

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 209 Anatomical Gifts
SPONSOR(S): Civil Justice & Courts Policy Committee; Health Care Regulation Policy Committee; Schwartz
TIED BILLS: None IDEN./SIM. BILLS: CS/SB 766

Table with 4 columns: REFERENCE, ACTION, ANALYST, STAFF DIRECTOR. Rows include Health Care Regulation Policy Committee, Civil Justice & Courts Policy Committee, and Health & Family Services Policy Council.

SUMMARY ANALYSIS

The bill revises Florida’s anatomical gift law to incorporate certain provisions from the Revised Uniform Anatomical Gift Act (2006) and make technical corrections. The bill:

- Defines what constitutes “reasonably available” when a procurement organization must contact a person for action with respect to making, amending, or revoking an anatomical gift;
• Eliminates a hospital or physician as an authorized donee of an anatomical gift;
• 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;
• Revises the manner in which a donor may amend or revoke an anatomical gift;
• Provides 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 knows of the amendment or revocation before an invasive procedure is made to the decedent’s body or the recipient’s body;
• Provides that in addition to a physician who attends a donor at the donor’s death or who certifies the death, the patient’s primary care physician may participate in the procedures to preserve the donor’s organs or tissues after death regardless of the number of qualified personnel present;
• Clarifies that a physician may serve on a voluntary capacity on the Board of Director’s of a procurement organization or may participate on any board, council, commission, or similar body relating to the organ and tissue procurement system;
• Provides for immunity to a person making an anatomical gift and the donor’s estate for the making or use of the anatomical gift;
• Authorizes 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;
• Provides for the validity of and the choice of Florida law to interpret a document of gift; and
• Requires 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 governing these working relationships.

The bill does not appear to have a fiscal impact on state or local government revenues or expenditures.

The effective date of the bill is July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Law

In 1969, the Legislature enacted legislation modeled after the national Uniform Anatomical Gift Act. Part V of chapter 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 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 makes 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 donor or actual notice that a member of a prior class opposes the gift.¹

In the absence of a written document making 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

¹ Section 765.512(4), F.S.

² Section 765.512(3), F.S.

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.

Purpose and Uses of Anatomical Gifts

Anatomical gifts may be made for purposes of transplantation, therapy, research, or education.⁵ In general terms, transplantation refers to the removal and grafting of one individual's body part into the body of another individual. Transplantation is necessary because the recipient's organ has failed or has been damaged by disease or injury. Research is a process of testing and observing, the goal of which is to obtain generalized 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.⁶ The need for organ donors is much greater than the number of people who actually donate. In 2008, there were 14,200 organs donated.⁷ As of March 7, 2009, there were 101,238 candidates on a waiting list for an organ.⁸ 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.⁹

Organs and tissues that can be transplanted include:

- Liver;
- Kidney;
- Pancreas;
- Heart;
- Lung;
- Intestine;
- Lung;

³ Section 765.514(1)(f), F.S.

⁴ Section 756.516(1), F.S.

⁵ Section 765.513, F.S.

⁶ 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). Available online at: <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63>. Last accessed on March 18, 2009.

⁷ The Organ Procurement and Transplantation Network, Data: Donors Recovered in the U.S. by Donor Type. Available online at: <http://www.optn.org/data/>. Last accessed on March 18, 2009.

⁸ The Organ Procurement and Transplantation Network, Data: Waiting List Candidates (March 18, 2009). Available online at: <http://www.optn.org/data/>. Last accessed on March 18, 2009.

⁹ Chapter 2008-222, L.O.F.

- Cornea;
- Middle Ear;
- Skin;
- Bone;
- Bone Marrow;
- Heart valves; and
- Connective tissue.

When an individual dies, he or she is evaluated for donor suitability given their current and past medical history and their age. The Organ Procurement Organizations (OPOs) determine the medical suitability of a donation.

Organ Procurement Organizations (OPOs)

OPOs become involved when a patient is identified as brain dead and therefore becomes a potential donor.¹⁰ The OPOs coordinate 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 Organ Procurement and Transplantation Network. Each OPO has its own board of directors and a medical director who is usually a transplant surgeon or physician.¹¹

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:¹²

- 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; 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.¹³

Effect of Proposed Changes

The bill 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.

