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# **Health Care Regulation Policy Committee**

**Tuesday, March 10, 2009  
2:45 PM – 5:00 PM  
Webster Hall (212 Knott Building)**

**REVISED 2**



# The Florida House of Representatives

## Health Care Regulation Policy Committee

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### **A G E N D A**

**March 10, 2009**

**2:45 PM - 5:00 PM**

**Webster Hall (212 Knott Building)**

- I. Opening Remarks by Chair Patronis**
- II. Consideration of the following bill(s):**
  - HB 209 Revised Uniform Anatomical Gift Act by Rep. Schwartz**
  - CS/HB 573 Health Facilities by Elder & Family Services Policy Committee, Rep. O'Toole**
- III. Presentation by the Leukemia and Lymphoma Society on Cancer Clinical Trials**
- IV. Workshop on Prescription Drug Distribution Regulation**
- V. Closing Remarks by Chair**
- VI. Adjournment**





HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 209  
SPONSOR(S): Schwartz  
TIED BILLS:

Revised Uniform Anatomical Gift Act

IDEN./SIM. BILLS: SB 492

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Policy Committee		Holt <i>HA</i>	Calamas <i>CC</i>
2) Civil Justice & Courts Policy Committee			
3) Health & Family Services Policy Council			
4) Health Care Appropriations Committee			
5) Criminal & Civil Justice Appropriations Committee			
6) Full Appropriations Council on General Government & Health Care			

SUMMARY ANALYSIS

The bill creates the *Revised Uniform Anatomical Gift Act* and substantially rewrites the existing statutes governing anatomical gifts and the statutory provisions governing organizations that collect organs and tissue. The bill repeals eight statutory sections, which are replaced with twenty-three statutory sections that address anatomical donations, authority in handling and processing donated bodies and parts and the relationships between organ procurement organizations and hospitals and medical examiners.

The bill has an indeterminate fiscal impact (see fiscal analysis).

The bill takes effect October 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.<sup>1</sup>

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.<sup>2</sup>

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.<sup>3</sup>

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<sup>1</sup> Section 765.512(4), F.S.

<sup>2</sup> Section 765.512(3), F.S.

<sup>3</sup> Section 765.514, F.S.

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.<sup>4</sup>

### **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.<sup>5</sup> In general terms, transplantation refers to the removal and grafting of one individual's body part into the body of another individual. 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). 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.<sup>6</sup> Transplantation is necessary because the recipient's organ has failed or has been damaged by disease or injury. Organ transplantation is one of the great advances in modern medicine. The need for organ donors is much greater than the number of people who actually donate. In 2008, there were 12,936 organs donated.<sup>7</sup> As of March 7, 2009, there were 101,002 candidates on a waiting list for an organ.<sup>8</sup> 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.<sup>9</sup>

### **Organs and tissues that can be transplanted include:**

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

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<sup>4</sup> Section 756.516, F.S.

<sup>5</sup> Section 765.513, F.S.

<sup>6</sup> 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=633> (last visited on March 3, 2009).

<sup>7</sup> The Organ Procurement and Transplantation Network, Data: Donors Recovered in the U.S. by Donor Type (February 2009). Available online at: <http://www.optn.org/latestData/rptData.asp> (last visited March 7, 2009).

<sup>8</sup> The Organ Procurement and Transplantation Network, Data: Waiting List Candidates (March 7, 2009). Available online at: <http://www.optn.org/data/> (last visited on March 7, 2009).

<sup>9</sup> Chapter 2008-222, L.O.F.

- Lung
- Cornea
- Middle Ear
- Skin
- Bone
- Bone Marrow
- Heart valves
- Connective tissue

When an individual dies they are evaluated for donor suitability given their current and past medical history and their age. The Organ Procurement 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. 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.

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

- conduct a thorough medical and social history of the potential donor to help determine the suitability of organs for transplantation
- work with hospital staff to offer the option of donation to the donor family
- ensure that the decision to donate is based on informed consent
- manage the clinical care of the donor once consent for donation is finalized
- enter the donor information into the UNOS computer to find a match for the donated organs
- coordinate the organ recovery process with the surgical teams and provide follow-up information to the donor family and involved hospital staff regarding the outcome of the donations

From the moment of consent for donation to the release of the donor's body to the morgue, all costs associated with the organ donation process are billed directly to the OPO.<sup>10</sup>

### **Effects of the Bill**

The bill creates the *Revised Uniform Anatomical Gift Act* and substantially rewrites the existing statutes governing anatomical gifts and the statutory provisions governing organizations that collect organs and tissue. The bill repeals eight statutory sections, which are replaced with twenty-three statutory sections that address anatomical donations, authority in handling and processing donated bodies and parts and the relationships between organ procurement organizations and hospitals and medical examiners.

The bill:

- Repeals current statutory sections that relate to the manner and process of indicating that an individual wishes to have all or part of his/her body donated for transplantation, therapy, research, or education (See s. 765.512, 765.513, 765.515, 765.516, and 765.517, F.S.).
- Repeals the recommended donor card format from law (See s.765.514, F.S.).
- Provides definitions for: adult, agent, anatomical gift, decedent, disinterested witness, document of gift, donor, donor registry, driver's license, eye bank, guardian, hospital, identification card,

<sup>10</sup> 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).



know, organ procurement organization, parent, part, person, physician, procurement organization, prospective donor, reasonably available, recipient, record, refusal, sign, state, technician, tissue, tissue bank, and transplant hospital.

- Provides that an individual may make an anatomical gift prior to their death by having their driver's licensed imprinted with a symbol, providing a statement in a living will; or in the case of a terminal illness or injury, a person communicates in the presence of two witnesses their desire to make an anatomical gift.
- Provides that an anatomical gift may be made by a person who is: emancipated; at least 16 years of age; or a parent, agent, or legal guardian of the person who would like to make the donation.
- Provides that anyone who makes their desire to donate known may use a donor card or included on a donor registry. If an individual is unable to sign a legal record stating their desire to be a donor of an anatomical gift then at least two adults (one must be a disinterested party) must witness a person sign a legal record at the direction of the donor. If a driver's license or identification card denotes a person's desire to be an anatomical gift donor and the card is revoked, suspended, expired, or cancelled the gift is still valid.
- Provides that an anatomical gift that is donated in a will takes effect upon the donor's death no matter if the will is in probate or if the will is invalidated.
- Provides that anatomical gift may be amended or revoked prior to the donor's death.
- Provides that an individual may refuse to make an anatomical gift of the their body or a body part by having a signed record, will, or any other form of communication that is witnessed by at least two adults, of which, one must be a disinterested witness.
- Provides that if a person has not expressly indicated they are opposed to making a donation, a person other than the donor is barred from making, amending, or revoking an anatomical gift of the donor's body or part if the donor made an anatomical gift. However, a donor's revocation of an anatomical gift is not a refusal and does not bar another person such as an agent or legal guardian from making an anatomical gift of the donor's body or body part.
- Provides who may make an anatomical gift of a decedent's body or body part.
- Provides how a person may make, amend, or revoke an anatomical gift of a decedent's body or body part.
- Provides that an anatomical gift may be made to a specific person, institution, or purpose if they are specifically named in the document of gift.
- Provides that certain persons must make a reasonable search of an individual who is dead or near death to find a document of gift or other information that may identify the individual as a donor or an individual who has made a refusal of donation. A person is not subject to criminal or civil liability for failing to make a reasonable search, but may be subject to administrative sanctions.
- Provides that a person is not required to deliver a document of gift or refusal to donate during a donor's lifetime to be effective. Upon or after death, an individual in possession of such a document must allow examination and copying of the document by an appropriate person.
- Provides that once a person is referred to a procurement organization, the organization must make a reasonable search of the statewide organ and tissue donor registry or any other registry that exists for the geographical area in which the person resides.
- Provides that a procurement organization must be allowed reasonable access to information contained in the records of the registry(s). The procurement organization is also allowed to conduct and reasonable examination of an individual at or near death to ensure the medical suitability of a part that could be the subject of an anatomical gift is suitable for transplantation, therapy, research, or education.
- Provides that a treating physician or the physician who determines the time of the decedent's death may not participate in the procedures for removing or transplanting a part from the decedent.
- Provides that each hospital in the state must enter into agreements or affiliations with procurement organizations for coordination of procurement and use of anatomical gifts.
- Provides that a person who intentionally falsifies, forges, conceals, defaces, obliterates a document of a gift, revocation, refusal, or amendment of a document of gift commits a third degree felony.

- Provides immunity from civil liability, criminal prosecution, or administrative proceedings if a person acts in accordance with the Revised Uniform Anatomical Gift Act.
- Provides that a person may presume that a document of gift or amendment of an anatomical gift is valid unless that person knows that it was not validly executed or was revoked. And if the document of gift is valid, the law of the state governs the interpretation of the document.
- Provides for definitions of advance healthcare directive, declaration, healthcare decision. Additionally, if an advanced directive is in conflict with the express or implied terms of a potential anatomical gift with regards to the administration of measures necessary to ensure the medical suitability of a part for transplantation or therapy the prospective donor's attending physician and prospective donor will confer to resolve the conflict. If the donor is incapable of resolving the conflict then an agent may resolve the conflict on their behalf. The conflict must be resolved as expeditiously as possible. Until the conflict is resolved, measures to ensure the medical suitability of the part may not be withheld or withdrawn unless, the measure is conflicts with appropriate end-of-life care.
- Provides that a medical examiner will cooperate with procurement organizations to maximize the opportunity to recover anatomical gifts for the purpose of transplantation, therapy, research, or education.
- Provides that if a postmortem examination is performed it should be conducted in a manner and period of time compatible with preserving the body or body part. If the recovery of a body part for donation conflicts with the postmortem examination the medical examiner is to consult with the procurement organization. The medical examiner can supervise the procurement process and deny recovery of a part if the part being recovered is involved in determining the decedent's cause or manner of death.
- Provides that a medical examiner will release upon request the name, contact information, and available medical and social history of the decedent, to include the postmortem results, to a procurement organization if the decedent's body is medically suitable for transplantation, therapy, research, or education.
- Repeals legislative intent and definitions (See s. 765.510, and 765.511, F.S.).
- Revises cross-references to conform to the changes in the bill.

## B. SECTION DIRECTORY:

Section 1. Creates s. 765.5101, F.S., relating to a short title.

Section 2. Creates s. 765.5102, F.S., relating to definitions.

Section 3. Creates s. 765.5103, F.S., relating to applicability.

Section 4. Creates s. 765.5104, F.S., relating to persons who may make an anatomical gift before the donor's death.

Section 5. Creates s. 765.5105, F.S., relating to manner of making an anatomical gift before the donor's death.

Section 6. Creates s. 765.5106, F.S., relating to amending or revoking an anatomical gift before the donor's death.

Section 7. Creates s. 765.5107, F.S., relating to refusal to make an anatomical gift; effect of refusal.

Section 8. Creates s. 765.5108, F.S., relating to preclusive effect of an anatomical gift, amendment, or revocation.

Section 9. Creates s. 765.5109, F.S. relating to who may make an anatomical gift of a decedent's body or part.

Section 10. Creates s. 765.5110, F.S., relating to the manner of making, amending or revoking an anatomical gift of a decedent's body or part.

Section 11. Creates s. 765.5111, F.S., relating to the persons who may receive an anatomical gift and the purpose of the gift.

Section 12. Creates s. 765.5112, F.S., relating to search and notification.

Section 13. Creates s. 765.5113, F.S., relating to the delivery of a document of a gift not required and right to examine.

Section 14. Creates s. 765.5114, F.S., relating to the rights and duties of procurement organizations and others.

Section 15. Creates s. 765.5115, F.S., relating to the coordination of procurement and use.

Section 16. Creates s. 765.5117, F.S., relating to prohibited acts.

- Section 17. Creates s. 765.5118, F.S., relating to immunity.
- Section 18. Creates s. 765.5119, F.S., relating to the law governing validity and choice of law as to execution of a document of a gift.
- Section 19. Transfers and renumbers s. 765.5155, F.S., to 765.5120, F.S.
- Section 20. Transfers and renumbers s. 765.51551, F.S., to 765.51201, F.S.
- Section 21. Creates s. 765.5121, F.S., relating to the effect of an anatomical gift on an advance healthcare directive.
- Section 22. Creates s. 765.5122, F.S., relating to the cooperation between medical examiners and procurement organizations.
- Section 23. Creates s. 765.5123, F.S., relating to the facilitation of an anatomical gift from a decedent whose body is under the jurisdiction of a medical examiner.
- Section 24. Creates s. 765.5124, F.S., relating to the uniformity of application and construction.
- Section 25. Creates s. 765.5125, F.S., relating to electronic signatures in global and national commerce act.
- Section 26. Repeals ss. 765.510, 765.511, 765.512, 765.513, 765.514, 765.515, 765.516, and 765.517 F.S.
- Section 27. Amends s. 381.0041, F.S., to correct a cross reference.
- Section 28. Amends s. 765.521, F.S., relating to donations as part of drivers license or identification card process.
- Section 29. Amends s. 765.522, F.S., relating to duty of certain hospital administrators; liability of hospital administrators, and organ procurement organizations, eye banks, and tissue banks.
- Section 30. Provides an effective date of October 1, 2009.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:  
Not applicable.

2. Expenditures:  
See Fiscal Comments.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:  
Not applicable.

2. Expenditures:  
Not applicable.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

### D. FISCAL COMMENTS:

The bill creates a third degree felony. The Criminal Justice Impact Conference has not estimated the impact of the additional felony. The analysis will be updated if the Criminal Justice Impact Conference assigns a value to the impact.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. 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:

Not applicable.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill sponsor plans on offering a proposed strike-all amendment that conforms to Senate bill 766.

Section 765.5103 of the bill appears to be trying to make the provisions of the bill apply retroactively to all anatomical gifts entered into by donors under current law. It is not clear whether the language provided in the bill would have this effect.

Section 765.5105(4) of the bill provides that an anatomical gift that is donated in a will takes effect upon the donor's death no matter if the will is in probate or if the will is invalidated. This may conflict with current probate and will contest laws under Chapters 731 and 732, F.S.

The language in section 765.5106 and section 765.5108 appear to conflict with one another. It is unclear who may revoke or amend an anatomical gift before the donor's death; or whether anyone may do so.

**IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES**

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 209**

COUNCIL/COMMITTEE ACTION

ADOPTED \_\_\_\_\_ (Y/N)  
ADOPTED AS AMENDED \_\_\_\_\_ (Y/N)  
ADOPTED W/O OBJECTION \_\_\_\_\_ (Y/N)  
FAILED TO ADOPT \_\_\_\_\_ (Y/N)  
WITHDRAWN \_\_\_\_\_ (Y/N)  
OTHER \_\_\_\_\_

1 Council/Committee hearing bill: Health Care Regulation Policy  
2 Committee

3 Representative(s) Schwartz offered the following:  
4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 765.511, Florida Statutes, is amended  
8 to read:

9 765.511 Definitions.--As used in this part, the term:

10 (1) "Agency" means the Agency for Health Care  
11 Administration.

12 (2) "Anatomical gift" or "gift" means a donation of all or  
13 part of a human body to take effect after the donor's death and  
14 to be used for transplantation, therapy, research, or education.

15 (3) ~~(1)~~ "Bank" or "storage facility" means a facility  
16 licensed, accredited, or approved under the laws of any state  
17 for storage of human bodies or body parts thereof.

18 (4) ~~(2)~~ "Death" means the absence of life as determined, in  
19 accordance with currently accepted medical standards, by the  
20 irreversible cessation of all respiration and circulatory  
21 function, or as determined, in accordance with s. 382.009, by  
22 the irreversible cessation of the functions of the entire brain,  
23 including the brain stem.

24 (5) "Decedent" means a deceased individual whose body or

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

25 body parts may be, or are, the source of an anatomical gift.

26 (6) "Department" means the Department of Highway Safety  
27 and Motor Vehicles.

28 (7) "Disinterested witness" means a witness other than a  
29 person listed in s. 765.512(3) or other family member.

