



The Florida Senate

Interim Report 2010-119

December 2009

Committee on Health Regulation

REVIEW OF THE REGULATION OF BLOOD BANKS

Issue Description

The supply of blood and blood products is critical to the health care system. Volunteer donors provide blood and blood components that are used for transfusion to patients. Recent newspaper articles exposed certain business arrangements and activities of persons associated with community blood banks, which are involved in the collection and processing of blood and blood components from volunteer donors, that prompted interest in the regulation and activities of community blood banks in Florida. Senate professional staff reviewed the regulation of community blood banks, market competition, and pricing of blood and blood components from the perspective of safeguarding the public health and minimizing the opportunities for fraudulent or harmful activities in this industry.

Background

A blood bank is a facility that engages in the manufacture of blood and blood components, including: collecting blood, processing blood components, product and compatibility testing, and storing and distributing blood products.¹ Florida law requires blood banks located in Florida to comply 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.²

Federal law classifies blood establishments as follows:³ community (non-hospital) blood bank, hospital blood bank, plasmapheresis center, product testing laboratory, hospital transfusion service, component preparation facility, collection facility, distribution center, broker/warehouse, and other. The focus of this report concerns community blood banks, hereinafter referred to as community blood centers, that are not owned and operated by hospitals. 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.

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.

¹ U.S. Food and Drug Administration (FDA). See Attachment J "Types of Blood Establishments" in "7342.001 - Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors" available at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/CompliancePrograms/ucm095226.htm> (Last visited on November 25, 2009).

² Section 381.06014, Florida Statutes (F.S.), defines blood establishment 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.

³ A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on November 25, 2009).

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.⁴

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).⁵

- 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 apheresis⁶ 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.

Regulation and Inspections

Federal

Human blood and blood products are characterized as both “biologics,”⁷ for purposes of regulation under the federal Public Health Service Act (PHS Act), as amended, and also as “drugs,” subject to regulation under applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).⁸ The Food and Drug Administration (FDA) through the Center for Biologics Evaluation and Research (CBER) regulates the collection of blood and blood components used for transfusion or the manufacture of pharmaceuticals derived from the blood and blood components.

⁴ Comments provided by the Executive Director of America's Blood Centers (ABC), a national association of not-for-profit community blood centers, to committee professional staff on November 16, 2009.

⁵ 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](http://www.aabb.org/Content/About%20Blood/Facts%20About%20Blood%20and%20Blood%20Banking/fabloodwhole.htm) (Last visited on November 25, 2009).

⁶ *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.

⁷ 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 November 25, 2009).

⁸ 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 November 25, 2009). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

Owners or operators of establishments that manufacture blood products, including community blood centers, are required to *register* with the CBER⁹ and list every blood product manufactured, prepared, or processed for commercial distribution. A registered blood bank must also have a biologics *license* for each product it distributes in interstate commerce.¹⁰ This license is issued upon a determination that the biological product is safe, pure, potent, and effective for its intended use, and the establishment where the product is manufactured meets standards designed to ensure the product is safe, pure, potent, and effective for its intended use. The license number must appear on the product label.

The CBER develops and enforces quality standards, inspects blood establishments, and monitors reports of errors, accidents and adverse clinical events.¹¹ The inspection of blood establishments is a systems-based approach focusing on the establishment's systems related to: quality assurance, donor eligibility (screening and deferral), product testing, quarantine/inventory management, and production and processing.¹² The inspection is intended to ensure that the establishment manufactures the product(s) according to Current Good Manufacturing Practice (CGMP) standards for blood and blood component regulations and any additional conditions of licensure incorporated in the establishment's approved Biologic License Application, if applicable. Inspections are generally conducted on a biennial schedule, but may be more frequent if conditions so warrant. If inspection findings indicate the potential for fraud, the appropriate FDA Office of Criminal Investigations office is alerted.

Community blood centers must also have a Clinical Laboratory Improvement Act (CLIA) license. Testing laboratories must register with the FDA and obtain certification by the Centers for Medicare and Medicaid Services (CMS) for infectious disease testing. The AABB (formerly the American Association of Blood Banks) is a recognized accrediting organization for CLIA licenses and blood banks.

State

The state of Florida does not issue a specific license as a blood bank. Section 381.06014, F.S., requires a community blood center operating in Florida to operate in a manner consistent with the provisions of 21 C.F.R. § 211 and §§ 600-640. If the community blood center 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.

Community blood centers in Florida are licensed as clinical laboratories by the Agency, unless otherwise exempt.¹³ 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 waste¹⁴ and radiation services.¹⁵ Some of the community blood centers are licensed by the DOH as a prescription drug wholesaler since they purchase and distribute prescription drugs, such

⁹ 21 C.F.R. § 607.20, unless exempt under 21 C.F.R. § 607.65.

¹⁰ The FDA licenses biological products under the authority of section 351(a) of the PHS Act and the license is regulated under 21 C.F.R. §§ 600 – 680. Exceptions to this requirement are described in 21 C.F.R. § 601.21 (Products Under Development) and § 601.22 (Products in Short Supply).

