HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 509 Blood Establishments
SPONSOR(S): Health Care Regulation Policy Committee; Tobia
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	12 Y, 0 N, As CS	Holt	Calamas
2)	Health & Family Services Policy Council		Holt	Gormley
3)				
4)				
5)				

SUMMARY ANALYSIS

Committee Substitute for House Bill 509 creates and revises multiple sections of the Florida Statutes relating to blood establishments. The bill:

- 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 determining the price to sell blood or blood components, received from volunteer donors, solely on the tax status of hospitals or other health care providers.
- Excludes from the definition of “wholesale distribution” certain drugs utilized in blood related services provided by a blood establishment, and allows a blood establishment to engage in the distribution of certain prescription drugs without having to obtain a distributors license.
- Requires blood establishments, utilizing the newly created exemption under wholesale distribution, to comply with all other requirements of Part I of Chapter 499.
- Exempts a blood establishment that manufactures certain prescription drugs from the requirement to be permitted as a prescription drug manufacturer.

The bill has no 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:

Current Situation

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 (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 derivatives[3] 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 waste[5] 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 apheresis[7] 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. This generally occurs when a county is contiguous to the general region in which two or more blood centers are located.

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

[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.

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 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 USBB, the for-profit community blood center in south Florida, 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 ..."[8]

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.[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. 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.[10]

The chart below reflects the range of costs reported by Florida hospitals responding to the Senate Committee on Health Regulation's interim survey.[11] The questionnaire asked for the average cost of a unit of the specified component paid by the hospital over the last 12 months. The cost to hospitals for a unit of RBCs and Leukoreduced RBCs might vary depending upon the blood type. Costs overall tended to be higher in south Florida.

	For-Profit Hospitals		Not-For-Profit Hospitals	
	Low	High	Low	High
RBCs	$ 147.50	$ 241.00	$ 148.00	$ 220.00
Plasma	$ 47.50	$ 77.00	$ 49.00	$ 59.00
Platelets	$ 520.00	$ 653.00	$ 506.00	$ 618.00
Leukoreduced RBCs	$ 178.50	$ 261.00	$ 175.00	$ 263.00

[8] 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.

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

[10] 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.

[11] 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 April 1, 2010).

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 Department of Health (DOH) as a prescription drug 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 erthropoietin (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 allows limited distribution of prescription drugs by blood establishments that would otherwise be prohibited. The types of drugs that may be distributed under the rule are limited to the following: 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. In order for this exception to apply, all health care services being provided must be related to a registered blood establishment's activities.

Prescription Drug Manufacturer Permit

Florida law requires a prescription drug manufacturer permit for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[20] 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 are exempt from the definition of wholesale distribution under s.

---

[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 April 1, 2010).

[13] The FDA "CPG 230.120 – Human Blood and Blood Products as Drugs" "Inspections, Compliance, Enforcement, and Criminal Investigations" available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograManual/ucm073863.htm (last visited on April 1, 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, Cosmetics, and Household Products.

[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 April 1, 2010).

[20] s. 499.01(a), F.S.

499.003(53) (d), F.S. 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.

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:

- Prohibiting public agencies from restricting the access to public facilities based on the tax status of the community blood center.
- Addressing 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.
- Prohibiting 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.

Effect of Proposed Changes

The bill 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. The bill prohibits blood establishments from determining the price to sell blood or blood components, received from volunteer donors, solely on the tax status of hospitals or other health care providers.

The bill allows blood establishments to engage in the distribution of certain prescription drugs without having to obtain a distributors license. Specifically, the bill mirrors FDA's rule by creating a limited exemption to the definition of "Wholesale distribution" for the sale, purchase, or trade by a registered blood establishment that qualifies as a health care entity of any:

- Drug indicated for bleeding, clotting disorder, anemia, or blood collection container approved under section 505 of the Prescription Drug Marketing Act.
- Drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative, as long as the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services provided by the blood establishment consist of collecting, processing, storing, or administering human hematopoietic stem or progenitor cells or performing diagnostic testing of specimens that are tested together with specimens undergoing routine donor testing.

The bill expands the state's exemption from whole distribution beyond FDA's rule by including drugs necessary for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of either a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician. This expansion creates a conflict between state and federal law. A blood establishment who performs the above therapeutic activities would be disqualified from the federal exclusion provided under 21 CFR § 203.22 (h), and would be considered a health care entity under federal law. Both state and federal law prohibits the sale, purchase or trade of a prescription drug that was purchased by… a health care entity.[21]

The bill requires a blood establishment that utilizes the exemption created above, to satisfy all other requirements of Part I Chapter 499, F.S., applicable to a wholesale distributor or retail pharmacy, which includes: prohibited acts; criminal acts; permits; storage and handling of prescription drugs; pedigree paper; registration of drugs, etc…

[21] *Id.*

Finally, the bill amends s. 499.01, F.S., relating to prescription drug manufacturer permit. It provides an exemption to the permitting requirement for a drug manufacturer for a blood establishment that is operating in a manner consistent with Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640 and manufactures prescription drugs described in the newly created exemption under "wholesale distribution". The bill authorizes a blood establishment to manufacture a wide range of prescription drugs beyond blood and blood components. For example a blood establishment could manufacture prescription drugs such as epinephrine, erythropoietin, and other recombinant DNA drugs without a Prescription Drug Manufacturer permit.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.06014, F.S., relating to blood establishments.
Section 2. Amends s. 499.003, F.S., relating to definitions.
Section 3. Amends s. 499.01, F.S., relating to permits.
Section 4. Provides that the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None

D. FISCAL COMMENTS:

None

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:

None

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill excludes “blood establishment” from the definition of “wholesale distribution” under Part I Chapter 499, F.S., and requires a “blood establishment” to meet all the other requirements of Part I Chapter 499, F.S., pertaining to wholesale distributor or retail pharmacy. As drafted, it is unclear which provisions of Part I Chapter 499, F.S., specifically permits, recordkeeping, and pedigree papers, are to be complied with by the blood establishment. It is also unclear as to whether these provisions are to be applied to the “blood establishment” as a “wholesale distributor” or a “retail pharmacy”.

Under ss. 499.005 (14), (15), F.S., it is unlawful for a person to perform or cause the performance of any of the following acts in this state:

- The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.
- The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

As currently drafted, the bill does not require a blood establishment to obtain a permit to distribute certain prescription drugs. Without such a permit, a blood establishment is not expressly authorized to perform the prohibited activities outlined above.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 31, 2010, the Health Care Regulation Policy Committee considered the bill, adopted a strike-all amendment, and reported the bill favorably. The amendment accomplishes the following:

- 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 determining the price to sell blood or blood components, received from volunteer donors, solely on the tax status of hospitals or other health care providers.
- Excludes from the definition of “wholesale distribution” certain drugs utilized in blood related services provided by blood establishment.
- Exempts a blood establishment that manufactures blood and blood components from the requirement to be permitted as a prescription drug manufacturer.