The bill:

- Provides definitions for agency, anatomical gift, decedent, department, disinterested witness, document of gift, donor registry, eye bank, guardian, identification card, organ procurement

¹⁰ The Organ Procurement and Transplantation Network, About Transplantation: Matching Process. Available online at: <http://www.optn.org/about/transplantation/matchingProcess.asp> (last visited on March 7, 2009).

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

organization, part of the body or body part, procurement, procurement organization, reasonably available, record, sign or signed, and tissue bank;

- Defines what constitutes “reasonably available” when a procurement organization must contact a person for action with respect to making, amending, or revoking an anatomical gift;
- Eliminates a hospital or physician as an authorized donee of an anatomical gift;
- 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;
- Revises the manner in which a donor may amend or revoke an anatomical gift;
- Provides 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 knows of the amendment or revocation before an invasive procedure is made to the decedent’s body or the recipient’s body;
- Provides that in addition to a physician who attends a donor at the donor’s death or who certifies the death, the patient’s primary care physician may participate in the procedures to preserve the donor’s organs or tissues after death regardless of the number of qualified personnel present;
- Clarifies that a physician may serve on a voluntary capacity on the Board of Director’s of a procurement organization or may participate on any board, council, commission, or similar body relating to the organ and tissue procurement system;
- Provides that a person who attempts to act in good faith and without negligence under the anatomical gift laws of another state or foreign country may not be subject to any civil action for damages, any criminal proceeding, or discipline, penalty or liability in any administrative proceeding;
- Provides for immunity to a person making an anatomical gift and the donor’s estate for the making or use of the anatomical gift;
- Authorizes 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;
- Provides for the validity of and the choice of Florida law to interpret a document of gift; and
- Requires 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 governing these working relationships.

B. SECTION DIRECTORY:

Section 1 amends s. 765.511, F.S., relating to definitions.

Section 2 amends s. 765.512, F.S., relating to persons who may make an anatomical gift.

Section 3 amends s. 765.513, F.S., relating to donees and purposes for which anatomical gifts may be made.

Section 4 amends s. 765.514, F.S., relating to the manner of making anatomical gifts.

Section 5 amends s. 765.515, F.S., relating to the delivery of a donor document.

Section 6 amends s. 765.5155, F.S., relating to the donor registry and education program.

Section 7 amends s. 765.51551, F.S., relating to the donor registry and public records exemption.

Section 8 amends s. 765.516, F.S., relating to a donor amendment or revocation of an anatomical gift.

Section 9 amends s. 765.517, F.S., relating to the rights and duties at death.

Section 10 amends s. 765.521, F.S., relating to donations as part of driver license or identification card process.

Section 11 amends s. 765.522, F.S., relating to the duty of hospital administrators, liability of hospital administrators and procurement organizations.

Section 12 amends s. 765.53, F.S., relating to the organ transplant advisory council membership and responsibilities.

Section 13 amends s. 765.541, F.S., relating to the certification of procurement organizations.

Section 14 amends s. 765.542, F.S., relating to requirements to engage in organ, tissue, or eye procurement.

Section 15 amends s. 765.543, F.S., relating to the Organ and Tissue Procurement and Transplantation Advisory Board creation and duties.

Section 16 amends s. 765.544, F.S., relating to the fees for organ and tissue donor education and procurement.

Section 17 amends s. 765.545, F.S., relating to physician supervision of cadaveric organ and tissue procurement coordinators.

Section 18 amends s. 765.547, F.S., relating to the cooperation between the medical examiner and procurement organization.

Section 19 amends s. 408.802, F.S., relating to applicability.

Section 20 amends s. 408.820, F.S., relating to exemptions.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

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:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax sharing with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Florida Medical Examiners Commission rule-making authority to establish cooperative responsibilities between medical examiners and procurement organizations.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 10, 2009, the Health Care Regulation Policy Committee adopted a strike-all amendment and reported the bill favorably. The amendment conformed to SB 766 with two changes:

- Provided the definition of “department” to mean the Department of Highway Safety and Motor Vehicles;
- Amended current law (providing immunity from civil actions and criminal prosecutions) to add immunity from administrative actions for those who act in good faith in accord with the anatomical gift laws of Florida, other states, or foreign countries.

The analysis is drafted to the committee substitute.

On March 24, 2009, the Civil Justice & Courts Policy Committee adopted two amendments to this bill. The amendments conform to CS/ CS/ SB 766 by revising the title language for s. 765.541, F.S., and s. 765.542, F.S. The bill was then reported favorably. This analysis is drafted to the bill as amended.