¹¹ U.S. Food and Drug Administration. "Vaccines, Blood & Biologics" "Blood & Blood Products" available at: <<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm>> (Last visited November 25, 2009).

¹² For descriptions of these systems see: U.S. Food and Drug Administration. "Vaccines, Blood & Biologics" "7342.001 - Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors" <<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/CompliancePrograms/ucm095226.htm>> (Last visited on November 25, 2009).

¹³ Rule 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

¹⁴ Rule ch. 64E-16, F.A.C., Biomedical Waste, and

¹⁵ 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.

as blood, blood components, derivatives, and other prescription drugs used in the collection, processing, and therapeutic activities conducted by the community blood centers.¹⁶

Findings and/or Conclusions

Competition

The American Red Cross is probably the most recognized name nationally in blood collection. It collects and provides nearly half of the national blood supply.¹⁷ Policy, procedures, pricing, distribution, and other operational activities are dictated nationally. At one time, the American Red Cross had a presence in south Florida, but during the later part of the 1990s it sold its operations to local, community operated blood centers. The American Red Cross has been under an Amended Consent Decree of Permanent Injunction since April 15, 2003, for deficiencies in its blood collection activities. Problems related to its activities have been an ongoing situation and as recently as November 2009, the FDA announced it had found widespread and persistent problems with the storage and distribution of blood supplies by the American Red Cross at at least 12 facilities across the United States.¹⁸ Although the American Red Cross does not collect donations in Florida, it does provide blood and blood components to some health care facilities in this state.

In Florida, the community-based model exists. In this model, the blood that is collected in the local community is distributed in that community first, with any excess 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. The chart in Appendix 1 displays the counties in Florida in which the community blood centers collect donations and distribute processed blood and blood components.¹⁹

Community blood centers occasionally overlap in their collection in certain counties. Based on survey results from the community blood centers, 11 counties in the state have competing community blood centers vying for blood donors in those counties. This generally occurs when a county is contiguous to the general region in which two or more blood centers are located. In addition, Orange County has two community blood centers collecting blood donations in that county. Miami-Dade County and Broward County have three community blood centers, one of which is a for-profit corporation, routinely collecting blood donations within those counties.

During the development of this report, 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 ..."²⁰

All the community blood centers responded to the committee's survey and indicated that they have competition in providing blood and blood components to health care facilities in the counties in which they collect blood donations. However, the community blood centers indicated that the practice of responding to competitive solicitations from hospitals and other health care facilities is not that prevalent in the counties in which they collect donations. HCA Healthcare, a for-profit corporation that owns numerous hospitals and health care facilities in Florida, recently attempted to engage in a competitive solicitation for blood services for its facilities in

¹⁶ Ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

¹⁷ <http://www.redcross.org/portal/site/en/menuitem.86f46a12f382290517a8f210b80f78a0/?vgnextoid=271a2aebdaadb110_VgnVCM10000089f0870aRCRD&vgnnextfmt=default> (Last visited on November 25, 2009).

¹⁸ The Wall Street Journal, Update: FDA Faults Red Cross For Blood-Supply Violations, November 2009, found at: <<http://www.nasdaq.com/asp/stock-market-news-story.aspx?storyid=200911121910dowjonesdjonline000818&title=update-fda-faults-red-cross-for-blood-supply-violations>> (Last visited on November 25, 2009).

¹⁹ Florida Blood Services, LifeSouth Community Blood Centers, and The Blood Alliance also regularly collect donations and distribute blood and blood components to hospitals and other health care providers in nearby states.

²⁰ 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.

Florida. For the most part, this process was ineffective because the community blood centers refused to bid for business at hospitals not located within their territories.²¹

Seven of eleven for-profit hospitals and four of eleven not-for-profit hospitals responding to the committee's survey indicated that they engaged in some form of competitive selection of blood services. However, price is not always the determining factor. Community blood centers may provide services in addition to meeting the health care facility's blood needs, such as performing transfusions, therapeutic apheresis, cross-matching,²² and consultation in atypical medical conditions. Therefore, for the health care facilities that rely on these services from a community blood center, especially on a 24-hour a day basis, it is necessary for the community blood center and the health care facility to be in close proximity.

Five of the six not-for-profit community blood centers have an exclusivity provision in their contract for the community blood center to be the sole provider of blood and blood component services to the hospital, except in an emergency. One of these community blood centers has two contracts, one in which the community blood center is the exclusive provider, and another contract in which the community blood center serves as a supplementary provider.

The community blood center industry in Florida has experienced a history of consolidations that has tended to more narrowly define operational territories and reduce competition. Within the past ten years, the following mergers and acquisitions have occurred:

- 1999 – Sarasota Community Blood Bank purchased GulfCoast Area Regional Blood Bank and changed the name to Suncoast Communities Blood Bank.
- 2004 – Community Blood Centers of South Florida purchased Memorial Healthcare System.
- 2004 – Manatee Community Blood Center merged with Florida Blood Services.
- 2005 – Florida's Blood Centers acquired South Florida Blood Banks.
- 2006 – Blood Center of St. Johns and Florida Georgia Blood Alliance merged. In 2007, the entity became The Blood Alliance.
- 2008 – Northwest Florida Blood Services merged with Florida Blood Services.
- 2009 – Bloodnet USA and Southeastern Community Blood Center merged with Florida Blood Services.

