

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 766

INTRODUCER: Health Regulation Committee and Senator Oelrich

SUBJECT: Anatomical Gifts

DATE: February 18, 2009 REVISED: _____

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

Please see Section VIII. for Additional Information:

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

I. Summary:

The committee substitute revises Florida’s anatomical gift law to incorporate certain provisions from the Revised Uniform Anatomical Gift Act (2006), make technical corrections, and improve the grammatical fluency of the law. Substantive changes include:

- Defining what constitutes “reasonably available” when a procurement organization must contact a person for action with respect to making, amending, or revoking an anatomical gift;
- Eliminating a hospital or physician as an authorized donee of an anatomical gift;
- Establishing a priority for the purposes of an anatomical gift if a priority is not designated in the document of gift so that an anatomical gift will be used first for transplantation or therapy if suitable, then for research or education;
- Revising the manner in which a donor may amend or revoke an anatomical gift;
- Providing that an oral statement that was made by a donor to amend or revoke an anatomical gift is effective only if the procurement organization, transplant hospital, or physician has actual notice of the amendment or revocation before an invasive procedure is made to the decedent’s body or the recipient’s body;
- Authorizing a physician who attends a donor at the donor’s death or who certifies the death, or the donor’s primary care physician to participate in the procedures to preserve the donor’s

organs or tissues after death, and that these physicians may serve in a voluntary capacity on the board of directors of a procurement organization or similar organization;

- Eliminating the need to act without negligence in order for certain immunities to apply;
- Providing for immunity to a person making an anatomical gift and the donor's estate for the making or use of the anatomical gift;
- Authorizing the reliance on representations as to the relationship of a person to the donor with respect to an anatomical gift, absent knowledge that the representation is untrue;
- Providing for the validity of and the choice of Florida law to interpret a document of gift; and
- Requiring a medical examiner and procurement organization to cooperate in order to maximize opportunities to recover anatomical gifts and for the Florida Medical Examiners Commission to adopt rules establishing responsibilities of each in furtherance of this objective.

This committee substitute creates s. 765.547, F.S., and substantially amends the following sections of the Florida Statutes: 765.511, 765.512, 765.513, 765.514, 765.515, 765.5155, 765.51551, 765.516, 765.517, 765.521, 765.522, 765.53, 765.541, 765.542, 765.543, 765.544, 765.545, 408.802, and 408.820.

II. Present Situation:

Florida Law Relating to Organ Donation

In 1969, the Florida Legislature enacted legislation modeled after the national Uniform Anatomical Gift Act (UAGA). Part V of ch. 765, F.S., establishes 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. Last year, the Legislature established the Joshua Abbott Organ and Tissue Registry (“online registry”) to increase and facilitate the donation and availability of organs, eyes, and tissue.

Section 765.512, F.S., identifies who may make an anatomical gift, including:

- A donor of his or her body or part who must be eligible to make a will.¹ This requires the donor to be competent (of sound mind) and either 18 or more years of age or an emancipated minor.²
- A health care surrogate is authorized to make an anatomical gift unless the health care surrogate knows that the principal intended otherwise.
- If a decedent has not made an anatomical gift or designated a health care surrogate, and provided there is no evidence to the contrary of the deceased donor's wishes, other 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, an adult grandchild, a grandparent, a close personal friend,³ the guardian of the person at the time of death, or a representative ad litem

¹ s. 765.512(1), F.S.

² s. 732.501, F.S.

³ A “close personal friend” is defined in s. 765.101, F.S., and means any person 18 years of age or older who has exhibited special care and concern for the patient, and who presents an affidavit to the health care facility or to the attending or treating physician stating that he or she is a friend of the patient; is willing and able to become involved in the patient's health care;

appointed by the court.⁴ These individuals are listed in the order of priority and an individual in a lower class may not make a gift if the person has actual notice of opposition by a member of a prior class.

