

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1485 Organ and Tissue Donation
SPONSOR(S): Healthcare Council; Hays
TIED BILLS: CS/HB 1487 **IDEN./SIM. BILLS:** CS/SB 2630

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Healthcare Council	17 Y, 0 N, As CS	Quinn-Gato/ Massengale	Gormley
2) Policy & Budget Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

CS/HB 1485 requires the Agency for Health Care Administration (“AHCA”) and the Department of Highway Safety and Motor Vehicles (“DHSMV”) to competitively procure and jointly contract with an entity for: (1) an interactive, web-based Organ and Tissue Donation Registry (the “Registry”); and (2) a continuing program to educate and inform medical professionals, state and local officers and employees, high school students, minorities and the public about anatomical gifts. The Registry shall be known as the “Joshua Abbott Organ and Tissue Registry,” and must allow donors to register online and which record organ and tissue donation records submitted through the driver’s license identification program or other sources. The Registry must be accessible 24 hours a day, seven days a week, and provide for secure and coded access through both electronic and telephonic means.

The bill requires the contractor provide a report to AHCA by December 31 of each year containing specified information and, in coordination with agency heads, determine convenient times, dates, and locations for providing education to employees. The contractor must use available community resources and may be assisted by volunteers to the maximum extent possible. The bill provides that costs for the Registry and education program are to be provided by AHCA from the Health Care Trust Fund and authorizes the contractor to receive and use voluntary contributions.

The bill modifies the standard form for designating a health care surrogate to allow a health care surrogate to make an anatomical gift on behalf of a decedent. The bill modifies existing law concerning the making of anatomical gifts by: (1) revising the priority list of individuals who may make an anatomical gift on behalf of a decedent to include adult grandchildren and a close personal friend of the decedent; (2) allowing a spouse to make an anatomical gift even if an adult child of the decedent objects; (3) specifying the means by which anatomical gifts may be made; (4) providing that anatomical gifts include “organs, tissues, or eyes” (5) providing that DHSMV must communicate a donor’s intent to either donate or withdraw a prior donation to the Registry; (6) removing provisions providing for DHSMV or AHCA to maintain the Registry; (7) including an authorization for a donor to remove his or her name from the Registry as a means of revoking an anatomical gift; (8) revising provisions relating to removal of organs after death; (9) revising current duties of hospital administrators to notify organ and tissue recovery programs or procurement organizations. Finally, the bill repeals ss. 765.5215 and 765.5216 relating to the education program for anatomical gifts and the organ and tissue donor education panel, respectively.

The bill has a fiscal impact of \$150,000 in AHCA’s Health Care Trust fund which is covered by revenues received from licenses, permits and fees and donations forwarded from DHSMV.

The effective date of the bill is July 1, 2008.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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DATE: 4/21/2008

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government—The bill reduces AHCA's responsibilities to maintain the Organ and Tissue Donor Registry by requiring AHCA and DHSMV to competitively procure and contract with a private entity to maintain and improve the Registry and provide education programs related to organ donation.

Empower families – This bill may 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:

Current Situation

Florida Law Relating to Organ Donation

In 1969, the Legislature enacted legislation modeled after the national Uniform Anatomical Gift Act, establishing a process by which individuals, their families, or others may donate organs and tissue.¹ 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 the person's body for transplantation or medical research. The statute provides that an adult donor's anatomical gift is irrevocable, unless revoked by the donor. The consent 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.²

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.³

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.⁴

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

¹ Part V of ch. 765, F.S.

² s. 765.512(4), F.S.

³ s. 765.512(3), F.S.

⁴ s. 765.514, F.S.

- 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.⁵

If the gift is made by a will, then the gift may be amended or revoked as provided above or in the same manner for amending or revoking wills.⁶

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 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. 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 AHCA. 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 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).

CS/SB 2102 (2008), which passed both the House and Senate, provides for the termination and transfer of remaining funds in the Florida Organ and Tissue Donor Education and Procurement Trust Fund to the Health Care Trust Fund within AHCA effective July 1, 2008. CS/SB 2101 has not yet been approved by the Governor.

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. Organs and tissues that can be transplanted include the liver, kidney, pancreas, heart, lung, intestine, cornea, middle ear, skin, bone, bone marrow, heart valves, and connective tissue. 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. As of

⁵ s. 765.516, F.S.

⁶ *Id.*

March 28, 2008, there were 98,177 candidates on the organ transplantation waiting list in the United States, 3,580 of which are on the waiting list in Florida. Of the total number of candidates on the waiting list in the United States, 1,966 are children.⁷ In Florida, there are a total of 77 children on the waiting list.⁸

Organ Procurement Organizations

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.⁹ OPOs coordinate the logistics between an organ donor's family, the donor organs, the transplant center(s), and the potential transplant candidate, and provide services to hospitals located within designated geographical areas of the U.S.

OPOs employ procurement coordinators to carry out the organization's mission. Once contacted by a hospital with a potential donor, the OPO staff:

- Conduct a thorough medical and social history of the potential donor to determine suitability of organs for transplantation;
- Work in coordination with hospital staff to communicate with the donor's family about transplantation;
- Ensure that donation decision is based on informed consent;
- Manage the clinical care of the donor;
- Enter the donor information into the United Network for Organ Sharing computer to find a match; 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 donation.

Once consent is obtained, all costs associated with the organ donation process are billed directly to the OPO.¹⁰

Donor Procurement and Registry Program

AHCA oversees Florida's organ procurement program. AHCA is required to certify OPOs, provide donor education, and maintain an organ and tissue donor registry¹¹ in cooperation with DHSMV. The agency provides DHSMV with donor registration forms who, in turn, forwards the executed forms to 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.¹² There are currently over 3.2 million registry participants.¹³

According to 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.¹⁴

⁷ www.Unos.org/data--United network for Organ Sharing; viewed on April 5, 2008.

⁸ www.Unos.org/data--United network for Organ Sharing; viewed on April 5, 2008.

⁹ See www.clevelandclinic.org; viewed April 5, 2008.

¹⁰ See <http://www.optn.org/about/transplantation/matchingProcess.asp>; viewed April 5, 2008.

¹¹ ss. 765.510-765.546, F.S.

¹² Agency for Health Care Administration 2008 Bill Analysis and Economic Impact Statement.

¹³ http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Organ_Donors/personal_stories.shtml; viewed on April 5, 2008.

¹⁴ See *supra* note 12.

Health Care Surrogate

A health care surrogate is a competent adult expressly designated by a principal to make health care decisions on behalf of the principal upon the principal's incapacity.¹⁵ Health care decisions include:

- 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.

Under current law, a health care surrogate is one of the persons authorized to make an anatomical gift on behalf of a decedent, unless the surrogate has actual notice of contrary indications by the decedent.¹⁶ The form suggested by statute for use in designating and health care surrogate excepts the health care surrogate's authority to make an anatomical gift.

Effect of Proposed Changes

The bill modifies the suggested form for designating a health care surrogate by removing language that precludes a health care surrogate designated by a principal from being able to make an anatomical gift on behalf of an incapacitated principal, and modifies cross references under the anatomical gift laws to clarify the purposes for which anatomical gifts can be made, which is effective upon the death of the principal or donor. In making these changes, the bill reorganizes provisions in current law for clarity purposes.

The bill provides that a health care surrogate designated by the donor may give all or any part of a deceased donor's body for the purposes specified in s. 765.513, F.S., unless actual notice of contrary indications were made by the donor prior to death. Further the bill adds an adult grandchild and a close personal friend of the decedent, as defined in s. 765.101, F.S., as persons that may make an anatomical gift on behalf of the deceased donor in the absence of an executed agreement to make such gift or a designation of a health care surrogate. The bill eliminates provisions that preclude a spouse from donating all or part of the decedent's body if the decedent's adult son or daughter objects, and provides that such gift cannot be made if there is evidence that establishes that the decedent would have objected to the gift on any grounds, not just religious grounds.

The bill creates additional methods by which an individual can make an anatomical gift, which include:

- Signing an organ and tissue donor card
- Registering online with the organ and tissue donor registry
- Signifying an intent to donate on a driver's license or identification card issued by DHSMV, revocation, suspension, expiration or cancellation of which does not invalidate the gift
- Expressing a wish to donate in a living will or other advance directive
- Including such a wish in an executed will

Further, the bill modifies the form of the uniform donor card provided for in statute, which authorizes the donation of "organs or other parts" by, instead, expressing that "organs, tissues and eyes" may be donated. The bill removes from s. 765.414, F.S., public policy provisions regarding restrictions on possible recipients of anatomical gifts; however, such restrictions are stated in s. 765.513, F.S., which

¹⁵ Section 765.101(16), F.S.

