HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 475 Blood Establishments
SPONSOR(S): Community & Military Affairs Subcommittee; Eisnaugle
TIED BILLS: **IDEN./SIM. BILLS:** SB 364

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	15 Y, 0 N	Entress	Calamas
2) Community & Military Affairs Subcommittee	14 Y, 0 N, As CS	Gibson	Hoagland
3) Health Care Appropriations Subcommittee	13 Y, 0 N	Pridgeon	Pridgeon
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Blood establishments, commonly referred to as blood banks, are regulated by chapter 381 and chapter 499, F.S., implemented by Department of Health (DOH) and the Department of Business and Professional Regulation (DBPR), respectively. The bill amends blood establishment laws to change current permitting requirements, require information disclosure, and change the use of not-for-profit blood establishments.

The bill creates a Restricted Prescription Drug Distributor Permit for blood establishments, which allows blood establishments to distribute certain prescription drugs essential to their operation. The bill authorizes blood establishments to engage in the wholesale distribution of certain drugs which are otherwise restricted from wholesale distribution. The bill eliminates the requirement of certain blood establishments to maintain a Prescription Drug Manufacturer Permit. In addition, the bill requires blood establishments to disclose certain financial and operational information, and authorizes the Department of Legal Affairs (DLA) to assess penalties for failure to do so.

The bill prohibits the for-profit or not-for-profit status from being the sole determinant of the service fee charged for the provision of blood. Similarly, the bill prohibits local governments from considering for-profit or not-for-profit status in determining use of public facilities by blood establishments.

The bill redefines the term “blood establishment” to include mobile units and defines the term “volunteer donor.”

The bill provides an effective date of July 1, 2012.

The bill has an indeterminate, but likely insignificant, fiscal impact to the Florida Drug, Device, and Cosmetic Trust Fund within DBPR. (See Fiscal Analysis).

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Florida law defines a "blood establishment" as "any person, entity, or organization, operating within the state, 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."[1]

There are many types of blood establishments under federal law, including community blood banks, hospital blood banks, and hospital transfusion centers.[2] There are currently four not-for-profit corporations[3] and one for-profit corporation[4] that operate community blood banks in Florida. The majority of blood establishments involved in the collection of blood from volunteer donors are community blood banks.[5] Many community blood banks in Florida collect blood from volunteers, but also perform a variety of health care services, such as performing blood transfusions and apheresis[6] procedures,[7] processing blood and blood components, product and compatibility testing, and storing and distributing blood and blood products.[8] These activities require the purchase and distribution of prescription drugs to operate.[9] For example, Albumin is used to replace fluid, Rh Immune Globulin is used to prevent incompatible maternal-fetal blood admixture, and Erthropietin is used to stimulate the production of red blood cells.[10]

Blood transfusions often occur as whole blood, but sometimes a primary component of blood may be transferred to a patient.[11] These components are red blood cells, plasma, platelets, and cryoprecipitated antihemophilic factor.[12] Since these components are transferred separate from one another, blood must be processed to separate one blood component from another and occasionally agents must be added to blood for increased safety.[13]

Regulation of Blood Establishments

In order to operate in Florida, a blood establishment must comply with state requirements and with federal regulations.[14] This requires a variety of regulations and permits regarding the prescription drugs necessary for operation.

---

[1] S. 381.06014, F.S.

[2] A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on January 10, 2011).

[3] The not-for-profit blood banks include: LifeSouth Community Blood Centers, Suncoast Communities Blood Bank, The Blood Alliance, and the newly formed blood bank consisting of the merger of Florida Blood Services in St. Petersburg with Community Blood Centers of Florida, Inc. in Miami and with Florida's Blood Centers, Inc. in Orlando. *See* http://www.bizjournals.com/tampabay/news/2011/07/27/florida-blood-banks-merger-advances.html (last accessed January 19, 2012).

[4] United States Blood Bank (USBB).

[5] *Id.*

[6] 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] DBPR e-mail correspondence, January 1, 2012; on file with Subcommittee Staff.

[8] The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, *available at*: http://www.flsenate.gov/publications/2010/senate/reports/interim_reports/pdf/2010-119hr.pdf.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] S. 381.06014, F.S., requires Blood Establishments to comply with Title 21 C.F.R. § 607.7.

Due to the nature of blood and the processes performed by blood establishments, federal regulation of drugs and biologics applies to blood establishments. Blood and blood components are considered "biologics" under the federal Public Health Service Act. Biologics "means a virus therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative…applicable to the prevention treatment, or cure of a disease or condition of human beings."[15]

Similarly, blood and blood components are also considered drugs, which apply the regulations of the Federal Food, Drug, and Cosmetic Act to blood and blood components.[16] The Food and Drug Administration (FDA) in combination with the Center for Biologics Evaluation and Research (CBER) regulate the collection of blood and blood components.[17] Blood establishments are required to register with the CBER and report every blood product manufactured, prepared, or processed for commercial distribution.[18] All registered blood establishments must also obtain a biologics license in order to distribute in interstate commerce.[19] The CBER inspects, monitors, and enforces these requirements for blood quality and safety purposes.[20] In addition, community blood centers must obtain a Clinical Laboratory Improvement Act (CLIA) License and testing laboratories must register with the FDA and obtain certification by the Centers for Medicare and Medicaid Services for infectious disease testing.[21]

In Florida, blood establishments where blood or blood products are collected are required to be licensed as clinical laboratories.[22] Blood establishments which only offer transfusions are not required to obtain this license.[23] As previously mentioned, some blood establishments perform duties in addition to transfusions, such as apheresis procedures.

In addition, to operate in Florida, a blood establishment must comply with the requirements of chapter 381, F.S., regarding public health and safety.[24] The DOH may make rules regarding the general public safety and the Agency for Health Care Administration (ACHA) may bring an injunction to cease operation if a threat to public safety is found.[25] Chapter 381, F.S., also requires Florida to comply with federal law regarding blood establishments.[26]

Additional regulation, specific to blood establishments, is located in chapter 499, F.S., which regulates the purchase and distribution of prescription drugs by blood establishments. A Prescription Drug Wholesale Distributor Permit is necessary to engage in the wholesale distribution of prescription drugs,[27] which is distribution of prescription drugs to persons other than a consumer or patient, but does not include "the sale, purchase, or trade of blood and blood components intended for transfusion."[28] Many establishments need to obtain and distribute prescription drugs not covered under the exemption for blood and blood components, such as Albumin.[29] As of 2009, many community blood centers were permitted as Prescription Drug Wholesalers under chapter 499, F.S.[30] However, blood establishments are currently considered by DBPR to be "health care entities," which are ineligible for a Prescription Drug Wholesale Distributor Permit under state law.[31] Federal law allows blood

[15] 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 10, 2011).
[16] *Supra* at note 8.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] Rule 59A-7.019, F.A.C.
[23] *Id.*
[24] S. 381.06014, F.S.
[25] *Id.*
[26] *Id.*
[27] S. 499.01(2)(d), F.S.
[28] S. 499.003(54), F.S.
[29] *Supra* at note 8.
[30] *Supra* at note 7.
[31] S. 499.012 (1)(d), F.S.

establishments to engage in the wholesale distribution of drugs necessary for their operation, even when categorized as health care entities.[32]

A Restricted Prescription Drug Distributor Permit is required to engage in the distribution of prescription drugs which is not considered "wholesale distribution."[33] This permit is available to health care entities, charitable organizations, reverse distributors, government programs, and institutional researchers, which may not qualify for a Prescription Drug Wholesale Distributor Permit.[34] Currently, DBPR does not allow blood establishments to obtain a Restricted Prescription Drug Distributor Permit.[35]

Under federal law, blood establishments are considered prescription drug manufacturers.[36] Under Florida law, a Prescription Drug Manufacturer Permit "is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs."[37] The fee associated with this permit is determined by DBPR and must be between $500 and $750 annually.[38] The current fee is $1500 every two years.[39] However, blood establishments have not been permitted as Prescription Drug Manufacturers.[40]

Florida law prohibits the wholesale distribution of any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization.[41]

Certain tax-exempt organizations are required to submit to the Internal Revenue Service a Form 990.[42] This form includes financial information about an organization, such as the total revenue of the organization and salaries and employee benefits.[43] These forms are submitted to the IRS and are usually available to the public.[44] Some blood establishments, such as Florida's Blood Centers currently offer governance documents on their websites.[45] While not directly financial information, these documents include policies related to conflict of interest, executive compensation and whistleblowers.[46]

Industry Issues

In 2009, a series of newspaper articles regarding Florida's Blood Centers was published. The articles addressed questionable financial management of Florida's Blood Centers, a not-for-profit blood establishment.[47] Florida Blood Centers made management changes in March 2010, including replacing the CEO.[48]

---

[32] The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published October 9, 2008.
[33] S. 499.01 (1)(g), F.S.
[34] Rule 64F-12.018, F.A.C.
[35] Department of Business and Professional Regulation, 2012 Bill Analysis, House Bill 475 (December 22, 2011).
[36] 21 C.F.R. § 607.7 (2011).
[37] S. 499.01(2)(a), F.S.
[38] S. 499.041(1)(a), F.S.
[39] *Supra* at note 34.
[40] *Supra* at note 35.
[41] S. 499.005(21), F.S.
[42] The Internal Revenue Service-Charitable Organizations, *available at*: http://www.irs.gov/charities/article/0,,id=152728,00.html (Last visited December 20, 2011).
[43] *Id.*
[44] *Id.*
[45] Florida's Blood Centers-Board of Directors, *available at*: http://floridasbloodcenters.org/about/board-of-directors.stml (Last visited December 20, 2011).
[46] *Id.*
[47] Dan Tracy, *Orlando blood-bank chief's pay raised to $605,000 -- then 42 jobs cut*, The Palm Beach Post, Feb. 19, 2010, *available at*: http://www.palmbeachpost.com/news/state/orlando-blood-bank-chiefs-pay-raised-to-605orlando-blood-bank-chiefs-pay-raised-to-605-253423.html.
[48] Dan Tracy, *Blood-bank chief Anne Chinoda resigns*, The Orlando Sentinel, March 10, 2010, *available at*: http://articles.orlandosentinel.com/2010-03-10/news/os-anne-chinoda-resigns-20100310_1_president-at-universal-orlando-fbc-anne-chinoda.

The Florida Senate issued an interim report in December of 2009 to study the regulation of blood banks.[49] The report studied the service fee charged to hospitals by blood banks for blood.[50] The Senate surveyed a number of hospitals to determine the average service fee of blood.[51] According to the survey, the service fee of blood paid by for-profit and not-for-profit hospitals per unit was not identical, but similar in range.[52] The median blood fee in Florida in 2008 and 2009 was consistent with or lower than the national median fees.[53] The fees associated with blood vary according to geographic region and depend on the following factors:

- Cost of collecting, testing, preparing components, labeling, storing and shipping blood;
- Recruiting and educating donors; and
- Quality assurance.[54]

The December 2009 Senate Interim Report cited an incident in which, the USBB, a for-profit blood establishment in south Florida, was denied access to meter rentals due to its for-profit status.[55] This lack of access was cited as a reason for the blood bank's inability to compete with not-for-profit community blood centers.[56]

The interim report recommended several changes to the regulation of blood establishments, including:

- Require disclosure information on the internet, including financial information, the process of collecting blood, and members and compensation for the board of directors;
- Prohibit the restriction of using public facilities based on the tax status of the blood establishment;
- Prohibit community blood centers from using the tax status of a hospital as the sole factor when determining the price of blood for sale; and
- Provide a method for blood establishments to engage in the distribution of prescription drugs and also act as a healthcare entity.[57]

Effect of Proposed Changes

The bill makes various regulatory changes related to financial transparency and permitting of blood establishments.

Financial Disclosure

The bill amends s. 381.06014, F.S., to require establishments that collect blood or components of blood from volunteer donors to disclose the following information on the internet:

- A description of the steps involved in collecting, processing, and distributing volunteer donations;
- The number of units of blood produced by the establishment, obtained from other sources, distributed to health care providers outside of the state, and distributed to entities which are not health care providers in the previous year; and

---

[49] *Supra* at note 8.
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] AABB, *Blood FAQ: What fees are associated with blood*, *available at*: http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx#a11 (Last visited December 20, 2011).
[55] *Supra* at note 8. According to the Senate Interim Report, correspondence between Senate Staff and the Miami Parking Authority, indicated that the Authority has a policy statement that provides, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive…" A representative from the Parking Authority indicated in a phone conversation with Senate committee staff that the Authority had received complaints concerning blood center staff standing in the middle of the street harassing people to donate, as well as, complaints that certain blood drives were not conducted in cooperation with a business in the vicinity. *See* Senate Interim Report 2010-119 at note 20.
[56] *Id.*
[57] *Id.*

- Administrative policies addressing conflict-of-interest, related-party transactions, whistleblowers, and executive compensation.

The website must be updated regarding any changes to these policies by March 1 of the following year. The reports of the units of blood distributed to health care providers outside of the state and distributed to entities which are not health care providers must include the aggregate for providers within the United States and its territories and outside of the United States and its territories. An establishment does not need to report units of blood distributed outside of the state if the blood donations are redistributed to health care entities in the same county in which they were collected. This must be reported by March 1 of each year. These disclosure requirements do not apply to hospitals that collect blood used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity. All blood establishments within a business entity can submit this information in a single submission.

All establishments, with the exception of hospitals that collect blood from volunteers, must also disclose on the Internet the Return of Organization Exempt from Income Tax and Internal Revenue Service Form 990 (if eligible for such return) for the previous 3 years. The Income Tax and Internal Revenue Service Form 990 must be made available 60 days after it was filed. If an establishment is ineligible for the Internal Revenue Service Form 990, the establishment must disclose a balance sheet, income statement, statement of changes in cash flow, and the expression of an option by an independent public account who audited for reviewed these documents. This information must be available on the establishment's website 120 days after the end of the establishment's fiscal year, and must remain on the website for 36 months.

Establishments which fail to disclose this information are liable for a civil penalty, to be assessed by the Department of Legal Affairs (DLA), within the Office of the Attorney General. DLA may assess this penalty each day that the disclosures are not met for a maximum fine of $10,000 per year. DLA may only assess this penalty once for business entities which have multiple establishments. DLA may terminate a civil action if the establishment agrees to pay a stipulated penalty, or may waive the civil penalty if the establishment shows good cause for why the disclosures were not made. Collected civil penalties accrue to the state and are deposited into to the General Revenue Fund unallocated.

Permitting

The bill amends s. 499.01, F.S., to exclude blood establishments that manufacture only those drugs described in s. 499.003(54)(d), F.S., (blood and blood components intended for transfusion) from the requirements to obtain a Prescription Drug Manufacturer Permit and register products under s. 499.015, F.S.

The bill amends s. 499.003, F.S., to include blood establishments as health care entities that may engage in the wholesale distribution of certain prescription drugs if they obtain a Restricted Prescription Drug Distributor Permit. Establishments that collect blood only from volunteer donors (as defined in s. 381.06014, F.S.), or pursuant to an authorized practitioner's order for medical treatment or therapy, and engage in wholesale distribution of prescription drugs, other than those defined in s. 499.003(54)(d), F.S., (blood and blood components intended for transfusion), must obtain a Restricted Prescription Drug Distributor Permit.

The bill allows the following drugs to be distributed under this permit:
- Prescription drugs for a bleeding or clotting disorder or anemia;
- Blood-collection containers;
- Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;
- Prescription drugs adopted in rule by DBPR[58] which are essential to services performed by blood establishments and authorized by distribution under federal law;

[58] In 2010, the legislature transferred the functions and duties of Ch. 499 from DOH to DBPR, ch. 2010-161, L.O.F. References to "department" within 499 refer to DOH, pursuant to s. 499.003(15), which has not yet been revised to reflect the transfer.

- Drugs necessary to collect blood from volunteers, or for blood establishment personnel to perform therapeutic procedures; and
- Drugs necessary to diagnose, treat, manage, and prevent any reaction of a volunteer or patient undergoing a therapeutic procedure, to the extent authorized by federal law.

The therapeutic procedures requiring the prescription drugs must be related to the activities of a registered establishment or consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimen if they are tested with specimens undergoing routine donor testing.

