

**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: SB 2630

INTRODUCER: Senator Oelrich

SUBJECT: Organ and Tissue Donation

DATE: March 27, 2008      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	Fav/1 amendment
2.			GO	
3.			HA	
4.				
5.				
6.				

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

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

**I. Summary:**

This bill modernizes the law for the organ and tissue donation program by establishing an online donor registry and revising provisions to more closely track the revised Uniform Anatomical Gift Act (UAGA). The bill modifies the list of persons who may make an anatomical gift and the persons whose objections prevent a gift from being made or accepted. The bill also reorganizes exiting statutory provisions for clarity.

The bill repeals the following sections of the Florida Statutes: 765.5215 and 765.5216.

This bill amends the following sections of the Florida Statutes: 765.203, 765.512, 765.514, 765.515, 765.516, 765.517, 765.521, and 765.522.

The bill creates s. 765.5155, F.S.

## II. Present Situation:

### Florida Law Relating to Organ Donation

In 1969, the Legislature enacted legislation modeled after the national UAGA, part V of ch. 765, F.S., establishing a process by which individuals, their families, or others may donate organs and tissue. One of the underlying expressions of legislative intent is to encourage the development of reconstructive medicine and surgery and to aid medical research by regulating the gift of the body, or parts of the body, after the death of a donor.

Section 765.512, F.S., provides guidelines by which any person making a will may give all or part of his body for the purpose of transplantation or for medical research. The statute provides that an adult donor's anatomical gift unless revoked by the donor, is irrevocable. The consent or concurrence of another person prior to the procurement of the organ or tissue is not required. However, it is common practice for those entities procuring organs or tissues to acquiesce to the wishes of the family or guardian even if it modifies or overrides a decedent's expressed wish to make an anatomical gift. The donee is prohibited from accepting the gift if the donee has actual notice of contrary wishes by the decedent or, if the spouse made the gift, an objection by an adult child, or a gift by a member of a class is opposed by a member of the same or a prior class.<sup>1</sup>

In the absence of a written document to make an anatomical gift, and provided there is no evidence to the contrary of the deceased donor's wishes, any family member from the specified classes of relatives or persons may make an anatomical gift of a decedent's body or part thereof, unless there is opposition from a member of the same or higher specified class of relatives. Persons who may donate all or part of a decedent's body include the spouse, an adult son or daughter, either parent, an adult brother or sister, a grandparent, the guardian of the person at the time of death, or a representative ad litem appointed by the court.<sup>2</sup>

A person may make an anatomical gift by a will or other signed document including a designation made during the application or renewal for a state-issued driver's license. If the donation is included in the donor's will, the donation becomes effective upon the donor's death without waiting for probate. The document must be executed in the presence of two witnesses.<sup>3</sup>

An amendment or revocation of an anatomical gift can be made through:

- A signed statement delivered to the donee;
- An oral statement made in the presence of two persons and communicated to the donor's family or attorney or to the donee;
- A statement made during a terminal illness or injury to an attending physician; or
- A signed document found on the donor's person or in the donor's effects.<sup>4</sup>

Section 119.0712(2), F.S., provides a public records exemption for personal identifying information contained in a motor vehicle record, which includes a motor vehicle operator's

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<sup>1</sup> Section 765.512(4), Florida Statutes (F.S.).

<sup>2</sup> S. 765.512(3), F.S.

<sup>3</sup> S. 765.514, F.S.

<sup>4</sup> S. 765.516, F.S.

permit or identification card issued by the Department of Highway Safety and Motor Vehicles (DHSMV). This information includes, but is not limited to social security number, driver's license number, name, address, telephone number, and medical or disability information. The DHSMV can release this information to another government agency in carrying out its functions or a private person or entity acting on behalf of a federal or state or local agency carrying out its functions.

Sections 320.08047 and 322.08, F.S., provide that individuals are permitted to make a voluntary contribution of \$1 to be deposited in the Florida Organ and Tissue Donor Education and Procurement Trust Fund for organ and tissue donor education and for maintaining the organ and tissue donor registry.

### **Florida Organ and Tissue Donor Education and Procurement Trust Fund**

Section 765.52155, F.S., creates the Florida Organ and Tissue Donor Education and Procurement Trust Fund. The trust fund is administered by the agency. In Fiscal Year 2006-07, revenues to this fund totaled \$392,071, of which \$256,377 was received from Licenses and Permits and Fees for the regulation of organ procurement organizations and \$135,694 was received from donations forwarded through the DHSMV. Current agency activities (other than regulatory) funded by the Florida Organ and Tissue Donor Education and Procurement Trust Fund include:

- Data storage equipment and programs used to enter data into the donor registry;
- Contracted services to record and index donor wills with signatures for access by health care facilities;
- Partial funding of a staff position responsible for coordinating donor will preparation for indexing and entry of wills into the registry; and
- Funding of a contract for donor education services (2005-06).