30 (8) "Document of gift" means any of the documents or  
31 mechanisms used in making an anatomical gift under s. 765.514.

32 (9)+3+ "Donor" means an individual who makes an anatomical  
33 a gift of all or part of his or her body.

34 (10) "Donor registry" means a database that contains  
35 records of anatomical gifts and amendments to, or revocations  
36 of, such gifts.

37 (11) "Eye bank" means an entity that is accredited by the  
38 Eye Bank Association of America or otherwise regulated under  
39 federal or state law to engage in the retrieval, screening,  
40 testing, processing, storage, or distribution of human eye  
41 tissue.

42 (12) "Guardian" means a person appointed pursuant to  
43 chapter 744. The term does not include a guardian ad litem.

44 (13)+4+ "Hospital" means a hospital licensed, accredited,  
45 or approved under the laws of any state and includes a hospital  
46 operated by the United States Government or a state, or a  
47 subdivision thereof, although not required to be licensed under  
48 state laws.

49 (14) "Identification card" means an official  
50 identification card issued by a governmental entity, state  
51 agency, or subdivision thereof.

52 (15) "Organ procurement organization" means an entity that  
53 is designated as an organ procurement organization by the  
54 Secretary of the United States Department of Health and Human  
55 Services and that engages in the retrieval, screening, testing,  
56 processing, storage, or distribution of human organs.

57 (16) "Part of the body" or "body part" means an organ,

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

58 eye, or tissue of a human being. The term does not include the  
59 whole body.

60 (17)(5) "Physician" or "surgeon" means a physician or  
61 surgeon licensed to practice under chapter 458 or chapter 459 or  
62 similar laws of any state. "Surgeon" includes dental or oral  
63 surgeon.

64 (18) "Procurement" means any retrieval, recovery,  
65 processing, storage, or distribution of human organs or tissues  
66 for transplantation, therapy, research, or education.

67 (19) "Procurement organization" means an organ procurement  
68 organization, eye bank, or tissue bank.

69 (20) "Reasonably available" means able to be contacted by  
70 a procurement organization in a timely manner without undue  
71 effort, and willing and able to act in a manner consistent with  
72 existing medical protocols necessary for the making of an  
73 anatomical gift.

74 (21) "Record" means information that is inscribed on a  
75 tangible medium or that is stored in an electronic or other  
76 medium and is retrievable in perceivable form.

77 (22) "Sign" or "signed" means, with the present intent to  
78 authenticate or adopt a record, to execute or adopt a tangible  
79 symbol, or attach to or logically associate an electronic  
80 symbol, sound, or process with the record.

81 (23) "Tissue bank" means an entity that is accredited by  
82 the American Association of Tissue Banks or otherwise regulated  
83 under federal or state law to engage in the retrieval,  
84 screening, testing, processing, storage, or distribution of  
85 human tissue.

86 Section 2. Subsections (1), (4), (5), (6), and (7) of  
87 section 765.512, Florida Statutes, are amended to read:

88 765.512 Persons who may make an anatomical gift.--

89 (1) Any person who may make a will may make an anatomical  
90 gift ~~give all or part of his or her body for any purpose~~  
91 ~~specified in s. 765.513. The gift is effective upon the death of~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

92 ~~the donor.~~

93 (a) If the decedent makes an anatomical gift by one of the  
94 methods listed in s. 765.514(1), and in the absence of actual  
95 notice of contrary indications by the decedent, the document or  
96 entry in the donor organ and tissue registry is legally  
97 sufficient evidence of the decedent's informed consent to donate  
98 an anatomical gift.

99 (b) An anatomical gift made by a qualified donor and not  
100 revoked by the donor, as provided in s. 765.516, is irrevocable  
101 after the donor's death. A family member, guardian,  
102 representative ad litem, or health care surrogate may not  
103 modify, deny, or prevent a donor's wish or intent to make an  
104 anatomical gift after the donor's death.

105 (4) A donee may not accept an anatomical gift if the donee  
106 has actual notice of contrary indications by the donor or actual  
107 notice that an anatomical a gift by a member of a class is  
108 opposed by a member of a prior class.

109 (5) The person authorized by subsection (3) may make the  
110 anatomical gift after the decedent's death or immediately before  
111 the decedent's death.

112 (6) An anatomical A gift ~~of all or part of a body~~  
113 authorizes:

114 (a) Any examination necessary to assure medical  
115 acceptability of the gift for the purposes intended.

116 (b) The decedent's medical provider, family, or a third  
117 party to furnish medical records requested concerning the  
118 decedent's medical and social history.

119 (7) Once the anatomical gift has been made, the rights of  
120 the donee are paramount to the rights of others, except as  
121 provided by s. 765.517.

122 Section 3. Section 765.513, Florida Statutes, is amended  
123 to read:

124 765.513 ~~Persons and entities that may become~~ Donees;  
125 purposes for which anatomical gifts may be made.--



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

126           (1) The following persons or entities may become donees of  
127 anatomical gifts of bodies or parts of them for the purposes  
128 stated:

129           ~~(a)(1) Any procurement organization or accredited~~  
130 ~~hospital, surgeon, or physician for medical or dental school,~~  
131 ~~college, or university for education, or research, advancement~~  
132 ~~of medical or dental science, therapy, or transplantation.~~

133           ~~(2) Any accredited medical or dental school, college, or~~  
134 ~~university for education, research, advancement of medical or~~  
135 ~~dental science, or therapy.~~

136           ~~(3) Any bank or storage facility for medical or dental~~  
137 ~~education, research, advancement of medical or dental science,~~  
138 ~~therapy, or transplantation.~~

139           ~~(b)(4) Any individual specified by name for therapy or~~  
140 ~~transplantation needed by him or her.~~

141           (2) If multiple purposes are set forth in the document of  
142 gift but are not set forth in any priority order, the anatomical  
143 gift shall be used first for transplantation or therapy, if  
144 suitable. If the gift cannot be used for transplantation or  
145 therapy, the gift may be used for research or education.

146           (3) ~~However,~~ The Legislature declares that the public  
147 policy of this state prohibits restrictions on the possible  
148 recipients of an anatomical gift on the basis of race, color,  
149 religion, gender ~~sex~~, national origin, age, physical disability  
150 handicap, health status, marital status, or economic status, and  
151 such restrictions are ~~hereby declared~~ void and unenforceable.

152           Section 4. Section 765.514, Florida Statutes, is amended  
153 to read:

154           765.514 Manner of making anatomical gifts.--

155           (1) A person may make an anatomical ~~a~~ gift of all or part  
156 of his or her body under s. 765.512(1) by:

157           (a) Signing an organ and tissue donor card.

158           (b) Registering online with the ~~organ and tissue~~ donor  
159 registry.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

160 (c) Signifying an intent to donate on his or her driver's  
161 license or identification card issued by the  
162 ~~department~~Department of Highway Safety and Motor Vehicles.  
163 Revocation, suspension, expiration, or cancellation of the  
164 driver's license or identification card does not invalidate the  
165 gift.

166 (d) Expressing a wish to donate in a living will or other  
167 advance directive.

168 (e) Executing a will that includes a provision indicating  
169 that the testator wishes to make an anatomical gift. The gift  
170 becomes effective upon the death of the testator without waiting  
171 for probate. If the will is not probated or if it is declared  
172 invalid for testamentary purposes, the gift is nevertheless  
173 valid to the extent that it has been acted upon in good faith.

174 (f) Expressing a wish to donate in a document other than a  
175 will. The document must be signed by the donor in the presence  
176 of two witnesses who shall sign the document in the donor's  
177 presence. If the donor cannot sign, the document may be signed  
178 for him or her at the donor's direction and in his or her  
179 presence and the presence of two witnesses who must sign the  
180 document in the donor's presence. Delivery of the document of  
181 gift during the donor's lifetime is not necessary to make the  
182 gift valid. The following form of written document is sufficient  
183 for any person to make an anatomical gift ~~give all or part of~~  
184 ~~his or her body~~ for the purposes of this part:

185 UNIFORM DONOR CARD

186  
187 The undersigned hereby makes this anatomical gift, if medically  
188 acceptable, to take effect on death. The words and marks below  
189 indicate my desires:

190 I give:

191 (a) .... any needed organs, tissues, or eyes;

192 (b) .... only the following organs, tissues, or eyes

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

193           ...[Specify the organs, tissues, or eyes]...  
194 for the purpose of transplantation, therapy, medical research,  
195 or education;

196           (c) .... my body for anatomical study if needed.

197 Limitations or special wishes, if any:

198     ...(If applicable, list specific donee; this must be arranged in  
199           advance with the donee.)...

200

201 Signed by the donor and the following witnesses in the presence  
202 of each other:

203

204     ...(Signature of donor)...                   ...(Date of birth of donor)...

205     ...(Date signed)...                           ...(City and State)...

206

207     ...(Witness)...                                 ...(Witness)...

208     ...(Address)...                                 ...(Address)...

209           (2) The anatomical gift may be made to a donee listed in  
210 s. 765.513, and the donee may be specified by name.

211           (3) Any anatomical gift by a health care surrogate  
212 designated by the decedent pursuant to part II of this chapter  
213 or a member of a class designated in s. 765.512(3) must be made  
214 by a document signed by that person or made by that person's  
215 witnessed telephonic discussion, telegraphic message, or other  
216 recorded message.

217           Section 5. Section 765.515, Florida Statutes, is amended  
218 to read:

219           765.515 Delivery of donor document.--

220           (1) If an anatomical a gift is made pursuant to s.  
221 765.521, the completed donor registration card shall be  
222 delivered to the ~~department~~Department of Highway Safety and  
223 ~~Motor Vehicles~~ and the department must communicate the donor's  
224 intent to the ~~organ and tissue~~ donor registry, but delivery is  
225 not necessary to the validity of the gift. If the donor  
226 withdraws the gift, the records of the ~~department~~Department of

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

227 ~~Highway Safety and Motor Vehicles~~ must be updated to reflect  
228 such withdrawal and the department must communicate the  
229 withdrawal to the ~~organ and tissue~~ donor registry for the  
230 purpose of updating the registry.

231 (2) If an anatomical a gift is made by the donor to a  
232 specified donee, the document of gift, other than a will, may be  
233 delivered to the donee to expedite the appropriate procedures  
234 immediately after death, but delivery is not necessary to the  
235 validity of the gift. ~~The Such~~ document of gift may be deposited  
236 in any hospital, bank, storage facility, or registry office that  
237 accepts such documents for safekeeping or to facilitate the  
238 donation of organs and tissue after death.

239 (3) At the request of any interested party upon or after  
240 the donor's death, the person in possession shall produce the  
241 document of gift for examination.

242 Section 6. Section 765.5155, Florida Statutes, is amended  
243 to read:

244 765.5155 ~~Organ and tissue~~ Donor registry; education  
245 program.--

246 (1) The Legislature finds that:

247 (a) There is a shortage of organ and tissue donors in this  
248 state willing to provide the organs and tissue that could save  
249 lives or enhance the quality of life for many persons.

250 (b) There is a need to encourage the various minority  
251 populations of this state to donate organs and tissue.

252 (c) A statewide ~~organ and tissue~~ donor registry having an  
253 online donor registration process coupled with an enhanced  
254 program of donor education will lead to an increase in the  
255 number of organ and tissue donors registered in this state, thus  
256 affording more persons who are awaiting organ or tissue  
257 transplants the opportunity for a full and productive life.

258 (2) The agency ~~for Health Care Administration~~ and the  
259 ~~department~~ Department of Highway Safety and Motor Vehicles shall  
260 jointly contract for the operation of a ~~an organ and tissue~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

261 donor registry and education program. The contractor shall be  
262 procured by competitive solicitation pursuant to chapter 287,  
263 notwithstanding any exemption in s. 287.057(5)(f). When awarding  
264 the contract, priority shall be given to existing nonprofit  
265 groups that are based within the state, have expertise working  
266 with ~~organ and tissue~~ procurement organizations, have expertise  
267 in conducting statewide organ and tissue donor public education  
268 campaigns, and represent the needs of the organ and tissue  
269 donation community in the state.

270 (3) The contractor shall be responsible for:

271 (a) The development, implementation, and maintenance of an  
272 interactive web-based ~~organ and tissue~~ donor registry that,  
273 through electronic means, allows for online organ donor  
274 registration and the recording of organ and tissue donation  
275 records submitted through the driver's license identification  
276 program or through other sources.

277 1. The registry must be maintained in a manner that  
278 allows, through electronic and telephonic methods, immediate  
279 access to organ and tissue donation records 24 hours a day, 7  
280 days a week.

281 2. Access to the registry must be through coded and secure  
282 means to protect the integrity of the data in the registry.

283 (b) A continuing program to educate and inform medical  
284 professionals, law enforcement agencies and officers, other  
285 state and local government employees, high school students,  
286 minorities, and the public about the laws of this state relating  
287 to anatomical gifts and the need for anatomical gifts.

288 1. Existing community resources, when available, must be  
289 used to support the program and volunteers may assist the  
290 program to the maximum extent possible.

291 2. The contractor shall coordinate with the head of a  
292 state agency or other political subdivision of the state, or his  
293 or her designee, to establish convenient times, dates, and

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

294 locations for educating that entity's employees.

295 (c) Preparing and submitting an annual written report to  
296 the agency ~~for Health Care Administration~~ by December 31 of each  
297 year. The report must include:

298 1. The number of donors on the registry and an analysis of  
299 the registration rates by location and method of donation;

300 2. The characteristics of donors as determined from  
301 registry information submitted directly by the donors or by the  
302 Department of Highway Safety and Motor Vehicles;

303 3. The annual dollar amount of voluntary contributions  
304 received by the contractor;

305 4. A description of the educational campaigns and  
306 initiatives implemented during the year and an evaluation of  
307 their effectiveness in increasing enrollment on the registry;  
308 and

309 5. An analysis of Florida's registry compared with other  
310 states' donor registries.

311 (4) Costs for the ~~organ and tissue~~ donor registry and  
312 education program shall be paid by the agency ~~for Health Care~~  
313 ~~Administration~~ from the funds deposited into the Health Care  
314 Trust Fund pursuant to ss. 320.08047 and 322.08, which are  
315 designated for maintaining the ~~organ and tissue~~ donor registry  
316 and education program. In addition, the contractor may receive  
317 and use voluntary contributions to help support the registry and  
318 provide education.

319 (5) The ~~organ and tissue~~ donor registry established by  
320 this section is designated as the "Joshua Abbott Organ and  
321 Tissue Registry."

322 Section 7. Section 765.51551, Florida Statutes, is amended  
323 to read

324 765.51551 ~~Organ and tissue~~ Donor registry; public records  
325 exemption.--

326 (1) Information held in the ~~organ and tissue~~ donor  
327 registry which identifies a donor is confidential and exempt

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

328 from s. 119.07(1) and s. 24(a), Art. I of the State  
329 Constitution.

330 (2) Such information may be disclosed to the following:

331 (a) ~~Organ, tissue, and eye~~ Procurement organizations that  
332 have been certified by the agency ~~for Health Care Administration~~  
333 for the purpose of ascertaining or effectuating the existence of  
334 a gift under s. 765.522.

335 (b) Persons engaged in bona fide research if the person  
336 agrees to:

337 1. Submit a research plan to the agency that specifies the  
338 exact nature of the information requested and the intended use  
339 of the information;

340 2. Maintain the confidentiality of the records or  
341 information if personal identifying information is made  
342 available to the researcher;

343 3. Destroy any confidential records or information  
344 obtained after the research is concluded; and

345 4. Not directly or indirectly contact, for any purpose,  
346 any donor or donee.

347 (3) This section is subject to the Open Government Sunset  
348 Review Act in accordance with s. 119.15 and shall stand repealed  
349 on October 2, 2013, unless reviewed and saved from repeal  
350 through reenactment by the Legislature.