A person may make an anatomical gift by:

- Signing an organ and tissue donor card (an example of a donor card is provided in law);
- Registering online with the organ and tissue donor registry;
- Signifying an intent to donate on his or her driver's license or identification card issued by the Department of Highway Safety and Motor Vehicles (DHSMV);
- Expressing a wish to donate in a living will or other advance directive;
- Executing a will or other signed document indicating the intention to make an anatomical gift. 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;⁵ or
- If a gift of a decedent's body or part is made by a health care surrogate or a member of the designed classes of other persons who may make a donation, by executing a document signed by the person or made by that person's witnessed telephonic discussion, telegraphic message, or other recorded message.

An anatomical gift made by the donor, 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 actual notice that a gift by a member of a class is opposed by a member of a prior class.

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;
- A signed document found on the donor's person or in the donor's effects;
- A donor removing his or her name from the organ and tissue donor registry; or
- The amendment or revocation of the will, if the gift is made by a will.⁶

Personal identifying information contained in a motor vehicle record, which includes a motor vehicle operator's permit or identification card issued by the DHSMV is confidential and exempt from the public records law under s. 119.0712(2), F.S. In addition, s. 765.51551, F.S., makes confidential and exempt personal identifying information in the organ and tissue donor registry.

and has maintained such regular contact with the patient so as to be familiar with the patient's activities, health, and religious or moral beliefs.

⁴ s. 765.512(3), F.S.

⁵ s. 765.514, F.S.

⁶ s. 765.516, F.S.

Sections 320.08047 and 322.08, F.S., provide that individuals may, as a part of paying vehicle license taxes or applying for a driver's license, make a voluntary contribution of \$1 to be deposited in the Health Care Trust Fund for organ and tissue donor education and for maintaining the organ and tissue donor registry.

Purposes and Uses of Anatomical Gifts

Anatomical gifts may be made for purposes of transplantation, therapy, research, or education.⁷ In general terms, transplantation refers to the removal and grafting of one individual's body part into the body of another individual. 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. Research is a process of testing and observing, the goal of which is to obtain generalizable knowledge, while therapy involves the processing and use of a donated part to develop and provide amelioration or treatment for a disease or condition. Education is intended to use the whole body or parts to teach medical professionals and others about human anatomy and its characteristics.⁸

Organ Procurement Organizations (OPOs)

The role of the OPO is very important in the organ transplantation 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). State certification is required for in state and out-of-state OPOs, tissue banks, and eye banks that retrieve, process, store or distribute organs and tissues in Florida. The Agency for Health Care Administration (Agency) is responsible for certifying and monitoring procurement organizations. 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 a hospital with a potential donor, the coordinator:

- Conducts a thorough medical and social history of the potential donor to help determine the suitability of organs for transplantation;
- Works with hospital staff to offer the option of donation to the donor family;
- Ensures that the decision to donate is based on informed consent;
- Manages the clinical care of the donor once consent for donation is finalized;
- Enters the donor information into the United Network for Organ Sharing computer to find a match for the donated organs; and

⁷ s. 765.513, F.S.

⁸ Revised Uniform Anatomical Gift Act (2006) last revised or amended in 2007; Comments by the National Conference of Commissioners on Uniform State Laws on the Revised Uniform Anatomical Gift Act (2006) under Section 5 found at <<http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63>> (last visited on February 12, 2009).

- Coordinates the organ recovery process with the surgical teams and provides 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.⁹

The Medicare Conditions of Participation require Medicare-participating hospitals to maintain affiliation agreements with OPOs to notify the OPO of individuals whose death is imminent or who have died in the hospital.¹⁰

Donor Procurement and Registry Program

The Agency oversees Florida's organ procurement program. The Agency is required to certify OPOs, provide donor education, and maintain an organ and tissue donor registry¹¹ in cooperation with the DHSMV. The Agency provides the 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.¹² There are currently approximately 5 million registry participants.¹³

The 2008 Legislature authorized the Agency and the DHSMV to contract for an online organ and tissue donor registry to replace the registry information process that has been maintained since 1998 with equipment that is considered obsolete by today's data systems standards. The Request for Proposals for a contractor to develop and operate a web-based organ and tissue donor registry and to provide a statewide education program was released on December 8, 2008. The anticipated contract start date is April 1, 2009.

Organ Transplantation Statistics

As of February 12, 2009, there were 100,787 candidates on the organ transplantation waiting list in the United States, and 3,575 candidates on the organ transplantation waiting list in Florida. Every day in the United States approximately 19 people die waiting for an organ¹⁴ From January through November 2008, 20,008 transplants were performed using organs from deceased donors.¹⁵

⁹ Cite. <http://www.optn.org/about/transplantation/matchingProcess.asp> (last visited on February 12, 2009).

¹⁰ 42 C.F.R. 482.45

¹¹ See ss. 765.510-765.546, F.S.

¹² See the Agency bill analysis, February 19, 2007, on file with the committee, Page 1.

¹³ The Agency presentation to the Senate Health Regulation Committee on January 14, 2009.

¹⁴ *The 2006 Revised Uniform Anatomical Gift Act-A Law to Save Lives* by Sheldon F. Kurtz, J.D., Christina Woodward Strong, J.D., and David Gerasimow, Student Research Assistant, Health Law Analysis, February 2007, found at <<http://www.anatomicalgiftact.org/Uploads/kurtzarticle.pdf>> (last visited on February 12, 2009).

¹⁵ United Network for Organ Sharing found at: <<http://www.unos.org/data/default.asp?displayType=usData>> (last visited February 27, 2009).

Uniform Anatomical Gift Act¹⁶

The National Conference of Commissioners on Uniform State Laws (NCCUSL) has been at the forefront of organ donation law since the promulgation of the original UAGA nearly four decades ago. In 2006, after more than 2 years of exhaustive study, the NCCUSL promulgated the Revised UAGA (2006) as a replacement for both the 1968 and 1987 versions of the Act. The 2006 revision was prepared with the active participation of the whole range of stakeholders. The Revised UAGA facilitates donations and modernizes the act to reflect changes in federal law and regulations governing organ procurement and allocation as well as changes in organ donation practices.¹⁷ Prior to the 2009 Legislative Sessions, 34 states have adopted the Revised UAGA of 2006. Some of these states have enacted variations to address state-specific concerns.

Guardianship

A guardian must be appointed by a court and must be expressly authorized to make health care decisions or designated as a plenary guardian to exercise all legal rights and powers of the ward. A court considers whether the ward has executed any valid advance health care directives when determining what, if any, authority to grant to the guardian regarding health care decisions. If after the appointment of a surrogate, a court appoints a guardian, the surrogate may continue to make health care decisions for the principal, unless the court has modified or revoked the authority of the surrogate.¹⁸

Florida Medical Examiners Commission

The Medical Examiners Commission is created in The Medical Examiners Act¹⁹ within the Department of Law Enforcement. Among other duties, the commission is to:

- Initiate cooperative polices with any agency of the state or political subdivisions;
- Investigate violations of the Medical Examiners Act and remove or suspend district medical examiners;
- Oversee the distribution of state funds for the medical examiner districts; and
- Ensure minimum and uniform standards of excellence, performance of duties, and maintenance of records so as to provide useful and adequate information to the state in regard to causative factors of those deaths investigated.

Rule 11G-2.006, F.A.C., provides for duties and standards of care of a medical examiner and incorporates by reference “Practice Guidelines for Florida Medical Examiners, Sponsored by the Florida Association of Medical Examiners.” These guidelines address a range of responsibilities, including activities related to anatomical gifts.

¹⁶ The Uniform Anatomical Gift Act (2006), last revised in 2007 is available at <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63> (last visited on February 12, 2009).

¹⁷ Home Page of the NCCUSL found at: <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=0&tabid=1> (last visited on February 12, 2009).

¹⁸ s. 765.205(3), F.S., and s. 744.3115, F.S.

¹⁹ Ch. 406, F.S.

III. Effect of Proposed Changes:

Section 1. Amends s. 765.511, F.S., to provide for additional definitions of terms used in part V of ch. 765, F.S. These terms include: “agency,” “anatomical gift,” “decedent,” “disinterested witness,” “document of gift,” “donor registry,” “eye bank,” “guardian,” “identification card,” “organ procurement organization,” “part of the body” or “body part,” “procurement,” “procurement organization,” “reasonably available,” “record,” “sign” or “signed,” and “tissue bank.”

Section 2. Amends s. 765.512, F.S., related to persons who may make an anatomical gift, to make technical changes so that the terminology is consistent with defined terms.

Section 3. Amends s. 765.513, F.S., to revise provisions related to donees of anatomical gifts. The committee substitute eliminates a hospital, surgeon, or physician for purposes of medical or dental education, research, therapy, or transplantation as a potential donee of an anatomical gift. The committee substitute also eliminates the advance of medical or dental science as a potential purpose or use of an anatomical gift. This section establishes a priority for the purposes of an anatomical gift if a priority is not designated in the document of gift so that an anatomical gift will be used first for transplantation or therapy if suitable, then for research or education.

Section 4. Amends s. 765.514, F.S., related to the manner in which a donor might make an anatomical gift of all or part of his or her body, to make technical changes so that the terminology is consistent with defined terms.

Section 5. Amends s. 765.515, F.S., related to delivery of a document of gift, to make technical changes so that the terminology is consistent with defined terms.

Section 6. Amends s. 765.5155, F.S., related to the organ and tissue donor registry and education program, to make technical changes so that the terminology is consistent with defined terms.

Section 7. Amends s. 765.51551, F.S., related to the public records exemption for personal identifying information in the donor registry, to make technical changes so that the terminology is consistent with defined terms.

Section 8. Amends s. 765.516, F.S., to revise the provisions related to a donor amending or revoking an anatomical gift. If a donor executes and delivers a signed statement to the donee, the committee substitute requires the signed statement to be witnessed by at least two adults, one of whom must be a disinterested witness. An oral statement made by a donor to amend or revoke an anatomical gift is effective only if the procurement organization, transplant hospital, or physician has actual notice of it before an incision is made to the decedent’s body or an invasive procedure to prepare the recipient has begun. The committee substitute provides for two additional methods by which a donor may amend or revoke a gift: executing a subsequent document of gift which amends or revokes the previous gift or portion of the gift either expressly or by inconsistency, and destroying or cancelling the document of gift or the portion of the document of gift used to make the gift with the intent to revoke the gift. Finally, the committee substitute corrects a cross-reference so that a revocation or amendment to a gift that was made in a will is properly executed.

Section 9. Amends s. 765.517, F.S., to:

- Authorize a physician who attends the donor at the donor's death, the physician who certifies the donor's death, or the donor's primary care physician to participate in, but not obstruct the procedures to preserve the donor's organs or tissues. These physicians may not be paid or reimbursed for this participation, be employed by or associated with a procurement organization, and may not participate in the procedures for removing or transplanting a part. However, these physicians may serve in a voluntary capacity on the board of directors of a procurement organization or similar organization;
- Expand the immunity provision to a person who attempts to act in good faith and in accord with the terms of Florida's anatomical gift law or the anatomical gift laws of another state or foreign country so that the person is not liable for damages in any civil action, subject to prosecution in any criminal proceeding, or liable in any administrative proceeding. In addition, the committee substitute extends the immunity from liability in any administrative proceeding to a person who acts in good faith and in accord with applicable anatomical gift laws. These immunities attach whether or not the person was acting negligently;
- Provide that the person making an anatomical gift and the donor's estate are not liable for any injury or damages that result from the making or use of the gift; and
- Authorize a person to rely upon the representation of an individual regarding his or her relationship to the donor or prospective donor, unless the person knows that the representation is untrue.