### **Organ and Tissue Procurement Process**

Organ procurement is the process of surgically removing an organ or tissue from one person (the donor) and placing it into another person (the recipient). Transplantation is necessary because the recipient's organ has failed or has been damaged by disease or injury. Organ transplantation is one of the great advances in modern medicine. Unfortunately, the need for organ donors is much greater than the number of people who actually donate. Every day in the United States 17 people die waiting for an organ and more than 80,000 men, women, and children await life-saving organ transplants. Organs and tissues that can be transplanted include liver, kidney, pancreas, heart, lung, intestine, cornea, middle ear, skin, bone, bone marrow, heart valves and connective tissue.

When an individual dies the deceased is evaluated for donor suitability given their current and past medical history and their age. The Organ Procurement Organization determines medical suitability for donation.

### **Organ Procurement Organizations (OPOs)**

The role of the OPO is very important in the matching process. The OPOs become involved when a patient is identified as brain dead and therefore becomes a potential donor. The OPO

coordinates the logistics between the organ donor's family, the donor organs, the transplant center(s), and the potential transplant candidate.

The OPOs provide organ recovery services to hospitals located within designated geographical areas of the U.S. The OPOs are non-profit organizations and, like transplant hospitals, are members of the Organ Procurement and Transplantation Network (OPTN). Each OPO has its own board of directors and a medical director on staff who is usually a transplant surgeon or physician.

The OPO employs highly trained professionals called procurement coordinators who carry out the organization's mission. Once contacted by the hospital with a potential donor, the OPO staff:

- Conduct a thorough medical and social history of the potential donor to help determine the suitability of organs for transplantation;
- Work with hospital staff to offer the option of donation to the donor family;
- Ensure that the decision to donate is based on informed consent;
- Manage the clinical care of the donor once consent for donation is finalized;
- Enter the donor information into the United Network for Organ Sharing computer to find a match for the donated organs; and
- Coordinate the organ recovery process with the surgical teams and provide follow-up information to the donor family and involved hospital staff regarding the outcome of the donations.

From the moment of consent for donation to the release of the donor's body to the morgue, all costs associated with the organ donation process are billed directly to the OPO.<sup>5</sup>

### **Donor Procurement and Registry Program**

The AHCA oversees Florida's organ procurement program. The AHCA is required to certify OPOs, provide donor education, and maintain an organ and tissue donor registry<sup>6</sup> in cooperation with the DHSMV. The agency provides the DHSMV with donor registration forms who, in turn forwards the executed forms to the AHCA. The AHCA also receives executed forms from other sources including community outreach or college campus efforts. Upon receipt, the documents are individually scanned, indexed and electronically linked with a corresponding donor record in the Organ and Tissue Donor registry.<sup>7</sup> There are currently over 3.2 million registry participants.<sup>8</sup> According to the AHCA, the registry information process has been maintained since 1998 with equipment that is considered obsolete by today's data system standards. Many of the handwritten documents are illegible and can never be indexed and linked to a data record in the registry. Further, the scanning, indexing and linking process began several years after the registry was implemented, thus many thousands of records do not have corresponding images.<sup>9</sup>

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<sup>5</sup> Cite. <http://www.optn.org/about/transplantation/matchingProcess.asp> (last visited on March 22, 2007)

<sup>6</sup> See ss. 765.510-765.546, F.S.

<sup>7</sup> See the AHCA bill analysis, February 19, 2007, on file with the committee, Page 1.

<sup>8</sup> [http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Organ\\_Donors/personal\\_stories.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Organ_Donors/personal_stories.shtml) (last visited March 22, 2007)

<sup>9</sup> See the AHCA bill analysis, February 19, 2007, on file with the committee, Page 1.

## Organ Transplantation Statistics

As of March 14, 2008, there were 98,433 candidates on the organ transplantation waiting list in the United States. From January through December 2007, 22,047 transplants were performed using organs from 8,089 deceased donors.<sup>10</sup> There were 3,755 candidates on the organ transplantation waiting list in Florida. Of the total number of candidates on the waiting list, 89 are children.