351 Section 8. Section 765.516, Florida Statutes, is amended  
352 to read:

353 765.516 Donor amendment ~~of the terms of~~ or the revocation  
354 of anatomical ~~the~~ gift.--

355 (1) A donor may amend the terms of or revoke an anatomical  
356 gift by:

357 (a) The execution and delivery to the donee of a signed  
358 statement witnessed by at least two adults, at least one of whom  
359 is a disinterested witness.

360 (b) An oral statement that is made in the presence of two  
361 persons, one of whom is ~~must~~ not be a family member, and

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

362 communicated to the donor's family or attorney or to the donee.  
363 An oral statement is effective only if the procurement  
364 organization, transplant hospital, or physician or technician  
365 has actual notice of the oral amendment or revocation before an  
366 incision is made to the decedent's body or an invasive procedure  
367 to prepare the recipient has begun.

368 (c) A statement made during a terminal illness or injury  
369 addressed to an attending physician, who must communicate the  
370 revocation of the gift to the procurement organization ~~that is~~  
371 ~~certified by the state.~~

372 (d) A signed document found on or about the donor's  
373 person.

374 (e) Removing his or her name from the ~~organ and tissue~~  
375 donor registry.

376 (f) A later-executed document of gift which amends or  
377 revokes a previous anatomical gift or portion of an anatomical  
378 gift, either expressly or by inconsistency.

379 (g) By the destruction or cancellation of the document of  
380 gift or the destruction or cancellation of that portion of the  
381 document of gift used to make the gift with the intent to revoke  
382 the gift.

383 (2) Any anatomical gift made by a will may also be amended  
384 or revoked in the manner provided for the amendment or  
385 revocation of wills or as provided in paragraph (1)(a)  
386 ~~subsection (1).~~

387 Section 9. Section 765.517, Florida Statutes, is amended  
388 to read:

389 765.517 Rights and duties at death.--

390 (1) The donee, pursuant to ~~as specified under the~~  
391 ~~provisions of s. 765.515(2),~~ may accept or reject an anatomical  
392 ~~the~~ gift. If the donee accepts a gift ~~of the entire body or a~~  
393 ~~part of the body~~ to be used for research or education ~~scientific~~  
394 purposes ~~other than a transplant,~~ the donee may authorize  
395 embalming and the use of the body in funeral services, subject



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

396 to the terms of the gift. If the gift is of a part of the body,  
397 the donee shall cause the part to be removed without unnecessary  
398 mutilation upon the death of the donor and before or after  
399 embalming. After removal of the body part, custody of the  
400 remainder of the body vests in the surviving spouse, next of  
401 kin, or other persons under obligation to dispose of the body.

402 (2) The time of death shall be determined by a physician  
403 who attends the donor at the donor's death or, if there is no  
404 such physician, the physician who certifies the death. After  
405 death, those physicians or the donor's primary care and in the  
406 absence of other qualified personnel, this physician may  
407 participate in, but may shall not obstruct, the procedures to  
408 preserve the donor's organs or tissues and may shall not be paid  
409 or reimbursed for such participation by, nor be associated with  
410 or employed by, a, an organ procurement organization, tissue  
411 bank, or eye bank. These physicians may This physician shall not  
412 participate in the procedures for removing or transplanting a  
413 part. However, this subsection does not prevent a physician from  
414 serving in a voluntary capacity on the board of directors of a  
415 procurement organization or participating on any board, council,  
416 commission, or similar body related to the organ and tissue  
417 procurement system.

418 (3) The organ procurement organizations organization,  
419 tissue bank, or eye bank, or hospital medical professionals  
420 under the direction thereof, may perform any and all tests to  
421 evaluate the deceased as a potential donor and any invasive  
422 procedures on the deceased body in order to preserve the  
423 potential donor's organs. These procedures do not include the  
424 surgical removal of an organ or penetrating any body cavity,  
425 specifically for the purpose of donation, until:

426 (a) It has been verified that the deceased's consent to  
427 donate appears in the organ and tissue donor registry or a  
428 properly executed donor card or document of gift is located; or

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

429 (b) If a properly executed ~~donor card or~~ document of gift  
430 cannot be located or the deceased's consent is not listed in the  
431 ~~organ and tissue~~ donor registry, a person specified in s.  
432 765.512(2) or (3) has been located, has been notified of the  
433 death, and has granted legal permission for the donation.

434 (4) All reasonable additional expenses incurred in the  
435 procedures to preserve the donor's organs or tissues shall be  
436 reimbursed by the ~~organ~~ procurement organization, ~~tissue bank,~~  
437 ~~or eye bank.~~

438 (5) A person who acts in good faith and without negligence  
439 in accord with the terms of this part or under the anatomical  
440 gift laws of this state or another state or a foreign country,  
441 or attempts to do so, is not liable for damages in any civil  
442 action, is not or subject to prosecution for his or her acts in  
443 any criminal proceeding, and may not be subject to any civil  
444 action for damages, may not be subject to any criminal  
445 proceeding, and may not be subject to discipline, penalty, or  
446 liability in any administrative proceeding.

447 (6) The provisions of this part are subject to the laws of  
448 this state prescribing powers and duties with respect to  
449 autopsies.

450 (7) The person making an anatomical gift and the donor's  
451 estate are not liable for any injury or damages that result from  
452 the making or use of the gift.

453 (8) In determining whether an anatomical gift has been  
454 made, amended, or revoked under this part, a person may rely  
455 upon the representation of an individual listed in s. 765.512,  
456 relating to the individual's relationship to the donor or  
457 prospective donor, unless the person knows that the  
458 representation is untrue.

459 Section 10. Section 765.521, Florida Statutes, is amended  
460 to read:

461 765.521 Donations as part of driver license or  
462 identification card process.--

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

463           (1) The agency ~~for Health Care Administration~~ and the  
464 ~~department~~Department of Highway Safety and Motor Vehicles shall  
465 develop and implement a program encouraging and allowing persons  
466 to make anatomical gifts as a part of the process of issuing  
467 identification cards and issuing and renewing driver licenses.  
468 The donor registration card distributed by the  
469 ~~department~~Department of Highway Safety and Motor Vehicles shall  
470 include the information required by the uniform donor card under  
471 s. 765.514 and such additional information as determined  
472 necessary by the department. The department shall also develop  
473 and implement a program to identify donors, which includes  
474 notations on identification cards, driver licenses, and driver  
475 records or such other methods as the department develops to  
476 clearly indicate the individual's intent to make an anatomical  
477 gift ~~donate the individual's organs, tissues, or eyes~~. A  
478 notation on an individual's driver license or identification  
479 card that the individual intends to make an anatomical gift  
480 ~~donate organs, tissues, or eyes~~ satisfies all requirements for  
481 consent to organ or tissue donation. The agency ~~for Health Care~~  
482 ~~Administration~~ shall provide the necessary supplies and forms  
483 from funds appropriated from general revenue or contributions  
484 from interested voluntary, nonprofit organizations. The  
485 department shall provide the necessary recordkeeping system from  
486 funds appropriated from general revenue. The  
487 ~~department~~Department of Highway Safety and Motor Vehicles and  
488 the agency ~~for Health Care Administration~~ shall incur no  
489 liability in connection with the performance of any acts  
490 authorized herein.

491           (2) The Department of Highway Safety and Motor Vehicles,  
492 after consultation with and concurrence by the agency ~~for Health~~  
493 ~~Care Administration~~, shall adopt rules to implement the  
494 provisions of this section according to the provisions of  
495 chapter 120.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

496 (3) Funds expended by the agency for ~~Health Care~~  
497 ~~Administration~~ to carry out the intent of this section may ~~shall~~  
498 not be taken from ~~any~~ funds appropriated for patient care.

499 Section 11. Section 765.522, Florida Statutes, is amended  
500 to read:

501 765.522 Duty of ~~certain~~ hospital administrators; liability  
502 of hospital administrators and, ~~organ~~ procurement organizations,  
503 ~~eye banks, and tissue banks.--~~

504 ~~(1) When used in this section, "hospital" means any~~  
505 ~~establishment licensed under chapter 395 except psychiatric and~~  
506 ~~rehabilitation hospitals.~~

507 ~~(1)(2)~~ If ~~Where~~, based on accepted medical standards, a  
508 hospital patient is a suitable candidate for organ or tissue  
509 donation, the hospital administrator or the hospital  
510 administrator's designee shall, at or near the time of death,  
511 notify the appropriate procurement organization ~~organ, eye, or~~  
512 ~~tissue recovery program~~, which shall access the ~~organ and tissue~~  
513 donor registry created by s. 765.5155 or any other donor  
514 registry to ascertain the existence of an entry in the registry  
515 which that has not been revoked, ~~a donor card~~, or a document of  
516 gift executed by the decedent. In the absence of an entry in the  
517 donor registry, a document of gift ~~donor card, organ donation~~  
518 ~~sticker or organ donation imprint on a driver's license~~, or  
519 other properly executed document, the procurement organization  
520 ~~organ, eye, or tissue recovery program~~ shall request:

521 (a) The patient's health care surrogate, as authorized in  
522 s. 765.512(2); or

523 (b) If the patient does not have a surrogate, or the  
524 surrogate is not reasonably available, any of the persons  
525 specified in s. 765.512(3), in the order and manner listed,

526  
527 to consent to the anatomical gift ~~of all or any part~~ of the  
528 decedent's body for any purpose specified in this part. Except  
529 as provided in s. 765.512, in the absence of actual notice of

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

530 opposition, consent need only be obtained from the person or  
531 persons in the highest priority class reasonably available.

532 (3) A document of gift is valid if made pursuant to a  
533 request required by this section shall be executed in accordance  
534 with this part or the laws of the state or country where it was  
535 executed and where the person making the anatomical gift was  
536 domiciled, has a place of residence, or was a citizen at the  
537 time the document of gift was executed pursuant to s. 765.514.

538 (4) ~~The agency for Health Care Administration shall~~  
539 establish rules and guidelines concerning the education of  
540 individuals who may be designated to perform the request and the  
541 procedures to be used in making the request. The agency is  
542 authorized to adopt rules concerning the documentation of the  
543 request, where such request is made.

544 (5) If a document of gift is valid under this section, the  
545 laws of this state govern the interpretation of the document of  
546 gift.

547 (6) A document of gift or amendment of an anatomical gift  
548 is presumed to be valid unless it was not validly executed or  
549 was revoked.

550 ~~(7)-(5)~~ There shall be no civil or criminal liability  
551 against any ~~organ procurement organization, eye bank, or tissue~~  
552 ~~bank~~ certified under s. 765.542, or against any hospital or  
553 hospital administrator or designee ~~who complies, when complying~~  
554 with the provisions of this part and agency the rules of the  
555 ~~agency for Health Care Administration or if when, in the~~  
556 exercise of reasonable care, a request for organ donation is  
557 inappropriate and the gift is not made according to this part  
558 and agency the rules of the agency for Health Care  
559 Administration.

560 ~~(8)-(6)~~ The hospital administrator or a designee shall, at  
561 or near the time of death of a potential ~~organ~~ donor, directly  
562 notify the affiliated organ procurement organization ~~designated~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

563 ~~by the United States Department of Health and Human Services~~ of  
564 the potential organ donor. ~~The~~ This organ procurement  
565 organization must offer any organ from such a donor first to  
566 patients on a Florida-based local or state organ sharing  
567 transplant list. For the purpose of this subsection, the term  
568 "transplant list" includes certain categories of national or  
569 regional organ sharing for patients of exceptional need or  
570 exceptional match, as approved or mandated by the Organ  
571 Procurement and Transplantation Network, or its agent. This  
572 notification may not be made to a tissue bank or eye bank in  
573 lieu of the organ procurement organization unless the tissue  
574 bank or eye bank is also designated as an organ procurement  
575 organization ~~by the United States Department of Health and Human~~  
576 ~~Services.~~

577 Section 12. Subsections (1), (5), and (6) of section  
578 765.53, Florida Statutes, are amended to read:

579 765.53 Organ Transplant Advisory Council; membership;  
580 responsibilities.--

581 (1) ~~There is hereby created within the agency for Health~~  
582 ~~Care Administration~~ A statewide technical Organ Transplant  
583 Advisory Council is created within the agency, consisting of  
584 twelve members who are physicians licensed under chapter 458 or  
585 chapter 459, to represent the interests of the public and the  
586 clients of the Department of Health or the agency. ~~The members~~  
587 ~~shall be physicians licensed according to chapter 458 or chapter~~  
588 ~~459.~~ A person employed by the agency may not be appointed as a  
589 member of the council.

590 (5) Members of the council shall receive no compensation,  
591 but shall be reimbursed for per diem and travel expenses by the  
592 agency ~~for Health Care Administration~~ in accordance with ~~the~~  
593 ~~provisions of~~ s. 112.061 while engaged in the performance of  
594 their duties.

595 (6) The responsibilities of the council shall be to  
596 recommend to the agency ~~for Health Care Administration~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

597 indications for adult and pediatric organ transplants. The  
598 council shall also formulate guidelines and standards for organ  
599 transplants and for the development of End Stage Organ Disease  
600 and Tissue/Organ Transplant programs. The recommendations,  
601 guidelines, and standards developed by the council are  
602 applicable only to those health programs funded through the  
603 agency ~~for Health Care Administration.~~

604 Section 13. Section 765.541, Florida Statutes, is amended  
605 to read:

606 765.541 Certification of procurement organizations ~~engaged~~  
607 ~~in the practice of cadaveric organ and tissue procurement.~~--The  
608 agency ~~for Health Care Administration~~ shall:

609 (1) Establish a program for the certification of  
610 organizations, corporations ~~agencies~~, or other entities engaged  
611 in the procurement of organs, tissues, and eyes for  
612 transplantation.†

613 (2) Adopt rules that set forth appropriate standards and  
614 guidelines for the program in accordance with ss. 765.541-  
615 765.546 and part II of chapter 408. These standards and  
616 guidelines must be substantially based on the existing laws of  
617 the Federal Government and this state and the existing standards  
618 and guidelines of the United Network for Organ Sharing (UNOS),  
619 the American Association of Tissue Banks (AATB), the South-  
620 Eastern Organ Procurement Foundation (SEOPF), the North American  
621 Transplant Coordinators Organization (NATCO), and the Eye Bank  
622 Association of America (EBAA). In addition, the agency ~~for~~  
623 ~~Health Care Administration~~ shall, before adopting these  
624 standards and guidelines, seek input from all ~~organ~~ procurement  
625 organizations, ~~tissue banks, and eye banks~~ based in this state.†

626 (3) Collect, keep, and make available to the Governor and  
627 the Legislature information regarding the numbers and  
628 disposition of organs, and tissues, and eyes procured by each  
629 certified procurement organization. ~~entity.~~†

630 (4) Monitor procurement organizations ~~participating~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

631 ~~facilities and agencies for program compliance, and~~

632 (5) Provide for the administration of the Organ and Tissue  
633 Procurement and Transplantation Advisory Board.

634 Section 14. Section 765.542, Florida Statutes, is amended  
635 to read:

636 765.542 Certification of ~~organ procurement organizations,~~  
637 ~~tissue banks, and eye banks.--~~

638 (1) The requirements of part II of chapter 408 apply to  
639 the provision of services that require licensure pursuant to ss.  
640 765.541-765.546 and part II of chapter 408 and to entities  
641 licensed or certified by or applying for such licensure or  
642 certification from the agency ~~for Health Care Administration~~  
643 pursuant to ss. 765.541-765.546. A person ~~An organization,~~  
644 ~~agency, or other entity~~ may not engage in the practice of organ  
645 procurement in this state without being designated as an organ  
646 procurement organization by the secretary of the United States  
647 Department of Health and Human Services and being appropriately  
648 certified by the agency ~~for Health Care Administration~~. ~~As used~~  
649 ~~in this subsection, the term "procurement" includes the~~  
650 ~~retrieval, processing, or distribution of human organs.~~ A  
651 physician or organ procurement organization based outside this  
652 state is exempt from these certification requirements if:

653 (a) The organs are procured for an out-of-state patient  
654 who is listed on, or referred through, the United Network for  
655 Organ Sharing System; and

656 (b) The organs are procured through an agreement of an  
657 organ procurement organization certified by the state.

