

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Date: January 28, 1998 Revised: 2/5/98 _____

Subject: Organ and Tissue Donation

	<u>Analyst</u>	<u>Staff Director</u>	<u>Reference</u>	<u>Action</u>
1.	<u>Williams</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/1 amendment</u>
2.	_____	_____	<u>WM</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

I. Summary:

Senate Bill 304 relates to anatomical gifts. The bill revises part X of chapter 732, F.S., as follows:

- Adds a definition for the term “death” in the context of organ and tissue donation;
- Specifies persons who may make an anatomical gift, if the decedent has not done so;
- Clarifies the ways by which an anatomical gift may be revoked;
- Revises language which provides immunity from civil and criminal liability for any hospital, or hospital administrator or designee to include any organ procurement organization, eye bank, or tissue bank, when performing organ or tissue donation recovery;
- Modifies the duties of a hospital administrator or his or her designee and organ procurement organizations with regard to organ procurement activities; and
- Authorizes the use of funds in the Florida Organ and Tissue Donor Education and Procurement Trust Fund to establish a statewide organ donor registry and to help develop the statewide organ donor education program.

In addition, the bill modifies several statutory provisions relating to organ and tissue-related trust fund revenue sources to expand the uses of such revenue.

The bill amends the following sections of the Florida Statutes: 320.08047, 322.08(7)(b), 381.6024(2) and (4)(b), 732.911, 732.912, 732.913, 732.914(5), 732.915(4), 732.916, 732.9216(1), 732.922; and creates one undesignated section of law.

II. Present Situation:

Chapter 69-88, Laws of Florida, created the Florida “Uniform Anatomical Gift Act.” Modeled after the national Uniform Anatomical Gift Act, Florida's law established the process by which individuals or their families may donate organs and tissues. These provisions are currently contained in part X of chapter 732, F.S., consisting of ss. 732.910-732.922, F.S. Section 732.11, F.S., provides relevant definitions.

Section 732.912, F.S., provides that any person who can make a will may donate all or part of his or her body for the purposes of transplantation, therapy, medical research, or education. Alternatively, any member of specified classes of relatives and other persons may make a gift of part or all of a decedent's body, in the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of the same or a prior class. These classes include, in order of priority, the spouse of the decedent, an adult son or daughter of the decedent, either parent of the decedent, an adult brother or sister of the decedent, a grandparent of the decedent, a guardian of the person at the time of his death, or a representative ad litem appointed by a court of competent jurisdiction upon petition heard ex parte filed by any person.

Section 732.913, F.S., specifies those persons who may become donees of anatomical gifts, and specifies the purposes for which such gifts may be used. This section also states as public policy the prohibition of restrictions on the possible recipients of an anatomical gift on the basis of race, color, religion, sex, national origin, age, physical handicap, health status, marital status, or economic status, and states that such restrictions are void and unenforceable.

Section 732.914, F.S., provides that an anatomical gift may be made by a will or by another document which is signed by the donor in the presence of two witnesses, who must sign the document in his or her presence. An anatomical gift may be made either to a specified donee or without specifying a donee. In the latter case, a gift may be accepted by the donor's attending physician, provided the physician does not participate in the removal or transplant procedures.

Amendment or revocation of an anatomical gift is addressed in s. 732.916, F.S. This section provides that an individual may revoke a donor authorization by a signed statement, an oral statement made to the donor's spouse or in the presence of two persons, by making a statement during a terminal illness or injury addressed to an attending physician, or by a signed document found on his person or in his effects.

Other features of the current law include a program administered by the Department of Highway Safety and Motor Vehicles (DHSMV) in which driver's license applicants express their consent to be an organ donor by completing a document and having their intent noted on the front of their driver's license. Section 732.915, F.S., requires these registration cards to be placed in a central registry developed by the Agency for Health Care Administration (AHCA) and DHSMV.

Section 381.0602, F.S., creates the Organ Transplant Advisory Council, and specifies the membership and responsibilities of the council. The purpose of the council is to recommend to AHCA indications for adult and pediatric transplants, and to formulate guidelines and standards for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. Recommendations, guidelines, and standards developed by the council are applicable only to those programs funded through AHCA. [It should be noted that this advisory group's recommendations have in the past also been used by the Children's Medical Services Program, now in the Department of Health.]