The following chart displays the revenues generated by the not-for-profit community blood centers for their fiscal year ending in 2008, and net assets/fund balance for 2008 and 2007, as reported in their IRS Form 990, Return of Organization Exempt From Income Tax. Several of the community blood centers have affiliated not-for-profit organizations or foundations that provide supplemental services and support for the community blood center. Some of these organizations also have significant net assets. Representatives from the industry point to the high expenses associated with operating community blood centers and the economies of scale that result from consolidation. Given the variance in the size of the operations and the increasing net assets of the larger organizations, senate professional staff concludes it is likely that additional mergers and acquisitions will occur.

²¹ Correspondence from HCA West Florida Division Supply Chain dated November 30, 2009.

²² Cross-matching is compatibility testing to establish the matching of a donor's blood or blood components with that of a potential recipient. See for example, 21 C.F.R. § 606.3.

Not-for-Profit Community Blood Centers	Total Revenue FYE 2008	Net Assets / Fund Balance at FYE 2008	Net Assets / Fund Balance at FYE 2007
Florida Blood Services	\$ 110,003,898 ²³	\$ 55,462,019	\$ 53,080,166
Bloodnet USA (merged in 2009)	20,317,732	10,879,822	11,159,216
Northwest Community Blood Centers, Inc. (merged in 2008)	1,764,088 (two months only)		4,473,472
Southeastern Community Blood Center, Inc. (merged in 2009)	12,171,556	7,331,523	6,344,896
Florida's Blood Centers	\$ 108,769,226	\$ 22,613,708	\$ 16,891,148
Community Blood Centers of South Florida	\$ 90,609,675	\$ 36,667,914	\$ 27,244,082
LifeSouth Community Blood Centers	\$ 64,091,057	\$ 18,541,089	\$ 18,459,185
The Blood Alliance / FL GA Blood Alliance	\$ 29,023,548	\$ 2,110,137	\$ 7,286,839
Suncoast Communities Blood Bank	\$ 9,584,807	\$ 6,716,036	\$ 6,037,084

Donor Incentives

The blood supply intended for transfusion that is collected by community blood centers relies on volunteer donors. Blood centers 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 routinely pay donors.²⁴

The label on blood and blood components intended for transfusion²⁵ must include, among other things, a donor classification statement to indicate whether the product was collected from a paid or volunteer donor. Although not illegal, hospitals generally will not accept a unit intended for transfusion that has come from a paid donor because of the increased risk associated with that collection. In order to qualify as a volunteer donor, the donor cannot receive monetary payment for a blood donation or an incentive that is readily converted to cash.²⁶ Common incentives might include T-shirts, event tickets, gift cards or gift certificates, music items, medical tests, and scholarship programs.

Two community blood centers indicated that donor incentives generally average between \$2.60 to \$3.95 per donation, with more expensive donor gifts provided for special drives and during low donation periods.²⁷ The amount spent on donor incentives by Florida's Blood Centers in 2008 was two to three times more than what the other community blood centers spent, averaging approximately \$9.94 per donation. As reported in the 2008 IRS Form 990 for Florida's Blood Centers,²⁸ the corporation paid \$1,257,575 for gift cards to Darden Restaurants, Inc., whose chief financial officer was²⁹ a member of the Board of Directors for Florida's Blood Centers. This related-party transaction equates to approximately \$3.50 of the \$9.94 per average donor. Florida's Blood Centers made comparable purchases of incentives in 2007 and 2006 and the amount for incentives paid to Darden Restaurants, Inc., in 2007 was a larger percentage of the total amount Florida's Blood Centers paid for donor incentives in that year.

²³ Florida Blood Services also performs large-scale screening and testing of blood samples for other blood centers throughout the country and territories. For the fiscal year ending in 2008, it reported revenue of \$40,243,182 related to client testing services.

²⁴ Blood derivatives are classified as prescription drugs and undergo extensive processing during manufacturing that essentially eliminates or significantly reduces the risk of transmission of illnesses that a donor may have.

²⁵ 21 C.F.R. § 606.121.

²⁶ The FDA "CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor" Available at: <http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm122798.htm> (Last visited on November 25, 2009).

²⁷ The average amount spent for donor incentives by the other not-for-profit community blood centers, as calculated by senate professional staff from information provided by the community blood centers, was consistent with this range, except as further described in the paragraph.

²⁸ A copy of the IRS Form 990 is on file with the Florida Senate Health Regulation Committee.

²⁹ This individual resigned from the board of directors of Florida's Blood Centers effective November 19, 2009 according to correspondence dated November 20, 2009 from the Florida's Blood Centers to Senate professional staff.