658 (2) A person ~~An organization, agency, or other entity~~ may  
659 not engage in tissue procurement in this state unless it is  
660 appropriately certified as a tissue bank by the agency ~~for~~  
661 ~~Health Care Administration~~. ~~As used in this subsection, the term~~  
662 ~~"procurement" includes any retrieval, processing, storage, or~~  
663 ~~distribution of human tissue for transplantation.~~

664 (3) A person ~~An organization, agency, or other entity~~ may



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

665 not engage in the practice of eye procurement in this state  
666 without being appropriately certified as an eye bank by the  
667 agency ~~for Health Care Administration. As used in this~~  
668 ~~subsection, the term "procurement" includes the retrieval,~~  
669 ~~processing, or distribution of human eye tissue.~~ Funeral  
670 directors or direct disposers who ~~that~~ retrieve eye tissue for  
671 an eye bank certified under this subsection are exempt from the  
672 certification requirements under this subsection.

673 (4) A limited certificate may be issued to a tissue bank  
674 or eye bank, certifying only those components of procurement  
675 which the bank has chosen to perform. The agency ~~for Health Care~~  
676 ~~Administration~~ may issue a limited certificate if it determines  
677 that the tissue bank or eye bank is adequately staffed and  
678 equipped to operate in conformity with the rules adopted under  
679 this section.

680 Section 15. Subsection (3) of section 765.543, Florida  
681 Statutes, is amended to read:

682 765.543 Organ and Tissue Procurement and Transplantation  
683 Advisory Board; creation; duties.--

684 (3) The board shall:

685 (a) Assist the agency ~~for Health Care Administration~~ in  
686 the development of necessary professional qualifications,  
687 including, but not limited to, the education, training, and  
688 performance of persons engaged in the various facets of organ  
689 and tissue procurement, processing, preservation, and  
690 distribution for transplantation;

691 (b) Assist the agency ~~for Health Care Administration~~ in  
692 monitoring the appropriate and legitimate expenses associated  
693 with organ and tissue procurement, processing, and distribution  
694 for transplantation and developing methodologies to assure the  
695 uniform statewide reporting of data to facilitate the accurate  
696 and timely evaluation of the organ and tissue procurement and  
697 transplantation system;

698 (c) Provide assistance to the Florida Medical Examiners

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

699 Commission in the development of appropriate procedures and  
700 protocols to ensure the ~~assure~~ continued improvement in the  
701 approval and release of potential ~~organ and tissue~~ donors by the  
702 district medical examiners and associate medical examiners;

703 (d) Develop with and recommend to the agency ~~for Health~~  
704 ~~Care Administration~~ the necessary procedures and protocols  
705 required to assure that all residents of this state have  
706 reasonable access to available organ and tissue transplantation  
707 therapy and that residents of this state can be reasonably  
708 assured that the statewide procurement transplantation system is  
709 ~~will be~~ able to fulfill their organ and tissue requirements  
710 within the limits of the available supply and according to the  
711 severity of their medical condition and need; and

712 (e) Develop with and recommend to the agency ~~for Health~~  
713 ~~Care Administration~~ any changes to the laws of this state or  
714 administrative rules or procedures ~~required~~ to ensure ~~assure~~  
715 that the statewide organ and tissue procurement and  
716 transplantation system is ~~will be~~ able to function smoothly,  
717 effectively, and efficiently, in accordance with the Federal  
718 Anatomical Gift Act and in a manner that assures the residents  
719 of this state that no person or entity profits from the  
720 altruistic voluntary donation of organs or tissues.

721 Section 16. Section 765.544, Florida Statutes, is amended  
722 to read

723 765.544 Fees; organ and tissue donor education and  
724 procurement.--

725 (1) In accordance with s. 408.805, an applicant or a  
726 certificateholder shall pay a fee for each application submitted  
727 under this part, part II of chapter 408, and applicable rules.  
728 The amount of the fee shall be as follows:

729 (a) An initial application fee of \$1,000 from organ  
730 procurement organizations and tissue banks and \$500 from eye  
731 banks.

732 (b) Annual fees to be used, in the following order of

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

733 priority, for the certification program, the advisory board,  
734 maintenance of the ~~organ and tissue~~ donor registry, and the  
735 organ and tissue donor education program ~~in the following~~  
736 ~~amounts~~, which may not exceed \$35,000 per organization:

737 1. Each ~~general~~ organ procurement organization shall pay  
738 the greater of \$1,000 or 0.25 percent of its total revenues  
739 produced from procurement activity in this state by the  
740 certificateholder during its most recently completed fiscal ~~year~~  
741 or operational year.

742 2. Each ~~bone and tissue~~ procurement organization ~~agency or~~  
743 ~~bone and tissue bank~~ shall pay the greater of \$1,000 or 0.25  
744 percent of its total revenues from procurement and processing  
745 activity in this state by the certificateholder during its most  
746 recently completed fiscal ~~year~~ or operational year.

747 3. Each eye bank shall pay the greater of \$500 or 0.25  
748 percent of its total revenues produced from procurement activity  
749 in this state by the certificateholder during its most recently  
750 completed fiscal ~~year~~ or operational year.

751 (2) The ~~agency for Health Care Administration~~ shall  
752 specify by rule the administrative penalties for the purpose of  
753 ensuring adherence to the standards of quality and practice  
754 required by this chapter, part II of chapter 408, and applicable  
755 rules of the agency for continued certification.

756 (3)(a) Proceeds from fees, administrative penalties, and  
757 surcharges collected pursuant to this section must be deposited  
758 into the Health Care Trust Fund.

759 (b) Moneys deposited in the trust fund pursuant to this  
760 section must be used exclusively for the implementation,  
761 administration, and operation of the certification program and  
762 the advisory board, for maintaining the ~~organ and tissue~~ donor  
763 registry, and for organ and tissue donor education.

764 (4) As used in this section, the term "procurement  
765 activity in this state" includes the bringing into this state

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

766 for processing, storage, distribution, or transplantation of  
767 organs or tissues that are initially procured in another state  
768 or country.

769 Section 17. Section 765.545, Florida Statutes, is amended  
770 to read:

771 765.545 Physician supervision of cadaveric organ and  
772 tissue procurement coordinators.--~~Organ Procurement~~  
773 ~~organizations, tissue banks, and eye banks~~ may employ  
774 coordinators, who are registered nurses, physician's assistants,  
775 or other medically trained personnel who meet the relevant  
776 standards for ~~organ procurement organizations, tissue banks, or~~  
777 ~~eye banks~~ as adopted by the agency for ~~Health Care~~  
778 ~~Administration~~ under s. 765.541, to assist in the medical  
779 management of organ donors or in the surgical procurement of  
780 cadaveric organs, tissues, or eyes for transplantation or  
781 research. A coordinator who assists in the medical management of  
782 organ donors or in the surgical procurement of cadaveric organs,  
783 tissues, or eyes for transplantation or research must do so  
784 under the direction and supervision of a ~~licensed~~ physician  
785 medical director pursuant to rules and guidelines ~~to be~~ adopted  
786 by the agency ~~for Health Care Administration~~. With the exception  
787 of organ procurement surgery, this supervision may be indirect  
788 supervision. For purposes of this section, the term "indirect  
789 supervision" means that the medical director is responsible for  
790 the medical actions of the coordinator, that the coordinator is  
791 operating under protocols expressly approved by the medical  
792 director, and that the medical director or his or her physician  
793 designee is always available, in person or by telephone, to  
794 provide medical direction, consultation, and advice in cases of  
795 organ, tissue, and eye donation and procurement. Although  
796 indirect supervision is authorized under this section, direct  
797 physician supervision is to be encouraged when appropriate.

798 Section 18. Section 765.547, Florida Statutes, is created  
799 to read:

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

800           765.547 Cooperation between medical examiner and  
801 procurement organization.--

802           (1) A medical examiner and procurement organization shall  
803 cooperate with each other in order to maximize opportunities to  
804 recover anatomical gifts for the purpose of transplantation,  
805 therapy, research, or education.

806           (2) The Florida Medical Examiners Commission shall adopt  
807 rules establishing cooperative responsibilities between medical  
808 examiners and procurement organizations to facilitate and  
809 expedite completion of the medical examiner's responsibilities  
810 under chapter 406 in a manner that will maximize opportunities  
811 to recover anatomical gifts.

812           (3) This part does not supersede any part of chapter 406  
813 relating to medical examiners and the disposition of dead  
814 bodies.

815           Section 19. Subsection (30) of section 408.802, Florida  
816 Statutes, is amended to read:

817           408.802 Applicability.--The provisions of this part apply  
818 to the provision of services that require licensure as defined  
819 in this part and to the following entities licensed, registered,  
820 or certified by the agency, as described in chapters 112, 383,  
821 390, 394, 395, 400, 429, 440, 483, and 765:

822           (30) Organ, and tissue, and eye procurement organizations  
823 agencies, as provided under part V of chapter 765.

824           Section 20. Subsection (29) of section 408.820, Florida  
825 Statutes, is amended to read:

826           408.820 Exemptions.--Except as prescribed in authorizing  
827 statutes, the following exemptions shall apply to specified  
828 requirements of this part:

829           (29) Organ, and tissue, and eye procurement organizations  
830 agencies, as provided under part V of chapter 765, are exempt  
831 from s. 408.810(5)-(10).

832           Section 21. This act shall take effect July 1, 2009.  
833  
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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

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**T I T L E   A M E N D M E N T**

Remove the entire title and insert:

A bill to be entitled  
An act relating to anatomical gifts; amending s. 765.511,  
F.S.; providing additional definitions; amending s.  
765.512, F.S.; conforming terms; amending s. 765.513,  
F.S.; revising the list of donees that may accept  
anatomical gifts and the purposes for which such gifts may  
be used; amending ss. 765.514, 765.515, 765.5155, and  
765.51551, F.S.; conforming terms; amending s. 765.516,  
F.S.; revising provisions relating to a donor's amendment  
or revocation of an anatomical gift; amending s. 765.517,  
F.S.; revising provisions relating to a donee's use of an  
anatomical gift at the time of the donor's death;  
providing liability protection for the person making a  
gift and for the donor's estate; amending s. 765.521,  
F.S.; conforming terms; amending s. 765.522, F.S.;  
providing that the laws of this state govern the  
interpretation of a valid document of gift, and that a  
document of gift is presumed to be valid; amending ss.  
765.53, 765.541, 765.542, 765.543, 765.544, and 765.545,  
F.S.; conforming terms; creating s. 765.547, F.S.;  
requiring medical examiners and procurement organizations  
to cooperate and maximize opportunities for organ  
donations; authorizing the Florida Medical Examiners  
Commission to adopt rules; amending ss. 408.802 and  
408.820, F.S.; conforming terms; providing an effective  
date.

Be It Enacted by the Legislature of the State of Florida:

1 A bill to be entitled  
 2 An act relating to the Revised Uniform Anatomical Gift  
 3 Act; creating s. 765.5101, F.S.; providing a short title;  
 4 creating s. 765.5102, F.S.; providing definitions;  
 5 creating s. 765.5103, F.S.; providing that the revised act  
 6 applies to an anatomical gift or amendment to, revocation  
 7 of, or refusal to make an anatomical gift, whenever made;  
 8 creating s. 765.5104, F.S.; specifying who may make an  
 9 anatomical gift before the donor's death; creating s.  
 10 765.5105, F.S.; providing the manner of making an  
 11 anatomical gift before the donor's death; creating s.  
 12 765.5106, F.S.; providing for amending or revoking an  
 13 anatomical gift before the donor's death; creating s.  
 14 765.5107, F.S.; specifying the manner of refusal to make  
 15 an anatomical gift; providing the effect of such a  
 16 refusal; creating s. 765.5108, F.S.; providing for the  
 17 preclusive effect of an anatomical gift, amendment, or  
 18 revocation in certain circumstances; providing exceptions;  
 19 creating s. 765.5109, F.S.; specifying who may make an  
 20 anatomical gift of a decedent's body or part; creating s.  
 21 765.5110, F.S.; specifying the manner of making, amending,  
 22 or revoking an anatomical gift of a decedent's body or  
 23 part; creating s. 765.5111, F.S.; specifying persons that  
 24 may receive an anatomical gift; providing for the purpose  
 25 of an anatomical gift; providing that a person may not  
 26 accept an anatomical gift if the person knows that the  
 27 gift was not effectively made under specified provisions  
 28 or if the person knows that the decedent made a refusal

29 that was not revoked; creating s. 765.5112, F.S.;

30 requiring specified persons to make a reasonable search of

31 an individual who the person reasonably believes is dead

32 or near death for a document of gift or other information

33 identifying the individual as a donor or as an individual

34 who made a refusal; providing duties if a document of gift

35 or a refusal to make an anatomical gift is located;

36 providing immunity from criminal or civil liability for

37 failure to discharge specified duties; creating s.

38 765.5113, F.S.; providing that delivery of a document of

39 gift is not a requirement for its effectiveness; requiring

40 a person in possession of a document of gift or a refusal

41 to make an anatomical gift with respect to the individual

42 to allow examination and copying of the document; creating

43 s. 765.5114, F.S.; specifying rights and duties of

44 procurement organizations when an individual has been

45 referred to them; allowing the person to whom a part

46 passes under specified provisions to conduct any

47 reasonable examination necessary to ensure the medical

48 suitability of the body or part for its intended purpose

49 unless otherwise prohibited; requiring a procurement

50 organization, upon the death of a minor who was a donor or

51 who had refused, to conduct a reasonable search for the

52 parents of the minor and provide them with an opportunity

53 to revoke or amend the gift or revoke the refusal;

54 providing that the rights of the person to whom a part

55 passes under a specified provision are superior to the

56 rights of all others with respect to the part; prohibiting



57 both the physician who attends the decedent at death and  
 58 the physician who determines the time of death from  
 59 participating in removing or transplanting a part;  
 60 creating s. 765.5115, F.S.; requiring each hospital in  
 61 this state to enter into agreements or affiliations with  
 62 procurement organizations for specified purposes; creating  
 63 s. 765.5117, F.S.; prohibiting intentional falsification,  
 64 forgery, and other acts concerning a document of gift, an  
 65 amendment or revocation of a document of gift, or a  
 66 refusal in order to obtain a financial gain; providing  
 67 criminal penalties; creating s. 765.5118, F.S.; providing  
 68 immunity in a civil action, criminal prosecution, or  
 69 administrative proceeding to a person who acts in  
 70 accordance with the act or with the applicable anatomical  
 71 gift law of another state, or attempts in good faith to do  
 72 so; providing immunity from liability to the donor and the  
 73 donor's estate for use of the gift; permitting reliance on  
 74 specified representations in determining whether an  
 75 anatomical gift has been made, amended, or revoked;  
 76 creating s. 765.5119, F.S.; specifying the law governing  
 77 validity of a document of gift; providing for the law  
 78 governing the interpretation of a document of gift in  
 79 certain circumstances; providing a presumption of  
 80 validity; renumbering s. 765.5155, F.S., relating to the  
 81 organ and tissue donor registry, as s. 765.5120, F.S.;  
 82 renumbering s. 765.51551, F.S., relating to an organ and  
 83 tissue donor registry public records exemption, as s.  
 84 765.51201, F.S.; creating s. 765.5121, F.S.; providing for

85 | the effect of an anatomical gift on an advance healthcare  
 86 | directive; creating s. 765.5122, F.S.; requiring  
 87 | cooperation between medical examiners and procurement  
 88 | organizations; creating s. 765.5123, F.S.; providing for  
 89 | facilitation of anatomical gifts from decedents whose  
 90 | bodies are under the jurisdiction of medical examiners;  
 91 | requiring persons with information requested by a medical  
 92 | examiner conducting a medicolegal examination about a  
 93 | donor or prospective donor whose body is under the  
 94 | examiner's jurisdiction to provide that information as  
 95 | expeditiously as possible; requiring a medical examiner  
 96 | and procurement organization to cooperate in the timely  
 97 | removal of a part when recovery of the part will not  
 98 | interfere with the examination; requiring consultation  
 99 | between a medical examiner and a procurement organization  
 100 | when the medical examiner believes that recovery of the  
 101 | part could interfere with the postmortem investigation  
 102 | into the decedent's cause or manner of death; requiring a  
 103 | medical examiner who intends to deny recovery to attend,  
 104 | if requested, the removal procedure for the part before  
 105 | making a final determination not to allow recovery of the  
 106 | part; requiring a medical examiner denying recovery to  
 107 | make specified recorded findings; requiring a procurement  
 108 | organization in certain circumstances, upon request, to  
 109 | provide the medical examiner with a records concerning a  
 110 | part assist in the postmortem examination; requiring a  
 111 | procurement organization to reimburse a medical examiner  
 112 | for additional costs incurred by the examiner who is

113 required to be present in certain circumstances; creating  
 114 s. 765.5124, F.S.; providing for uniformity of application  
 115 and construction of the revised act; creating s. 765.5125,  
 116 F.S.; providing for relation of the revised act to the  
 117 Electronic Signatures in Global and National Commerce Act;  
 118 repealing s. 765.510, F.S., relating to a legislative  
 119 declaration; repealing s. 765.511, F.S., relating to  
 120 definitions; repealing s. 765.512, F.S., relating to  
 121 persons who may make an anatomical gift; repealing s.  
 122 765.513, F.S., relating to persons and entities that may  
 123 become donees and purposes for which anatomical gifts may  
 124 be made; repealing s. 765.514, F.S., relating to manner of  
 125 making anatomical gifts; repealing s. 765.515, F.S.,  
 126 relating to delivery of a donor document; repealing s.  
 127 765.516, F.S., relating to amendment of the terms of or  
 128 the revocation of the gift; repealing s. 765.517, F.S.,  
 129 relating to rights and duties at death; amending ss.  
 130 381.0041, 765.521, and 765.522, F.S.; revising cross-  
 131 references to conform to changes made by the act;  
 132 providing an effective date.

