

**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:** CS/SB 364

**INTRODUCER:** Health Regulation Committee and Senator Gaetz

**SUBJECT:** Blood Establishments

**DATE:** November 7, 2011      **REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Steele	Stovall	HR	Fav/CS
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

**Please see Section VIII. for Additional Information:**

- |                              |                                     |   |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes        |
| B. AMENDMENTS.....           | <input type="checkbox"/>            | Technical amendments were recommended   |
|                              | <input type="checkbox"/>            | Amendments were recommended             |
|                              | <input type="checkbox"/>            | Significant amendments were recommended |

**I. Summary:**

This bill requires blood establishments to comply with certain business practices and disclose specified information on the Internet, exempts blood establishments from obtaining a manufacturing permit, and establishes a permit and process for blood establishments to distribute certain prescription drugs to facilitate the delivery of medical care involving blood and blood components.

There is a positive fiscal impact to community blood centers intending to engage in the wholesale distribution of certain prescription drugs in order to provide health care services typically provided by blood establishments. There is a minimal fiscal impact to the state of Florida from the proposed legislative changes. The proposed permitting cost is \$600 biennially, compared to the current annual cost of \$800.

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

## II. Present Situation:

### Regulatory Background

A blood establishment is defined in s. 381.06014, F.S., to mean any person, entity, or organization, operating within Florida, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

The state of Florida does not issue a specific license as a blood establishment. Florida law<sup>1</sup> requires a blood establishment operating within the state to operate in a manner consistent with the provisions of federal law in Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640, relating to the manufacture and regulation of blood and blood components. If the blood establishment does not operate accordingly and is operating in a manner that constitutes a danger to the health or well-being of blood donors or recipients, the Agency for Health Care Administration (AHCA) or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the establishment.

Federal law classifies blood establishments as:<sup>2</sup> 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,<sup>3</sup> routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by the AHCA, unless otherwise exempt.<sup>4</sup> As a part of this license, the facility is inspected at least every 2 years.<sup>5</sup> The AHCA may accept surveys or inspections conducted by private accrediting organizations in lieu of conducting an inspection.<sup>6</sup> The clinical laboratory personnel are required to maintain professional licensure by the Department of Health (DOH). Community blood centers must also

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<sup>1</sup> Section 381.06014, F.S.

<sup>2</sup> A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on October 25, 2011).

<sup>3</sup> Blood derivatives are classified as prescription drugs. *See* s. 499.003(43), F.S. and s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

<sup>4</sup> *See* ch. 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

<sup>5</sup> Section 483.061(1), F.S.

<sup>6</sup> Section 483.061(4), F.S.

have appropriate licenses issued by the DOH and comply with laws related to biomedical waste<sup>7</sup> and radiation services.<sup>8</sup>

### **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).<sup>9</sup> RBCs are prepared from whole blood by removing the plasma. They are given to surgery and trauma patients, and 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 up to 10 years.

- Leukoreduced RBCs are filtered to contain a lesser amount of white blood cells than would normally be present in whole blood or RBC units. Leukoreduction is recommended to improve the safety of blood transfusions by reducing the possibility of post-transfusion infection or reaction that may result from pathogens concentrated in white blood cells.
- Plasma is the liquid portion of the blood that carries clotting factors and nutrients. It may be obtained through apheresis<sup>10</sup> 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 7 years. It is thawed before it is transfused.
- Cryoprecipitated AHF is the portion of plasma that is rich in certain clotting factors. It is removed from plasma by freezing and then slowly thawing the plasma. Cryoprecipitated AHF is used to prevent or control bleeding in individuals with hemophilia and von Willebrand disease.
- Platelets control blood clotting in the body, and are used to stop bleeding associated with cancer and surgery. Units of platelets are prepared by using a centrifuge to separate the platelet-rich plasma from the donated unit of whole blood. Platelets also may be obtained from a donor by the process of apheresis, which results in about six times as many platelets as a unit of platelets obtained from the whole blood. Platelets are stored at room temperature for up to 5 days.

### **Community Blood Centers**

Currently, there are four not-for-profit corporations<sup>11</sup> and one for-profit corporation<sup>12</sup> that operate community blood centers in Florida.<sup>13</sup> Several hospital-owned blood centers operate in

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<sup>7</sup> See ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.

<sup>8</sup> See 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.

<sup>9</sup> Blood component definitions from: AABB, *Whole Blood and Blood Components*, available at:

<http://www.aabb.org/resources/bct/bloodfacts/Pages/fabloodwhole.aspx> (Last visited on October 25, 2011).

<sup>10</sup> *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.

<sup>11</sup> The not-for-profit corporations include: LifeSouth Community Blood Centers, Suncoast Communities Blood Bank, The Blood Alliance and a new center with a name as of yet to be determined from the merger of Community Blood Centers of South Florida, Florida Blood Services, Florida's Blood Centers. A copy of the press release of the merger is available at <http://www.tampabay.com/news/health/three-of-the-states-largest-blood-banks-vote-to-merge/1181899> (last visited on October 28, 2011).

Florida as well, primarily collecting blood or blood components to be used in each hospital's own facilities. At least one community blood center without a fixed location in Florida collects blood and blood components with a mobile blood-collection vehicle from volunteer donors, and distributes blood and blood components to health care providers in Florida.

The for-profit community blood center was notified of a policy that impairs its ability to engage in blood collection activities and compete with not-for-profit community blood centers. According to internal correspondence within the Miami Parking Authority dated October 13, 2009, "Meter rentals for blood mobile agencies will only be granted to non-profit companies conducting a blood drive ..."<sup>14</sup>

### **Pricing**

The cost of blood and blood components is primarily based on the cost of labor and required safety testing. In addition to screening, collecting, processing (separation), and testing, blood centers must 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.<sup>15</sup>

Generally, the median fees charged by community blood centers in Florida are at or near the lowest median fees nationally.<sup>16</sup> 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 question of the average cost of a unit of specified blood components paid by the hospital over the last 12 months, it appeared that the for-profit hospitals and not-for-profit hospitals sampled were not paying an equivalent price for blood and blood components.<sup>17</sup>

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<sup>12</sup> The for-profit corporation is the United States Blood Bank (USBB).

<sup>13</sup> However, on November 18, 2010, the Community Blood Centers of Florida, Florida's Blood Centers, and Florida Blood Services announced they had received approval from each of their Boards to pursue a merger. A copy of the press release and a video of the announcement are available at [http://www.floridasbloodcenters.org/news/news.shtml?portalProcess\\_dd\\_0\\_1\\_1=showPublicPosting&calendar\\_entry\\_id=744](http://www.floridasbloodcenters.org/news/news.shtml?portalProcess_dd_0_1_1=showPublicPosting&calendar_entry_id=744) (Last visited on October 25, 2011).

<sup>14</sup> 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.

<sup>15</sup> AABB, *Blood FAQ: What fees are associated with blood?*, available at <http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx#a11> (Last visited on October 25, 2011). See also 21 C.F.R. Part 606, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=606&showFR=1&subpartNode=21:7.0.1.1.3.6> (Last visited on October 25, 2011).

<sup>16</sup> 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](http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-119hr.pdf) (Last visited on October 25, 2011).

<sup>17</sup> *Ibid.*

## Licensure to Handle Prescription Drugs

Human blood and blood products are characterized as both “biologics,”<sup>18</sup> 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).<sup>19</sup> Some community blood centers are licensed by the Department of Business and Professional Regulation (DBPR)<sup>20</sup> 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.<sup>21</sup>

The Florida Drug and Cosmetic Act (the Act),<sup>22</sup> as well as federal law,<sup>23</sup> prohibits the sale, purchase, or trade (wholesale distribution) of a prescription drug that was purchased by a health care entity or donated or supplied at a reduced price to a charitable organization. A community blood center is a health care entity<sup>24</sup> and the not-for-profit community blood centers are charitable organizations.<sup>25</sup> Some of the community blood centers in Florida, however, 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 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 these products. In the past, the DOH provided denial notices to blood establishments seeking a renewal of the prescription drug wholesaler permit.<sup>26</sup> The Act

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<sup>18</sup> 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](http://www.law.cornell.edu/uscode/42/usc_sec_42_00000262----000-.html) (Last visited on October 25, 2011).

<sup>19</sup> The FDA, *Inspections, Compliance, Enforcement, and Criminal Investigations: CPG 230.120 – Human Blood and Blood Products as Drugs*, available at:

<http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm073863.htm> (Last visited on October 25, 2011). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.

<sup>20</sup> Effective October 1, 2011, the regulatory authority over, ch. 499, F.S., The Florida Drug and Cosmetic Act was transferred to the DBPR from the DOH. See s. 27, ch. 2010-161, L.O.F.

<sup>21</sup> Part I, ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

<sup>22</sup> Section 499.005(21), F.S.

<sup>23</sup> 21 U.S.C. 353(c)(3)(A)(ii)(I) (Section 503(c)(3)(A)(ii)(I) of the FD&C Act).

