The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Community Affairs Committee

BILL:	CS/SB 1818
INTRODUCER:	Health Regulation Committee; and Health Regulation Committee
SUBJECT:	Blood Establishments
DATE:	April 5, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.	Howes	Yeatman	CA	**Favorable**
3.			HA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	[x]	Statement of Substantial Changes
B. AMENDMENTS.....	[ ]	Technical amendments were recommended
	[ ]	Amendments were recommended
	[ ]	Significant amendments were recommended

I. Summary:

The committee substitute (CS) for Senate Bill 1818:

- Defines a volunteer donor for purposes of blood donations;
- Prohibits local governments from restricting access to public facilities or infrastructure for volunteer blood drives based on the tax status of a blood establishment conducting the blood drive;
- Prohibits a blood establishment from considering the tax status of certain customers when determining the price at which to sell blood or a blood component that was obtained from volunteer donors;
- Requires a blood establishment that collects blood or blood components from volunteer donors, except hospitals, to disclose information on its Internet website concerning: a description of the activities of the blood establishment related to collecting and distributing volunteer blood donations; the number of units by component that are produced, obtained from other sources, and distributed; policies related to corporate conduct and executive compensation; and financial-related data. Failing to disclose this information as required in the bill subjects the blood establishment's clinical laboratory license to disciplinary action in the form of an administrative fine;

- Exempts a blood establishment that manufactures blood and blood components from the requirement to be permitted as a prescription drug manufacturer and register products;
- Authorizes certain blood establishments to obtain a restricted prescription drug distributor permit to engage in the wholesale distribution of certain prescription drugs to health care entities; and
- Authorizes the Department of Health (DOH) to adopt rules related to certain activities with prescription drugs by blood establishments.

This bill substantially amends the following sections of the Florida Statutes: 381.06014, 483.201, 499.003, 499.005, and 499.01.

II. Present Situation:

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 law[1] 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 (Agency) 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 derivatives[3] routinely pay donors.

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

[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 on March 5, 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.

every two years. The Agency 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 DOH. Community blood centers must also have appropriate licenses issued by the DOH and must comply with laws related to biomedical waste[5] and radiation services.[6]

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).[7]

- 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 apheresis[8] 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 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.

Community Blood Centers

Currently, there are six not-for-profit corporations and one for-profit corporation that operate community blood centers in Florida. 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

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

[6] Rule ch. 64E-5, F.A.C., Control of Radiation Hazards. If a blood center irradiates blood products using radioactive materials, the location in which this occurs must be licensed. If a blood center irradiates blood products using a machine, then the community blood center must register the machine.

[7] 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 5, 2010).

[8] *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.

have a fixed location in Florida, 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.

Recently, the for-profit community blood center received notification of a policy that impairs its ability to engage in blood collection activities and compete with the not-for-profit community blood centers. According to correspondence dated October 13, 2009, between officials within the Miami Parking Authority, that policy statement provides, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive ..."[9]

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. 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.[10] As a part of The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, professional staff surveyed a small sample of for-profit and not-for-profit hospitals. Based on responses to the committee's survey question requesting the average cost of a unit of specified blood components paid by the hospital over the last 12 months, it appeared that for-profit hospitals and not-for-profit hospitals were not paying an equivalent price for blood and blood components.[11]

Licensure to handle prescription drugs

Human blood and blood products are characterized as both "biologics,"[12] for purposes of regulation under the federal Public Health Service Act, as amended, and also as "drugs," subject to regulation under applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[13] Some of the community blood centers are licensed by the DOH as a prescription drug

[9] A copy of the correspondence is on file with the Florida Senate Health Regulation Committee. A representative from the Miami Parking Authority indicated in a telephone conversation with professional committee staff that they had received complaints concerning staff from blood centers standing in the middle of the street harassing people to donate and blood drives that were not conducted in cooperation with a business in the vicinity.

[10] See The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, found at: http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-119hr.pdf (Last visited on March 5, 2010).

[11] Ibid.

[12] The term "biologics" or "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings.
See http://www.law.cornell.edu/uscode/42/usc_sec_42_00000262----000-.html (Last visited on March 5, 2010).

[13] The FDA "CPG 230.120 – Human Blood and Blood Products as Drugs" "Inspections, Compliance, Enforcement, and Criminal Investigations" available at:

wholesaler since they purchase and distribute prescription drugs, such as blood, blood components, blood derivatives, and other prescription drugs used in the collection, processing, and therapeutic activities conducted by the community blood centers.[14]

The Florida Drug and Cosmetic Act (the Act),[15] as well as federal law,[16] prohibits the sale, purchase or trade (wholesale distribution) of a prescription drug that was purchased by… a health care entity. A community blood center is a health care entity,[17] however, some of the community blood centers in this state are licensed as prescription drug wholesalers in order to purchase and distribute certain prescription drugs that are needed by community blood centers and hospitals to deliver health care services that are traditionally performed by, or in cooperation with, community blood centers. For example, some community blood centers offer hospitals the full range of blood-related products, such as albumin (to replace fluid), Rh Immune Globulin (to prevent incompatible maternal-fetal blood admixture), and erythropoietin (to stimulate the production of RBCs), as well as trained personnel and expertise in handling those products. The Act and licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.[18]

In November 2008, the FDA's rule to address this dilemma in federal law became effective.[19] That rule provides for exceptions to authorize a registered blood establishment that qualifies as a health care entity to sell, purchase, or trade certain prescription drugs that would otherwise be prohibited. The DOH suggested that the authorizations in the federal rule should be included in the Act, but could be more narrowly crafted to limit the sale, purchase, or trade of these prescription drugs *to a health care entity* to avoid unintended consequences or the opportunity for community blood centers to compete in the marketplace as a prescription drug wholesaler.