133

134 Be It Enacted by the Legislature of the State of Florida:

135

136 Section 1. Section 765.5101, Florida Statutes, is created  
 137 to read:

138 765.5101 Short title.--Sections 765.5101-765.5125 may be  
 139 cited as the "Revised Uniform Anatomical Gift Act."

140 Section 2. Section 765.5102, Florida Statutes, is created  
 141 to read:

142 765.5102 Definitions.--As used in ss. 765.5101-765.5125,  
 143 the term:

144 (1) "Adult" means an individual who is at least 18 years  
 145 of age.

146 (2) "Agent" means an individual who is:

147 (a) Authorized to make healthcare decisions on the  
 148 principal's behalf by a power of attorney for healthcare; or

149 (b) Expressly authorized to make an anatomical gift on the  
 150 principal's behalf by any other record signed by the principal.

151 (3) "Anatomical gift" means a donation of all or part of a  
 152 human body to take effect after the donor's death for the  
 153 purpose of transplantation, therapy, research, or education.

154 (4) "Decedent" means a deceased individual whose body or  
 155 part is or may be the source of an anatomical gift. The term  
 156 includes a stillborn infant and, subject to restrictions imposed  
 157 by law other than ss. 765.5101-765.5125, a fetus.

158 (5) "Disinterested witness" means a witness other than a  
 159 spouse, child, parent, sibling, grandchild, grandparent, or  
 160 guardian of the individual who makes, amends, revokes, or  
 161 refuses to make an anatomical gift, or another adult who  
 162 exhibited special care and concern for the individual. The term  
 163 does not include a person to whom an anatomical gift could pass  
 164 under s. 765.5111.

165 (6) "Document of gift" means a donor card or other record  
 166 used to make an anatomical gift and includes a statement or

167 symbol on a driver's license, identification card, or donor  
 168 registry.

169 (7) "Donor" means an individual whose body or part is the  
 170 subject of an anatomical gift.

171 (8) "Donor registry" means a database that contains  
 172 records of anatomical gifts and amendments to or revocations of  
 173 anatomical gifts.

174 (9) "Driver's license" means a license or permit issued by  
 175 the Department of Highway Safety and Motor Vehicles to operate a  
 176 vehicle, whether or not conditions are attached to the license  
 177 or permit.

178 (10) "Eye bank" means a person licensed, accredited, or  
 179 regulated under federal or state law to engage in the recovery,  
 180 screening, testing, processing, storage, or distribution of  
 181 human eyes or portions of human eyes.

182 (11) "Guardian" means a person appointed by a court to  
 183 make decisions regarding the support, care, education, health,  
 184 or welfare of an individual. The term does not include a  
 185 guardian ad litem.

186 (12) "Hospital" means a facility licensed as a hospital  
 187 under the law of any state or a facility operated as a hospital  
 188 by the United States, a state, or a subdivision of a state.

189 (13) "Identification card" means an identification card  
 190 issued by the Department of Highway Safety and Motor Vehicles.

191 (14) "Know" means to have actual knowledge.

192 (15) "Organ procurement organization" means a person  
 193 designated by the Secretary of the United States Department of  
 194 Health and Human Services as an organ procurement organization.

195       (16) "Parent" means a parent whose parental rights have  
 196 not been terminated.

197       (17) "Part" means an organ, an eye, or tissue of a human  
 198 being. The term does not include the whole body.

199       (18) "Person" means an individual, corporation, business  
 200 trust, estate, trust, partnership, limited liability company,  
 201 association, joint venture, public corporation, government or  
 202 governmental subdivision, agency, or instrumentality or any  
 203 other legal or commercial entity.

204       (19) "Physician" means an individual authorized to  
 205 practice medicine or osteopathy under the law of any state.

206       (20) "Procurement organization" means an eye bank, organ  
 207 procurement organization, or tissue bank.

208       (21) "Prospective donor" means an individual who is dead  
 209 or near death and who has been determined by a procurement  
 210 organization to have a part that could be medically suitable for  
 211 transplantation, therapy, research, or education. The term does  
 212 not include an individual who has made a refusal.

213       (22) "Reasonably available" means able to be contacted by  
 214 a procurement organization without undue effort and willing and  
 215 able to act in a timely manner consistent with existing medical  
 216 criteria necessary for the making of an anatomical gift.

217       (23) "Recipient" means an individual into whose body a  
 218 decedent's part has been or is intended to be transplanted.

219       (24) "Record" means information that is inscribed on a  
 220 tangible medium or that is stored in an electronic or other  
 221 medium and is retrievable in perceivable form.

222       (25) "Refusal" means a record created under s. 765.5107  
 223 that expressly states an intent to bar other persons from making  
 224 an anatomical gift of an individual's body or part.

225       (26) "Sign" means, with the present intent to authenticate  
 226 or adopt a record:

227       (a) To execute or adopt a tangible symbol; or

228       (b) To attach to or logically associate with the record an  
 229 electronic symbol, sound, or process.

230       (27) "State" means a state of the United States, the  
 231 District of Columbia, Puerto Rico, the United States Virgin  
 232 Islands, or any territory or insular possession subject to the  
 233 jurisdiction of the United States.

234       (28) "Technician" means an individual determined to be  
 235 qualified to remove or process parts by an appropriate  
 236 organization that is licensed, accredited, or regulated under  
 237 federal or state law. The term includes an enucleator.

238       (29) "Tissue" means a portion of the human body other than  
 239 an organ or an eye. The term does not include blood unless the  
 240 blood is donated for the purpose of research or education.

241       (30) "Tissue bank" means a person licensed, accredited, or  
 242 regulated under federal or state law to engage in the recovery,  
 243 screening, testing, processing, storage, or distribution of  
 244 tissue.

245       (31) "Transplant hospital" means a hospital that furnishes  
 246 organ transplants and other medical and surgical specialty  
 247 services required for the care of transplant patients.

248       Section 3. Section 765.5103, Florida Statutes, is created  
 249 to read:

250           765.5103 Applicability.--Sections 765.5101-765.5125 apply  
 251 to an anatomical gift or amendment to, revocation of, or refusal  
 252 to make an anatomical gift, whenever made.

253           Section 4. Section 765.5104, Florida Statutes, is created  
 254 to read:

255           765.5104 Persons who may make an anatomical gift before  
 256 the donor's death.--Subject to s. 765.5108, an anatomical gift  
 257 of a donor's body or part may be made during the life of the  
 258 donor for the purpose of transplantation, therapy, research, or  
 259 education in the manner provided in s. 765.5105 by:

260           (1) The donor, if the donor is an adult or if the donor is  
 261 a minor and is:

262           (a) Emancipated; or

263           (b) Authorized under state law to apply for a driver's  
 264 license because the donor is at least 16 years of age.

265           (2) An agent of the donor, unless the power of attorney  
 266 for healthcare or other record prohibits the agent from making  
 267 an anatomical gift.

268           (3) A parent of the donor, if the donor is an  
 269 unemancipated minor.

270           (4) The donor's guardian.

271           Section 5. Section 765.5105, Florida Statutes, is created  
 272 to read:

273           765.5105 Manner of making an anatomical gift before the  
 274 donor's death.--

275           (1) A donor may make an anatomical gift:



276 (a) By authorizing a statement or symbol indicating that  
 277 the donor has made an anatomical gift to be imprinted on the  
 278 donor's driver's license or identification card;

279 (b) In a will;

280 (c) During a terminal illness or injury of the donor, by  
 281 any form of communication addressed to at least two adults, at  
 282 least one of whom is a disinterested witness; or

283 (d) As provided in subsection (2).

284 (2) A donor or other person authorized to make an  
 285 anatomical gift under s. 765.5104 may make a gift by a donor  
 286 card or other record signed by the donor or other person making  
 287 the gift or by authorizing that a statement or symbol indicating  
 288 that the donor has made an anatomical gift be included on a  
 289 donor registry. If the donor or other person is physically  
 290 unable to sign a record, the record may be signed by another  
 291 individual at the direction of the donor or other person and  
 292 must:

293 (a) Be witnessed by at least two adults, at least one of  
 294 whom is a disinterested witness, who have signed at the request  
 295 of the donor or the other person.

296 (b) State that it has been signed and witnessed as  
 297 provided in paragraph (a).

298 (3) Revocation, suspension, expiration, or cancellation of  
 299 a driver's license or identification card upon which an  
 300 anatomical gift is indicated does not invalidate the gift.

301 (4) An anatomical gift made by will takes effect upon the  
 302 donor's death whether or not the will is probated. Invalidation

303 of the will after the donor's death does not invalidate the  
 304 gift.

305 Section 6. Section 765.5106, Florida Statutes, is created  
 306 to read:

307 765.5106 Amending or revoking an anatomical gift before  
 308 the donor's death.--

309 (1) Subject to s. 765.5108, a donor or other person  
 310 authorized to make an anatomical gift under s. 765.5104 may  
 311 amend or revoke an anatomical gift by:

312 (a) A record signed by:

313 1. The donor;

314 2. The other person; or

315 3. Subject to subsection (2), another individual acting at  
 316 the direction of the donor or the other person if the donor or  
 317 other person is physically unable to sign; or

318 (b) A later-executed document of gift that amends or  
 319 revokes a previous anatomical gift or portion of an anatomical  
 320 gift, either expressly or by inconsistency.

321 (2) A record signed pursuant to subparagraph (1)(a)3.  
 322 must:

323 (a) Be witnessed by at least two adults, at least one of  
 324 whom is a disinterested witness, who have signed at the request  
 325 of the donor or the other person.

326 (b) State that it has been signed and witnessed as  
 327 provided in paragraph (a).

328 (3) Subject to s. 765.5108, a donor or other person  
 329 authorized to make an anatomical gift under s. 765.5104 may  
 330 revoke an anatomical gift by the destruction or cancellation of

331 the document of gift, or the portion of the document of gift  
 332 used to make the gift, with the intent to revoke the gift.

333 (4) A donor may amend or revoke an anatomical gift that  
 334 was not made in a will by any form of communication during a  
 335 terminal illness or injury addressed to at least two adults, at  
 336 least one of whom is a disinterested witness.

337 (5) A donor who makes an anatomical gift in a will may  
 338 amend or revoke the gift in the manner provided for amendment or  
 339 revocation of wills or as provided in subsection (1).

340 Section 7. Section 765.5107, Florida Statutes, is created  
 341 to read:

342 765.5107 Refusal to make an anatomical gift; effect of  
 343 refusal.--

344 (1) An individual may refuse to make an anatomical gift of  
 345 the individual's body or part by:

346 (a) A record signed by:

347 1. The individual; or

348 2. Subject to subsection (2), another individual acting at  
 349 the direction of the individual if the individual is physically  
 350 unable to sign;

351 (b) The individual's will, whether or not the will is  
 352 admitted to probate or invalidated after the individual's death;  
 353 or

354 (c) Any form of communication made by the individual  
 355 during the individual's terminal illness or injury addressed to  
 356 at least two adults, at least one of whom is a disinterested  
 357 witness.

358 (2) A record signed pursuant to subparagraph (1)(a)2.

359 must:

360 (a) Be witnessed by at least two adults, at least one of  
 361 whom is a disinterested witness, who have signed at the request  
 362 of the individual.

363 (b) State that it has been signed and witnessed as  
 364 provided in paragraph (a).

365 (3) An individual who has made a refusal may amend or  
 366 revoke the refusal:

367 (a) In the manner provided in subsection (1) for making a  
 368 refusal;

369 (b) By subsequently making an anatomical gift pursuant to  
 370 s. 765.5105 that is inconsistent with the refusal; or

371 (c) By destroying or canceling the record evidencing the  
 372 refusal, or the portion of the record used to make the refusal,  
 373 with the intent to revoke the refusal.

374 (4) Except as otherwise provided in s. 765.5108(8), in the  
 375 absence of an express, contrary indication by the individual set  
 376 forth in the refusal, an individual's unrevoked refusal to make  
 377 an anatomical gift of the individual's body or part bars all  
 378 other persons from making an anatomical gift of the individual's  
 379 body or part.

380 Section 8. Section 765.5108, Florida Statutes, is created  
 381 to read:

382 765.5108 Preclusive effect of an anatomical gift,  
 383 amendment, or revocation.--

384 (1) Except as otherwise provided in subsection (7) and  
 385 subject to subsection (6), in the absence of an express,

386 contrary indication by the donor, a person other than the donor  
 387 is barred from making, amending, or revoking an anatomical gift  
 388 of a donor's body or part if the donor made an anatomical gift  
 389 of the donor's body or part under s. 765.5105 or an amendment to  
 390 an anatomical gift of the donor's body or part under s.  
 391 765.5106.

392 (2) A donor's revocation of an anatomical gift of the  
 393 donor's body or part under s. 765.5106 is not a refusal and does  
 394 not bar another person specified in s. 765.5104 or s. 765.5109  
 395 from making an anatomical gift of the donor's body or part under  
 396 s. 765.5105 or s. 765.5110.

397 (3) If a person other than the donor makes an unrevoked  
 398 anatomical gift of the donor's body or part under s. 765.5105 or  
 399 an amendment to an anatomical gift of the donor's body or part  
 400 under s. 765.5106, another person may not make, amend, or revoke  
 401 the gift of the donor's body or part under s. 765.5110.

402 (4) A revocation of an anatomical gift of a donor's body  
 403 or part under s. 765.5106 by a person other than the donor does  
 404 not bar another person from making an anatomical gift of the  
 405 body or part under s. 765.5105 or s. 765.5110.

406 (5) In the absence of an express, contrary indication by  
 407 the donor or other person authorized to make an anatomical gift  
 408 under s. 765.5104, an anatomical gift of a part is neither a  
 409 refusal to give another part nor a limitation on the making of  
 410 an anatomical gift of another part at a later time by the donor  
 411 or another person.

412 (6) In the absence of an express, contrary indication by  
 413 the donor or other person authorized to make an anatomical gift

414 under s. 765.5104, an anatomical gift of a part for one or more  
 415 of the purposes set forth in s. 765.5104 is not a limitation on  
 416 the making of an anatomical gift of the part for any of the  
 417 other purposes by the donor or any other person under s.  
 418 765.5105 or s. 765.5110.

419 (7) If a donor who is an unemancipated minor dies, a  
 420 parent of the donor who is reasonably available may revoke or  
 421 amend an anatomical gift of the donor's body or part.

422 (8) If an unemancipated minor who signed a refusal dies, a  
 423 parent of the minor who is reasonably available may revoke the  
 424 minor's refusal.

425 Section 9. Section 765.5109, Florida Statutes, is created  
 426 to read:

427 765.5109 Who may make an anatomical gift of a decedent's  
 428 body or part.--

429 (1) Subject to subsections (2) and (3) and unless barred  
 430 by s. 765.5107 or s. 765.5108, an anatomical gift of a  
 431 decedent's body or part for purpose of transplantation, therapy,  
 432 research, or education may be made by any member of the  
 433 following classes of persons who is reasonably available, in the  
 434 order of priority listed:

435 (a) An agent of the decedent at the time of death who  
 436 could have made an anatomical gift under s. 765.5104(2)  
 437 immediately before the decedent's death.

438 (b) The spouse of the decedent.

439 (c) Adult children of the decedent.

440 (d) Parents of the decedent.

441 (e) Adult siblings of the decedent.

442 (f) Adult grandchildren of the decedent.

443 (g) Grandparents of the decedent.

444 (h) An adult who exhibited special care and concern for  
 445 the decedent.

446 (i) The persons who were acting as the guardians of the  
 447 person of the decedent at the time of death.

448 (j) Any other person having the authority to dispose of  
 449 the decedent's body.

450 (2) If there is more than one member of a class listed in  
 451 paragraphs (1)(a), (c), (d), (e), (f), (g), or (i) who is  
 452 entitled to make an anatomical gift, an anatomical gift may be  
 453 made by a member of the class unless that member or a person to  
 454 whom the gift may pass under s. 765.5111 knows of an objection  
 455 by another member of the class. If an objection is known, the  
 456 gift may be made only by a majority of the members of the class  
 457 who are reasonably available.

458 (3) A person may not make an anatomical gift if, at the  
 459 time of the decedent's death, a person in a prior class under  
 460 subsection (1) is reasonably available to make or to object to  
 461 the making of an anatomical gift.

462 (4) A health care surrogate designated by the decedent  
 463 pursuant to part II of this chapter may give all or any part of  
 464 the decedent's body for any purpose specified in s. 765.5111  
 465 absent actual notice of contrary indications by the decedent.

466 Section 10. Section 765.5110, Florida Statutes, is created  
 467 to read:

468 765.5110 Manner of making, amending, or revoking an  
 469 anatomical gift of a decedent's body or part.--

470 (1) A person authorized to make an anatomical gift under  
 471 s. 765.5109 may make an anatomical gift by a document of gift  
 472 signed by the person making the gift or by that person's oral  
 473 communication that is electronically recorded or is  
 474 contemporaneously reduced to a record and signed by the  
 475 individual receiving the oral communication.

476 (2) Subject to subsection (3), an anatomical gift by a  
 477 person authorized under s. 765.5109 may be amended or revoked  
 478 orally or in a record by any member of a prior class who is  
 479 reasonably available. If more than one member of the prior class  
 480 is reasonably available, the gift made by a person authorized  
 481 under s. 765.5109 may be:

482 (a) Amended only if a majority of the reasonably available  
 483 members agree to the amending of the gift; or

484 (b) Revoked only if a majority of the reasonably available  
 485 members agree to the revoking of the gift or if they are equally  
 486 divided as to whether to revoke the gift.

487 (3) A revocation under subsection (2) is effective only  
 488 if, before an incision has been made to remove a part from the  
 489 donor's body or before invasive procedures have begun to prepare  
 490 the recipient, the procurement organization, transplant  
 491 hospital, or physician or technician knows of the revocation.

492 Section 11. Section 765.5111, Florida Statutes, is created  
 493 to read:

494 765.5111 Persons who may receive an anatomical gift;  
 495 purpose of an anatomical gift.--

496 (1) An anatomical gift may be made to the following  
 497 persons named in the document of gift:



498       (a) A hospital; an accredited medical school, dental  
 499 school, college, or university; an organ procurement  
 500 organization; or other appropriate person, for research or  
 501 education.

502       (b) Subject to subsection (2), an individual designated by  
 503 the person making the anatomical gift if the individual is the  
 504 recipient of the part.

505       (c) An eye bank or tissue bank.

506       (2) If an anatomical gift to an individual under paragraph  
 507 (1)(b) cannot be transplanted into that individual, the part  
 508 passes in accordance with subsection (7) in the absence of an  
 509 express, contrary indication by the person making the anatomical  
 510 gift.

511       (3) If an anatomical gift of one or more specific parts or  
 512 all parts is made in a document of gift that does not name a  
 513 person described in subsection (1) but identifies the purpose  
 514 for which an anatomical gift may be used, the following rules  
 515 apply:

516       (a) If the part is an eye and the gift is for the purpose  
 517 of transplantation or therapy, the gift passes to the  
 518 appropriate eye bank.

519       (b) If the part is tissue and the gift is for the purpose  
 520 of transplantation or therapy, the gift passes to the  
 521 appropriate tissue bank.

522       (c) If the part is an organ and the gift is for the  
 523 purpose of transplantation or therapy, the gift passes to the  
 524 appropriate organ procurement organization as custodian of the  
 525 organ.

526 (d) If the part is an organ, an eye, or tissue and the  
 527 gift is for the purpose of research or education, the gift  
 528 passes to the appropriate procurement organization.

529 (4) For the purpose of subsection (3), if there is more  
 530 than one purpose of an anatomical gift set forth in the document  
 531 of gift but the purposes are not set forth in any priority, the  
 532 gift must be used for transplantation or therapy, if suitable.  
 533 If the gift cannot be used for transplantation or therapy, the  
 534 gift may be used for research or education.

535 (5) If an anatomical gift of one or more specific parts is  
 536 made in a document of gift that does not name a person described  
 537 in subsection (1) and does not identify the purpose of the gift,  
 538 the gift may be used only for transplantation or therapy, and  
 539 the gift passes in accordance with subsection (7).

540 (6) If a document of gift specifies only a general intent  
 541 to make an anatomical gift by words such as "donor," "organ  
 542 donor," or "body donor," or by a symbol or statement of similar  
 543 import, the gift may be used only for transplantation or  
 544 therapy, and the gift passes in accordance with subsection (7).

545 (7) For purposes of subsections (2), (5), and (6), the  
 546 following rules apply:

547 (a) If the part is an eye, the gift passes to the  
 548 appropriate eye bank.

549 (b) If the part is tissue, the gift passes to the  
 550 appropriate tissue bank.

551 (c) If the part is an organ, the gift passes to the  
 552 appropriate organ procurement organization as custodian of the  
 553 organ.

554       (8) An anatomical gift of an organ for transplantation or  
 555 therapy, other than an anatomical gift under paragraph (1)(b),  
 556 passes to the organ procurement organization as custodian of the  
 557 organ.

558       (9) If an anatomical gift does not pass pursuant to  
 559 subsections (1)-(8) or the decedent's body or part is not used  
 560 for transplantation, therapy, research, or education, custody of  
 561 the body or part passes to the person under obligation to  
 562 dispose of the body or part.

563       (10) A person may not accept an anatomical gift if the  
 564 person knows that the gift was not effectively made under s.  
 565 765.5105 or s. 765.5110 or if the person knows that the decedent  
 566 made a refusal under s. 765.5107 that was not revoked. For  
 567 purposes of the subsection, if a person knows that an anatomical  
 568 gift was made on a document of gift, the person is deemed to  
 569 know of any amendment or revocation of the gift or any refusal  
 570 to make an anatomical gift on the same document of gift.

571       (11) Except as otherwise provided in paragraph (1)(b),  
 572 nothing in ss. 765.5101-765.5125 affects the allocation of  
 573 organs for transplantation or therapy.

574       Section 12. Section 765.5112, Florida Statutes, is created  
 575 to read:

576       765.5112 Search and notification.--

577       (1) The following persons shall make a reasonable search  
 578 of an individual who the person reasonably believes to be dead  
 579 or near death for a document of gift or other information  
 580 identifying the individual as a donor or as an individual who  
 581 made a refusal:

582 (a) A law enforcement officer, firefighter, paramedic, or  
 583 other emergency rescuer finding the individual.

584 (b) If no other source of the information is immediately  
 585 available, a hospital, as soon as practical after the  
 586 individual's arrival at the hospital.

587 (2) If a document of gift or a refusal to make an  
 588 anatomical gift is located by the search required by paragraph  
 589 (1)(a) and the individual or deceased individual to whom it  
 590 relates is taken to a hospital, the person responsible for  
 591 conducting the search shall send the document of gift or refusal  
 592 to the hospital.

593 (3) A person is not subject to criminal or civil liability  
 594 for failing to discharge the duties imposed by this section but  
 595 may be subject to administrative sanctions.

596 Section 13. Section 765.5113, Florida Statutes, is created  
 597 to read:

598 765.5113 Delivery of a document of gift not required;  
 599 right to examine.--

600 (1) A document of gift need not be delivered during the  
 601 donor's lifetime to be effective.

602 (2) Upon or after an individual's death, a person in  
 603 possession of a document of gift or a refusal to make an  
 604 anatomical gift with respect to the individual shall allow  
 605 examination and copying of the document of gift or refusal by a  
 606 person authorized to make or object to the making of an  
 607 anatomical gift with respect to the individual or by a person to  
 608 whom the gift could pass under s. 765.5111.

609 Section 14. Section 765.5114, Florida Statutes, is created  
 610 to read:

611 765.5114 Rights and duties of procurement organizations  
 612 and others.--

613 (1) When a hospital refers an individual at or near death  
 614 to a procurement organization, the organization shall make a  
 615 reasonable search of the records of the statewide organ and  
 616 tissue donor registry and any donor registry that the  
 617 organization knows exists for the geographical area in which the  
 618 individual resides to ascertain whether the individual has made  
 619 an anatomical gift.

620 (2) A procurement organization must be allowed reasonable  
 621 access to information in the records of the statewide organ and  
 622 tissue donor registry to ascertain whether an individual at or  
 623 near death is a donor.

624 (3) When a hospital refers an individual at or near death  
 625 to a procurement organization, the organization may conduct any  
 626 reasonable examination necessary to ensure the medical  
 627 suitability of a part that is or could be the subject of an  
 628 anatomical gift for transplantation, therapy, research, or  
 629 education from a donor or a prospective donor. During the  
 630 examination period, measures necessary to ensure the medical  
 631 suitability of the part may not be withdrawn unless the hospital  
 632 or procurement organization knows that the individual expressed  
 633 a contrary intent.

634 (4) Unless prohibited by law other than ss. 765.5101-  
 635 765.5125, at any time after a donor's death, the person to whom  
 636 a part passes under s. 765.5111 may conduct any reasonable

637 examination necessary to ensure the medical suitability of the  
 638 body or part for its intended purpose.

639 (5) Unless prohibited by law other than ss. 765.5101-  
 640 765.5125, an examination under subsection (3) or subsection (4)  
 641 may include an examination of all medical and dental records of  
 642 the donor or prospective donor.

643 (6) Upon the death of a minor who was a donor or had  
 644 signed a refusal, unless a procurement organization knows the  
 645 minor is emancipated, the procurement organization shall conduct  
 646 a reasonable search for the parents of the minor and provide the  
 647 parents with an opportunity to revoke or amend the anatomical  
 648 gift or revoke the refusal.

649 (7) Upon referral by a hospital under subsection (1), a  
 650 procurement organization shall make a reasonable search for any  
 651 person listed in s. 765.5109 having priority to make an  
 652 anatomical gift on behalf of a prospective donor. If a  
 653 procurement organization receives information that an anatomical  
 654 gift to any other person was made, amended, or revoked, it shall  
 655 promptly advise the other person of all relevant information.

656 (8) Subject to s. 765.5111(9) and s. 765.5123, the rights  
 657 of the person to whom a part passes under s. 765.5111 are  
 658 superior to the rights of all others with respect to the part.  
 659 The person may accept or reject an anatomical gift in whole or  
 660 in part. Subject to the terms of the document of gift and ss.  
 661 765.5101-765.5125, a person who accepts an anatomical gift of an  
 662 entire body may allow embalming, burial, or cremation, and use  
 663 of remains in a funeral service. If the gift is of a part, the  
 664 person to whom the part passes under s. 765.5111, upon the death

665 of the donor and before embalming, burial, or cremation, shall  
 666 cause the part to be removed without unnecessary mutilation.

667 (9) Neither the physician who attends the decedent at  
 668 death nor the physician who determines the time of the  
 669 decedent's death may participate in the procedures for removing  
 670 or transplanting a part from the decedent.

671 (10) A physician or technician may remove a donated part  
 672 from the body of a donor that the physician or technician is  
 673 qualified to remove.

674 Section 15. Section 765.5115, Florida Statutes, is created  
 675 to read:

676 765.5115 Coordination of procurement and use.--Each  
 677 hospital in this state shall enter into agreements or  
 678 affiliations with procurement organizations for coordination of  
 679 procurement and use of anatomical gifts.

680 Section 16. Section 765.5117, Florida Statutes, is created  
 681 to read:

682 765.5117 Prohibited acts.--A person who, in order to  
 683 obtain financial gain, intentionally falsifies, forges,  
 684 conceals, defaces, or obliterates a document of gift, an  
 685 amendment or revocation of a document of gift, or a refusal  
 686 commits a felony of the third degree, punishable as provided in  
 687 s. 775.082, s. 775.083, or s. 775.084.

688 Section 17. Section 765.5118, Florida Statutes, is created  
 689 to read:

690 765.5118 Immunity.--

691 (1) A person who acts in accordance with ss. 765.5101-  
 692 765.5125 or with the applicable anatomical gift law of another

693 state, or attempts in good faith to do so, is not liable for  
 694 such an act in a civil action, criminal prosecution, or  
 695 administrative proceeding.

696 (2) Neither the person making an anatomical gift nor the  
 697 donor's estate is liable for any injury or damage that results  
 698 from the making or use of the gift.

699 (3) In determining whether an anatomical gift has been  
 700 made, amended, or revoked under ss. 765.5101-765.5125, a person  
 701 may rely upon representations of an individual listed in s.  
 702 765.5109(1)(b), (c), (d), (e), (f), (g), or (h) relating to the  
 703 individual's relationship to the donor or prospective donor  
 704 unless the person knows that the representation is untrue.

705 Section 18. Section 765.5119, Florida Statutes, is created  
 706 to read:

707 765.5119 Law governing validity; choice of law as to  
 708 execution of a document of gift; presumption of validity.--

709 (1) A document of gift is valid if executed in accordance  
 710 with:

711 (a) Sections 765.5101-765.5125;

712 (b) The laws of the state or country where it was  
 713 executed; or

714 (c) The laws of the state or country where the person  
 715 making the anatomical gift was domiciled, has a place of  
 716 residence, or was a national at the time the document of gift  
 717 was executed.

718 (2) If a document of gift is valid under this section, the  
 719 law of this state governs the interpretation of the document of  
 720 gift.



721 (3) A person may presume that a document of gift or  
 722 amendment of an anatomical gift is valid unless that person  
 723 knows that it was not validly executed or was revoked.

724 Section 19. Section 765.5155, Florida Statutes, is  
 725 transferred and renumbered as s. 765.5120, Florida Statutes.

726 Section 20. Section 765.51551, Florida Statutes, is  
 727 transferred and renumbered as 765.51201, Florida Statutes.

728 Section 21. Section 765.5121, Florida Statutes, is created  
 729 to read:

730 765.5121 Effect of an anatomical gift on an advance  
 731 healthcare directive.--

732 (1) As used in this section, the term:

733 (a) "Advance healthcare directive" means a power of  
 734 attorney for healthcare or a record signed or authorized by a  
 735 prospective donor containing the prospective donor's direction  
 736 concerning a healthcare decision for the prospective donor.

