

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: Governmental Operations Committee

BILL: CS/CS/SB 1350

INTRODUCER: Governmental Operations Committee, Health Policy Committee, Senator Oelrich and others

SUBJECT: Organ and Tissue Donation

DATE: April 19, 2007

REVISED: _____

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

I. Summary:

The bill transfers responsibility for maintaining the organ and tissue donor registry from the Agency for Health Care Administration to the Florida Coalition on Donation, Inc., to an existing private non-profit corporation established by organ procurement organizations. Costs to maintain the registry is paid for by funds from the voluntary contribution of \$1 from driver's license applicants, collected by the Department of Highway Safety and Motor Vehicles.

The bill provides 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 clarifies the criteria under which persons may make anatomical gifts and provides technical revisions to the Uniform Donor Card. 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 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

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

¹ See s. 765.512(4), F.S.

² See s. 765.512(3), F.S.

³ See s. 765.514, F.S.

⁴ See s. 765.516, F.S.

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 card 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 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 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.

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 his or her current and past medical history and 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 United States. 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 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

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

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 there exists a shortage of organ and tissue donors in the state; there is a need to encourage minority populations to donate organs and tissue; 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 the Florida Coalition on Donation has been established as a not-for-profit entity by the certified Florida organ procurement organizations.

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)

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, Inc.

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.

Subsection (3) is amended to specify if a decedent is not included in the donor registry, or has not designated a surrogate, 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 a donor's driver's license or identification card may be imprinted with a statement or symbol indicating 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 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 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 the procurement agencies 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 the coalition may receive voluntary contributions to support its activities and the registry and 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, except for the transition costs, 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 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 s. 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 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 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 when complying with the provisions of the part and the rules of the agency or, when in the exercise of reasonable care, a request for organ donation is inappropriate and the gift is not made according to the section and rules adopted by the agency. 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 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 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 the funds raised from the voluntary contribution are not subject to the general revenue service charge.

Section 22. The sum of \$607,000 in nonrecurring funds is appropriated from the Florida Organ and Tissue Procurement Trust Fund to the agency for the purpose of contracting with the coalition for the orderly transition of the registry.

Section 23. 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:

The bill expressly provides that records and meetings of the Florida Coalition on Donation are open to the public in accordance with s. 119.07(1), s. 286.011, and s. 24, Art. I of the State Constitution, unless otherwise made exempt by law. As this private entity is performing a state responsibility established in statute, it would appear to meet the definition of an “agency” for purposes of chapter 119, F.S., when performing duties related to the maintenance of the registry and for educational purposes. If, however, there are other functions that this private entity performs that are not functions delegated by the state or that are performed on behalf of the state, those functions would not typically be covered by open records and meetings requirements. This bill, however, expressly includes all records and meetings of the coalition within open records and meetings requirements.

C. Trust Funds Restrictions:

The bill 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.

The bill also amends s. 765.544(2), F.S., to delete 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.

The bill amends ss. 320.08047 and 322.08(6), F.S., to provide 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.

The sum of \$607,000 in nonrecurring funds is appropriated from the Florida Organ and Tissue Procurement Trust Fund to the agency for the purpose of contracting with the coalition for the orderly transition of the registry.

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:

None.

VII. Related Issues:

This bill transfers statutory responsibilities of the Agency for Health Care Administration (AHCA or the agency) regarding the organ and tissue donation registry to an existing private corporation, the Florida Coalition on Donation, Inc., (coalition) a private, not-for-profit entity, established by organ procurement organizations.

While placing legal responsibility for a public program with an existing private corporation in statute, this bill does not provide for the typical oversight mechanisms that ensure governmental accountability. For example, no state officer, such as the Governor or the secretary of AHCA or the DHSMV, appoints the directors of the board of the entity. Additionally, the bill does not provide for approval of the articles of incorporation and bylaws, or any changes thereto. Further, the bill does not require that the coalition operate pursuant to a written contract with the agency that establishes contractual standards and obligations regarding the registry.

While the bill delegates responsibility for the registry program to a private corporation, it does not expressly prohibit the coalition from subcontracting responsibility for maintaining the registry.

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.

The bill states both the coalition and the department have administrative responsibilities for the registry. The bill does not identify what these “administrative duties” are, specifically delegate those “administrative duties” to one entity or another, or specify how any disputes between these two entities are to be resolved.

The bill provides that neither the DHSMV nor the coalition have *any* liability “. . . 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. The DHSMV is a state entity already covered by s. 768.28, F.S., which provides a limited waiver of sovereign immunity for torts. This provision of the bill cloaks the DHSMV with no liability for any act authorized by the section. The coalition, which is an existing, private corporation, established by other existing private corporations, would not appear to be covered by the limited waiver in s. 768.28, F.S. This provision extends protection from liability to this private corporation for any act in connection with the performance of acts authorized in the section. Arguably, misfeasance and malfeasance would not be contemplated to be covered as they would not be “acts authorized herein.”

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. This provision appears to grant this private entity authority to enter any state or local building or workplace without coordination with the agency head or other person responsible for such building or workplace, including protected areas.

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.

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.