¹⁶ Section 765.512(2), F.S.

is not modified by this bill. The bill also modifies existing provisions which allow an attending physician to accept an anatomical gift as a donee if the donee is not specified by name, but which prevent the physician from participating in procedures for removing or transplanting a part. Instead, the bill provides that a donee is an entity listed in s. 765.513 and may be specified by name.

The bill amends the current organ and tissue donation registry program operated by AHCA and DHSMV by: (1) requiring that completed donor registration cards be delivered to DHSMV which, in turn, shall communicate the donor's intent to the new, outsourced organ and tissue registry created in the bill (see below); (2) requiring that DHSMV communicate the withdrawal of a gift to the organ and tissue donation registry for purposes of updating the registry; and (3) eliminating the requirement that DHSMV and AHCA develop and implement the electronic organ and tissue donation registry.

The bill creates s. 765.5155 relating to the organ and tissue donor registry and education program, which shall be known as the "Joshua Abbott Organ and Tissue Registry." In doing so, the bill provides legislative findings concerning:

- The shortage of organ and tissue donors in Florida
- The need to encourage minority populations in the state to donate organs and tissue
- The belief that a statewide online donor registration process for organ and tissue donors coupled with an enhanced donor education program will lead to an increase in the number of organ and tissue donors registered in the state

The bill requires AHCA and DHSMV to jointly contract, through competitive solicitation pursuant to chapter 287, with a private entity for the operation of an organ and tissue donor registry and education program. The bill requires that the competitive procurement occur pursuant to chapter 287, notwithstanding any exemption provided for in s. 287.057(5)(f), F.S., and requires priority to be given to existing nonprofit groups that are based within the state, have expertise working with organ and tissue procurement organizations, have expertise in conducting statewide organ and tissue donor public education campaigns, and represent the needs of the organ and tissue donation community in the state.

The contractor must develop, implement, and maintain an interactive, web-based organ and tissue donation registry that allows for organ donor registration and the recording of organ and tissue donation records submitted through the driver's license identification program or other sources through electronic means. The registry must be immediately accessible 24-hours a day, seven days a week through electronic and telephonic means, and must be accessed through coded and secure means to protect the integrity of the data in the registry. The contractor must also develop a continuing 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 Florida law related to anatomical gifts and the need for anatomical gifts in the state. By December 31 of each year, the contractor must submit an annual report to AHCA detailing the following:

- The number of donors on the registry and an analysis of the registration rates by location and method of donation
- The characteristics of donors as determined from registry information submitted directly by donors or by DHSMV
- The annual dollar amount of voluntary contributions received by the contractor
- A description of the educational campaigns and initiatives implemented during the year and an evaluation of their effectiveness in increasing enrollment on the registry
- An analysis of the registry compared with other states' donor registries

In support of the program, the program may use volunteers to the maximum extent possible, and must use available community resources. The contractor is required to coordinate with the head of an applicable entity or his or her designee, to establish convenient times, dates, and locations for educating that entity's employees in furtherance of its education program.

Costs that are designated for maintaining the registry and education programs are to be paid by AHCA from the Health Care Trust Fund pursuant to ss. 320.8047 and 322.08, F.S., and the contractor is authorized to receive and use voluntary contributions to help support the purposes of the program.

The bill amends terms for revoking anatomical gifts by including a provision that allows a gift to be revoked when a donor removes his or her name from the organ and tissue registry, and provides new provisions that allow an organ procurement organization to surgically remove an organ or penetrate a body cavity for the purpose of donation if it has been verified that the deceased individual consented to donate his or her organs in the organ and tissue donation registry. This change creates an addition to current law, which allows such when a properly executed donor card is located or, if such cannot be located, a person authorized to make an anatomical gift on behalf of a deceased individual (as provided for in s. 765.512(2)-(3)) has granted such permission.

The bill specifies that DHSMV may include a notation on an individual's driver license or identification card that, in addition to donating his or her organs and tissue, the individual intends to donate his or her eyes. Moreover, the bill amends the requirement in existing law that hospital administrator or designee access the organ and tissue donor registry to ascertain the existence of a donor card or document executed by the decedent that has not been revoked. Instead, the hospital administrator must notify the appropriate organ, eye, or tissue recovery program, which shall then be responsible for determining whether the decedent has expressed an intent to donate organs, eyes or tissue through the donor registry, a donor card, the driver's license or identification program at DHSMV, or through other means. If no such express intent is located by the organ, eye, or tissue recovery program, then the program may request permission from a health care surrogate or other persons specified in s. 765.512(3). Additionally, the bill requires that the hospital administrator or designee to, at or near the time of death, notify the affiliated organ procurement organization designated by the United States Department of Health and Human Services of the potential organ donor, and provides that transplant lists are those that are approved or mandated by the Organ Procurement and Transplantation Network or its agents, in lieu of the United Network for Organ Sharing, which is in current law.

Finally, the bill repeals ss. 765.5215 and 765.5216, F.S., relating to the education program concerning anatomical gifts and the organ and tissue donor education panel. Further, the bill includes a number of deletions of cross references and clean-up language to conform to the changes in the bill and provide clarity in existing law.

The effective date of the bill is July 1, 2008.

C. SECTION DIRECTORY:

Section 1. Amends s. 765.203, F.S.; relating to the suggested form of designating a health care surrogate.

Section 2. Amends s. 765.512, F.S.; relating to persons who may make anatomical gifts.

Section 3. Amends s. 765.514, F.S.; relating to the manner of making anatomical gifts.

Section 4. Amends s. 765.515, F.S.; relating to the delivery of donor documents; organ and tissue donation registry.

Section 5. Creates s. 765.5155, F.S.; relating to organ and tissue donor registry; education program.

Section 6. Amends s. 765.516, F.S.; relating to amendment of the terms or the revocation of the gift.

Section 7. Amends s. 765.517, F.S.; relating to rights and duties at death.

Section 8. Amends s. 765.521, F.S.; relating to donations as part of drivers license or identification care process.

Section 9. Amends s. 765.522, F.S.; relating to duty of certain hospital administrators; liability of hospital administrators; organ procurement organizations, eye banks, and tissue banks.

Section 10. Repeals ss. 765.5215 and 765.5216, F.S.; relating to education program relating to anatomical gifts and organ and tissue donor education panel, respectively.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

In Fiscal Year 2006-2007, revenues to the Florida Organ and Tissue Donor Education and Procurement Trust Fund totaled \$392,071, with \$256,377 received from Licenses and Permits and Fees and \$135,694 from donations forwarded through the Department of Highway Safety and Motor Vehicles (DHSMV).

2. Expenditures:

The agency estimates it will require \$150,000 per year in budget authority to contract for the development and operation of the organ donor registry. The agency has sufficient budget authority to cover this cost.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will likely create greater opportunity for families, through enhanced organ donor education and registry information and accessibility, to make a life-saving gift after death.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This legislation does not appear to require counties or municipalities to spend funds or take any action requiring the expenditure of funds; reduce the authority that municipalities or counties have to

raise revenue in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

No sponsor statement provided.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On April 17, 2008, the Healthcare Council adopted four amendments to the bill. The amendments do the following:

- The first amendment modifies the bill to add a close personal friend of the decedent to the priority list of individuals who may make an anatomical gift on behalf of a decedent.
- The second amendment modifies provisions in the bill to provide that the contractor administering the organ and tissue donation registry and education program in the bill must coordinate with the head of agencies to establish convenient times, dates, and locations for employee education regarding organ donation.
- The third amendment removed provisions in the bill providing AHCA with rulemaking authority to allow researchers to access organ and tissue donation records upon agreeing to comply with certain requirements. This provision was, instead, included in HB 1487 as an exception to the public records exemption created in that bill.
- The fourth amendment changes the trust fund from which funds will be used to maintain the donor registry from the Florida Organ and Tissue Donor Education and Procurement Trust Fund to the Health Care Trust Fund.

The bill, as amended, was reported favorably by the Healthcare Council as a Council Substitute. The analysis reflects the Council Substitute.