

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 509

Blood Establishments

SPONSOR(S): Tobia

TIED BILLS:

IDEN./SIM. BILLS:

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	<u>Health Care Regulation Policy Committee</u>	<u></u>	<u>Holt</u>	<u>Calamas</u>
2)	<u>Health Care Appropriations Committee</u>	<u></u>	<u></u>	<u></u>
3)	<u>Health & Family Services Policy Council</u>	<u></u>	<u></u>	<u></u>
4)	<u></u>	<u></u>	<u></u>	<u></u>
5)	<u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

House Bill 509 amends s. 381.06014, F.S., relating to blood establishments.

- Exempts hospitals licensed under chapter 395 “Hospital Licensing and Regulations” from the definition of blood establishments.
- Creates an annual disclosure requirement to be filed with the Agency for Health Care Administration (AHCA) for all blood establishments, except hospitals. The disclosure includes the following information:
 - Audited Financial Statements.
 - An inventory of blood products, by type, for the beginning and ending of the reporting period.
 - The source of the blood products collected during the reporting period.
 - General administrative and overhead costs, including salaries, associated with blood products.
 - The destination of all blood products disseminated by the blood establishment.
 - The blood establishment’s net pricing (price less all applicable discounts, rebates, and any other contractual or policy deductions) for the blood establishment’s 25 largest providers or recipients of certain blood products.
- Establishes a \$10,000 fee for collecting the financial and disclosure information.
- Provides AHCA rulemaking authority to implement the provisions of s. 381.06014, F.S.

The bill will have an insignificant positive fiscal impact to the Health Care Trust Fund within AHCA (See Fiscal Impact).

The bill takes effect upon becoming law.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Regulatory Background

A blood establishment is defined in s. 381.06014, F.S., to mean any person, entity, or organization, operating within Florida, 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.

The state of Florida does not issue a specific license as a blood establishment. Florida law¹ requires a blood establishment operating in Florida to operate in a manner consistent with the provisions of federal law in Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600 640, relating to the manufacture and regulation of blood and blood components. If the blood establishment does not operate accordingly, and is operating in a manner that constitutes a danger to the health or well-being of blood donors or recipients, the Agency for Health Care Administration (AHCA), or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the establishment.

Federal law classifies blood establishments as follows:² community (non-hospital) blood bank ("community blood center"), hospital blood bank, plasmapheresis center, product testing laboratory, hospital transfusion service, component preparation facility, collection facility, distribution center, broker/warehouse, and other. Community blood centers are primarily engaged in collecting blood and blood components from voluntary donors to make a safe and adequate supply of these products available to hospitals and other health care providers in the community for transfusion. Blood establishments that focus on the collection of plasma that is not intended for transfusion, but is intended to be sold for the manufacture of blood derivatives³ routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by AHCA, unless otherwise exempt.⁴ As a part of the clinical laboratory license, the facility is inspected at least every two years.

¹ s. 381.06014, F.S.

² A description of these classifications may be found at: <<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm>> (Last visited March 29, 2010).

³ Blood derivatives are classified as prescription drugs.

⁴ Rule 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

AHCA may accept surveys or inspections conducted by a private accrediting organization in lieu of conducting its own inspection. The clinical laboratory personnel are required to maintain professional licensure by the Department of Health (DOH). Community blood centers must also have appropriate licenses issued by DOH and must comply with laws related to biomedical waste⁵ and radiation services.

Blood and Blood Components

Blood may be transfused to patients as whole blood or as one of its primary components: red blood cells (RBCs), plasma, platelets, and cryoprecipitated antihemophilic factor (AHF).⁶

RBCs are prepared from whole blood by removing the plasma, and are given to surgery and trauma patients, along with patients with blood disorders like anemia and sickle cell disease. RBCs have a shelf life of 42 days, or they may be treated and frozen for storage of up to 10 years. Leukoreduced RBCs are filtered to contain a lesser amount of white blood cells than would normally be present in whole blood or RBC units. Leukoreduction is recommended to improve the safety of blood transfusions by reducing the possibility of post-transfusion infection or reaction that may result from pathogens concentrated in white blood cells.

Plasma is the liquid portion of the blood that carries clotting factors and nutrients. It may be obtained through apheresis⁷ or separated from whole blood, which is referred to as recovered plasma. It is given to trauma patients, organ transplant recipients, newborns and patients with clotting disorders. Fresh frozen plasma (FFP) is plasma frozen within hours after donation in order to preserve clotting factors and may be stored up to seven years. It is thawed before it is transfused.

