HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1401 Blood Establishments/Operating Requirements
SPONSOR(S): Adams and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 1582 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)		Chavis	Collins
2) Health Care			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 1401 creates Part V of ch. 483, F.S., relating to blood establishments. The bill prohibits blood establishments from operating in this state without having the proper federal registration or authorization. Provides that such operation is a "nuisance," inimical to the public health, welfare, and safety; and authorizes the Agency for Health Care Administration or any state attorney to bring an action to enjoin such operation of any such establishment.

Provides an effective date of October 1, 2003.

Blood establishments that collect blood for the purposes of transfusions, manufacture of a biological product, or for other medical purposes are not regulated under state law. The federal Food and Drug Administration (FDA), licenses these facilities only if they ship blood or blood products across state lines; otherwise such facilities may only be registered with the FDA. In the event the FDA prohibits such an establishment from the interstate transport of such materials, the FDA has little administrative authority to prevent them from operating within a state.

In 2002, a federal licensed blood bank located in Miami, Florida, had its license revoked by the FDA due to "shoddy donor practices." Neither the Agency for Health Care Administration nor the Department of Health had statutory authority to prevent the blood bank from continuing its intra-state procurement and distribution of blood and blood components. The department sought an injunction against the blood bank as a "…sanitary nuisance…" The department subsequently entered into a settlement agreement with the blood bank to cease and desist all operations until the blood bank had its FDA license re-instated.

No fiscal impact to the Agency for Health Care Administration is anticipated.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[]	N/A[x]
2. Lower taxes?	Yes[]	No[]	N/A[x]
3. Expand individual freedom?	Yes[]	No[]	N/A[x]
4. Increase personal responsibility?	Yes[]	No[]	N/A[x]
5. Empower families?	Yes[x]	No[]	N/A[]

For any principle that received a "no" above, please explain:

B. EFFECT OF PROPOSED CHANGES:

HB 1401 creates Part V of ch. 483, F.S., relating to blood establishments. The bill prohibits blood establishments from operating in this state without having the proper federal registration or authorization. Provides that such operation is a "nuisance," inimical to the public health, welfare, and safety; and authorizes the Agency for Health Care Administration or any state attorney to bring an action to enjoin such operation of any such establishment.

Provides an effective date of October 1, 2003.

The Business of Blood

Blood testing, blood collection, processing, storage and transfusion are major international big money enterprises. While a barrel of crude oil costs about $25, a barrel of plasma can yield products easily worth $90,000 and much more.[1]

Each year, Americans alone donate over 16 million units of blood, which are tested and processed into more than 26 million units of blood and blood derivative products. About 4.8 million Americans receive blood transfusions of various kinds from these blood products each year.

Federal Regulation of Blood Establishments

The United States government regulates human blood as both a drug and a biologic. The Food, Drug, and Cosmetics Act includes blood in the definition of a drug and mandates registration of all drug manufacturers. The Food and Drug Administration (FDA) enforces the Food, Drug, and Cosmetics Act. The Public Health Services Act of 1902 regulates biologic products that are shipped through interstate commerce. An amendment to this Act specifically requires that any blood bank intending to ship blood or blood products in interstate commerce be licensed. Blood banks that do not ship blood or blood products need only be registered with the FDA (21 C.F.R. s. 607). The FDA conducts rigorous inspection of all licensed facilities (21 C.F.R. ss. 601, 606, *et seq.*)

The Division of Biologic Standards as part of the National Institute of Health (NIH) issued the first blood bank license in 1946. The current licensing agency is the Center for Biologics Evaluation and Research (CBER). CBER is a center within the FDA. Biologics License Applications (BLAs) must be filed for each blood component collected. Currently, any blood bank that is involved in interstate commerce of blood products must be licensed by FDA/CBER and is subject to periodic inspections.

[1]BLOODBOOK.COM, "THE BUSINESS OF BLOOD: FACTS ABOUT BLOOD AND THE BUSINESS OF BLOOD. THIS PAGE AND THE LINKS PRESENTED HERE, ADDRESS THE UNSPOKEN STORY." [http://www.bloodbook.com/business.html]

Additionally, every blood bank is required to register with the FDA under Title 21, Code of Federal Regulations 640.

Registered facilities must comply with current good manufacturing practice regulations even if they do not necessarily participate in interstate commerce. Both registered and licensed facilities are subject to FDA inspections to ensure compliance with regulatory standards. The focus of inspections includes donor screening, blood-borne infectious disease testing, the donor deferral registry, product quarantine and error reporting. Other regulatory agencies or regulations potentially involved include the Occupational Safety and Health Administration (OSHA),[2] the Joint Commission on Accreditation of Healthcare Organizations (JCAHO),[3] the Clinical Laboratory Improvement Act (CLIA),[4] and the American Association of Blood Banks (AABB).[5]

Compliance with state and federal regulations is mandatory. There are instances where state regulations are more stringent than federal. Generally the stricter of the two regulations must be followed.

Specifically, section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) requires drug and device manufacturers, including manufacturers of biological products, to register with U.S. Department of Food and Drug Administration (FDA). Title 21, Code of Federal Regulations, spells out the registration requirements for manufacturers of human blood and blood products. Unless exempt, any establishment that manufacturers human blood or blood products by chemical, physical, biological, or other means must register. This includes the following operations:

- Manipulation, sampling, testing, or utilization of control procedures, whether applied to the final product or to any other part of the manufacturing process;
- Repackaging or otherwise changing the containers, wrapper or labeling of any blood or blood products package in furtherance of distribution of the product from the original place of manufacture to the person who makes the final delivery to the ultimate consumer;
- Processing and any other work that is performed on human blood or blood products; and
- Testing, such as blood grouping and compatibility testing, when performed by a non-Medicare approved establishment in conjunction with transfusion of blood or blood components.

Agency for Health Care Administration

At the current time, blood establishments that collect blood for the purposes of transfusions, manufacture of a biological product, or for other medical purposes are not regulated under state law, although under Florida law, all blood banks are required to perform to comply with the testing procedures outlined in ss. 381.004 (HIV testing), and 381.0041 (donation and transfer of human tissues; testing requirements), F.S.

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[2] OSHA's mission is to assure a safe and healthy work environment. OSHA requires an exposure control plan for all employers of workers who could potentially be exposed to blood-borne pathogens. OSHA regulations can be enforced through direct inspections or institution-wide inspections. Direct inspections are often the result of a complaint.

[3] JCAHO evaluates and accredits nearly 19,000 health care organizations and programs in the United States. JCAHO has developed and adopted professional-based standards against which these organizations are evaluated. Eligibility to participate in the Medicare program and in state Medicaid programs depends on JCAHO accreditation.

[4] CLIA requirements are specific to laboratory testing. CLIA defines three categories of laboratory tests and specifies the qualifications required to perform these tests.

[5] The AABB is one of 6 organizations that has been deemed eligible to conduct CLIA inspections. The mission of the AABB is to establish and promote the highest standard of care for patients and donors in all aspects of blood banking and transfusion medicine. Participation in AABB is strictly voluntary. The AABB publishes the Standards for Blood Banks and Transfusion Services. The AABB conducts its own inspections to ensure compliance with its standards. The AABB also publishes the Accreditation Requirements Manual, which is a reference for AABB inspectors.

The United States Blood Bank – Miami, Florida

On July 19, 2002, the FDA shut down the "United States Blood Bank," a small Miami blood bank, due to poor manufacturing practices. In a letter dated July 10, 2002, the FDA ordered the blood bank to close after inspectors found at least 20 safety violations. According to the FDA, the determinations were of a serious nature and constituted a danger to health. The FDA indicated that the blood bank had:

- Failed to prepare the skin of donors at the site of phlebotomy in a careful and through manner that gave maximum assurance of a sterile container of blood.
- Failed to collect blood by aseptic methods in a sterile system to protect against contamination.
- Failed to follow its own standard operating procedures.
- Failed to adequately determine donor suitability in accordance with standard operating procedures. [It was noted that two donors had significant adverse reactions for anemia subsequent to donation and were hospitalized.]
- Failed to adequately determine donor suitability in accordance with standard operating procedures, in that donors were accepted even though they provided disqualifying or potentially disqualifying information.
- Failed to implement an adequate quality assurance program.

Furthermore, complaints made by medical professionals who were donating blood concerning the substandard procedures were not addressed.

Prior to closing, the blood bank supplied about 10% of the units of blood used at Jackson Memorial Hospital in Miami each year and about 25% of the units of blood used at Memorial Regional Hospital in Hollywood, each year.

After becoming aware of the situation, the Agency for Health Care Administration (agency) conducted an investigation and concluded that the agency did not have the statutory authority to prevent the intra-state procurement and distribution of blood and blood components by the facility. While the facility did hold an agency license (Certificate of Exemption) to perform the hemoglobin tests, the agency had no authority not directly related to the hemoglobin testing procedure itself.

After consultation with the Department of Health (department), the agency and the department determined that the department would pursue an injunction against the USBB, as a "…sanitary nuisance that constitute[s] an imminent threat to the public health, safety, and welfare of the residents and visitors to the State of Florida." Prompt action to file an injunction was hindered due to the difficulty in obtaining timely attestations from federal authorities regarding this matter. The department subsequently made a settlement agreement with the USBB to cease and desist all operations until the USBB had its FDA license re-instated. The license has not been re-instated as of this date.

C. SECTION DIRECTORY:

Section 1. Creates Part V of Chapter 483, F.S., relating to blood establishments. Providing a definition, requiring federal registration or authorization for operation, providing for cessation of operation, and providing for injunctory relief by the Agency for Health Care Administration or any state attorney in the name of the state, when such establishment poses a danger to the public health, welfare, and safety.

Section 2. Provides an effective date of October 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Agency for Health Care Administration has requested certain technical changes be made to the bill specifying the specific parts of the Code of Federal Regulations to which a blood establishment must adhere, and specifies that the agency will use the FDA inspection reports in determining if a blood establishment is operating in a manner that constitutes a danger to the health, safety, and welfare of the donors and recipients.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES