

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 361 W/CS

Blood Donor Protection Act

SPONSOR(S): Cretul

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			
3) Health & Families Council			
4) _____			
5) _____			

SUMMARY ANALYSIS

HB 361 w/CS establishes the Blood Donor Protection Act. This act protects the identity of donors of blood or blood components. 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.

Currently, confidentiality of donor identity or identifying characteristics by a blood bank or agent are limited to statute referring to HIV testing and the donation and transfer of human tissue. In Alachua county a court case is pending involving an a child who received a blood transfusion, was exposed to West Nile virus and died 18 months later. The attorneys involved are now attempting to subpoena the names of the blood donors. An argument can be raised that current statute only relates to testing of HIV infected blood, not West Nile virus.

The language of this act protects blood donors and states that a blood bank or their affiliate can not be compelled to disclose a donor's identity or identifying characteristics. Ensuring blood donors that their identities and the highly personal and sensitive information that they provide to blood banks will remain confidential is crucial to maintaining an adequate and safe blood supply in Florida. In recent years, blood banks in Florida have been faced with a shortage of volunteer donors and have found it necessary to issue urgent calls for blood when supplies become critically low. Donor confidentiality plays an integral role in encouraging donors to regularly donate and encourages new donations. Donor confidentiality is essential to maintain a safe blood supply by ensuring that donors will truthfully reveal sensitive information, such as exposure to viruses on screening questionnaires. Guaranteeing the confidentiality of blood donors is essential to securing a safe blood supply in Florida.

The effective date is July 1, 2005.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Safeguard personal liberty-The bill increases privacy of the individual blood donor. The bill will limit court issued subpoenas to blood banks requesting information on blood donors.

B. EFFECT OF PROPOSED CHANGES:

Effects of the Bill

This bill will create the Blood Donor Protection Act. This act provides a general confidentiality statement that covers all donors of blood and blood components. The language of this act protects a blood donor and states that a blood bank or their affiliate can not be compelled to disclose a donor's identity or identifying characteristics.

Limits of Confidentiality in Florida Statutes

Currently, confidentiality of donor identity or identifying characteristics by a blood bank or agent are limited to statute referring to HIV¹ testing and the donation and transfer of human tissue. Other diseases of public health significance are appearing within the state of Florida and need to be addressed. The intent of Blood Donor Protection Act is to provide a general confidentiality statement that covers all donors of blood and blood components. The language of this act protects a blood donor and states that a blood bank or their affiliate can not be compelled to disclose a donor's identity or identifying characteristics.

Pending Litigation

In Alachua County a court case is pending involving an immunosuppressed² child who received over 50 units of blood during a transfusion. The child died 18 months later. The indirect cause of death was exposure to the West Nile virus³. The attorneys involved are now attempting to subpoena the names of the donors from a local blood bank. An argument can be raised that current statute only relates to testing of HIV, not West Nile Virus. Other issues have arisen were law enforcement entities have tried to subpoena blood donor information in an attempt to match a blood type from blood found at crime scenes. Parents have also tried to compel blood bank personnel to release test results of the blood their children donated.

Importance of Confidentiality

Guaranteeing the confidentiality of blood donors is essential to securing a safe blood supply in Florida. Blood banks are heavily regulated by federal and state agencies. There are numerous mandated safeguards utilized by blood banks to ensure that infected blood and plasma does not enter the blood supply. However, the blood supply can not be tested for certain diseases such as the human form of mad cow disease⁴, and SARS⁵ since screening tests for these diseases do not currently exist. In October of 2003, the first test to assist doctors in diagnosing cases of West Nile virus was released.

Background of Court Decisions and Legislative Action

¹ Human immunodeficiency virus is the virus that causes AIDS.

² Immunosuppressed defined is a person whose immune response is inadequate.

³ West Nile Virus is a flavivirus commonly found in Africa, West Asia, and the Middle East. It is closely related to St. Louis encephalitis virus which is also found in the United States. The virus can infect humans, birds, mosquitoes, horses and some other mammals. Encephalitis refers to an inflammation of the brain.

⁴ Mad cow disease, is a rare degenerative and fatal nervous system disorder. There is reason to believe that the human form of Cruetzfeldt-Jakob disease (vCJD) occurs when humans eat beef contaminated with bovine spongiform encephalopathy (BSE or "mad cow"). This new form of CJD has appeared in residents of the United Kingdom (UK) and France, and a single individual in Italy. Cases have occurred in other countries, including one in the United States that have been tracked to a UK origin. Currently, there is no screening test in humans for the disease. The UK has reported two presumptive transfusion transmitted cases of vCJD.