Section 10. Amends s. 765.521, F.S., related to donations as a part of the driver's license or identification card process, to make technical changes so that the terminology is consistent with defined terms.

Section 11. Amends s. 765.522, F.S., related to responsibilities of hospitals and procurement organizations, to make technical changes so that the terminology is consistent with defined terms and to address issues concerning the validity of a document of gift and conflict of laws. Specifically, this section is amended to provide that:

- A document of gift is valid if executed in accordance with:
 - Florida's anatomical gift laws in part V of ch. 765, F.S.; or
 - The laws of the state or country where it was executed and where the person making the anatomical gift was domiciled, has a place of residence, or was a citizen at the time the document of gift was executed;
- If a document of gift is valid under these provisions then Florida's laws govern the interpretation of the document of gift; and
 - A document of gift or amendment is presumed to be valid unless it was not validly executed or was revoked.

Section 12. Amends s. 765.53, F.S., related to the Organ Transplant Advisory Council, to make technical changes so that the terminology is consistent with defined terms.

Section 13. Amends s. 765.541, F.S., related to the certification of procurement organizations by the Agency, to make technical changes so that the terminology is consistent with defined terms.

Section 14. Amends s. 765.542, F.S., related to the certification of procurement organizations by the Agency, to make technical changes so that the terminology is consistent with defined terms.

Section 15. Amends s. 765.543, F.S., related to the Organ and Tissue Procurement and Transplantation Advisory Board, to make technical changes so that the terminology is consistent with defined terms.

Section 16. Amends s. 765.544, F.S., related to fees for certification as a procurement organization, to make technical changes so that the terminology is consistent with defined terms.

Section 17. Amends s. 765.545, F.S., related to physician supervision of cadaveric organ and tissue procurement coordinators, to make technical changes so that the terminology is consistent with defined terms.

Section 18. Creates s. 765.547, F.S., to require cooperation between medical examiners and procurement organizations and require the Florida Medical Examiners Commission to adopt rules establishing cooperative responsibilities between medical examiners and procurement organizations in order to facilitate and expedite the medical examiner's responsibilities and maximize the recovery of anatomical gifts. The committee substitute provides that the anatomical gifts law in part V of ch. 765, F.S., does not supersede any part of ch. 406, F.S., relating to medical examiners and the disposition of dead bodies.

Section 19. Amends s. 408.802, F.S., to clarify that eye procurement organizations are subject to the general health care licensing provisions in the Health Care Licensing Procedures Act found in part II of ch. 408, F.S.

Section 20. Amends s. 408.820, F.S., to clarify that eye procurement organizations are subject to the same exemptions from the general health care licensing provisions in the Health Care Licensing Procedures Act as organ and tissue procurement organizations.

Section 21. Provides an effective date of July 1, 2009.

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 provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Medical Examiners Commission within the Department of Law Enforcement may incur incidental costs related to adopting additional rules to govern the working relationships of medical examiners and procurement organizations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS by Health Regulation Committee on February 18, 2009:**

- Further conforms the use of defined terms;
- Provides that an oral statement amending or revoking an anatomical gift is only effective if the procurement organization or physician has “actual notice” of it before an invasive procedure occurs rather than “knowing” of it (this eliminates imputed knowledge, for example, when they should have known about an oral amendment or revocation);
- Reinstates the prohibition on a physician who attends the donor’s death or certifies the death from being associated with a procurement organization, but authorizes the physician to serve in a voluntary capacity on the board of directors of a procurement organization or similar organization; and
- Provides more specificity in the rulemaking authority granted to the Florida Medical Examiners Commission to facilitate and expedite completion of the medical examiner’s responsibilities in a manner that will maximize opportunities to recover anatomical gifts.

B. Amendments:

None.

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