The bill requires that the storage, handling, and recordkeeping of the drugs distributed under a Restricted Prescription Drug Distributor Permit comply with current standards for these activities in s. 499.0121, F.S. While some Restricted Prescription Drug Distributor Permits are exempt from the pedigree paper requirements of s. 499.01212, F.S., the bill excludes blood establishments from this exemption and thus blood establishments must comply with s. 499.01212, F.S. The health care entity receiving these drugs must either be licensed as a closed pharmacy or provide health care services at the blood establishment. The bill allows DBPR to make rules regarding the distribution of prescription drugs by blood establishments as necessary.

The bill does not specify the permit fee for blood establishments to obtain a Restricted Prescription Drug Distributor Permit. Under current law, Restricted Prescription Drug Distributor Permit annual fees may range between $200 and $300, as determined by DBPR.[59] Similar permits include the Restricted Prescription Drug Distributor Permit for health care entities and for charitable organizations, both of which charge a fee of $600 every two years.[60]

Current law prohibits wholesale distribution of drugs donated or supplied at a reduced price to a charitable organization and drugs purchased by public or private hospitals.[61] The bill amends s. 499.005, F.S., to allow the wholesale distribution of the prescription drugs listed above, even when those drugs were purchased by a public or private hospital or healthcare entity or were donated or supplied at reduced price to a charitable organization.

The bill amends s. 381.06014, F.S., to redefine the term “blood establishments.” The term “blood establishments” was altered to include mobile units which conduct activities of blood establishments. The term “volunteer donor” is created in the bill and defined as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion. The container of the donation must qualify for labeling with the statement “volunteer donor” under federal law.

The bill amends s. 381.06014, F.S., to prevent local governments from restricting the use of public facilities based on for-profit or not-for-profit status. The bill also prohibits establishing the service fee of blood received from volunteer donors and sold to hospitals or healthcare providers solely on for-profit or not-for-profit status.

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 of terms used in this part.

Section 3: amends 499.005 F.S., relating to prohibited acts.

Section 4: amends s. 499.01 F.S., relating to permits.

Section 5: provides an effective date of July 1, 2012.

[59] S. 499.041(4), F.S.
[60] *Supra* at note 34.
[61] *Supra* at note 41.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Blood establishments required to obtain a Restricted Prescription Drug Distributor Permit would pay an annual fee between $300 and $600, to be determined by DBPR. DBPR estimates annual revenues to be between $3,000 and $5,100 annually.[62] If blood establishments do not comply with the disclosure requirements DLA could impose fines, up to $10,000 per establishment, which would be deposited into the General Revenue Fund.[63]

2. Expenditures:

DBPR will have to create an additional Restricted Prescription Drug Distributor Permit, which may require expenditures for department processes, training for employees, and updates to the computer systems and web pages.[64] It is anticipated that this workload can be handled within existing budget authority and department resources. Both DLA[65] and DBPR may have increased expenses if the bill's regulatory penalties result in increased administrative appeals.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill increases the commercial freedom of blood establishments, since blood establishments would be allowed to wholesale distribute certain prescription drugs.[66]

D. FISCAL COMMENTS:

The bill does not provide a licensure fee for blood establishments to obtain a Restricted Prescription Drug Distributor Permit, rather state law requires Restricted Prescription Drug Distributor permits to be between $200 and $300 annually. The Prescription Drug Wholesale Distributor Permit, which was previously used by blood establishments, but is now prohibited, cost $800 annually. Although the previous cost of a permit was more expensive, the bill will likely cause a positive fiscal impact since there are currently no Prescription Drug Wholesale Distributor permits distributed to blood centers.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

---

[62] Department of Business and Professional Regulation, Email to Health Care Appropriations Subcommittee, February 3, 2012.
[63] Department of Legal Affairs, 2012 Bill Analysis, House Bill 475 (November 9, 2011).
[64] *Id.*
[65] *Id.*
[66] *Id.*

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DLA and DBPR sufficient rulemaking authority to implement the regulations of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 25, 2012, the Community & Military Affairs adopted a title amendment to reflect the rulemaking authority granted to DBPR in the bill.