⁵ SARS is severe acute respiratory syndrome: a respiratory disease of unknown etiology that apparently originated in mainland China in 2003. SARS is characterized by fever and coughing or difficulty breathing or hypoxia and can be fatal.

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 from the disease. In an attempt to prove the source of his exposure to AIDS, Mr. Rasmussen subpoenaed the South Florida Blood Service, Inc. for "any and all records, documents, and other material indicating the names and addresses of the blood donors." In 1987, the Florida Supreme Court ruled in *Rasmussen v. South Florida Blood Service, Inc.*, that privacy interests of blood donors and society's interest in maintaining a strong volunteer blood donation system outweighed the victim's interest.

In 1985, the Legislature passed s. 381.606 F.S., whereby preserving the confidentiality of blood donors by prohibiting anyone from being compelled to identify or provide any identifying characteristics of any individual who was the subject of a serologic test⁶. The intent of the legislation was to assure donors that the information divulged to blood banks, would be confidential, thereby encouraging blood donation and candid disclosure of all personal information on screening questionnaires by donors.

Following the Rasmussen decision, the legislature passed s. 381.004, 381.0041 and removed 381.606 from the Florida Statutes.

The new statutes address HIV testing and ways to preserve donor confidentiality. Currently, s. 381.0041 (9) F.S., discusses donation of human tissue and testing requirements, such that all blood banks shall be governed by the confidentiality provisions of s. 381.004(3). This section states that the identity of any person upon whom a test for HIV has been performed and their test results are confidential and exempt from the provisions of the state policy on public records⁷.

Blood Banks

According to the American Association of Blood Banks (AABB) an average of 23 million units of blood components are 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. The AABB website mentions four key aspects of blood banking 1) donating blood, 2) protecting the blood supply, 3) ensuring its proper use, and 4) the risks involved for donors as well as recipients.

Blood banks must perform certain screening tests on all donated blood. Screening tests are conducted to look for:

- 1) Unexpected red blood cell antibodies that could cause reactions in the recipient (such as those made as a result of a previous transfusion or pregnancy)
- 2) Current and past transmissible infections

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 (a serious but relatively rare illness in the U.S.) and Syphilis. However, diseases that can be contracted by the public are constantly appearing and screening tools for these diseases may not exist.

Storing Blood Safely

Red blood cells must be stored under refrigeration and can be kept for a maximum of 42 days or 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. So, the potential for litigation may extend for several years.

Blood Donation

⁶ 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.

Donors must meet certain criteria to ensure their safety and the safety of the recipients. Rules of eligibility have been established by the U.S. Food and Drug Administration (FDA), although some donor centers may have additional requirements. A donation screening questionnaire is comprehensive and is usually a couple pages long. All information gathered is self-disclosed by the donor.

The screening questionnaire has specific questions under each category, but 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.

The physical includes measurement of weight, blood pressure, pulse, and temperature as well as a test for anemia, which requires just a few drops of blood from your finger.

To protect the health of both the donor and the recipient, the health history questionnaire asks about potential exposure to transfusion-transmissible diseases, such as viruses like HIV, hepatitis B and C, and HTLV I and II as well as parasitic diseases that cause malaria, babesiosis, and Chagas' disease.

Certain people 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
- Hemophiliacs
- 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/has had cancer
- Anyone who has had babesiosis or Chagas' disease
- Anyone who has taken Tegison for psoriasis
- Anyone with Cruetzfeldt-Jakob disease (CJD) or who has an immediate family member with CJD
- Because of CJD, anyone who has spent time in the United Kingdom between 1980-1996 that adds up to 3 months or more; anyone who, from 1980 to the present, spent time in Europe that adds up to 5 years or more; and anyone who received a blood transfusion in the UK between 1980 and the present.

There also may be some restrictions if you are taking certain medications at the time of donation. You may be ineligible to donate or deferred for a period of time.

C. SECTION DIRECTORY:

Section 1. Creates s. 381.0043 (1) and (2) F.S., to provide a popular name and add statutory provisions to protect the identity of blood donors.

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 spend funds or 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 revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health has expressed concern that the phrase "Notwithstanding any other statutory provisions," would now prevent blood banks from disclosing identifying information that is required to contain a public health outbreak. For example, s. 381.0031 F.S., provides that the laboratories, which by definition includes blood banks, shall immediately report the existence of a disease or suspect disease of public health significance to the Department of Health. This act would exempt blood banks from compliance.

An amendment was adopted to address this problem.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On February 23, 2005, the Health Care Regulation Committee adopted an amendment sponsored by Representative Cretul. The amendment rewrites the language of the Act to remove the notwithstanding clause. See "Drafting issues or other comments".

This analysis is drafted to the committee substitute.