The state's regulation of organ and tissue procurement organizations was formalized with the passage of chapters 91-271 and 91-429, Laws of Florida. These provisions created the following sections of statute relating to the indicated topics:

Section	Subject
381.6021	Certification of organizations engaged in the practice of cadaveric organ and tissue procurement
381.6022	Certification of organ procurement organizations, tissue banks, and eye banks
381.6023	Organ and Tissue Procurement and Transplantation Advisory Board; creation; duties
381.6024	Fees; Florida Organ and Tissue Donor Education and Procurement Trust Fund
381.6025	Physician supervision of cadaveric organ and tissue procurement coordinators
381.6026	Procurement of cadaveric organs by out-of-state physicians

Section 381.6024(4)(b), F.S., limits the use of the Organ and Tissue Donor Education and Procurement Trust Fund revenue "exclusively for the implementation, administration, and operation of the certification program and the advisory board."

Funding for the organ and tissue donation program activities comes from two sources. Under ss. 320.08047 and 322.08(7)(b), F.S., applicants or renewals for vehicle registration and drivers licenses, respectively, are asked if they would like to make a \$1 voluntary contribution, for deposit into the Florida Organ and Tissue Donor Education and Procurement Trust Fund created under s. 732.92155, F.S. Under s. 381.6024(2), F.S., each general organ procurement organization, or each bone and tissue procurement agency or bone and tissue bank is assessed the greater of \$1,000 or .05 percent of their total revenues, up to a maximum of \$35,000 annually.

Under chapter 96-418, Laws of Florida, s. 732.92155, F.S., the Organ and Tissue Donor Education Trust Fund and the Organ and Tissue Procurement and Transplantation Board Trust Fund were combined to create the Organ and Tissue Donor Education and Procurement Trust Fund. However, the separate spending authority for each source of funds was maintained.

Specifically, moneys deposited in the trust fund pursuant to s. 381.6024(5), F.S., must be used exclusively for the implementation, administration, and operation of the certification program and advisory board. The education program is to be implemented with funds collected pursuant to ss. 320.08047 and 322.08(7)(b), F.S.

As of November 1997, nearly \$160,000 had been generated from voluntary contributions, and over \$450,000 had been generated from assessments. The donor registry is estimated to cost \$300,000 to initiate and \$125,000 is necessary to initiate AHCA's donor education campaign. Since the voluntary contributions for program activities have been less than and slower than expected, funding has been inadequate to develop education initiatives or to establish the donor registry. As a result, AHCA has proposed that all funds in the Organ and Tissue Donor Education and Procurement Trust Fund be made available to assist with organ and tissue donation initiatives. This was a unanimous recommendation by the Organ and Tissue Donor Education Panel and the Organ and Tissue Procurement and Transplantation Advisory Board during their combined meeting July 11, 1997. There is a budget amendment pending in the governor's Office with this request, which will allow the use of trust fund revenue immediately. Statutory provisions will need to be modified to reflect this policy change.

Current practice is for DHSMV to send the donor documents to AHCA where they are stored in a central location. However, there is currently no mechanism in place to get copies of the donor document to the appropriate hospital in the event a donor dies. The agency is requesting that other funds in the trust fund be made available on a one-time basis for these purposes. If this fund authorization is granted, the agency proposes to make the organ donor registry available to hospitals across the state via the Internet. Security codes will be used to prevent the disclosure of private medical records to the public.

Federal law provides that states cannot certify an entity for organ procurement unless the entity is designated as such by the Secretary of the federal Department of Health and Human Services. In order for an organ procurement organization (OPO) to be so certified, the OPO must follow guidelines established by the national Organ Procurement Transplant Network regarding the priority of recipients who receive organs. The allocation of organs is federally mandated in the following order of priority: local, statewide, regional, and national. Unique exceptions are authorized, including "status one" patients (the most critically ill) and a six-antigen kidney match.

Currently, as specified under s. 732.922, F.S., if an organ donor is near death and the organs are suitable for donation and there is a known organ donation status, the hospital notifies the organ procurement organization and the organs are harvested. If there is no known organ donation status, the hospital administrator or his designee then proceeds to request any of the persons in the specified classes to consent to donation of organs.

As a matter of policy, Florida organ procurement organizations operate in the following manner. Solid organs (kidney, liver, pancreas, pancreas islet cell, heart, heart-lung, and lung) deemed suitable for transplantation are offered first to patients on the status one waiting list, which means a critical patient who will die without an organ transplant. Next, organs go to the local transplant

list, followed by the statewide list, the regional list, and then the national list. There are exceptions made to this procedure for patients who closely match the antigen type of the organ or for patients of exceptional need.

