SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 1582

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Saunders

SUBJECT: Blood Establishments

DATE: April 9, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable/CS
2.			AHS	
3.			AP	
4.				
5.				
6.				

I. Summary:

The committee substitute defines *blood establishment* and prohibits any entity in Florida from conducting activities of a blood establishment, unless it has a valid and current authorization from the Food and Drug Administration or other federal governmental authority to do so. A blood establishment that does not have such an authorization is required to cease operation. A blood establishment without such designation that does not cease operation would be considered a nuisance and inimical to the public health. The bill gives the Agency for Health Care Administration or any state attorney the power to enjoin such an entity from operating in the state of Florida.

This bill creates one unnumbered section of law.

II. Present Situation:

Regulation of Blood Establishments

Currently, blood establishments that collect blood for the purposes of transfusion, manufacture of a biological product, or for other medical purposes are not regulated under Florida law. The federal Food and Drug Administration (FDA) registers all blood establishments and licenses these facilities only if they ship blood or blood products across state lines.

The FDA and the Center for Biologics Evaluation and Research (CBER) are responsible for regulatory oversight of the U.S. blood supply. CBER regulates the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components, such as clotting factors, and establishes standards for the products themselves. CBER initiated a Blood Action Plan in July 1997, which addresses highly focused areas of concern such as emergency operations, response to emerging diseases, and updating of

regulations. The Department of Health and Human Services (HHS) accepted this plan in March 1998.

Typically blood is collected from voluntary donors through a network of nonprofit community and hospital blood banks. Human blood and blood products can transmit infections such as hepatitis, cytomegalovirus, syphilis, malaria, and human immunodeficiency virus (HIV). Over a period of years, the FDA has progressively strengthened overlapping safeguards that protect patients from unsuitable blood and blood products. Blood donors are asked specific, direct questions about risk factors that could indicate possible infection with a transmissible disease. The FDA reports that this "up-front" screening eliminates approximately 90 percent of unsuitable donors. FDA also requires blood centers to maintain lists of unsuitable donors to prevent the use of collections from them. Blood donations are tested for a number of different infectious agents.

In a recent incident in Florida, a blood establishment lost its FDA authorization due to its failure to adhere to good manufacturing practices in the collection of blood. These violations put the health of blood donors and recipients at risk. The FDA was able to prevent the facility from shipping blood and blood products to other states. However, there was not an effective regulatory mechanism to enable the Agency for Health Care Administration to prevent the facility from collecting and shipping blood and blood products within Florida.

III. Effect of Proposed Changes:

The CS/SB 1582 defines *blood establishment* to be any person, entity or organization operating in Florida that examines an individual for the purpose of blood donation; or that collects, processes, stores, tests or distributes blood or blood components from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product. The bill prohibits any entity in Florida from conducting such activities unless it is operated in a manner consistent with the provisions of parts 211 and 600-640 of Title 21, C.F.R., which provide authority for the Food and Drug Administration's oversight of the nation's blood supply.

A blood establishment that does not operate in accordance with those federal regulations and in a manner that constitutes a danger to the health or well-being of blood donors or recipients, as evidenced by the federal Food and Drug Administration's inspection process, will be declared a nuisance and inimical to the public health. The bill gives the Agency for Health Care Administration or any state attorney the power to enjoin such an entity from operating in the state of Florida.

The bill will take effect July 1, 2003.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

A blood establishment would have to operate in accordance with Federal Drug Administration regulations in order to operate in Florida.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.