737 (b) "Declaration" means a record signed by a prospective  
 738 donor specifying the circumstances under which life support  
 739 services may be withheld or withdrawn from the prospective  
 740 donor.

741 (c) "Healthcare decision" means any decision regarding the  
 742 health care of the prospective donor.

743 (2) If a prospective donor has a declaration or advance  
 744 healthcare directive and the terms of the declaration or  
 745 directive and the express or implied terms of a potential  
 746 anatomical gift are in conflict with regard to the  
 747 administration of measures necessary to ensure the medical  
 748 suitability of a part for transplantation or therapy, the

749 prospective donor's attending physician and prospective donor  
 750 shall confer to resolve the conflict. If the prospective donor  
 751 is incapable of resolving the conflict, an agent acting under  
 752 the prospective donor's declaration or directive, or, if none or  
 753 the agent is not reasonably available, another person authorized  
 754 by law other than ss. 765.5101-765.5125 to make healthcare  
 755 decisions on behalf of the prospective donor, shall act for the  
 756 donor to resolve the conflict. The conflict must be resolved as  
 757 expeditiously as possible. Information relevant to the  
 758 resolution of the conflict may be obtained from the appropriate  
 759 procurement organization and any other person authorized to make  
 760 an anatomical gift for the prospective donor under s. 765.5109.  
 761 Before resolution of the conflict, measures necessary to ensure  
 762 the medical suitability of the part may not be withheld or  
 763 withdrawn from the prospective donor if withholding or  
 764 withdrawing the measures is not contraindicated by appropriate  
 765 end-of-life care.

766 Section 22. Section 765.5122, Florida Statutes, is created  
 767 to read:

768 765.5122 Cooperation between medical examiners and  
 769 procurement organizations.--

770 (1) A medical examiner shall cooperate with procurement  
 771 organizations to maximize the opportunity to recover anatomical  
 772 gifts for the purpose of transplantation, therapy, research, or  
 773 education.

774 (2) If a medical examiner receives notice from a  
 775 procurement organization that an anatomical gift might be  
 776 available or was made with respect to a decedent whose body is

777 under the jurisdiction of the medical examiner and a postmortem  
 778 examination is going to be performed, unless the medical  
 779 examiner denies recovery in accordance with s. 765.5123, the  
 780 medical examiner or designee shall conduct a postmortem  
 781 examination of the body or the part in a manner and within a  
 782 period compatible with its preservation for the purposes of the  
 783 gift.

784 (3) A part may not be removed from the body of a decedent  
 785 under the jurisdiction of a medical examiner for  
 786 transplantation, therapy, research, or education unless the part  
 787 is the subject of an anatomical gift. The body of a decedent  
 788 under the jurisdiction of the medical examiner may not be  
 789 delivered to a person for research or education unless the body  
 790 is the subject of an anatomical gift. This subsection does not  
 791 preclude a medical examiner from performing the medicolegal  
 792 investigation upon the body or parts of a decedent under the  
 793 jurisdiction of the medical examiner.

794 Section 23. Section 765.5123, Florida Statutes, is created  
 795 to read:

796 765.5123 Facilitation of an anatomical gift from a  
 797 decedent whose body is under the jurisdiction of a medical  
 798 examiner.--

799 (1) Upon request of a procurement organization, a medical  
 800 examiner shall release to the procurement organization the name,  
 801 contact information, and available medical and social history of  
 802 a decedent whose body is under the jurisdiction of the medical  
 803 examiner. If the decedent's body or part is medically suitable  
 804 for transplantation, therapy, research, or education, the

805 medical examiner shall release postmortem examination results to  
 806 the procurement organization. The procurement organization may  
 807 make a subsequent disclosure of the postmortem examination  
 808 results or other information received from the medical examiner  
 809 only if relevant to transplantation or therapy.

810 (2) The medical examiner may conduct a medicolegal  
 811 examination by reviewing all medical records, laboratory test  
 812 results, X rays, other diagnostic results, and other information  
 813 that any person possesses about a donor or prospective donor  
 814 whose body is under the jurisdiction of the medical examiner  
 815 which the medical examiner determines may be relevant to the  
 816 investigation.

817 (3) A person who has any information requested by a  
 818 medical examiner pursuant to subsection (2) shall provide that  
 819 information as expeditiously as possible to allow the medical  
 820 examiner to conduct the medicolegal investigation within a  
 821 period compatible with the preservation of parts for the purpose  
 822 of transplantation, therapy, research, or education.

823 (4) If an anatomical gift has been or might be made of a  
 824 part of a decedent whose body is under the jurisdiction of the  
 825 medical examiner and a postmortem examination is not required,  
 826 or the medical examiner determines that a postmortem examination  
 827 is required but that the recovery of the part that is the  
 828 subject of an anatomical gift will not interfere with the  
 829 examination, the medical examiner and procurement organization  
 830 shall cooperate in the timely removal of the part from the  
 831 decedent for the purpose of transplantation, therapy, research,  
 832 or education.

833       (5) If an anatomical gift of a part from the decedent  
 834 under the jurisdiction of the medical examiner has been or might  
 835 be made, but the medical examiner initially believes that the  
 836 recovery of the part could interfere with the postmortem  
 837 investigation into the decedent's cause or manner of death, the  
 838 medical examiner shall consult with the procurement organization  
 839 or physician or technician designated by the procurement  
 840 organization about the proposed recovery. After consultation,  
 841 the medical examiner may allow the recovery.

842       (6) After the consultation under subsection (5), in the  
 843 absence of mutually agreed-upon protocols to resolve conflict  
 844 between the medical examiner and the procurement organization,  
 845 if the medical examiner intends to deny recovery, the medical  
 846 examiner or designee, at the request of the procurement  
 847 organization, shall attend the removal procedure for the part  
 848 before making a final determination not to allow the procurement  
 849 organization to recover the part. During the removal procedure,  
 850 the medical examiner or designee may allow recovery by the  
 851 procurement organization to proceed or, if the medical examiner  
 852 or designee reasonably believes that the part may be involved in  
 853 determining the decedent's cause or manner of death, may deny  
 854 recovery by the procurement organization.

855       (7) If the medical examiner or designee denies recovery  
 856 under subsection (6), the medical examiner or designee shall:

857       (a) Explain in a record the specific reasons for not  
 858 allowing recovery of the part.

859       (b) Include the specific reasons in the records of the  
 860 medical examiner.

861 (c) Provide a record with the specific reasons to the  
 862 procurement organization.

863 (8) If the medical examiner or designee allows recovery of  
 864 a part under subsection (4), subsection (5), or subsection (6),  
 865 the procurement organization shall, upon request, cause the  
 866 physician or technician who removes the part to provide the  
 867 medical examiner with a record describing the condition of the  
 868 part, a biopsy, a photograph, and any other information and  
 869 observations that would assist in the postmortem examination.

870 (9) If a medical examiner or designee is required to be  
 871 present at a removal procedure under subsection (6), upon  
 872 request the procurement organization requesting the recovery of  
 873 the part shall reimburse the medical examiner or designee for  
 874 the additional costs incurred in complying with subsection (6).

875 Section 24. Section 765.5124, Florida Statutes, is created  
 876 to read:

877 765.5124 Uniformity of application and construction.--In  
 878 applying and construing this uniform act, consideration must be  
 879 given to the need to promote uniformity of the law with respect  
 880 to its subject matter among states that enact it.

881 Section 25. Section 765.5125, Florida Statutes, is created  
 882 to read:

883 765.5125 Relation to Electronic Signatures in Global and  
 884 National Commerce Act.--Sections 765.5101-765.5125 modify,  
 885 limit, and supersede the Electronic Signatures in Global and  
 886 National Commerce Act, 15 U.S.C. ss. 7001 et seq., but do not  
 887 modify, limit, or supersede s. 101(a) of that act, 15 U.S.C. s.

888 7001, or authorize electronic delivery of any of the notices  
 889 described in s. 103(b) of that act, 15 U.S.C. s. 7003(b).

890 Section 26. Sections 765.510, 765.511, 765.512, 765.513,  
 891 765.514, 765.515, 765.516, and 765.517, Florida Statutes, are  
 892 repealed.

893 Section 27. Paragraph (c) of subsection (2) of section  
 894 381.0041, Florida Statutes, is amended to read:

895 381.0041 Donation and transfer of human tissue; testing  
 896 requirements.--

897 (2) Notwithstanding the provisions of subsection (1),  
 898 written, informed consent to perform testing shall not be  
 899 required:

900 (c) When an unrevoked anatomical gift has been made  
 901 pursuant to s. 765.5105 ~~765.514~~, by will or other written  
 902 instrument, and the donor is deceased or incompetent.

903 Section 28. Subsection (1) of section 765.521, Florida  
 904 Statutes, is amended to read:

905 765.521 Donations as part of driver license or  
 906 identification card process.--

907 (1) The Agency for Health Care Administration and the  
 908 Department of Highway Safety and Motor Vehicles shall develop  
 909 and implement a program encouraging and allowing persons to make  
 910 anatomical gifts as a part of the process of issuing  
 911 identification cards and issuing and renewing driver licenses-  
 912 ~~The donor registration card distributed by the Department of~~  
 913 ~~Highway Safety and Motor Vehicles shall include the information~~  
 914 ~~required by the uniform donor card under s. 765.5105(1) (a)~~  
 915 ~~765.514 and such additional information as determined necessary~~

916 ~~by the department.~~ The department shall also develop and  
 917 implement a program to identify donors, which includes notations  
 918 on identification cards, driver licenses, and driver records or  
 919 such other methods as the department develops to clearly  
 920 indicate the individual's intent to donate the individual's  
 921 organs, tissues, or eyes. A notation on an individual's driver  
 922 license or identification card that the individual intends to  
 923 donate organs, tissues, or eyes satisfies all requirements for  
 924 consent to organ or tissue donation. The Agency for Health Care  
 925 Administration shall provide the necessary supplies and forms  
 926 from funds appropriated from general revenue or contributions  
 927 from interested voluntary, nonprofit organizations. The  
 928 department shall provide the necessary recordkeeping system from  
 929 funds appropriated from general revenue. The Department of  
 930 Highway Safety and Motor Vehicles and the Agency for Health Care  
 931 Administration shall incur no liability in connection with the  
 932 performance of any acts authorized herein.

933 Section 29. Subsections (2) and (3) of section 765.522,  
 934 Florida Statutes, are amended to read:

935 765.522 Duty of certain hospital administrators; liability  
 936 of hospital administrators, organ procurement organizations, eye  
 937 banks, and tissue banks.--

938 (2) Where, based on accepted medical standards, a hospital  
 939 patient is a suitable candidate for organ or tissue donation,  
 940 the hospital administrator or the hospital administrator's  
 941 designee shall, at or near the time of death, notify the  
 942 appropriate organ, eye, or tissue recovery program, which shall  
 943 access the organ and tissue donor registry created by s.



944 765.5120 ~~765.5155~~ to ascertain the existence of an entry in the  
 945 registry that has not been revoked, a donor card, or a document  
 946 executed by the decedent. In the absence of an entry in the  
 947 donor registry, donor card, organ donation sticker or organ  
 948 donation imprint on a driver's license, or other properly  
 949 executed document, the organ, eye, or tissue recovery program  
 950 shall request:

951 (a) The patient's health care surrogate, as authorized in  
 952 s. 765.5109(4) ~~765.512(2)~~; or

953 (b) If the patient does not have a surrogate, or the  
 954 surrogate is not reasonably available, any of the persons  
 955 specified in s. 765.5109(1) ~~765.512(3)~~, in the order and manner  
 956 listed,

957  
 958 to consent to the gift of all or any part of the decedent's body  
 959 for any purpose specified in this part. Except as provided in s.  
 960 765.5109 ~~765.512~~, in the absence of actual notice of opposition,  
 961 consent need only be obtained from the person or persons in the  
 962 highest priority class reasonably available.

963 (3) A gift made pursuant to a request required by this  
 964 section shall be executed pursuant to s. 765.5110 ~~765.514~~.

965 Section 30. This act shall take effect October 1, 2009.







HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 573  
SPONSOR(S): O'Toole and others  
TIED BILLS:

Health Facilities

IDEN./SIM. BILLS: CS/SB 620

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Elder & Family Services Policy Committee	10 Y, 0 N, As CS	Ciccone	Ciccone
2)	Health Care Regulation Policy Committee		Calamas	Calamas <i>CEC</i>
3)	Health & Family Services Policy Council			
4)	Finance & Tax Council			
5)				

SUMMARY ANALYSIS

CS/HB 573 expands the definition of "health facility" within part III of ch. 154, F. S., related to health facility authorities, to include facilities that provide independent living, assisted living, dementia care, or hospice services. The bill allows these types of facilities to be eligible to access financing through debt (bonds) issued by a health facility authority.

The bill has no direct fiscal impact on state funds.

The bill takes effect upon becoming a law.

## 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:

##### Current Situation:

Background: In 1974, the Health Facilities Authorities Law<sup>1</sup> was enacted to assist health facilities within each county or municipality with additional means and assistance in the development and maintenance of health-care related facilities and services as determined to be needed by the community. A health facility<sup>2</sup> means any non-for-profit private corporation authorized by law to provide:

- Hospital or nursing home care services in accordance with ch. 395, F.S., relating to hospital licensing and regulation or ch. 400, F.S., relating to nursing home licensing and regulation;
- Life care services in accordance with ch. 651, F.S., relating to continuing care contracts; and
- Facilities licensed under ch. 393, F.S., relating to development disabilities, and ch. 394, F.S., relating to mental health.

A Health Facilities Authority is a public corporation created by s. 154.207, F.S.; or any board, body, commission, or department of a county or municipality succeeding to the principal functions of the public corporation or to whom the powers and responsibilities authorized by the law are given by the local agency. Current law provides that a local agency may create a health facility authority if the governing body<sup>3</sup> of the local agency determines there is a need for an authority by adopting an ordinance or resolution. The governing body is required to appoint five persons, who must be residents of the local agency and as members, to serve 4-year staggered terms. The authority annually elects one of its members as chair and one as vice chair. Authority members are uncompensated; however they are paid for necessary expenses incurred while performing the duties of the authority. There are currently 32 Health Facilities Authorities operating in 23 counties in Florida.<sup>4</sup>

Section 154.207(9), F.S., provides that any authority member who is employed by, or receives income from a health facility under consideration by the authority may not vote on any matter related to that facility. All meetings of the authority, and its records, books, documents and papers are open and available to the public in accordance with the Public Meetings Law in s. 286.011, F.S.<sup>5</sup>

<sup>1</sup> Part III of ch. 154, F.S.

<sup>2</sup> s. 154.215(8), F.S.

<sup>3</sup> The governing body means the board, commission, or other governing body in which the general legislative powers of the local agency are vested. See s. 154.205(7), F.S.

<sup>4</sup> Official List of Special Districts Online, maintained by the Florida Department of Community Affairs, see <http://www.floridaspecialdistricts.org/OfficialList/criteria.cfm> (last visited on February 22, 2009)

<sup>5</sup> s. 154.207(7), F.S.

Purpose of the Authority: Section 154.209, F.S., provides that the purpose of the health facility authority is to assist health facilities in the acquisition, construction, financing, and refinancing of projects in any incorporated or unincorporated area within the geographical limits of the local agency. If the authority finds that there will be a benefit or a cost savings to a health facility located within its jurisdiction, the authority may issue bonds for the health facility to finance projects for the health facility or for another not-for-profit corporation under common control with that health facility that is located outside the geographical limits of the local agency or outside the state.<sup>6</sup>

Section 154.205(10), F.S., defines a health facility project as any structure, facility, machinery, equipment, or other property suitable for use by a health facility in connection with its operations or proposed operations, including without limitation:

- Real property;
- A clinic, computer facility, dining hall, firefighting facility, fire prevention facility, food service and preparation facility, health care facility, long-term care facility, facility, hospital, interns' residence, laboratory, laundry, maintenance facility, nurses' residence; nursing home, nursing school, office, parking area, pharmacy, recreational facility, research facility, storage facility, utility, or X-ray facility, or any combination of these; and
- Other structures or facilities related, required, or useful for health care purposes, research, or the operation of a health facility, including facilities or structures essential or convenient for the orderly conduct of the health facility and other similar items necessary or convenient for the operation of a particular facility or structure in the manner for which its use is intended; excluding fuel, supplies, or other items customarily charged at current operating expenses.

