

The Florida Senate
PROFESSIONAL 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: Health Policy Committee

BILL: CS/SB 1350

INTRODUCER: Health Policy Committee and Senator Oelrich

SUBJECT: Organ and Tissue Donation

DATE: March 14, 2007

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. Bedford	Wilson	HP	Fav/CS
2. _____	_____	TR	_____
3. _____	_____	GO	_____
4. _____	_____	TA	_____
5. _____	_____	_____	_____
6. _____	_____	_____	_____

I. Summary:

This bill provides legislative findings and intent relating to organ and tissue donation and the donor registry. This bill makes several statutory revisions to encourage organ and tissue donation through enhanced education and donor registration by coordinating services among the Florida Coalition on Donation, Inc., (coalition) a not-for-profit entity, the Department of Highway Safety and Motor Vehicles (DHSMV or department) and the Agency for Health Care Administration (the agency or AHCA).

The bill transfers the maintenance of the organ and tissue donor registry from the agency to the coalition and provides that the cost to maintain the registry is paid for by funds from the voluntary contribution of \$1 from driver's license applicants, collected by the DHSMV. The bill provides that the organ and tissue donor registry required to be maintained by the coalition be designated as the "Joshua Abbott Organ and Tissue Donor Registry." The bill provides specific duties for the coalition including operating and maintaining the donor registry and developing and implementing, with the DHSMV, a coordinated program to allow individuals to make anatomical gifts. The bill specifies that records and meetings of the coalition will be open to the public, unless otherwise made exempt by law.

The bill clarifies the criteria under which persons may make anatomical gifts and provides technical revisions to the Uniform Donor Card. The bill provides a mechanism to coordinate the transfer of organ donation information between the DHSMV and the coalition and stipulates that the DHSMV must adopt rules to provide for verification of a donor's identity. The bill requires the DHSMV and the coalition to share administrative responsibilities including submitting an annual report to the Legislature regarding donor registry and demographic information. The bill requires the agency to continue to maintain oversight and certification responsibilities regarding

organ procurement organizations and to assess fees for this purpose. The bill renames the Florida Organ and Tissue Donor Education and Procurement Trust Fund as the Florida Organ and Tissue Procurement Trust Fund.

This bill amends ss. 765.511, 765.512, 765.514, 765.515, 765.516, 765.517, 765.521, 765.5215, 765.52155, 765.522, 765.544, 215.20, 320.08047, and 322.08, F.S.

This bill creates s. 765.5201, F.S., and five undesignated sections of law.

This bill repeals s. 765.5216, F.S.

II. Present Situation:

Florida Law Relating to Organ Donation

In 1969, the Legislature enacted legislation modeled after the national Uniform Anatomical Gift Act, 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.¹

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.²

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.³

¹ See section 765.512(4), F.S.

² See section 765.512(3), F.S.

³ See section 765.514, F.S.

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.⁴

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 permit or identification cards issued by the 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 2005-06, revenues to this fund totaled \$431,663.16, of which \$285,122.40 was received from Licenses and Permits and Fees and \$146,540.76 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 (2005-2006).

The Florida Coalition on Donation

The Florida Coalition on Donation (coalition) was founded in 1997 as a non-profit organization and is a member of the national Coalition on Donation. The coalition is an alliance of organ, tissue, and eye donor programs in Florida and individuals and organizations that hold a common interest in life-saving and life-enhancing donation and transplantation. The overriding mission of the coalition is to inspire all people to donate life through organ and tissue donation. The coalition is funded largely by its membership dues and through some donations.

⁴ See section 765.516, F.S.

The primary reason for forming the coalition was to create an entity that could coordinate and handle large organ donor informational programs, including implementing national organ donor campaigns. The coalition uses a variety of outreach efforts, including Get Carded, a college based campaign; Workplace Partnership For Life, an employer driven program; and billboard and movie theatre advertisements.

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.⁵

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 registry⁶ 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.⁷ There are currently over 3.2 million registry participants.⁸ 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.⁹

Organ Transplantation Statistics

As of February 16, 2007, there were 95,146 candidates on the organ transplantation waiting list in the United States. Of the total number of candidates on the waiting list, 1,948 are children. From January through November 2006, 26,691 transplants were performed using organs from 13,582 donors.¹⁰

As of February 16, 2007, there were 3,300 candidates on the organ transplantation waiting list in Florida. Of the total number of candidates on the waiting list, 68 are children. From January through November 2006, 1,663 transplants were performed using organs provided from donors.¹¹

III. Effect of Proposed Changes:

Section 1. Creates an undesignated section of law expressing legislative findings and intent regarding organ and tissue donation. The Legislature finds that there exists a shortage of organ

⁵ Cite. <http://www.optn.org/about/transplantation/matchingProcess.asp> (last visited on March 13, 2007)

⁶ See ss. 765.510-765.546, F.S.

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

⁸ http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Organ_Donors/personal_stories.shtml (last visited March 13, 2007)

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

¹⁰ Cite. www.Unos.org/data United Network for Organ Sharing – found under National Data – Numbers update periodically (last visited March 13, 2007)

¹¹ Cite. www.Unos.org/data United Network for Organ Sharing – found under National Data – Numbers update periodically (last visited March 13, 2007)

and tissue donors in the state; there is a need to encourage minority populations to donate organs and tissue; that an enhanced donor education program with an online registration process developed and implemented by a private not-for-profit entity, in cooperation with the department, and the reporting of results to the agency and the Legislature will lead to an increase in the number of organ and tissue donors registered in Florida; and that the Florida Coalition on Donation has been established as a not-for-profit entity by the certified Florida organ procurement organizations.

The intent of the Legislature is that the funds collected pursuant to ss. 320.08047 and 322.08(6)(b), F.S., will be used to maintain the donor registry and for educational purposes aimed at increasing the number of organ and tissue donors.

Section 2. Amends s. 765.511, F.S., which provides definitions relating to anatomical gifts, to add a definition for the Florida Coalition on Donation.

Section 3. Amends subsections 765.512(2) and (3), F.S., as follows:

Subsection (2) is amended to recognize, for purposes of informed consent to donate, a donor joining the organ donor registry or expressing the intent to donate with an identification card, in addition to intent shown on a driver's license or in some other written form. This subsection is also amended to specify that an unemancipated minor can designate his or her intent to donate on a driver's license or identification card and that the designation will have the same effect as that of an adult once the minor attains the age of majority.

Subsection (3) is amended to specify that if a decedent is not included in the donor registry, certain identified family members, guardians or appointed individuals can donate all or any part of the decedent's body for organ and tissue removal.

Section 4. Amends section 765.514, F.S., to add new language with regard to the manner of executing anatomical gifts.

Subsection (1) is amended to add that a donor's driver's license or identification card may be imprinted with a statement or symbol indicating that the individual is a registered donor. Any change in the status of the driver's license or identification card will not invalidate the anatomical gift. This subsection also adds the authorization of the donor to be included on the donor registry and specifies that an individual can make such an authorization through online access to the registry. This subsection also requires the department to adopt rules to provide for verification of the identity of such individuals in a manner similar to the verification of identity for online driver's license renewal. This subsection also amends the Uniform Donor Card specified in statute, specifically to add tissue and eyes and to require an advance arrangement with a donee if the donor wants the donation to go to a specific donee.

Section 5. Amends section 765.515, F.S., to clarify the delivery of donor information and the maintenance of the organ and tissue donor registry.

Subsection (1) is amended to allow an anatomical gift to be made pursuant to s. 765.521, F.S., and to delete the gift being made through the program established by the agency and the

department. This subsection is also amended to state that if an anatomical gift is withdrawn, the department shall communicate the withdrawal to the coalition for the purpose of updating the donor registry.

Subsection (2) is amended to allow a gift by a donor to a specified recipient to be made pursuant to s. 765.521, F.S., rather than through the program established by the agency and the department.

Subsection (4) is amended to substitute the coalition as the designee to maintain an organ and tissue donor registry and to delete the reference to the agency and the department. This subsection also recognizes eye procurement in addition to organ and tissue procurement agencies. It is further amended to specify that the procurement agencies that are certified by the agency to obtain consent for donation and screening of potential donors, the coalition, and the department be added to the parties allowed access to information stored on the donor registry.