Cryoprecipitated AHF is the portion of plasma that is rich in certain clotting factors. It is removed from plasma by freezing and then slowly thawing the plasma. Cryoprecipitated AHF is used to prevent or control bleeding in individuals with hemophilia and von Willebrand's disease.

Platelets control blood clotting in the body, and are used to stop bleeding associated with cancer and surgery. Units of platelets are prepared by using a centrifuge to separate the platelet-rich plasma from the donated unit of whole blood. Platelets also may be obtained from a donor by the process of apheresis, which results in about six times as many platelets as a unit of platelets obtained from the whole blood. Platelets are stored at room temperature for up to five days.

Florida Community Blood Centers

Many blood banks operate, collect and distribute in a local community, and any excess blood is distributed to other communities in Florida, or nationally, as needed. Accordingly, the community blood centers generally collect and provide blood services to health care facilities in the same geographic area. Community blood centers occasionally overlap in their collection in certain counties.

Currently, there are six not-for-profit corporations that operate community blood centers in Florida and one for-profit corporation. The not-for-profit corporations include: Community Blood Centers of South Florida; Florida Blood Services (includes the recent mergers of Bloodnet USA, Northwest Florida Blood Services, and Southeastern Community Blood Center); Florida's Blood Centers; LifeSouth Community Blood Centers; Suncoast Communities Blood Bank; and The Blood Alliance, formerly Florida Georgia Blood Alliance and the Blood Center of the St. Johns. The for-profit corporation is United States Blood Bank (USBB). Several hospital-owned blood centers operate in this state as well, primarily collecting for their own use. At least one community blood center that does not have a fixed location in Florida

⁵ Rule ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.

⁶ Blood component definitions from: AABB "Whole Blood and Blood Components" available at:

http://www.aabb.org/Content/About_Blood/Facts_About_Blood_and_Blood_Banking/fabloodwhole.htm (Last visited on March 29, 2010).

⁷ *Ibid*. Apheresis is a process in which blood is drawn from the donor into an apheresis instrument that separates the blood into its components, retains the desired component, and returns the remainder of the blood to the donor.

collects blood and blood components using a mobile blood-collection vehicle from volunteer donors and distributes blood and blood components to health care providers in Florida.

Community blood centers collect about 93–94 percent, hospitals collect 5–6 percent, and the military collects 1-2 percent of the national blood supply.⁸

Pricing

The cost of blood and blood components is primarily based on the cost of labor and required testing to ensure the safety of the blood collected. A donor must be educated and screened to ensure they are in good health prior to making a donation. Each specimen of blood taken is subject to an initial test, which can cost \$52 - \$66 per unit. If an initial test reveals a positive condition that would make the unit unusable, the unit is subject to confirmatory testing. The price of a confirmatory test varies considerably depending upon the test(s) that must be run, one of which may cost as much as \$170.

In addition to screening, collecting, processing (separation), and testing, blood centers must ensure that they implement procedures for labeling, including expiration dating; tracking and tracing the donation; deferral; public health reporting and donor follow-up as applicable; blood component quarantining in temperature-controlled environments until testing indicates the unit may be released for use; continued storage in temperature-controlled environments for released units; transportation and handling; and environmentally appropriate disposal of supplies and unusable units.

Generally, the median fees charged by community blood centers in Florida are at, or near, the lowest median fees nationally.⁹

Corporate Information

Section 220.22, F.S., requires corporations and artificial entities that conduct business, or earn or receive income in Florida, including out-of-state corporations, to file a Florida corporate income tax return unless exempt, regardless of whether a tax is due.

Section 607.1620, F.S., requires for profit corporations to file annual financial statements with shareholders within a 120 days of the close of each fiscal year. For nonprofit corporations, s. 607.1605, F.S., entitles a director of a corporation to inspect and copy the books, records, and documents of a corporation at a reasonable time to the extent reasonably related to the performance of a director's duties.

The revised IRS Form 990, for 2008 (for filings beginning in 2009) solicits additional information pertaining to governance, management, and certain disclosures provide for more transparency in activities of tax exempt organizations. Of particular importance are questions concerning whether the organization has a written conflict of interest policy that requires the annual disclosure of interests that could give rise to conflicts, whether the organization monitors and enforces compliance with that policy, and more detailed information about determining the compensation of the organization's CEO/Executive Director.¹⁰

Senate Interim Project Report 2010-119

During the 2009-2010 interim, the Senate Committee on Health Regulation reviewed the regulation of blood banks (a.k.a. community blood centers). The recommendations concerning legislative action in the resulting report included:

⁸ The Florida Senate, Committee on Health Regulation, Interim Report 2010-119 (December 2009).

