

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 455 Organ and Tissue Donation
SPONSOR(S): Healthcare Council and Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1350

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Committee on Health Innovation</u>	<u>9 Y, 0 N</u>	<u>Ciccione</u>	<u>Calamas</u>
2) <u>Healthcare Council</u>	<u>12 Y, 0 N, As CS</u>	<u>Ciccione</u>	<u>Gormley</u>
3) <u>Policy & Budget Council</u>	<u></u>	<u>Leznoff</u>	<u>Hansen</u>
4) <u></u>	<u></u>	<u></u>	<u></u>
5) <u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

CS/HB 455 provides legislative findings and intent relating to organ and tissue donation and the donor registry. The bill provides statutory revisions to encourage organ and tissue donation through enhanced education and donor registration by coordinating services among the Florida Coalition on Donation, Inc., a not-for-profit entity (Coalition), the Department of Highway Safety and Motor Vehicles (DHSMV) and the Agency for Health Care Administration (the Agency).

The bill designates the organ and tissue donor registry as the "Joshua Abbott Organ and Tissue Donor Registry" and transfers the maintenance of this registry from the Agency to the Coalition. The bill provides that the cost to maintain the registry is paid for by funds from a \$1 voluntary contribution per driver's license applicant, collected by DHSMV. 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 adopt rules to provide for verification of a donor's identify. The bill requires that the DHSMV and the Coalition share administrative responsibilities including submitting an annual report to the Legislature regarding donor registry and demographic information. The bill requires the Agency to maintain its oversight and certification responsibilities regarding organ procurement organizations, to assess fees for this purpose, and to deposit such fees in the Health Care Trust Fund.

The bill specifies that the Department of Motor Vehicles collect the voluntary contribution of \$1 per driver's license application and renewal fee and distribute to the Coalition to enhance donor education and to maintain the organ and tissue donor registry.

The bill has no fiscal impact on state or local governments.

The bill provides for an effective date of July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government—This bill reduces the Agency for Health Care Administration's responsibilities to maintain the Organ and Tissue Donor Registry by transferring this function to the private, not-for-profit Florida Coalition on Donation, Inc.

Empower families – this bill should provide greater opportunity for families, through enhanced organ donor education and registry information and accessibility, to make a life-saving gift after death.

B. EFFECT OF PROPOSED CHANGES:

The bill makes statutory changes relating to organ and tissue donation and the donor registry to create a more effective organ and tissue donation registry, continue organ procurement organization oversight and certification, and distribute donor information and driver's license contributions to enhance donor education and registry information. The bill renames the current Organ and Tissue Education and Procurement Trust Fund as the Organ and Tissue Procurement Trust Fund. The bill privatizes the maintenance of Florida's organ and tissue donor registry by transferring the registry from the Agency for Health Care Administration (Agency) to the Coalition for Donation (Coalition). The bill makes no changes to the Agency's organ procurement organization certification program and requires that the Agency continue to maintain its oversight of organ procurement organizations and to deposit such regulatory fees into the Health Care Trust Fund. The bill requires that the Department of Highway Safety and Motor Vehicles coordinate donor application and registry information with the Coalition and disburse monies collected from driver's license fee contributions to the Coalition to provide donor education and maintain the donor registry.

Background:

Florida Law

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 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 who may make a will may give all or part of his or her 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 indications by the decedent, or if the spouse made the gift, an objection by an adult son or daughter 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

¹ See Section 765.512(4), F. S.

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;
- An oral 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

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 primary reason for forming the Florida 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 Donation Process

Organ donation 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
- Lung
- Cornea
- Middle Ear

² See Section 765.512(3), F.S.

³ See Section 765.514, F.S.

⁴ See Section 756.516, F.S.

- Skin
- Bone
- Bone Marrow
- Heart valves
- Connective tissue

When an individual dies they are evaluated for donor suitability given their current and past medical history and their age. The Organ Procurement Organization (OPO) determines medical suitability for donation.⁵

Organ Procurement Organizations (OPOs)

The role of the organ procurement organization (OPO) is very important in the matching process. 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.

