a manner that constitutes a danger to the health or
5	well-being of donors or recipients, as evidenced by the
6	federal Food and Drug Administration's inspection process is
7	in violation of this section and shall immediately cease all
8	operations in the state.
9	(4) The operation of a blood establishment in a manner
10	not consistent with the provisions of parts 211 and 600-640 of
11	Title 21, Code of Federal Regulations and in a manner that
12	constitutes a danger to the health or well-being of blood
13	donors or recipients as evidenced by the federal Food and Drug
14	Administration's inspection process is declared a nuisance and
15	inimical to the public health, welfare, and safety. The Agency
16	for Health Care Administration or any state attorney may bring
17	an action for an injunction to restrain such operations or
18	enjoin the future operation of the blood establishment.
19	Section 2. This act shall take effect July 1, 2003.
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21	STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
22	COMMITTEE SUBSTITUTE FOR Senate Bill 1582
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24	The Committee Substitute adds proper references to the code of Federal Regulation and specifies that Food and Drug Administration inspections will provide evidence of unsafe activity.
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