Since 1986, the United Network for Organ Sharing (UNOS), a nonprofit organization based in Richmond, Virginia, has had a federal contract to operate the national Organ Procurement and Transplantation Network. (The federal Department of Health and Human Services has ultimate responsibility for the network.) The UNOS national patient waiting list for organ transplants contained 57,004 total registrations nationwide as of November 19, 1997. [Note: UNOS policies allow patients to be listed with more than one transplant center (multiple listing), and thus the number of registrations may be greater than the actual number of patients.] The number of transplants performed during January - December 1996 was 19,410. [Note: Based on UNOS Scientific Registry data as of April 23, 1997, double kidney, double lung, heart-lung and kidney-pancreas transplants are each counted as one transplant.]

While approximately 2,000 new patients are added to the national transplantation waiting list each month, 1,000 patients are removed due to transplantation or various medical reasons. From January 1, 1992, to December 31, 1996, there has been a 79 percent increase in the number of persons waiting for a kidney transplant, a 63 percent increase in those awaiting a heart transplant, and an 446 percent increase in the number waiting for a liver transplant. In 1996, 3,916 individuals on the national waiting list for transplants died while waiting for an organ to become available for them, or an average of 10 to 11 people per day. These deaths could have been avoided if there were a sufficient supply of donor organs. There were 5,416 cadaveric donors in the U.S. in 1996, and 3,524 living donors.

Organ transplant recipients are selected on the basis of urgency of need and compatibility of body size and blood chemistries, not race, sex, or creed.

III. Effect of Proposed Changes:

Section 1. Amends s. 320.08047, F.S., relating to voluntary contribution for organ and tissue donor education as part of vehicle registration, to specifically authorize such donated funds for maintaining the organ and tissue donor registry.

Section 2. Amends s. 322.08(7)(b), F.S., relating to voluntary contribution for organ and tissue donor education as part of the driver license issuance process, to specifically authorize such donated funds for maintaining the organ and tissue donor registry.

Section 3. Amends s. 381.6024, F.S., relating to fees for the Florida Organ and Tissue Donor Education and Procurement Trust Fund, to specify, in order of priority, the uses of such revenue for: the certification program, the advisory body, and as new uses, the maintenance of the organ and tissue donor registry and the organ and tissue donor education program.

Section 4. Effective July 1, 1999, amends s. 381.6024, F.S., relating to fees for the Florida Organ and Tissue Donor Education and Procurement Trust Fund, as amended by this act, to reduce the assessments for organ procurement organizations, tissue and bone procurement organizations, and eye banks from the current 0.5 percent of total revenues from procurement and processing activities, to 0.25 percent of such revenue.

Section 5. Amends s. 732.911, F.S., relating to definitions used under part X of chapter 732, F.S., to define “death,” as “the absence of life as determined, in accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, including the brain stem.”

Section 6. Amends s. 732.912, F.S., relating to persons who may make an anatomical gift, to: specify that the order of priority set forth must be followed when obtaining consent for a gift; clarify that the objection of an adult son or daughter is only relevant when the spouse is making the gift; and incorporate technical and conforming revisions.

Section 7. Amends s. 732.913, F.S., relating to persons who may become donees and purposes for which anatomical gifts may be made, to clarify that entities, in addition to persons, may become the receiver of an anatomical gift.

Section 8. Amends s. 732.914(5), F.S., relating to the manner of executing an anatomical gift, to incorporate a technical, conforming change.

Section 9. Amends s. 732.915(4), F.S., relating to the organ and tissue donor registry, to incorporate technical and conforming revisions, and to delete language relating to procurement agency assessments which duplicates language found in s. 381.6024, F.S., in sections 3 and 4 of this bill.

Section 10. Amends s. 732.916, F.S., relating to amendment or revocation of an anatomical gift, to modify the actions necessary for a donor to amend or revoke an anatomical gift as follows: modifying the provision relating to a terminal illness situation, such that an attending physician, upon receiving a statement of desire to revoke a gift, is then required to communicate the revocation to the procurement organization certified by the state; and deleting language authorizing a donor to revoke an anatomical gift by destruction, cancellation, or mutilation of the document.