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

OPOs employ highly trained professionals called procurement coordinators who carry out the organization's mission. Once contacted by the hospital with a potential donor, 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 UNOS computer to find a match for the donated organs
- 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.⁶

Donor Procurement and Registry Program

The Agency for Health Care Administration (Agency) oversees Florida's organ procurement program. The Agency is required to certify OPOs, provide donor education, and maintain an organ and tissue donor registry⁷ in cooperation with the Department of Highway Safety and Motor Vehicles (DHSMV). The Agency provides DHSMV with donor registration forms who, in turn forwards the executed forms to the Agency. The Agency 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.⁸ There are currently over 3.2 million registry participants.⁹ According to the Agency, 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

⁵ See www.clevelandclinic.org

⁶ Cite. www.optn.org/transplantation

⁷ See s. 765-510-546, F.S.

⁸ Cite. www.fdhc.state.fl.us/MCHA/HealthFacilityRegulation/Organ/Donors

⁹ See the Agency for Health Care Administration Bill Analysis, February 19, 2007, on file with the Committee.

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.

National 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

Florida Statistics

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

C. SECTION DIRECTORY:

Section 1. Provides legislative intent relating to organ and tissue donations and use of funds.

Section 2. Amends s. 765.511, F.S., relating to the definition of the Florida Coalition on Donation; renumbers subsequent subsections.

Section 3. Amends s.765.512, F.S., relating to anatomical gifts and the organ and tissue donor registry.

Section 4. Amends s. 765.514, F. S., relating to executing anatomical gifts; renumbers subsequent sections.

Section 5. Amends s. 765.515, F.S., relating to anatomical gift information; donor documentation; donor registry maintenance and administration.

Section 6. Provides new language relating to the transfer of donor registry information from the Agency for Health Care Administration to the Florida Coalition on Donation.

Section 7. Provides new language designating the organ and tissue donor registry maintained by the Florida Coalition on Donation as the "Joshua Abbott Organ and tissue Donor Registry."

Section 8. Amends s. 765.515, F.S., provides new language relating to the expiration of this section upon completion of the transfer of the donor registry.

Section 9. Amends s. 765.516, F.S., relating to anatomical gift revocation.

Section 10. Amends s. 765.517, F.S., relating to donor rights and duties.

Section 11. Creates s. 765.5201, F.S., relating to the Florida Coalition on Donation meetings; provides duties and responsibilities of the Florida Coalition on Donation.

Section 12. Amends s. 765.521, F.S., relating to driver license donations; corrects cross reference.

¹⁰ Cite: www.Unos.org/data United network for Organ Sharing

¹¹ Cite: www.Unos.org/data United network for Organ Sharing.

Section 13. Amends s. 765.5215, F.S., relating to anatomical gift education programs; use of funds for education purposes: deletes obsolete language.

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

Section 15. Repeals s. 765.5216, F.S., relating the organ and tissue donor education panel.

Section 16. Amends s. 765.522, F.S., relating to duties of certain hospital administrators; liability of hospital administrators, organ procurement organizations, eye banks, and tissue banks.

Section 17. Amends s. 765.544, F.S., relating to fees and use of funds.

Section 18. Provides new language relating to use of organ and tissue trust fund monies regarding the transition of the organ and tissue donor registry and donor registration notification; expiration of this section upon completion of the donor registry transfer.

Section 19. Amends s. 215.20, F.S., relating to trust fund contributions to the General Revenue Fund.

Section 20. Amends s. 320.08047, F.S., relating to voluntary contribution for organ and tissue donor education.

Section 21. Amends s. 322.08, F.S., relating to license application voluntary contributions; corrects cross references.

Section 22. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

CS/HB 455 renames the current Florida Organ and Tissue Donor Education and Procurement Trust Fund as the Florida Organ and Tissue Procurement Trust Fund. The bill directs the Agency to continue regulating Organ Procurement Organizations and deposit these regulatory fees into the Health Care Trust Fund.