⁹ The regional median fees were provided by ABC in an email to staff in the Florida Senate Health Regulation Committee dated November 17, 2009. The median fees for Florida were obtained from information submitted by the community blood centers in response to a committee survey.

¹⁰ A description of the changes to IRS Form 990 may be found at: <http://www.irs.gov/charities/article/0,,id=218938,00.html>

- Improve the transparency concerning blood collection and distribution activities.
- Provide information pertaining to the blood center's policies for related-party transactions.
- Identify members of the board of directors and the compensation of officers, directors, and key employees.
- Identify costs involved in collecting, processing, and distributing donated blood.
- Prohibit public agencies from restricting the access to public facilities based on the tax status of the community blood center.
- Address the statutory obstacle that prohibits a community blood center, because it is a health care entity, from maintaining licensure as a prescription drug wholesale distributor and engaging in the wholesale distribution of prescription drugs.
- Prohibit a community blood center from using the tax status of a hospital or other health care facility as the sole factor when determining the price for the sale of blood or blood components.

Effects of the Bill

The bill provides legislative findings that blood establishments in the state have historically not been subject to financial disclosure or public disclosure of their basic operations. It provides for legislative intent that blood establishments in the state be subject to financial reporting requirements and transparency concerning the supply, sources, cost, pricing, and destinations of blood products.

The bill amends s. 381.06014, F.S., exempting hospitals licensed under chapter 395 "Hospital Licensing and Regulations" from the definition of blood establishments and creating an annual disclosure requirement for blood establishments.

The bill requires blood establishments to file an annual report with AHCA and disclose the following information:

- Audited Financial Statements
- An inventory of blood products, by type, for the beginning and ending of the reporting period
- The source of the blood products collected during the reporting period, including:
 - Individual donors (identity not disclosed)
 - Blood service providers (name, business address and quantity)
- General administrative and overhead costs, including salaries, associated with blood products and itemized by:
 - Collection costs
 - Processing costs
 - Testing costs
 - Storage costs
 - Distribution costs
- The destination of all blood products disseminated by the blood establishment, including:
 - Name of the recipient
 - Delivery in-state or out-of state
 - Blood product type and quantity
- The blood establishment's net pricing (price less all applicable discounts, rebates, and any other contractual or policy deductions) for the blood establishment's 25 largest providers or recipients of the following blood products:
 - Leukocyte-reduced red blood cells
 - Non-leukocyte-reduced red blood cells
 - Leukocyte-reduced platelet pheresis
 - Leukocyte-reduced platelets
 - Fresh frozen plasma, and cryoprecipitate

The bill also requires AHCA to assess a \$10,000 fee to cover the costs of collecting the required disclosure information.

Finally, the bill grants AHCA rulemaking authority to implement the provisions of s. 381.06014, F.S.

B. SECTION DIRECTORY:

Section 1. Creates an unnumbered section relating to legislative findings and intent.

Section 2. Amends s. 381.06014, F.S., relating to blood establishments.

Section 3. Provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill establishes a fee that has an insignificant positive fiscal impact to the Health Care Trust Fund within AHCA (see Fiscal Comments below).

2. Expenditures:

None. AHCA staff indicated its current Fiscal Analysis Unit performs a comparable function and could incorporate seven additional reporting units into its current workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Entities that meet the definition of blood establishments pursuant to s. 381.06014, F.S., will be assessed a \$10,000 fee to cover cost of collecting and maintaining the information obtained from the annual disclosure requirements established by the bill.

D. FISCAL COMMENTS:

The complete fiscal impact is unknown. However, seven community blood centers are identified in "The Florida Senate Interim Report 2010-119 *Review of the Regulation of Blood Banks*" which could generate \$70,000 in fees.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable, the bill does not appear to affect municipal or county governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the AHCA rulemaking authority to implement the provisions of s.381.06014, F.S., (establishing the annual disclosure requirements for blood establishments and the related fee).

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not distinguish between blood establishments utilizing volunteer donors versus paid donors, a factor used to separate community blood centers from the other blood establishments which would include plasmapheresis centers and others.

The bill as currently drafted does not clearly indicate how “general administrative and overhead costs” are to be “itemized separately and with specificity”.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES