HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 361 CS Blood Donor Protection Act
SPONSOR(S): Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1094

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	10 Y, 0 N, w/CS	Hamrick	Mitchell
2) Civil Justice Committee	5 Y, 0 N, w/CS	Kruse	Billmeier
3) Health & Families Council	9 Y, 0 N	Hamrick	Moore
4)			
5)			

SUMMARY ANALYSIS

HB 361 CS establishes the Blood Donor Protection Act. The bill provides that a blood bank, subsidiary, affiliate, employee, or agent of a blood bank may not be compelled to disclose the identity or identifying characteristics of any donor of blood or blood components. However, the bill provides that if the donor gives written consent, or if any local, state, or federal governmental public health authority requires disclosure by law, the blood bank may reveal the identity of the donor or identifying characteristics of the donor.

This bill does not have a fiscal impact on state or local government.

This bill will take effect July 1, 2005.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard personal liberty- The bill may provide increased privacy protection for a blood or blood component donor.

B. EFFECT OF PROPOSED CHANGES:

Confidentiality of Donor Information

The confidentiality of information held by blood banks in this state is referenced in s. 381.0041(9), F.S., which states that blood banks are governed by the confidentiality provisions of s. 381.004(3), F.S.

Under s. 381.004(3)(e), F.S., the disclosure of a donor's identity or a donor's identifying characteristics by a blood bank or agent as to HIV testing and the HIV test results is confidential and exempt from the provisions of s. 119.07(1), F.S.[1] This subsection states that "[n]o person who has obtained or has knowledge of a test result…may disclose or be compelled to disclose the identity of any person upon whom a test is performed, or the results of such a test." The donor's identity or test results may be disclosed to certain persons or entities, such as:

- The subject of the test or the subject's legally authorized representative;
- Health care providers who consult between themselves regarding diagnosis and treatment;
- The Department of Health under rules for reporting and controlling the spread of disease;
- Employees of facilities or programs that care for developmentally disabled persons, who are directly involved in the care of that person and who have a need to know; and
- Medical and nonmedical personnel who have had significant exposure during a course of treatment.[2]

Court Decisions and Legislative Action

In 1982, Donald Rasmussen was hit by a truck while sitting on a park bench. While hospitalized for his injuries, Mr. Rasmussen received a blood transfusion. A year later he was diagnosed with AIDS and subsequently died a year later. In an attempt to prove the source of his exposure to AIDS, Mr. Rasmussen subpoenaed the South Florida Blood Service, Inc. for information on the identities of blood donors.[3] In 1987, the Florida Supreme Court ruled against allowing the release of the identity of the donors' information because society's interest in maintaining a strong and healthy blood supply outweighed the victim's interest.[4]

In 1985, the Legislature passed s. 381.606 F.S., which prohibited any person from being compelled to identify or provide any identifying characteristics of any individual who was the subject of a serologic test[5]. Following the *Rasmussen* decision, the legislature passed ss. 381.004 and 381.0041, F.S., and repealed s. 381.606, F.S. Blood banks are also subject to federal regulations,[6] but these regulations do not specifically provide that a blood donor's identity must be kept confidential.

---

[1] Section 381.004(3)(e), F.S..
[2] Section 381.004(3)(e) 1.-15., F.S.
[3] *Rasmussen v. South Florida Blood Service, Inc.*, 500 So. 2d 533, 534 (Fla. 1987)
[4] *Id.* at 538.
[5] A serologic test is a laboratory method for detecting the presence and/or level of antibodies to an infectious agent in serum from a person. Antibodies are substances made by the body's immune system to fight a specific infection.
[6] *See* e.g. 21 CFR 630 (2004).

Blood Banks

According to the American Association of Blood Banks (AABB), an average of 23 million units of blood components is transfused to patients annually in the United States. Blood transfusions may be used to treat individuals suffering from conditions such as emergency trauma, major surgery, and severe anemia, which may be caused from chemotherapy, cancer, sickle cell disease, and thalassemia. Blood banks must perform certain screening tests on all donated blood. Each unit of donated blood is tested for: Hepatitis B and C, HIV Types I & II, Human T-Lymphotropic Virus, (HTLV) types I and II, and Syphilis.[7] However, screening tools have not yet been developed for some diseases.

Blood Donation

Rules of eligibility for donors have been established by the U.S. Food and Drug Administration (FDA), although some donor centers may have additional requirements. A donor screening questionnaire is comprehensive, and all information is self-disclosed by the donor. To protect the health of both the donor and the recipient, the questionnaire asks about potential exposure to certain transfusion-transmissible diseases.

Blood donors must be at least:

- 17 years of age (although some states permit younger people to donate if they have parental consent);
- In good health;
- Weigh at least 110 pounds; and
- Pass a physical and health history examination prior to donation.

Certain individuals are not permitted to donate blood due to public health concerns, such as:

- Anyone who has ever used illegal intravenous (IV) drugs;
- Men who have had sexual contact with other men since 1977;
- Anyone with a positive test for HIV;
- Men and women who have engaged in sex for money or drugs since 1977;
- Anyone who has had hepatitis since his or her eleventh birthday;
- Anyone who has had babesiosis or Chagas' disease;
- Anyone who has taken Tegison for psoriasis;
- Anyone with Crueutzfeldt-Jakob disease (CJD) or who has an immediate family member with CJD; and
- Anyone who has spent time in the United Kingdom between 1980-1996 that adds up to 3 months or more; and anyone who, from 1980 to the present, spent time in Europe that adds up to 5 years or more, because of the risk of exposure to CJD.

Red blood cells must be stored in refrigeration and can be kept for a maximum of 42 days, or may be frozen for up to 10 years. Platelets can be stored at room temperature for a maximum of 5 days. Fresh frozen plasma can be kept frozen for up to 1 year.[8]

The bill provides that a blood bank or subsidiary or affiliate may not be compelled to disclose the identity or identifying characteristics of any person who donates blood or any blood components. The bill also provides that the provisions of the bill do not apply if the donor has provided written consent to disclose the donor's identity or identifying characteristics or if disclosure is required by law to any local, state, or federal governmental public health authority. The bill also provides a title for the act which is the "Blood Donor Protection Act." The bill will take effect July 1, 2005.

---

[7] American Association of Blood Banks, *All About Blood*, *available at* http://www.aabb.org/All_About_Blood/FAQs/aabb_faqs.htm (last visited March 1, 2005).

[8] *Id.*

C. SECTION DIRECTORY:

Section 1. Creates s. 381.0043, F.S., to provide a popular name and to provide that a blood bank or subsidiary or affiliate may not be compelled to disclose the identity or identifying characteristics of any person who donates blood or any blood components. The bill also provides that the provisions of the bill do not apply if the donor has provided written consent to disclose the donor's identity or identifying characteristics or if disclosure is required by law to any local, state, or federal governmental public health authority.

Section 2. Provides an effective date of July 1, 2005.

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 take an action requiring the expenditure of funds, nor does it reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor does it reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On February 23, 2005, the Health Care Regulation Committee considered the bill and adopted one amendment. The amendment removed the notwithstanding clause. The notwithstanding clause would have exempted compliance with s. 381.0031, F.S. This section provides that blood banks are required to immediately report the existence of a disease or suspect disease of public health significance to the Department of Health. The amendment provides that if a blood donor gives consent, or if local, state, or federal governmental authorities requires it by law, a blood bank could divulge the identity of a blood donor. The bill, as amended, was reported favorably as a committee substitute.

On March 9, 2005, the Civil Justice Committee considered the bill and adopted one amendment. The amendment narrowed the types of governmental authorities that may require, by law, disclosure of a donor's identity or identifying characteristics to *public health* authorities. The bill, as amended, was reported favorably as a committee substitute.