Conducting blood drives at high schools is prevalent throughout the country and in Florida. High school students³⁰ learn at a young age the altruistic benefit of voluntary, repeat donation.³¹ Community Blood Centers of South Florida, Florida's Blood Centers, and Suncoast Community Blood Center provide opportunities for the high school donors to earn scholarships. Scholarships are paid directly to the post-secondary institution that the student attends. The community blood centers in Florida generally do not pay the individual school or school board for hosting blood drives. However, Florida's Blood Centers' scholarship program also provides a financial contribution to participating schools, ranging from \$5,500 – \$9,500, based on collected units of blood. The 2008 IRS Form 990 for Florida's Blood Centers indicates that a total of \$57,365 was paid directly to high schools as part of the scholarship program.

Recent newspaper articles reported the arrest of Beverly Gallagher, who was employed by the Community Blood Centers of South Florida³² to serve as director of The Scholarship Assistance Foundation (Foundation)³³ and to coordinate the high school blood drives in Broward, Palm Beach, and Miami-Dade Counties. Concurrently, she also served on the Broward County School Board. Her arrest concerned activities related to her position with the Broward County School Board and there have been no reports of criminal charges related to illegal activity with respect to her employment as director of the Foundation.

The newspaper articles³⁴ also reported that the Community Blood Centers of South Florida was not paying scholarships as reported on its IRS Form 990s. Community Blood Centers of South Florida pays \$20 per unit of blood collected from blood drives at public and private high schools in Broward and Palm Beach Counties and private high schools in Miami-Dade County into its scholarship program.³⁵ Scholarship monies are earmarked for students of each school based on the amount earned. A separate committee for each county included in the scholarship program makes the selection of recipients.³⁶ Scholarship monies are paid directly to the post-secondary institution in which the student enrolls upon submission of a request for funds from the post-secondary institution. The president of Community Blood Centers of South Florida explained that there is a timing delay between notification of the award and submission of the request for funds by the post-secondary institution. Approximately 10 percent of the scholarships are not disbursed within 30 months after the award. At this point, unclaimed scholarships are available to be awarded to another student from that high school.³⁷

³⁰ A minor who has reached the age of 17 years may give consent to the donation, without compensation, of his or her blood; unless the parent or parents of the minor specifically object, in writing, to the donation. (s. 743.06, F.S.).

³¹ See, for example, the response from Florida's Blood Centers to questions posed by professional staff of the Florida Senate Health Regulation Committee concerning high school blood drives.

³² Per conversation between professional staff of the Health Regulation Committee and the president of Community Blood Centers of South Florida on November 30, 2009, Ms. Gallagher was terminated from this position due to her arrest for activities related to her position with the Broward County School Board.

³³ The Community Blood Centers of South Florida's scholarship program is operated through its direct support organization, The Scholarship Assistance Foundation. The Foundation's sole purpose is to receive, hold, and make expenditures in the form of scholarships for the benefit of public and private high school students pursuing higher education.

³⁴ See, for example, articles in the South Florida Sun-Sentinel dated September 25, 2009 and October 1, 2009, on file with the Florida Senate Health Regulation Committee.

³⁵ The Community Blood Centers of South Florida pays the scholarship funds for the public high schools in Miami-Dade County into the county's College Assistance Program (CAP).

³⁶ Community Blood Centers of South Florida's IRS Form 990 for fiscal year ending September 30, 2008, a copy of which is on file with the Florida Senate Health Regulation Committee.

³⁷ Per conversation between professional staff of the Health Regulation Committee and the president of Community Blood Centers of South Florida on November 30, 2009.

Availability and Resource Sharing

The U.S. Department of Health and Human Services funds a biennial National Blood Collection and Utilization Survey, which is conducted by the AABB. According to the 2007 report, the most recent one available, the available supply of usable whole blood and RBC units exceeded the transfusions of allogeneic³⁸ whole blood/RBCs by 7.8 percent.³⁹ First-time donors accounted for 28.5 percent of the successful donations.

Hospitals responding to the committee's survey indicated that there is an adequate supply of RBCs and Leukoreduced RBCs although, on occasion, certain types of RBCs (such as O-negative) may be in short supply. None of the hospitals indicated that elective surgery or other activities needed to be rescheduled or altered. However, several hospitals expressed concern with the availability of platelets. This may be, in part, due to the limited shelf-life of platelets.

Senate professional staff became aware of donor concerns that the community blood centers are selling locally collected donations outside the local area despite representations that the blood is collected for local use.⁴⁰

Generally, pursuant to each contract, the community blood center is responsible to supply all blood and blood components needed by the health care facility. If collections by the community blood center are inadequate to meet those needs, at least three national associations are available to facilitate resource sharing. The National Blood Exchange (NBE), operated by the AABB, is available to community blood centers throughout the country and to hospitals. The other two resource sharing programs, Group Services for ABC and the program through the Blood Centers of America, are limited to member community blood centers.

The community blood centers in Florida routinely participate in these resource sharing programs, as both buyers and sellers, as supply varies throughout the year. At certain times of the year, summertime and the November – December holiday season, donations decline.

