

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Governmental Oversight and Productivity Committee

BILL: CS/SB 1094

SPONSOR: Governmental Oversight and Productivity Committee and Senator Smith

SUBJECT: Blood Donor Protection Act

DATE: April 13, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/1 amendment</u>
2.	<u>Rhea</u>	<u>Wilson</u>	<u>GO</u>	<u>Fav/CS</u>
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill creates the “Blood Donor Protection Act” to provide that a blood bank or subsidiary or affiliate of a blood bank or an employee or agent of a blood bank or a subsidiary or affiliate of an agent or employee of a blood bank may not be compelled to disclose the identity or any identifying characteristics of a person who donates blood or any blood component. The prohibition for compelling a blood bank or its agent to disclose the identity or any identifying characteristics of a person who donates the blood or blood component does not apply if written consent is obtained from the donor to disclose the donor’s identity or any identifying characteristics of the donor and does not preclude disclosure to a local, state, or federal governmental public health authority as required by law.

This bill creates section 381.0043, Florida Statutes.

II. Present Situation:

The 1985 Legislature passed s. 1, ch. 85-52, Laws of Florida, codified at s. 381.606(4), F.S., to prohibit any person from being compelled to identify or provide identifying characteristics which, if disclosed, would identify any individual who receives or has received a serologic test. “Serological” or “serology” refers to laboratory tests of the blood used to determine the amount of a specific antibody, measure the effectiveness of medical treatment, and detect certain kinds of microorganisms and other infectious agents.¹ Under s. 381.606(4), F.S. (1985), any person who disclosed the serologic test result to another person, unless the disclosure was to the person receiving the test, was liable for a first degree misdemeanor punishable by imprisonment of up to 1 year and the imposition of a fine of up to \$1,000.

¹ *American Medical Association Complete Medical Encyclopedia* (2003).

In 1988, the Legislature repealed s. 381.606, F.S.,² and created ss. 21 and 22 of ch. 88-380, L.O.F., as part of comprehensive legislation addressing HIV/AIDS. Section 22, ch. 88-380, L.O.F., codified at s. 381.6105(8), F.S.(1988 Supplement), provided that all blood banks shall be governed by the confidentiality provisions of s. 381.609(2), F.S. (1988 Supplement). Section 381.609(2), F.S., (1988 Supplement) provided that no test result shall be revealed to the person upon whom the test was performed without affording that person the immediate opportunity for individual, face-to-face counseling about specified information regarding the test results and HIV infection. Section 381.609(2), F.S., (1988 Supplement), provided that no person, who has obtained or has knowledge of a test result pursuant to this section, 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 in a manner which permits identification of the subject of the test and specified persons or entities.

Section 381.609(2), F.S. (1988 Supplement) is now codified in s. 381.004(3), F.S. With specified exceptions, s. 381.004(3)(e), F.S., provides that “no person who has obtained or has knowledge of a test result pursuant to this section 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 in a manner which permits identification of the subject of the test.” In effect, ss. 381.0041(9) and 381.004(3)(e), F.S., prohibit the disclosure of a donor’s identity or a donor’s identifying characteristics by a blood bank regarding the HIV testing and the HIV test results are confidential and exempt from the Public Records Law when held by an agency subject to the Public Records Law. Disclosures may be made to:

- The subject of the test or the subject's legally authorized representative;
- Any person, including third-party payors, designated in a legally effective release of the test results executed prior to or after the test by the subject of the test or the subject's legally authorized representative;
- An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee participates in the administration or provision of patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a need to know such information;
- Health care providers consulting between themselves or with health care facilities to determine diagnosis and treatment;
- The Department of Health, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by state law;
- A health facility or health care provider which procures, processes, distributes, or uses human body parts from a deceased person, with respect to medical information regarding that person; or semen provided prior to July 6, 1988, for the purpose of artificial insemination;

² See s. 56, ch. 88-360, L.O.F.

- Health facility staff committees, for the purposes of conducting program monitoring, program evaluation, or service reviews pursuant to chapters 395 and 766, F.S.;
- Authorized medical or epidemiological researchers who may not further disclose any identifying characteristics or information;
- A person allowed access by a court order which is issued in compliance with the specified restrictions;
- A person allowed access by order of a judge of compensation claims of the Division of Administrative Hearings;
- Those employees of the department or of child-placing or child-caring agencies or of family foster homes, licensed pursuant to s. 409.175, F.S., who are directly involved in the placement, care, control, or custody of such test subject and who have a need to know such information; adoptive parents of such test subject; or any adult custodian, any adult relative, or any person responsible for the child's welfare;
- Those employees of residential facilities or of community-based care programs that care for developmentally disabled persons, pursuant to chapter 393, F.S., who are directly involved in the care, control, or custody of such test subject and who have a need to know such information;
- A health care provider involved in the delivery of a child can note the mother's HIV test results in the child's medical record;
- Medical personnel or nonmedical personnel who have been subject to a significant exposure during the course of medical practice or in the performance of professional duties, or individuals who are the subject of the significant exposure; and
- The medical examiner shall disclose positive HIV test results to the department in accordance with rules for reporting and controlling the spread of disease.

The Florida Supreme Court affirmed a lower appellate court's decision to quash a subpoena served on a blood bank to obtain the names and addresses of certain persons who had donated blood.³ The Florida Supreme Court held that the privacy interests of the volunteer blood donors and society's interest in maintaining a strong blood donation system outweighed the plaintiff's interest in obtaining the discovery sought. The plaintiff had been injured in an automobile accident, hospitalized, and transfused with 51 units of blood and later was diagnosed with AIDS. Subsequently, in an action against the owner and operator of the vehicle that struck him, the plaintiff served the blood bank with a subpoena duces tecum seeking the names and addresses of the 51 individuals who donated the blood he had received, claiming that the information was necessary in order to assist in proving that the AIDS was most likely acquired from the donated

³ *Rasmussen v South Florida Blood Service, Inc* 500 So.2d 533. (1987, Fla).

blood and thus was an aggravation of the injuries initially sustained in the accident. The trial court denied the blood bank's motion to quash the subpoena and ordered that the information requested be disclosed, but on appeal, the court disagreed after balancing the competing interests and certified the question to the state Supreme Court for review.

Blood banks are subject to federal regulations. The regulations require blood banks to keep the identity of blood donors confidential.⁴ 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. However, screening tools have not yet been developed for some diseases.

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.

Generally, blood donors must be at least 17 years of age, 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 babesiosis⁵ or Chagas' disease⁶;
- Anyone who has taken Tegison® for psoriasis⁷;
- Anyone with Creutzfeldt-Jakob disease (CJD)⁸ 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.⁹

⁴ See 21 CFR 630.

⁵ Babesiosis is a rare parasitic disease that is transmitted to people by infected ticks.

⁶ Chagas' disease is a parasitic disease.

⁷ Tegison® used to treat severe cases of psoriasis.

⁸ Creutzfeldt-Jakob disease (CJD) is a rare, degenerative, invariably fatal brain disorder.

⁹ See material from the American Association of Blood Banks and the American Red Cross in "Why Give Blood in January?" Medical Authors and Editors: Barbara K. Hecht, Ph.D. and Frederick Hecht, M.D. from the website <<http://www.medicinenet.com>>.

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.

III. Effect of Proposed Changes:

The bill creates s. 381.0043, F.S., cited as the “Blood Donor Protection Act,” to provide that a blood bank or subsidiary or affiliate of a blood bank or an employee or agent of a blood bank or a subsidiary or affiliate of an agent or employee of a blood bank may not be compelled to disclose the identity or any identifying characteristics of a person who donates blood or any blood component. The prohibition for compelling a blood bank or its agent to disclose the identity or any identifying characteristics of a person who donates the blood or blood component does not apply if written consent is obtained from the donor to disclose the donor’s identity or any identifying characteristics of the donor and does not preclude disclosure to a local, state, or federal governmental public health authority as required by law.

The bill takes effect on July 1, 2005.

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 this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not provide any exceptions to the bill's prohibition on the disclosure of the identity of donors by a blood bank and its agent to permit disclosure to the Department of Health, for reporting and controlling the spread of disease, as otherwise provided by state law.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
