An act relating to blood establishments; defining the term "blood establishment"; providing standards for the operation of a blood establishment; declaring a blood establishment that does not meet those standards to be 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 does not meet the standards and that endangers donors or recipients; providing an effective date.

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

## Section 1. Blood establishments.--

(1) As used in this section, the term "blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

(2) Any blood establishment operating in the state may not conduct any activity defined in subsection (1) unless that blood establishment is operated in a manner consistent with the provisions of parts 211 and 600-640 of Title 21, Code of Federal Regulations.

(3) Any blood establishment determined to be operating 1 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 4 Regulations, and in a manner that constitutes a danger to the 5 health or well-being of donors or recipients as evidenced by 6 the federal Food and Drug Administration's inspection reports 7 and the revocation of the blood establishment's license or registration shall be in violation of this part and shall 8 9 immediately cease all operations in the state. (4) The operation of a blood establishment in a manner 10 not consistent with the provisions of parts 211 and 600-640 of 11 12 Title 21, Code of Federal Regulations and in a manner that 13 constitutes a danger to the health or well-being of blood 14 donors or recipients as evidenced by the federal Food and Drug 15 Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency 16 17 for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or 18 19 enjoin the future operation of the blood establishment. 20 Section 2. This act shall take effect July 1, 2003. 21 22 23 24 25 26 27 28 29 30 31 2