The DOH recently noted that blood establishments have not been permitted under the Act as a prescription drug manufacturer and have not registered the prescription drugs that they manufacture (the blood and blood components) with the DOH, notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of the prescription drugs that blood establishments manufacture have been exempted from the definition of wholesale distribution under s. 499.003(53)(d), F.S., for years. This situation applies to the community blood centers as well as other types of blood establishments, such as the establishments that collect plasma from paid donors.

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http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograManual/ucm073863.htm (Last visited on March 5, 2010). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

[14] Ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

[15] s. 499.005(21), F.S.

[16] 21 U.S.C. 353(c)(3)(A)(ii)(l) (Section 503(c)(3)(A)(ii)(l) of the FD&C Act).

[17] A health care entity is defined as a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. See s. 499.003(23), F.S. The federal definition, found at 21 C.F.R. § 203.3(q), is similar.

[18] The DOH indicated in an email to Florida Senate Health Regulation Committee staff, dated November 12, 2009, that at the present time, they are not aware of any serious abuses or action by the licensed community blood centers that may pose a public health threat.

[19] The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published on October 9, 2008, is available at: http://edocket.access.gpo.gov/2008/pdf/E8-24050.pdf (Last visited on March 5, 2010).

Senate Interim Project Report 2010-119
During the 2009-2010 interim, professional staff of 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 are to: prohibit public agencies from restricting the access to or use of public facilities or infrastructure for the collection of blood and blood components based on the tax status of the community blood center; 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 at which it offers to sell or sells blood or blood components to the hospital or other health care facility; and address the statutory obstacle in Florida law concerning a community blood center distributing prescription drugs in a manner that is consistent with federally authorized distributions, with certain additional safeguards. This committee substitute implements the committee's instruction to draft a proposed committee bill in accordance with the professional staff's recommendations as well as additional provisions to increase transparency in the activities of community blood centers and address other glitches in Florida law related to the permitting of blood establishments.

III. Effect of Proposed Changes:

Section 1 amends s. 381.06014, F.S., to define a volunteer donor as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under federal regulations.

The committee substitute prohibits a local government from restricting access to or use of a public facility or public infrastructure for collecting blood or blood components from voluntary donors based on whether the blood establishment is a for-profit or not-for-profit corporation. Additionally, the committee substitute prohibits a blood establishment from using as the sole factor whether a hospital or other health care entity is a for-profit or not-for-profit corporation when the blood establishment sets the service fee (price) at which it will sell blood and blood components collected from voluntary donors to the hospital or other health care entity.

The committee substitute requires a blood establishment that collects blood or blood components from volunteer donors to disclose information on its Internet website concerning its activities. A hospital that collects blood or blood components from volunteer donors for its own use is not required to disclose this information. The disclosures may be cumulative for all blood establishments (branches) within the business entity. The information required to be disclosed includes:

- A description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations. This information is to be presented in a manner that is appropriate for the donating public;
- The number of units by component (whole blood, red blood cells, leukoreduced red blood cells, fresh frozen plasma or equivalent, recovered plasma, platelets, and cryoprecipitated AHF) that the blood establishment:
  - Produced (such as units that passed quality control and are available for use),
  - Obtained from other sources,

  - Distributed to health care providers that are located outside the state. However, if the blood center collects donations in a county outside Florida and distributes to health care providers in that county, then the distributions made to that county must be excluded. This distribution information must be aggregated by health care providers that are located within the United States and its territories or outside the United States and its territories, and
  - Distributed to entities that are health care providers. This information must be aggregated by purchasers that are located within the United States and its territories or outside the United States and its territories.

  This information must be on the establishment's website by March 1 of each year reflecting data from the preceding calendar year;
- The blood establishment's policies pertaining to conflicts of interest, related-party transactions, and determining executive compensation. If any changes are made to any of these policies, the revised document must be on the blood establishment's website by the following March 1; and
- Either the most recent three years of a not-for-profit blood establishment's Form 990 that have been reported to the Internal Revenue Services, which must be posted within 30 calendar days after filing, or an audited or reviewed balance sheet, income statement, and statement of changes in cash flow, along with the expression of opinion on these statements from a certified public accountant, which must be posted within 120 days following the end of the fiscal year for a for-profit blood establishment and which must remain on the website for 36 months.

The clinical laboratory license of a blood establishment that fails to disclose this information is subject to an administrative fine as provided in section 2 of the bill.