## Uniform Anatomical Gift Act<sup>11</sup>

The National Conference of Commissioners on Uniform State Laws (“NCCUSL”) has been at the forefront of organ donation law since the promulgation of the original UAGA nearly four decades ago. In 2006, after more than 2 years of exhaustive study, the NCCUSL promulgated the Revised UAGA (2006) as a replacement for both the 1968 and 1987 versions of the Act. The 2006 revision was prepared with the active participation of the whole range of stakeholders. The Revised UAGA facilitates donations and modernizes the act to reflect changes in federal law and regulations governing organ procurement and allocation as well as changes in organ donation practices. The Act brings needed uniformity where minutes are too precious to permit wasting time deciphering divergence in state laws.<sup>12</sup>

## Health Care Surrogate

A health care surrogate is a competent adult expressly designated by a principle to make health care decisions on behalf of the principal upon the principal’s incapacity.<sup>13</sup> A health care decision includes:

- Informed consent, refusal of consent, or withdrawal of consent to any and all health care, including life-prolonging procedures and mental health treatment, unless otherwise stated in the advance directives;
- The decision to apply for private, public, government, or veterans’ benefits to defray the cost of health care;
- The right of access to all records of the principal reasonably necessary for a health care surrogate to make decisions involving health care and to apply for benefits; and
- The decision to make an anatomical gift.

In the current organ and tissue donor law, one of the persons authorized to make an anatomical gift on behalf of a decedent is a health care surrogate, unless the surrogate has actual notice of contrary indications by the decedent.<sup>14</sup> A suggested form, provided in statute, for a person

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<sup>10</sup> United Network for Organ Sharing found at: <<http://www.unos.org/data/default.asp?displayType=usData>> (last visited March 22, 2008).

<sup>11</sup> The Uniform Anatomical Gift Act (2006) is available at <<http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63>> (Last visited on March 22, 2008).

<sup>12</sup> Home Page of the NCCUSL found at: <<http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=0&tabid=1>> (Last visited on March 22, 2008).

<sup>13</sup> S. 765.101(16), F.S.

<sup>14</sup> S. 765.512(2), F.S.

(principle) to designate a health care surrogate excepts the health care surrogate's authority to make an anatomical gift.

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 765.203, F.S., to modify the suggested form for designating a health care surrogate to remove the provision that the health care surrogate may not make a health care decision for anatomical gifts, unless the principle has executed an anatomical gift declaration pursuant to law. This eliminates the inconsistency in the definition of health care decision and the organ and tissue donor law.

**Section 2.** Amends s. 765.512, F.S., to reorganize existing provisions in this section and s. 765.514, F.S., to clarify who may make an anatomical gift and how an anatomical gift may be made. The persons who may make an anatomical gift include the donor, a health care surrogate, or a member of one of the classes of persons listed. Two classes of persons are added to this list, an adult grandchild of the decedent and a close personal friend, as defined in s. 765.101, F.S.<sup>15</sup> A member of one of the classes would no longer be prohibited from making an anatomical gift if another member of the same class objects. The bill also removes the prohibition against a spouse making an anatomical gift, and a donee from accepting an anatomical gift from a spouse, if any adult son or daughter objects.

**Section 3.** Amends s. 765.514, F.S., to reorganize and clarify existing provisions that were in s. 765.512, F.S., and this section, and to provide for the donation of anatomical gifts by registering online with the organ and tissue donor registry. The methods for making anatomical gifts include, signing a donor card, registering online, signifying an intention to donate on a driver's license or identification card, expressing a wish in a living will or other advance directive, specifying the intention in a will, or executing some other type of document. The uniform donor card is modified to specify that "parts" includes tissues or eyes. Provisions allowing a donation to be made to a physician are deleted to comply with current federal law. Since the medical procedures related to organ procurement have become so specialized, language that authorizes a donor to designate a physician to carry out the procedures is also deleted.

**Section 4.** Amends s. 765.515, F.S., to require the DHSMV and the AHCA to communicate the donor's intent to make an anatomical gift or revoke a gift to the organ and tissue donor registry. Language for the existing registry is moved to a new section of law to facilitate establishing an online registry.

**Section 5.** Creates s. 765.5155, F.S., related to the organ and tissue donor registry and education program. Legislative findings and intent are provided. The AHCA and the DHSMV are to contract jointly for the operation of an organ and tissue donor registry and education program. Selection of the contractor is to comply with the state competitive solicitation requirements.

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<sup>15</sup> A close personal friend is defined in s. 765.101, F.S., as any person 18 years of age or older who has exhibited special care and concern for the patient, and who presents an affidavit to the health care facility or to the attending or treating physician stating that he or she is a friend of the patient; is willing and able to become involved in the patient's health care; and has maintained such regular contact with the patient so as to be familiar with the patient's activities, health, and religious or moral beliefs.

Priority is to be given to existing nonprofit groups based in Florida that have expertise working with organ and tissue procurement organizations, have expertise in public education campaigns, and represent the needs of the organ and tissue donation community in Florida.

The contractor's responsibilities include:

- Developing, implementing, and maintaining an interactive web-based organ and tissue donor registry that:
  - Allows online organ donor registration;
  - Allows recording records submitted through the driver's license identification program or through other sources;
  - Allows immediate access to records 24 hours a day, 7 days a week; and
  - Protects the integrity of data in the registry by limiting access;
- Providing an ongoing program to educate and inform medical professionals, law enforcement agencies and officers, other state and local government employees, high school students, minorities, and the public about anatomical gifts; and
- By December 31 of each year, submitting a written report to the AHCA addressing:
  - The number of donors on the registry and an analysis of those registered,
  - The dollar amount of contributions received,
  - A description of the education campaigns and initiatives along with an evaluation of their effectiveness in increasing enrollment on the registry, and
  - An analysis of Florida's registry compared with other states' registries.

The contractor is to use available community resources, including volunteers, to support the educational program and is authorized access to state and local government buildings and workplaces to further the educational program.

The AHCA may adopt rules to authorize bona fide researchers to access the registry upon the submission of a detailed research plan that addresses the exact nature of the information requested and the intended use of the information and an agreement to: maintain the confidentiality of the information if personal identifying information is accessed; destroy any confidential information obtained; and not to contact either directly or indirectly, any donor or donee.

Funding of the organ and tissue donor registry and education program are to be paid from the Florida Organ and Tissue Donor Education and Procurement Trust Fund in the AHCA and by voluntary contributions.

The organ and tissue donor registry is named the Joshua Abbott Organ and Tissue Registry.

**Section 6.** Amends s. 765.516, F.S., to recognize that if a person removes his or her name from the donor registry, the anatomical gift is revoked.

**Section 7.** Amends s. 765.517, F.S., to include that the organ and tissue donor registry is to be accessed to verify whether a donation has been recorded before any invasive procedures begin.

**Section 8.** Amends s. 765.521, F.S., to include eyes as a body part that may be specifically donated. Grammatical corrections have also been made.

**Section 9.** Amends s. 765.522, F.S., to assign responsibility to the appropriate organ, eye, or tissue recovery program, rather than the hospital, to access the organ and tissue donor registry or other applicable documentation to ascertain the existence of a valid gift. The language is also updated to reflect the current agencies or organizations for certain functions.

**Section 10.** Repeals ss. 765.5215 and 765.5216, F.S. The provisions in s. 765.5215, F.S., related to the educational program are included in other parts of the bill. The AHCA indicated that the Organ and Tissue Donor Education Panel in s. 765.5216, F.S., was no longer needed to effectively operate the program.

**Section 11.** Provides an effective date of July 1, 2008.

#### **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:**

This bill affects the public records requirements of Article I, Section 24(a) of the Florida Constitution and a separate bill, SB 2610, provides the provisions to comply with these constitutional requirements.

**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:**

None.

**B. Private Sector Impact:**

The bill provides for competitive procurement of a contractor to develop, implement, and maintain the organ and tissue donor registry and the educational program. The bill anticipates that the contractor will obtain contributions in excess of the state appropriations to operate the registry and educational program. The estimated amount available for contracted services will not exceed \$150,000.

The on-line donor registry should facilitate the donation process, resulting in increased donors throughout the state. Accordingly, the lives of those in need of organ or tissue transplants will benefit through greater availability of life-sustaining organs, tissues, or eyes.

C. **Government Sector Impact:**

The DHSMV and the AHCA must jointly contract for a vendor to develop, implement, and maintain the registry and provide education to the targeted audience. The bill provides that as a part of the educational program, the contractor may access buildings and workplace areas of all state agencies and political subdivisions of the state. This is to be accomplished in coordination with the head of the applicable entity or his or her designee. The AHCA is to develop rules allowing for bona fide researchers to access data within the registry.

VI. **Technical Deficiencies:**

None.

VII. **Related Issues:**

“Close personal friend” is defined in s. 765.101, F.S., as any person 18 years of age or older who has exhibited special care and concern for the patient, and who presents an affidavit to the health care facility or to the attending or treating physician stating that he or she is a friend of the patient; is willing and able to become involved in the patient’s health care; and has maintained such regular contact with the patient so as to be familiar with the patient’s activities, health, and religious or moral beliefs. Since this term is already defined, it could be substituted for the phrase used on lines 150-151 in the class of persons who may donate all or any part of a decedent’s body, which may be vague for implementation purposes.

VIII. **Additional Information:**

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

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

None.

B. **Amendments:**

**Barcode 453514 by Health Regulation on March 26, 2008:**

Replaces a description of an additional class of persons who may make an anatomical gift if a decedent has not made a gift and there is no notice of contrary indications by the decedent or actual notice of opposition by a member of a prior class. A close personal friend, as defined in s. 765.101, F.S., replaces another adult who exhibited special care and concern for the decedent.