Donated funds collected by the \$1 per driver's license applicant and renewal process would be collected by the Department of Highway Safety and Motor Vehicles and distributed to the Florida Coalition on Donation for donor education and donor registry maintenance.

In fiscal year 2005-06, revenues to the Florida Organ and Tissue Donor Education and Procurement Trust Fund totaled \$431,663, \$285,122 received from regulatory activities and \$146,541 from donations forwarded through the Department of Highway Safety and Motor Vehicles. 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.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

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

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Agency for Health Care Administration: None.

The Department of Motor Vehicles: The Department of Motor Vehicles shall adopt rules to provide for donor identification verification.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill transfers administration of the organ and tissue donor registry from AHCA to the private, not-for-profit, Florida Coalition on Donation. It makes some administrative adjustments to reflect the new relationship between the Coalition and the DHSMV, and amends general provisions on organ and tissue donation.

Currently, the registry is maintained by AHCA via voluntary \$1 donations from drivers' license applicants and regulatory fees, which go into the currently named Organ and Tissue Donor Education and Procurement Trust Fund--renamed in the proposal as the Organ and Tissue Procurement Trust fund. The bill provides that \$1 voluntary donations would be collected by DHSMV and distributed directly to the Coalition. The bill also provides that AHCA regulatory fees be deposited into the Health Care Trust Fund. As a result, no new funds will flow into the Organ and Tissue Donor Procurement and Education Trust Fund, and it sunsets next year.

D. STATEMENT OF THE SPONSOR

Every 35 hours, someone who is awaiting an organ transplant in Florida will die because there are not enough organ donors. While we know we cannot stop this completely, CS/HB 455 will work to decrease this number by encouraging more people to register to become donors.

CH/HB 455 creates a private-public partnership of Florida's organ donor registry by moving it from the Agency for Health Care Administration and creating the Florida Coalition on Donation. Under the new partnership, the Coalition will work to maintain a website and registry to educate and encourage citizens to become donors and easily update the records of previously registered donors. The website also will allow procurement organizations (entities that secure organ and tissue donations) to quickly access information to determine an individual's donor designation.

Under the current system to become a donor a person has to go to the Department of Motor Vehicles (DMV) to register. This new website will allow for registration from anywhere. Organizations can hold registration drives, kiosks can be set up anywhere, and e-mails can be sent to encourage people to give the gift of life. There are a series of safeguards to ensure the person registering is in fact the person he or she is claiming to be.

In addition to the new website, the Coalition will be implementing educational campaigns to inform people about the benefits of organ and tissue donation. Currently AHCA develops programming to educate medical professionals, law enforcement agencies and officers, high school students, state and local government employees, and the public. The Coalition would expand that effort by adding programs that specifically target minority communities, where donor numbers tend to be lower.

In states that have adopted similar laws, there has been almost a doubling of the registry. This great bill has the potential to save more lives in Florida. It will give the people awaiting a transplant the opportunity for a full and productive life.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 6, 2007, the Health Innovation Committee adopted one amendment to the bill. This amendment does the following:

- Provides language regarding records and meetings of the Florida Coalition on Donation and clarifies that such records and meetings 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.

The bill was reported favorable with one amendment.

On March 27, 2007, the Health Care Council reported the bill favorable with council substitute. The council substitute differs from the bill that passed out of the Health Innovation Committee, as follows:

- Specifies that the authorization of the donor is included on the donor registry and provides that authorization may be made online.
- Provides that the Department of Highway Safety and Motor Vehicles adopt rules regarding online donor identity verification similar to online driver's license renewal identity verification, and provides that online authorization is legally binding.
- Designates the organ and tissue donor registry as the "Joshua Abbott Organ and Tissue Donor Registry."
- Provides that organ procurement organization fees assessed by the Agency for Health Care Administration are deposited into the Health Care Trust Fund.

The staff analysis reflects the CS/HB 455.