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 Health Regulation Committee

BILL:	SPB 7050
INTRODUCER:	For consideration by the Health Regulation Committee
SUBJECT:	Blood Establishments
DATE:	January 26, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson		**Pre-meeting**
2.				
3.				
4.				
5.				
6.				

I. Summary:

The proposed committee 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 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; and 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.

This bill substantially amends the following sections of the Florida Statutes: 381.06014, 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

[1] s. 381.06014, F.S.

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 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 Department of Health (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.

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[2] A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on January 26, 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.

[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 January 26, 2010).

- 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'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.

Community Blood Centers

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

Recently, the USBB 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

[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.

[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.

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 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

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[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 January 26, 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 January 26, 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/ComplianceProgramManual/ucm073863.htm> (Last visited on January 26, 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.

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.

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 proposed committee bill implements the committee's instruction to draft a proposed committee bill in accordance with the professional staff's recommendations.

III. Effect of Proposed Changes:

Section 1. Amends s. 381.06014, F.S., to prohibit 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 proposed committee bill 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 price at which it will sell blood and blood components collected from voluntary donors to the hospital or other health care entity.

Section 2. Amends s. 499.005, F.S., to authorize the wholesale distribution of certain prescription drugs, as described in section 3 of the proposed committee bill, by certain blood establishments that meet the definition of a health care entity.

Section 3. Amends s. 499.01, F.S., to authorize certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell prescription drugs to another

[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 January 26, 2010).

health care entity. The proposed committee bill 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;
- The distributions may be made to a health care entity, only;
- 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; or
  - A drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative; and
- The blood establishment may only provide healthcare 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 proposed committee bill 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.

Section 4. Provides an effective date of July 1, 2010.

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 the bill have no adverse impact on public records or open meetings issues under the requirements of Article I, Section 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.

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

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.

Community blood centers that choose 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.

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.)

None.

B. Amendments:

None.