Section 11. Amends s. 732.9216, F.S., relating to the organ and tissue donor education panel, to incorporate technical and conforming revisions.

Section 12. Amends s. 732.922, F.S., relating to the duty of hospital administrators, to: clarify the circumstances under which a hospital administrator or his or her designee must seek an organ donation; clarify language which provides civil or criminal liability protection for any hospital, or hospital administrator or designee; extend civil and criminal liability protection to any organ

procurement organization, eye bank, or tissue bank; and direct the hospital administrator or his or her designee, at or near the time of death, to directly notify the affiliated Health Care Financing Administration designated organ procurement organization of all potential organ donors. When so notified, organ procurement organizations must offer any organ from these donors first to patients on a Florida-based local or state organ sharing transplant list. A definition of “transplant list” is provided for this context. This notification must not be made to a tissue bank or eye bank unless HCFA designated it as an organ procurement organization.

Section 13. Provides a severability clause.

Section 14. Provides for the act to take effect upon becoming law, except as otherwise provided.

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 this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

Effective July 1, 1999, the bill amends s. 381.6024, F.S., as amended by this act, to reduce organ, tissue, bone, and eye procurement agency assessments from 0.5 to 0.25 percent of total revenues from procurement and processing activities.

B. Private Sector Impact:

The bill may result in an increase in the number of organs and tissues available for transplant.

C. Government Sector Impact:

The bill provides funding for the establishment of a donor registry and for donor education, which, to date, have not been implemented by AHCA due to inadequate funding for these purposes, and due to restrictions on the uses of trust fund revenue. The Agency for Health Care Administration estimates the need for start-up funding of \$300,000 for the donor registry and \$125,000 for the donor education campaign. These amounts are currently available in the Florida Organ and Tissue Donor Education and Procurement Trust Fund. Authority to use the trust fund revenue for these purposes is the subject of a budget amendment pending in the Governor's Office.

VI. Technical Deficiencies:

The bill makes inconsistent reference to Florida certified organ procurement organizations and federally designated organ procurement organizations. See, for example, section 10 of the bill on page 9, lines 22-25, and section 12 of the bill on page 12, lines 8-23.

VII. Related Issues:

Section 5 of the bill amends s. 732.911, F.S., to provide a definition of "death" in the context of organ and tissue procurement. A portion of this definition cross-references s. 382.009, F.S., a part of the vital statistics statute. The vital statistics statute delineates a clear process for the determination of brain death including currently accepted reasonable medical standards, multiple physician involvement, family involvement, and malpractice protections provided under s. 766.10, F.S.

The added definition in s. 732.911, F.S., also includes the irreversible cessation of all respiration and circulatory function as part of the definition of death. It appears that this addition is simply a codification of the common law definition of death that the Florida Supreme Court recognized as valid as recently as 1992. In *re T.A.C.P.*, 609 So.2d 588 (1992), the court stated:

Initially, we must start by recognizing that section 382.009, Florida Statutes (1991), provides a method for determining death in those cases in which a person's respiratory and circulatory functions are maintained artificially. Sec. 382.009(4), Fla.Stat. (1991) Likewise, we agree that a cardiopulmonary definition of death must be accepted in Florida as a matter of our common law, applicable whenever section 382.009 does not govern. Thus, if cardiopulmonary function is not being maintained artificially as stated in section 382.009, a person is dead who has sustained irreversible cessation of circulatory and respiratory functions as determined in accordance with accepted medical standards. We have found no credible authority arguing that this definition is inconsistent with the existence of death, and we therefore need not labor the point further.

. . . We believe, for example, that our adoption of the cardiopulmonary definition of death today is required by public necessity and, in any event, merely formalizes what has been common practice in this state for well over a century.

To summarize: We hold that Florida common law recognizes the cardiopulmonary definition of death as stated above; and Florida statutes create a “whole-brain death” exception applicable whenever cardiopulmonary function is being maintained artificially. There are no other legal standards for determining death under present Florida law.

Footnote 10 in this ruling stated, “Adoption of this common law definition essentially brings Florida into harmony with the Uniform Determination of Death Act, which embodies the same two standards contained separately in our common law definition and in section 382.009, Florida Statutes (1991).”

VIII. Amendments:

#1 by Health Care:

Amends ss. 322.21(1) and 732.921(1), F.S., to reduce the driver’s license fee by \$5 for persons who register to become organ donors when applying for or renewing a driver’s license.