<sup>24</sup> 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.

<sup>25</sup> See Internal Revenue Service, *Exemption Requirements - Section 501(c)(3) Organizations*, updated November 15, 2010, available at <http://www.irs.gov/charities/charitable/article/0,,id=96099,00.html> (Last visited on October 25, 2011).

<sup>26</sup> Information obtained by Florida Senate Health Regulation Committee staff via a telephone conference with representatives from the DOH on January 5, 2011.

and the licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.<sup>27</sup>

In November 2008, the FDA's rule to address this dilemma in federal law became effective.<sup>28</sup> 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 to include in the Act the authorizations in the federal rule, but with more narrowly crafted language 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.

Blood establishments have not been permitted under the Act as a prescription drug manufacturer and have not registered the prescription drugs that they manufacture (the blood and blood components) with the DOH (going forward from October 1, 2011, with the DBPR), notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of prescription drugs manufactured by blood establishments is exempted from the definition of wholesale distribution under s. 499.003(54)(d), F.S. This situation applies to community blood centers, as well as other types of blood establishments (e.g. establishments collecting plasma from paid donors).

### **Restricted Prescription Drug Distributor Permit**

The Act is found in part I of ch. 499, F.S. The DBPR is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.<sup>29</sup> The DBPR issues 20 types of permits to persons (defined to include business entities) who qualify to engage in activity regulated under the Act. A prescription drug must be held under a permit or license, until dispensed to a patient, at which point the practitioner's prescription represents the authority for the patient to possess the prescription drug.<sup>30</sup>

One of the permits issued by the DBPR under the Act is the Restricted Prescription Drug Distributor (RPDD) Permit.<sup>31</sup> The biennial fee for the RPDD permit is \$600 and the permit is valid for 2 years, unless suspended or revoked.<sup>32</sup>

A RPDD permit is required for any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution."<sup>33</sup> The DBPR issues various RPDD

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<sup>27</sup> 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.

<sup>28</sup> 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 October 25, 2011).

<sup>29</sup> Section 499.002, F.S.

<sup>30</sup> Section 499.03(1), F.S.

<sup>31</sup> Section 499.01(2)(g), F.S.

<sup>32</sup> Chapter 64F-12.018, F.A.C., Fees.

<sup>33</sup> Under s. 499.003(54)(a), F.S., the sale, purchase, or trade of blood and blood components intended for transfusion are specifically excluded from the definition of wholesale distribution.

permits to eligible persons, including certain health care entities, for limited distributions of prescription drugs that are authorized under the Act.

### **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 following Legislative action was recommended: 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.

In the 2010 general legislative session, SB 1818 sought to implement the committee staff's recommendations as well as additional provisions to increase transparency in the activities of community blood centers and address other glitches in Florida law related to the permitting of blood establishments. The Florida Senate passed bills in the 2010 Legislative Session (SB 1818) and the 2011 Legislative Session (SB 94); however, neither bill passed the Legislature.

### **III. Effect of Proposed Changes:**

**Section 1** amends s. 381.06014, F.S., to redefine "blood establishment" to clarify that a person, entity, or organization that uses a mobile unit within the state and performs any of the activities under the definition of "blood establishment" is also a blood establishment. The term "volunteer donor" is created and defined as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under federal regulations.

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

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

- A description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations.

- The number of units that the blood establishment:
  - Produced (such as units that passed quality control and are available for use),
  - Obtained from other sources,
  - Distributed to health care providers that are located outside the state. However, if the blood center collects donations in a county outside Florida and distributes to health care providers in that county, then the distributions made to that county must be excluded. This distribution information must be the aggregate of health care providers that are located within the United States and its territories or outside the United States and its territories, and
  - Distributed to entities that are not health care providers. This information must be the aggregate of purchasers that are located within the United States and its territories or outside the United States and its territories.

This information must be on the establishment's website by March 1 of each year reflecting data from the preceding calendar year;

- The blood establishment's policies pertaining to conflicts of interest, related-party transactions, whistle-blowers, and determining executive compensation. If any changes are made to any of these policies, the revised document must be on the blood establishment's website by the following March 1; and
- Either the most recent 3 years of a not-for-profit blood establishment's Form 990 that have been reported to the Internal Revenue Services, which must be posted within 60 calendar days after filing, or an audited or reviewed balance sheet, income statement, and statement of changes in cash flow, along with the expression of opinion on these statements from an independent certified public accountant, which must be posted within 120 days following the end of the fiscal year for a for-profit blood establishment and which must remain on the website for 36 months. However, hospitals that collect blood or blood components from volunteer donors are exempt from these financial disclosure requirements.

