



HB 1401

2003
CS

CHAMBER ACTION

The Committee on Health Care recommends the following:

Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to blood establishments; creating part V of chapter 483, F.S., consisting of s. 483.911, F.S.; defining the term "blood establishment"; requiring that a blood establishment be operated in compliance with federal regulations for blood establishments in order to operate in the state; declaring a blood establishment that is operating in a manner that is not consistent with such federal regulations a nuisance; authorizing the Agency for Health Care Administration or any state attorney to bring an action for injunction to cease operations or enjoin future operations of any blood establishment that is operating in a manner not consistent with such federal regulations; providing an effective date.

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

Section 1. Part V of chapter 483, Florida Statutes, consisting of section 483.911, Florida Statutes, is created to read:



29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56

PART V

BLOOD ESTABLISHMENTS

483.911 Blood establishments.--

(1) DEFINITION.--For the purposes of this part, a "blood establishment" means any entity, organization, or person operating within the state that examines an individual or individuals for the purpose of blood donation or that collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion or any other medical purpose or for the production of any biological product.

(2) OPERATION.--Any blood establishment operating in the state shall be prohibited from those activities specified in subsection (1) unless that blood establishment is operated in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640.

(3) CESSATION OF OPERATION.--Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of 21 C.F.R. parts 211 and 600-640 and in a manner that constitutes a danger to the health or well being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection process shall be in violation of this part and shall immediately cease all operations in the state.

(4) INJUNCTION.--The operation of a blood establishment in a manner not consistent with the provisions of 21 C.F.R. parts 211 and 600-640 and in a manner that constitutes a danger to the health or well being of both donors or recipients as evidenced



HB 1401

2003
CS

57 by the federal Food and Drug Administration's inspection process
58 is declared a nuisance, inimical to the public health, welfare,
59 and safety. The Agency for Health Care Administration or any
60 state attorney in the name of the people of the state may bring
61 an action for an injunction to restrain such operations or to
62 enjoin the future operation of any blood establishment.

63 Section 2. This act shall take effect October 1, 2003.