The coalition and the department shall have administrative responsibilities for the registry. The coalition must submit an annual written report to the Legislature regarding numbers, changes and general characteristics of donors. This subsection also requires the coalition to provide the department, upon request, with a list of names of individuals who joined the donor registry online for the purpose of confirming identities. This subsection is also amended to state that the coalition may receive voluntary contributions to support its activities and the registry and that the orderly transition of the donor registry responsibilities from the agency to the coalition be paid from the Florida Organ and Tissue Procurement Trust Fund. This subsection also states that costs for maintaining the registry shall be paid from funds collected from the driver license voluntary \$1 contribution and any other funds available to the coalition for this purpose.

Section 6. Creates an undesignated section of law to specify that upon implementation of the donor registry amendments, the coalition shall assume responsibility for all aspects of the donor registry and the agency shall provide the coalition with the current registry information, including donor registration documents for all previously registered donors.

Section 7. Creates an undesignated section of law to designate the organ and tissue donor registry maintained by the coalition as the “Joshua Abbott Organ and Tissue Donor Registry.”

Section 8. Creates an undesignated section of law to specify that section 765.515(4)(e)1, F.S., as amended by the bill, shall expire upon completion of the transition of the donor registry from the agency to the coalition and the notification of potential donors of the changes to the registration process.

Section 9. Amends s. 765.516(1), F.S., to allow a donor to amend or revoke an anatomical gift by the removal of a donor’s name, by the donor, from the donor registry.

Section 10. Amends s. 765.517(3), F.S., to show that verification of the deceased’s consent to donate may appear in the donor registry.

Section 11. Creates s. 765.5201, F.S., This section states that that records and meetings of the coalition must be open to the public unless exempt by law.

Section 12. Amends s. 765.521, F.S., to delete all references to the agency and to add the coalition as being jointly responsible, with the department, for implementing a program to encourage people to make anatomical gifts as part of the process of issuing identification cards and issuing and renewing driver licenses for persons wishing to be donors, as well as supplying the necessary supplies and forms through funds collected under ss. 320.08047 and 322.08(6)(b), F.S.

Section 13. Amends s. 765.5215, F.S., with regard to educational programs relating to anatomical gifts, to delete all references to the agency and to add a requirement that the coalition will assume the development of a program to educate Florida citizens relating to anatomical gifts. The legislative language creating a demonstration project targeting potential donors in the nonwhite, Hispanic, and Caribbean population groups within the state is deleted.

Section 14. Amends s. 765.52155, F.S., to rename the Florida Organ and Tissue Donor Education and Procurement Trust Fund to the Florida Organ and Tissue Procurement Trust Fund.

Section 15. Repeals s. 765.5216, F.S., which establishes the Organ and Tissue Donor Education Panel to advise the agency.

Section 16. Amends s. 765.522(2), F.S., to instruct a hospital administrator or designee to notify the appropriate organ, tissue, or eye recovery program which shall in turn access the registry to ascertain the existence of a suitable donor's request. Subsection (5) adds the coalition to the list of organizations and individuals exempt from civil or criminal liability. Subsection (6) designates the United States Department of Health and Human Services as the designating agency for the organ procurement organizations that are contacted.

Section 17. Amends s. 765.544(2), F.S., to delete maintenance of the organ and tissue donor registry and the organ and tissue donor education program from the list of recipients of certain fees assessed by the agency. Subsection (4) changes the name from the Florida Organ and Tissue Donor Education and Procurement Trust Fund to the Florida Organ and Tissue Procurement Trust Fund. This subsection also deletes the language that calls for moneys deposited in the trust fund to be used for maintaining the organ and tissue donor registry, and for organ and tissue donor education.

Section 18. Creates an undesignated section of law to authorize use of funds from the Florida Organ and Tissue Donor Education and Procurement Trust Fund for the transition of the donor registry from the agency to the coalition, including the notification to potential donors of the changes in the registration process. This section will expire upon the conclusion of the transition process.