In the resource sharing programs, excess collections are listed, with a price, by a community blood center. A community blood center, or a hospital in the case of the NBE, may purchase through the program the units desired to meet its needs. There are also long-term contracting opportunities available through these programs. For example, a community blood center that routinely cannot collect an adequate supply to meet its obligations may contract, through the program, with another community blood center to supply blood or blood products. Currently, only the Florida's Blood Centers and Community Blood Centers of South Florida participate in long-term contracts where they are the supplier of blood or blood products to other entities. According to Florida's Blood Centers, the purchasers are located outside the United States and are companies that produce lifesaving pharmaceutical products from blood plasma—in excess of transfusion needs—which would otherwise not be used by Florida's Blood Centers.⁴¹ Community Blood Centers of South Florida has a contract to supply 90 units of RBCs weekly to a northeastern blood center.

Florida Blood Services acts as a regional hub for national disaster or military needs. Upon notification of an emergency need for blood, Florida Blood Services immediately responds by providing blood it has on hand to a military installation or as directed. This blood may be shipped out of the country. The other community blood centers participating in the spoke/hub arrangement are notified and immediately help replenish Florida Blood Services' stock.

³⁸ In an allogeneic donation, the recipient is unknown at the time of the donation. In a directed donation, the donor identifies the intended recipient, and in an autologous donation, the donor is donating for himself or herself.

³⁹ The 2007 National Blood Collection and Utilization Survey Report is available at: http://www.aabb.org/Documents/Programs_and_Services/Data_Center/07nbcusrpt.pdf (Last visited on November 25, 2000).

⁴⁰ See, for example, notes of a telephone conversation on file with the Senate Committee on Health Regulation.

⁴¹ Other community blood centers noted that they sell excess or recovered plasma to brokers in Florida. See survey results on file with the Florida Senate Committee on Health Regulation.

Safety and Pricing

All the community blood centers in Florida are, at a minimum, accredited by the AABB. Community blood centers are required to report, to the CBER, any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected.⁴² None of the community blood centers in Florida reported receiving a Warning Letter from the FDA or other regulatory / licensing entity, or had a license suspended or revoked related to its blood collection activities within the last five years.

The U.S. Biovigilance Network, a surveillance system through the National Healthcare Safety Network, was initiated in 2006 to enhance patient safety and protect health in transfusion and transplantation medicine while also reducing overall costs to the health care system. It is a public/private collaboration between the federal government and organizations involved in blood collection, transfusion, and tissue and organ transplantation. Two of the four components in the network directly affect the donor and recipient of blood and blood components. These modules are expected to be open to all participants in early 2010.

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 prior to making a donation. Generally a donor must be in good health, as indicated by: normal temperature; blood pressure within normal limits; adequate hemoglobin level; freedom from acute respiratory diseases; freedom from infectious skin disease at the site of phlebotomy (where the blood will be drawn); freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examination; and freedom from skin punctures or scars indicative of addiction to self-injected narcotics. Additional donor screening is required to rule out viral hepatitis and other specified conditions.

Testing must be conducted on a specimen of blood taken from the donor, including testing for: determination of blood group; determination of Rh factors; Human Immunodeficiency Virus, types 1 and 2 (anti-HIV and HIV-1 Antigen (HIV-1 AG)); Hepatitis B Virus (HBsAg and anti-HBc); Hepatitis C Virus (anti-HCV); Human T-Cell Lymphotropic Virus, types I and II (anti-HTLV-I/II); and syphilis. Although not presently required by the FDA, testing for Chagas Disease has become an industry standard.

An initial testing panel costs between \$52 - \$66 per unit,⁴³ and every unit is tested notwithstanding donations from regular, repeat donors. 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. If the result of all confirmatory testing is negative, the community blood center may follow FDA specified re-entry protocols for use of the donation.

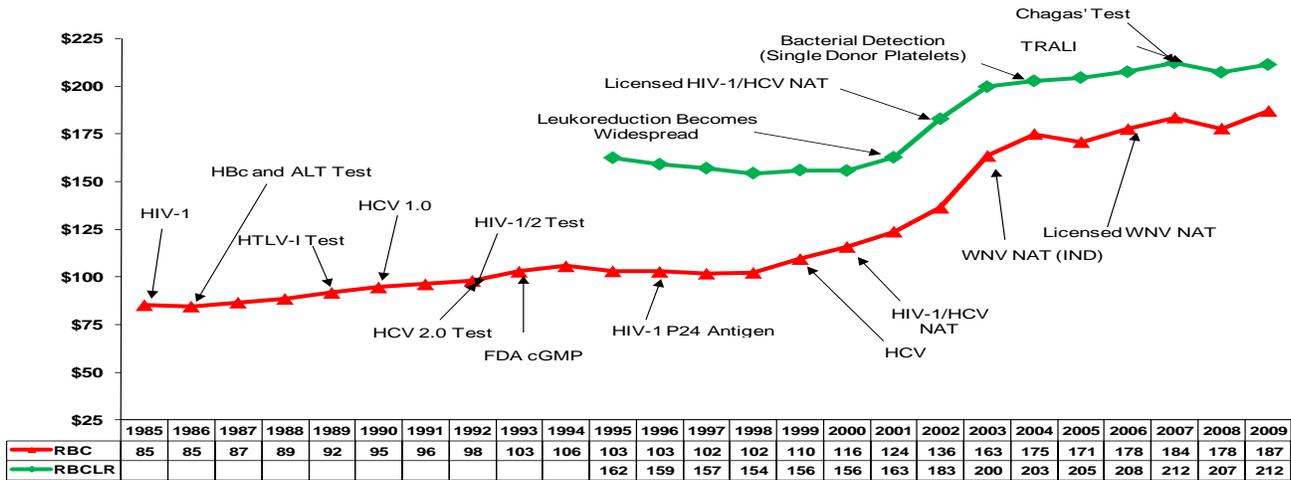
The following chart reflects the impact that additional safety testing has had on the price of RBCs throughout the country, adjusted for inflation, since the mid-1980s.⁴⁴

⁴² 21 C.F.R. § 606.171.

⁴³ Testing cost estimates were obtained by committee professional staff from Qualtex Laboratories, in Texas.

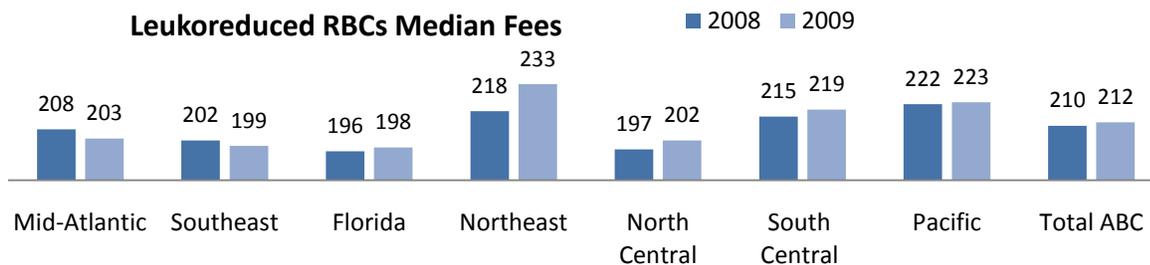
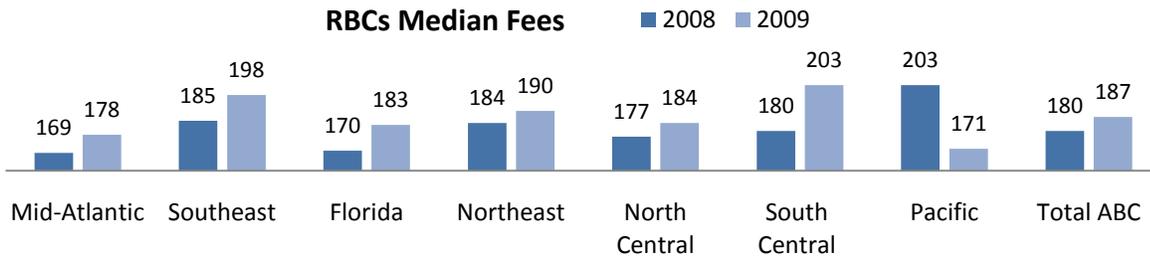
⁴⁴ The chart was provided by ABC in an email to staff in the Florida Senate Health Regulation Committee dated November 17, 2009.

**America's Blood Centers
Safety Measures and Median Red Cell Service Fees in Current Dollars
1985 - 2009**



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.

The following two charts depict the median fees charged to hospitals or other health care facilities for RBCs and Leukoreduced RBCs in Florida for 2008 and 2009 compared with regions throughout the country.⁴⁵ Generally, the median fees charged by community blood centers in Florida are at or near the lowest median fees nationally.



⁴⁵ 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.

The chart to the right reflects the range of costs reported by hospitals responding to the committee's survey question 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

A hospital incurs additional fees when the hospital / physician determines that a patient requires a transfusion. A sample of blood is taken from the patient for cross-matching for an acceptable unit to transfuse. The patient's blood type and Rh factor is determined and an antibody screen is run. If the antibody screen is positive, then additional testing is required. Based on these tests, an acceptable donated unit(s) is found. A nurse or other appropriate medical practitioner then administers or infuses the blood to the patient. The range in hospital charges for a single outpatient procedure of transfusing leukoreduced RBC to an anemic patient in 2008 was \$674 to \$1,174.⁴⁶

Corporate Governance⁴⁷

Members of the Board of Directors for the not-for-profit community blood centers, unless they are also officers of the corporation, serve without compensation. Most of the community blood centers have a set term for a member of the Board of Directors, upon which the Director may be re-elected. Only one corporation had a maximum number of terms or years that a Director may serve on the board.

All of the not-for-profit community blood centers had a written conflict of interest policy, code of ethics, or both. Generally, these documents require members of the Board of Directors to disclose direct or indirect financial or other interests and abstain from voting on an issue in which a potential conflict of interest exists.