Section 2 amends s. 483.201, F.S., to add the failure of a blood establishment that collects blood or blood components from volunteer donors to disclose the information required by s. 381.06014 regarding the blood establishment's activities to the grounds for which disciplinary action may be taken against a blood establishment's clinical laboratory license. If multiple blood establishments are operated by the blood establishment, the fines may be assessed against only one of the clinical laboratory licenses of the business entity. A $1,000 fine may be assessed for each day for which the disclosure is not made, up to a maximum amount of $10,000 for each annual reporting period.

Section 3 amends s. 499.003, F.S., to revise the definition of a health care entity to authorize a blood establishment that collects blood or blood components from volunteer donors to be a health care entity and engage in the wholesale distribution of prescription drugs in accordance with the requirements contained in section 5 of the proposed committee bill related to the restricted prescription drug distributor permit for a blood establishment.

Section 4 amends s. 499.005, F.S., to remove the prohibition against the wholesale distribution by a blood establishment that collects blood or blood components from volunteer donors if the blood establishment is operating in compliance with the requirements contained in section 5 of the proposed committee bill related to the restricted prescription drug distributor permit for a blood establishment.

Section 5 amends s. 499.01, F.S., to exempt a blood establishment that only manufactures blood and blood components from the requirements to be permitted as a prescription drug manufacturer and register the products it manufacturers.

The committee substitute also requires certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell and distribute prescription drugs to another health care entity. The committee substitute provides for certain restrictions on this authorization, including:

- The permit may be issued only to a blood establishment that is located in Florida;
- The permit may be issued to a blood establishment that collects blood and blood components from volunteer donors only or pursuant to an authorized practitioner's order for medical treatment or therapy;
- The distributions may be made only to a health care entity that is licensed as a closed pharmacy or provides health care services at the location where the health care entity receives the prescription drugs;
- The prescription drugs that may be distributed pursuant to the restricted prescription drug distributor permit are limited to:
  - A prescription drug that is indicated for a bleeding disorder, clotting disorder, or anemia;
  - A blood collection container that is approved under s. 505 of the federal FD&C Act related to new drugs;
  - A drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative; or
  - A prescription drug that is essential to services performed or provided by blood establishments and is authorized for distribution by blood establishments under federal law if it is identified in rules adopted by the DOH; and
- The blood establishment may only provide health care services that:
  - Are related to its activities as an FDA-registered blood establishment;
  - Consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells; or
  - Consist of performing diagnostic testing of specimens if these specimens are tested together with specimens undergoing routine donor testing.

In addition, the committee substitute provides that a blood establishment that is permitted as a restricted prescription drug distributor must comply with all the storage, handling, and recordkeeping requirements with which a prescription drug wholesale distributor must comply. This includes providing pedigree papers[20] upon the wholesale distribution of these prescription drugs.

The DOH is authorized to adopt rules related to the distribution, transportation, storage, and recordkeeping of prescription drugs by blood establishments. These rules may include requirements for the use of prescription drugs in mobile blood-collection vehicles.

Section 6 provides an effective date of July 1, 2010.

[20] A pedigree paper contains information required by s. 499.01212, F.S., regarding the sale and distribution of a prescription drug.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None

B. Public Records/Open Meetings Issues:

None

C. Trust Funds Restrictions:

None

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Instead of paying $900 annually for a prescription drug wholesale distributor permit and employing a certified designated representative, a community blood center that intends to engage in the wholesale distribution of certain prescription drugs in order to provide healthcare services typically provided by blood establishments will pay a $500 fee biennially for a restricted prescription drug distributor permit.

B. Private Sector Impact:

Community blood centers that collect donations of blood and blood components from volunteer donors will need to ensure that pricing considerations for the sale of blood and blood components are not based solely on the whether the customer is a for-profit corporation or not-for-profit corporation.

A community blood center that collects donations of blood and blood components from volunteer donors, except hospitals, will be required to post certain information concerning its activities on its Internet website.

A community blood center that chooses to engage in the wholesale distribution of certain prescription drugs may lawfully do so if it is permitted as a restricted prescription drug distributor and complies with the requirements of that permit.

C. Government Sector Impact:

Governmental agencies may not limit the use of public infrastructure for the purpose of collecting voluntary donations of blood or blood components solely upon whether the corporation collecting the blood is for-profit or not-for-profit.

The DOH will need to adopt rules related to the permitting of a blood establishment as a restricted prescription drug distributor and other activities of blood establishments that are regulated under the Act.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on March 9, 2010:
The committee substitute:

- Requires a blood establishment that collects blood or blood components from volunteer donors, except a hospital, to disclose information on its website related to its activities and policies concerning corporate conduct;
- Exempts a blood establishment that manufactures only blood and blood components from the requirement to be permitted as a prescription drug manufacturer and register products; and
- Authorizes the DOH to adopt rules to identify additional prescription drugs that might be distributed by a blood establishment with a restricted prescription drug distributor permit and to facilitate the use of prescription drugs in blood mobiles.

B. Amendments:

None.