A blood establishment failing to make the required disclosures is liable for a civil penalty up to \$10,000 per year, which is to be enforced by the Department of Legal Affairs (Department). If multiple blood establishments, under the common control of one business entity, fail to meet the disclosure requirements, the civil penalty may only be assessed against one of the business entity's blood establishments. The Department may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. The Department is authorized to waive the civil penalty if the blood establishment shows good cause for the failure to disclose. All civil penalties collected must be deposited into the General Revenue Fund unallocated.

**Section 2** amends s. 499.003, F.S., to revise the definition of a health care entity to authorize a blood establishment that collects blood or blood components from volunteer donors to be a health care entity and engage in the wholesale distribution of prescription drugs in accordance with the requirements contained in section 4 of the bill related to the restricted prescription drug distributor permit for a blood establishment.

**Section 3** amends s. 499.005, F.S., to remove the prohibition against the wholesale distribution of prescription drugs by a blood establishment that collects blood or blood components from volunteer donors if the blood establishment is operating in compliance with the requirements contained in section 4 of the bill related to the restricted prescription drug distributor permit for a blood establishment.



This section comports with federal law. The federal regulation (21 C.F.R. § 203.20) uses the same language prohibiting sales by health care entities and charitable organizations as does section 3 of the bill (s. 499.005(21)). The federal regulation then provides exclusions in 21 C.F.R. § 203.22, which includes an exclusion stating that the prohibition does not apply to registered blood establishments that qualify as a health care entity.

**Section 4** amends s. 499.01, F.S., to exempt a blood establishment that only manufactures blood and blood components from the requirements to be permitted as a prescription drug manufacturer and register the products it manufactures.

The bill also requires certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell and distribute prescription drugs to another health care entity. The 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 or pursuant to an authorized practitioner's order for medical treatment or therapy;
- The distributions may be made only to a health care entity that is licensed as a closed pharmacy or provides health care services at the location where the health care entity receives the prescription drugs;
- The prescription drugs that may be distributed pursuant to the restricted prescription drug distributor permit are limited to:
  - A prescription drug that is indicated for a bleeding disorder, clotting disorder, or anemia;
  - A blood-collection container that is approved under s. 505 of the federal FD&C Act related to new drugs;
  - A drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative;
  - A prescription drug that is essential to services performed or provided by blood establishments and is authorized for distribution by blood establishments under federal law if it is identified in rules adopted by the DBPR; or
  - To the extent it is permitted by federal law, a drug necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures; and to diagnose, treat, manage and prevent any reaction of either a volunteer blood donor or a patient undergoing therapeutic procedures; and
- The blood establishment may only provide health care services that:
  - Are related to its activities as an FDA-registered blood establishment;
  - Consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells; or
  - Consist of performing diagnostic testing of specimens if these specimens are tested together with specimens undergoing routine donor testing.

In addition, the bill provides that a blood establishment 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<sup>34</sup> upon the wholesale distribution of these prescription drugs.

The DBPR is authorized to adopt rules related to the distribution of prescription drugs by blood establishments.

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

#### **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 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.

#### **V. Fiscal Impact Statement:**

##### **A. Tax/Fee Issues:**

Instead of paying \$800 annually for a prescription drug wholesale distributor permit and a \$150 fee for certification of a designated representative, a community blood center that intends to engage in the wholesale distribution of certain prescription drugs in order to provide health care services typically provided by blood establishments will pay a \$600 fee biennially for a restricted prescription drug distributor permit.<sup>35</sup>

##### **B. Private Sector Impact:**

Blood establishments 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 whether the customer is a for-profit corporation or not-for-profit corporation.

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

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<sup>34</sup> A pedigree paper contains information required by s. 499.01212, F.S., regarding the sale and distribution of a prescription drug.

<sup>35</sup> See ch. [64F-12.018](#), F.A.C., Fees.

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

**C. Government Sector Impact:**

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

The DBPR will incur costs to adopt rules for the permitting of a blood establishment as a restricted prescription drug distributor and other activities of blood establishments that are regulated under the Act. Revenues may be reduced as a result of the reduced permitting fees, but the impact will be minimal.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Regulation Committee on November 3, 2011:**

The title was revised to substitute the Department of Business and Professional Regulation for the Department of Health to reflect the current department with regulatory responsibility for the Act.

**B. Amendments:**

None.