Section 19. Amends s. 215.20(4), F.S., to change the name of the trust fund that will fund agency regulatory activities from The Florida Organ and Tissue Donor Education and Procurement Trust Fund to The Florida Organ and Tissue Procurement Trust Fund.

Section 20. Amends s. 320.08047, F.S., to provide that the funds raised through the current voluntary contribution of \$1.00 through the collection process for vehicle license taxes must be

distributed to the Florida Coalition On Donation rather than being deposited into the Florida Organ and Tissue Donor Education Procurement Trust Fund.

Section 21. Amends s. 322.08(6), F.S., relating to the application for a driver's license, to provide that the voluntary contribution of \$1.00 must be distributed to the Florida Coalition on Donation. Reference to the deposit of these contributions into the Florida Organ and Tissue Donor Education and Procurement Trust Fund is deleted. The bill specifies that the funds raised from the voluntary contribution are not subject to the general revenue service charge.

Section 22. The act would take effect July 1, 2007.

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:

On page 11, lines 12-17, the bill requires the Florida Coalition on Donation to provide the department with a list of the names of individuals who joined the donor registry on line. This information does not appear to be covered by the existing public records exemption under 119.0712(2), F.S. If the intent is for personal identifying information from the online registration of donors to remain confidential and exempt a separate public records bill must be passed by a two-thirds vote of each house of the Legislature.

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:

This bill affects those individuals in need of receiving an organ or tissue donation by changing the process of donor registration.

C. Government Sector Impact:

Provisions of the bill would change the existing Florida Organ and Tissue donor Education and Procurement Trust Fund into a trust fund that would provide for agency regulatory activities only. Donated funds would be distributed to the Florida Coalition on Donation for donor education and the donor registry. In fiscal year 2005-06, revenues to

the Florida Organ and Tissue Donor Education and Procurement Trust Fund totaled \$431,663.16, with \$285,122.40 received from regulatory activities and \$146,540.76 from donations forwarded through the department. Since the agency would no longer be responsible for donor education and the donor registry, the reduction in voluntary contributions would not impact state operations.

The bill requires some program modifications to be made to the Driver License Software Systems. The department will absorb costs associated with these modifications within existing resources.

VI. Technical Deficiencies:

Page 14, line 2, delete line 2. Insert cards. on line 2. Insert 3. Developing a program to educate state and local on line 3 at the beginning of the line.

VII. Related Issues:

Sections 19 and 20 of the bill delete the requirement that funds raised through the driver license voluntary \$1 contribution for organ and tissue donor education and for maintaining the organ and tissue donor registry be deposited in the Florida Organ and Tissue Donor Education and Procurement Trust Fund. Instead, the bill requires the contributions to be distributed to the Florida Coalition on Donation. This change raises the following issues:

- The department will need to deposit those funds in one of its trust funds until it disburses the funds to the coalition. The bill does not specify which trust fund will hold the funds raised through the voluntary contributions.
- The bill does not specify how frequently the funds are to be distributed to the coalition.
- It is unclear whether an appropriation is required for disbursement of the funds and whether the funds are to be disbursed through a grant or contract. The bill does not include provisions to ensure accountability for the use of the funds.
- It is unclear whether the auditing provisions of s. 215.97, F.S., would apply.

On page 10, line 30, and page 11, lines 1 and 2, the bill states that both the coalition and the department have administrative responsibilities for the registry. The bill does not specify how any disputes between these two entities are to be resolved.

On page 15, lines 18 through 20, the bill provides immunity from liability to the coalition in connection with the performance of any acts authorized by s. 765.521, F.S., which requires the development and implementation of a program encouraging and allowing persons to make anatomical gifts as a part of the process of issuing identification cards and issuing and renewing driver licenses. It is unclear how this immunity relates to sovereign immunity.

On page 17, lines 14 through 19, the bill gives the coalition, for the sole purpose of furthering its educational responsibilities regarding organ and tissue donation, access to the buildings and workplace areas of all state and local governmental entities. It is unclear whether any restrictions should apply.

The bill provides for a transition of the organ and tissue donor registry from the agency to the coalition, but does not specify a completion date for the transition.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