For the most recent three fiscal years, some of the not-for-profit community blood centers had varying degrees of related-party transactions with businesses in which corporate officers, directors, or family members of officers or directors were involved. Generally, the community blood centers did not engage in business dealings with related parties, or if they did so, the impact of the transaction was minimal and insignificant to the operation of the blood center.⁴⁸ However, reported related-party transactions that exceeded \$100,000 include:

- Bloodnet USA reported in its IRS Form 990 returns that the spouse of the Executive Director performed construction/repair services for that community blood center in the amount of \$198,012 in 2008, \$252,071 in 2007, and \$168,004 in 2006. Bloodnet USA has since merged with Florida Blood Services, which did not report any related-party transactions for 2008;
- Florida Blood Services disclosed in its IRS Form 990 for 2007 and 2006 that a member of its Board of Directors and the son of the past Chairman of the Board of Directors are investment advisors for two separate investment accounts;
- Florida's Blood Centers reported in its IRS Form 990 returns:
 - Paying Darden Restaurants, Inc., \$1,257,575 in 2008,⁴⁹ \$1,640,091 in 2007, and \$1,597,500 in 2006 for donor incentives;
 - Paying Holland & Knight LLP, a law firm in which a member of the Board of Directors is a partner \$166,679, in 2007. Legal fees for Florida's Blood Centers that year totaled \$523,674, which is at least

⁴⁶ Data provided by the Agency's Florida Center.

⁴⁷ Unless otherwise specified, the information related to corporate governance was obtained from the IRS Form 990s for the not-for-profit community blood centers and from responses to the committee's survey of the community blood centers.

⁴⁸ For example, some board members are affiliated with contract hospital customers; a spouse of an officer/director is a partner in a law firm providing legal services to the blood bank that reported total legal fees of less than \$5,000 for each of the last two fiscal years; and minor construction, carpentry, and painting services are provided by companies owned by board members.

⁴⁹ This was the only related-party transaction reported by Florida's Blood Centers for 2008.

double the legal fees paid by the other community blood centers in any year for the three years reviewed. Florida's Blood Centers responded to the committee's inquiry concerning litigation and legal service needs during fiscal year 2006-2007 that they were in litigation but did not need extraordinary legal services during that timeframe; and

- Paying Eidson Insurance, premiums totaling \$899,869 for various insurance coverages that were brokered through that business whose principal is a member of the Board of Directors; and
- LifeSouth Community Blood Centers has contracted with Gulf Atlantic Airways, Inc., d/b/a University Air Center (UAC) since October 1, 2004. UAC provides air transportation services for deliveries between and among its offices in Florida, Atlanta, and several cities in Alabama. UAC is owned by a member of the Board of Directors. The disclosure in the IRS Form 990 indicates UAC's fees are less expensive than competitor's bids.

At the Board of Director's meeting of Florida's Blood Centers held on November 19, 2009, the board unanimously adopted several changes to modernize its governance policies. Some of the actions include: prohibiting related-party transactions, to be fully implemented in stages over the next few months; imposing term limits for members of the board of directors; and appointing a Governance Committee responsible for recommending changes to the organization's by-laws and policies regarding a variety of governance issues, including executive compensation and board committee structure.

Total compensation (base salary plus incentives, deferred compensation, and other benefits) increased from 2007 to 2008 for the chief executive officer (CEO) of Florida Blood Services, Southeastern Community Blood Center, and LifeSouth Community Blood Centers. Total compensation decreased from 2007 to 2008 for the CEO of Community Blood Centers of South Florida, Florida's Blood Centers, Suncoast Communities Blood Bank, and Bloodnet USA. The following chart reflects the reported total compensation for the CEO of the not-for-profit community blood centers in Florida and comparable salaries for CEOs of not-for-profit community blood centers in other parts of the country for their fiscal year ending 2007. This chart is sorted in descending order of total revenue for fiscal year ending 2007 to facilitate a comparison of salaries based on one factor that affects compensation, the approximate size of the organization.

Not-for-Profit Community Blood Centers	Total Revenue FYE 2008	Total Revenue FYE 2007	CEO Total Compensation for FYE 2008	CEO Total Compensation for FYE 2007
New York Blood Center (New York, NY)		\$345,803,000		\$713,783
Blood Center of Wisconsin (Milwaukee, WI)		119,318,588		535,623
Florida's Blood Centers	108,769,226	95,384,268	\$534,448	596,906
Gulf Coast Regional Blood Center (Houston, TX)		92,859,693		362,361
Florida Blood Services	110,003,898	91,846,459	598,303	540,198
Lifesource (Glenville, IL)		88,675,993		372,185
Community Blood Centers of South Florida	90,609,675	79,695,670	600,021	728,147
South Texas Blood and Tissue Center (San Antonio, TX) President, CEO & Medical Director		74,245,967		516,644
LifeSouth Community Blood Centers	64,091,057	58,582,170	226,556	206,552
The Blood Alliance / FL GA Blood Alliance	29,023,548	25,553,067	289,834	267,619
Community Blood Centers of the Carolinas (Charlotte, NC)		21,196,871		176,027
Bloodnet USA	20,317,732	19,545,411	205,456	215,493
Southeastern Community Blood Center	12,171,556	10,754,667	173,375	159,361
Suncoast Communities Blood Bank	9,584,807	7,970,653	233,124	239,949

The revised IRS Form 990, for 2008 (for filings beginning in 2009) solicits additional information pertaining to governance, management, and certain disclosures that provides 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.

Licensure to handle prescription drugs

The Florida Drug and Cosmetic Act (the Act),⁵⁰ as well as federal law,⁵¹ 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,⁵² 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.⁵³

In November 2008, the FDA's rule to address this dilemma in federal law became effective.⁵⁴ 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.

Additional Activities

Some of the community blood centers provide training and laboratory experience for various medical technologists, training in blood banking technology, and rotations for pathology and hematology residents from local colleges and universities to help students attain licensure or certification in their respective field. Some of the community blood centers work with research institutions in the state and are engaged in marrow donor programs. Others provide meeting facilities and industry training opportunities, offer center tours as community educational outreach, and engage in other community endeavors.

Options and/or Recommendations

Senate professional staff concludes that the community blood center model is presently working to provide a safe and adequate supply of blood and blood components to hospitals and other health care facilities within this state. However, the industry in Florida would be well-served by taking steps to improve competition within Florida's borders and to monitor corporate complacency with respect to organizational activities and expenditures.

⁵⁰ S. 499.005(21), F.S.

⁵¹ 21 U.S.C. 353(c)(e)(A)(ii)(I) (Section 503(c)(3)(A)(ii)(I) of the FD&C Act).

⁵² 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.

⁵³ 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.

⁵⁴ The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published on October 9, 2008, is available at: <<http://frwebgate3.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=16694514530+1+2+0&WAISaction=retrieve>> (Last visited on November 25, 2009).

Senate professional staff recommends that the community blood centers improve transparency concerning blood collection and distribution activities to improve the public trust in this critical, life-saving aspect of health care. Such disclosures may help boost and maintain the level of voluntary donations, especially during traditionally low collection periods. For example, blood collection sites should make available hand-outs or post disclosures in the facility or on the Internet that describe:

- Where the blood center distributes the blood it collects, such as the percentages distributed locally and to other states or regions, its activities concerning resource sharing with other community blood centers experiencing a shortage, and other distributions of the voluntary collections;
- Information pertaining to the blood center's policies for related-party transactions and self-dealing. The community blood centers that have not prohibited related-party transactions outright, should amend by-laws or other applicable documents addressing ethics and conflict of interest policies to require a competitive selection process prior to board approval of a related-party transaction;
- The identity of members of the Board of Directors and the compensation of officers, directors, and key employees, or how to access that information on a timely basis. The community blood centers should provide for a maximum length of service that a director may serve on the board without taking a break in service; and
- The process and costs involved in collecting, processing, and distributing donated blood, as well as the processing fees the community blood center charges to hospitals and other health care providers.

Senate professional staff also recommends that the Legislature enact legislation to:

- Prohibit public agencies from restricting the access to or use of public facilities or infrastructure 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 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 a prescription drug. Florida's laws should authorize the purchase and distribution of prescription drugs necessary for the safe delivery of health care services traditionally performed by community blood centers. This licensure and regulation should recognize the multiple roles that community blood centers serve in the health care delivery system. Additionally, this legislation should be consistent with recent federal rulemaking to the extent necessary to protect persons within the state of Florida and activities performed by community blood centers within this state.

APPENDIX 1

Florida counties in which the community blood centers collect and distribute blood and blood products.

County	Collections							Distributions						
	CBCSF	FBS	FBC	LCBC	SCBB	BA	USBB	CBCSF	FBS	FBC	LCBC	SCBB	BA	USBB
Broward														
Miami-Dade														
Orange														
Palm Beach														
Monroe														
Manatee														
Bay														
Calhoun														
Escambia														
Franklin														
Gadsden														
Gulf														
Hillsborough														
Holmes														
Indian River														
Jackson														
Jefferson														
Leon														
Liberty														
Madison														
Okaloosa														
Pasco														
Pinellas														
Polk														
Santa Rosa														
Taylor														
Wakulla														
Walton														
Washington														
Marion														
Sumter														
Charlotte														
Sarasota														
Brevard														
Flagler														
Glades														
Hendry														
Highlands														
Lake														
Lee														
Martin														
Okeechobee														
Osceola														
St. Lucie														
Seminole														
Volusia														

COUNTY	Collections							Distributions						
	CBCSF	FBS	FBC	LCBC	SCBB	BA	USBB	CBCSF	FBS	FBC	LCBC	SCBB	BA	USBB
Baker														
Clay														
Alachua														
Bradford														
Citrus														
Columbia														
Dixie														
Gilchrist														
Hamilton														
Hernando														
Lafayette														
Levy														
Putnam														
Suwannee														
Union														
DeSoto														
Duval														
Nassau														
St. Johns														
Collier														
Hardee														

CBCSF – Community Blood Centers of South Florida
 FBS – Florida Blood Services
 FBC – Florida’s Blood Centers
 LCBC – LifeSouth Community Blood Centers
 SCBB – Suncoast Communities Blood Bank
 BA – The Blood Alliance
 USBB – United States Blood Bank