Powers of the Authority: To achieve its purpose, the authority is authorized to:<sup>7</sup>

- Sue and be sued;
- Purchase, lease, receive by gift or otherwise, or obtain options for the acquisition of, any real or personal property for the acquisition, construction, operation, or maintenance of any project;
- Construct, acquire, own lease, repair, maintain, extend, expand, improve rehabilitate, renovate, furnish, and equip projects and to pay all or part of these costs from the proceeds of bonds of the authority or from any other funds made available to the authority for such purpose;
- Make and execute agreements of lease, contracts, deeds, mortgages, notes, and other instruments necessary or convenient in the exercise of its powers and functions;
- Sell, lease, exchange, mortgage, transfer, or otherwise dispose of, or to grant options for any such puposes with respect to any project, any real or personal property or interest therein;
- Pledge or assign any money, rents, charges, fees, or other revenues and any proceeds derived from sales of preoperty, insurance, or condemnation awards;
- Fix, charge, and collect rents, fees, and charges for the use of any project;
- Issue bonds for the purpose of providing funds to pay all or any part of the cost of any project and to issue refunding bonds;
- Employ consulting engineers, architects, surveyors, attorneys, accountants, financial experts, and such other employees and agents as may be necessary and to fix their compensation;
- Acquire existing projects, reimburse any health facility for the cost of such project, and refund outstanding obligations, mortgages, or advances issued, made, or given by a health facility for the cost of the project;
- Mortgage any project and site for the benefit of the holders of the bonds issued to finance that project;
- Participate in and to issue bonds for the purpose of establishing and maintaining a self-insurance pool, as provided under the state Insurance code, on behalf of a health facility or a group of health facilities in order to resolve issues related to an act or omission of the health facility, its employees, or agents in the performance of health care or health-care related functions;
- Issue special obligation revenue bonds for the purpose of establishing and maintaining the self-insurance pool and related reserve funds;

<sup>6</sup> s. 154.247, F.S.

<sup>7</sup> s. 154.209, F.S.

- Participate in and issue bonds and other forms of indebtedness for the purpose of establishing and maintaining an accounts receivable program on behalf of a health facility or group of health facilities;
- Issue and renew its negotiable notes;
- Issue revenue bonds for the purpose of paying all or any part of the cost of any part of the cost of any project or for acquiring existing or completed health facilities projects and negotiable bond anticipation notes payable out of revenue derived by the authority from the sale, operation, or leasing of any project.

Revenue bonds issued by an authority under the Law are not a debt, liability, obligation, or a pledge of the faith and credit of the local agency, the state, or any political subdivision but are payable solely from the revenues of the project.<sup>8</sup>

#### Licensed Facilities:

Assisted Living Facilities (ALF) are residential care facilities that provide housing, meals, personal care, and supportive services to elders and disabled adults who are unable to live independently. The facilities are licensed and regulated by the Agency for Health Care Administration (AHCA) under Part II of chapter 408, F.S., Part I of Chapter 429.F.S., and Chapter 58A-14, F.A.C., and are intended to be a less costly alternative to more restrictive institutional settings for individuals who do not require 24-hour nursing supervision. Generally, ALFs provide supervision, assistance with personal and supportive services, and assistance with administration of medications. ALFs range in size from less than 5 residents to several hundred. Currently, there are 2,707 ALFs serving approximately 78,000 residents.<sup>9</sup>

Adult Family-Care Homes are private residences that are licensed to provide a full-time family-type living arrangement in a private home to frail elderly and disabled adults who are unrelated to each other and who are unable to live independently. The adult family-care home provider must live in the home. These facilities are licensed and regulated by AHCA under Part II of chapter 408, F.S., Part II of chapter 429, F.S., 435, F.S., and Chapter 58A-14, F.A.C. Currently, there 503 licensed facilities serving approximately 2,200 residents

Adult Day Care Centers are for facilities that provide programs and services for adults (age 18 years of age or older) who need a protective setting during the day. Program participants live in their own homes, assisted living facilities or adult family care homes and come to the day care center during the day and receive basic services such as social and health activities, self-care training; rest, and nutritional services and optional services such as speech, occupational and physical therapy. These facilities are licensed and regulated by AHCA under Part II of chapter 408, F.S., Part III of chapter 429, F.S., and Chapter 58A-6, F.A.C. Currently, there are 159 facilities and approximately 7,757 beds.

Continuing Care Retirement communities are entities that provide varying levels of care to residents who are generally 55 years of age and older. CCRCs provide a continuum of care to accommodate a resident's changing needs and available services may range from independent live-in houses or apartments, to assisted living facilities, to skilled nursing facilities. CCRS operate under a certificate of authority issued under Chapter 651, F.S., relating to continuing care contracts as a part of the Florida Insurance Code. Health care services and facilities within a CCRC are regulated by AHCA under chapter laws specific to the services or facilities. Currently, there are 75 licenses issued to CCRCs serving approximately 30,000 residents.<sup>10</sup>

Hospices are entities that provide end-of-life services in private homes, assisted living facilities, adult family care homes, hospitals, or hospice facilities for terminally ill patients. Hospices are licensed and regulated by AHCA under Part IV of Chapter 400, F.S., and Chapter 58A-2, F.A.C. Currently, there are 41 licensed hospice facilities in the state.

<sup>8</sup> s. 154.223, F.S.

<sup>9</sup> License and facility data relating to Assisted Living Facilities, Adult Family-Care Homes, Adult Day Care Centers, and Hospices received from the Agency for Health Care Administration, August 2008.

<sup>10</sup> License and resident data received from the Department of Financial Services, August 2008.



Effect of the Bill:

CS/HB 573 expands the definition of a "health facility" under Chapter 154, F.S., for the purpose of allowing additional types of health facilities to receive assistance from a health facilities authority.

The bill clarifies the list of current health facilities--hospital services, nursing home care services, life care services and services for the developmentally disabled and the mentally ill--and provides additional facilities such as independent living, assisted living, dementia care, or hospice services to be eligible to access financing through debt (bonds) issued by a health facility authority.

This bill should facilitate the private sector development of senior health-related services and housing options to address the increased projected demand for such services in Florida.

**B. SECTION DIRECTORY:**

Section 1. Amends s. 154.205(8), F.S., relating to the definition of a "health facility".

Section 2. Provides an effective date of upon the bill becoming a law.

**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:**

This bill provides health facility authorities the option to assist private not-for-profit entities with the funding of healthcare related services and housing options, primarily for the elderly. This bill should facilitate private sector development of such senior living and other not-for-profit health facilities. increases.

**D. FISCAL COMMENTS:**

None.

### **III. COMMENTS**

#### **A. CONSTITUTIONAL ISSUES:**

##### **1. Applicability of Municipality/County Mandates Provision:**

The provisions of this bill have no impact on municipalities and counties under the requirements of Article VII, Section 18 of the Florida Constitution.

##### **2. Other:**

None.

#### **B. RULE-MAKING AUTHORITY:**

None.

#### **C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

### **IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES**

On March 3, 2009, the Elder and Family Services Policy Committee adopted one amendment by the bill sponsor that expands the definition of a "health facility" under chapter 154, F.S., for the purpose of allowing additional types of health facilities to receive assistance from a health facilities authority.

The bill was reported favorably as a Committee Substitute. The analysis reflects the Committee Substitute.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. CS/HB 573

COUNCIL/COMMITTEE ACTION

ADOPTED \_\_\_\_\_ (Y/N)  
ADOPTED AS AMENDED \_\_\_\_\_ (Y/N)  
ADOPTED W/O OBJECTION \_\_\_\_\_ (Y/N)  
FAILED TO ADOPT \_\_\_\_\_ (Y/N)  
WITHDRAWN \_\_\_\_\_ (Y/N)  
OTHER \_\_\_\_\_

1 Council/Committee hearing bill: Health Regulation Policy  
2 Committee  
3 Representative(s) O'Toole offered the following:

**Amendment (with directory and title amendments)**

Remove line(s) 23-28 and insert:

(e) Services for the mentally ill under chapter 394;

(f) Assisted living services in accordance with chapter

429; or

(g) Hospice services in accordance with chapter 400.

Health facility also includes any private corporation organized  
not for profit which offers independent living facilities and  
services as part of a retirement community that provides nursing  
home care services or assisted living services on the same  
campus. ~~hospital or nursing home care services in accordance~~  
~~with chapter 395 or chapter 400 or life care services in~~  
~~accordance with chapter 651, and also includes facilities~~  
~~licensed under chapter 393 and 394.~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

22  
23  
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**T I T L E   A M E N D M E N T**

Remove line(s) 2-6 and insert:

An act related to health facilities; amending s. 154.205, F.S.; redefining the term "health facility" to include not-for-profit corporations providing assisted living services, hospice services or certain independent living services; providing an effective date.

1                   A bill to be entitled  
 2           An act relating to health facilities; amending s. 154.205,  
 3           F.S.; redefining the term "health facility" for the  
 4           purpose of allowing additional types of health facilities  
 5           to receive assistance from a health facilities authority;  
 6           providing an effective date.

7  
 8   Be It Enacted by the Legislature of the State of Florida:

9  
 10           Section 1. Subsection (8) of section 154.205, Florida  
 11   Statutes, is amended to read:

12           154.205 Definitions.--The following terms, whenever used  
 13   in this part, shall have the following meanings unless a  
 14   different meaning clearly appears from the context:

- 15           (8) "Health facility" means any private corporation  
 16   organized not for profit and authorized by law to provide:  
 17           (a) Hospital services in accordance with chapter 395;  
 18           (b) Nursing home care services in accordance with chapter  
 19           400;  
 20           (c) Life care services in accordance with chapter 651;  
 21           (d) Services for the developmentally disabled under  
 22           chapter 393;  
 23           (e) Services for the mentally ill under chapter 394; or  
 24           (f) Independent living, assisted living, dementia care, or  
 25           hospice services ~~hospital or nursing home care services in~~  
 26           ~~accordance with chapter 395 or chapter 400 or life care services~~  
 27           ~~in accordance with chapter 651, and also includes facilities~~  
 28           ~~licensed under chapters 393 and 394.~~

CS/HB 573

2009

29 | Section 2. This act shall take effect upon becoming a law. |

**Leukemia &  
Lymphoma Society  
Presentation**





## **Claudio Anasetti, M.D.**

Dr. Anasetti is the Division Chief, Blood & Marrow Transplant. He joined Moffitt Cancer Center in April 2004.

Dr. Anasetti received his medical degree in 1980 from the University of Perugia, Italy, where he also completed his Residency in Internal Medicine. A Fellowship in Immunology at Children's Memorial Hospital, Oklahoma City, followed in 1983. A second Fellowship in Oncology at the University of Washington and Fred Hutchinson Cancer Research Center, in Seattle, was completed in 1985.



Dr. Anasetti is the author or coauthor of more than 60 articles in peer-reviewed publications.

His research interests include antibody targeting of the T cell receptor and CD28 to prevent GVHD in mouse models and human transplants. His clinical interests include clinical blood and bone marrow transplantation; immunogenetics and donor selection; prevention and treatment of graft-versus-host disease.

Dr. Anasetti was PI on an R21, Co-PI on a two P01 awards and recently completed work as PI on an R01.

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### EDUCATION/EXPERIENCE

- 2007-Current Senior Medical Liaison Hematology/Oncology  
-Therapeutic Lead, Chronic Myelogenous Leukemia, Chronic Lymphocytic Leukemia  
-Clinical Trial Lead
- 2005-2007 Hematology/Oncology Medical Science Liaison  
Bristol Myers-Squibb Company  
-Clinical Trial Point Melanoma  
-Therapeutic Lead, Chronic Lymphocytic Leukemia  
-Completed MD Anderson Hematology Preceptorship  
-Completed MD Anderson Hematology Board Review
- 2001-2005 Research Scientist  
Lexicon Genetics, Inc.  
The Woodlands, TX 77384
- 1997-2001 Postdoctoral Fellow, Department of Genetics,  
St Jude Children's Research Hospital, Memphis, TN
- 2000-2001 Adjunct Instructor, Southwest Tennessee Community College
- 1994-1997 Postdoctoral Fellow, Department of Genetics,  
Samuel Lunenfeld Research Institute, Mount Sinai Hospital, Toronto, ON,  
Canada
- 1988-1994 PhD, Biomedical Sciences,  
University of Tennessee-Oak Ridge Graduate School of Biomedical  
Sciences, Oak Ridge National Laboratory, Oak Ridge, TN 37831
- 1986-1988 Graduate Studies in Biology  
Arkansas State University  
Jonesboro, AR 72401
- 1982-1986 Bachelor of Science, Biology  
Arkansas Tech University  
Russellville, AR

## PROFESSIONAL MEMBERSHIPS

American Society Hematology  
American Medical Writer's Association  
Drug Information Association  
American Association of Pharmaceutical Scientists

## PUBLICATIONS

### **Publications:**

Cintia Carella, Mark **Potter**, Jacqueline Bonten, Jerold E. Rehg, Geoffrey Neale and Gerard C. Grosveld: The ETS factor TEL2 is a hematopoietic onco-protein. *Blood* 2006; 107(3): 1124-32.

Kawagoe H, **Potter** M, Ellis J, Grosveld GC. TEL2, an ETS factor expressed in human leukemia, regulates monocytic differentiation of U937 Cells and blocks the inhibitory effect of TEL1 on ras-induced cellular transformation. *Cancer Res.* 2004; 64(17):6091-100.

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## **Andrew W. Stein**

Andy has been a resident of Panama City, Florida for 23 years. He had previously resided in Boca Raton, Florida. He and his wife, Barbara, have three children, Matthew 26, Megan, 23, and Zachary, 20. Andy is the President of Summit Bank, headquartered in Panama City, and had previously served as the CEO of a community bank and a senior officer of a major regional banking company. He is involved in many civic and philanthropic activities including serving on the Board of Trustees, previously serving as Chairman, of Bay Medical Center, a 353 bed tertiary care, public hospital in Panama City, Florida. He also served on the Panama City/Bay County Airport Authority Board of Directors. Andy and Barbara are currently chairing the inaugural Leukemia Cup Regatta at Bay Point, raising funds for the Leukemia and Lymphoma Society, to further their mission.

Andy and Barbara's 26 year old son, Matthew, was diagnosed with acute lymphocytic leukemia (ALL) in August 2006, and received a bone marrow transplant in November 2006. His brother, Zachary was his donor. Matthew is now disease free. He is married to Michaile and works and lives in the Tampa Bay area.

**Beth Shankle-Anderson, Esq.**

Beth Shankle-Anderson is an attorney who focuses her practice on administrative and appellate law. She has practiced at private law firms and a government agency and is now a sole practitioner devoting much of her practice to pro bono work. She is a volunteer attorney with the Autism Legislative Project from Chicago where she has researched autism legislation in over fifteen states. The research has been used by Senator Dick Durbin (D – Illinois) and then-Senator Barack Obama in the proposed “Autism Treatment Acceleration Act”. The bill will be reintroduced by Senator Durbin this year.

Beth is an advocate and volunteer for the Leukemia & Lymphoma Society having been profoundly affected by lymphoma herself. As a child, her father was diagnosed with Non-Hodgkins Lymphoma and succumbed to the illness four months later.

As the current Mrs. Tallahassee, Beth is involved with many causes that include the Making Memories Breast Cancer Foundation, the American Heart Association, the American Red Cross, and the Early Learning Coalition where she serves as a “Celebrity Reader” to preschool children. She is also involved in the local Junior League where she has participated in a number of events helping underprivileged children.

## **Richard Fess**

Richard A. Fess, Florida Insurance and Real Estate Broker  
Lake Mary, Florida resident  
Married to Julie Fess, 4 children  
US Army Veteran

### The Leukemia & Lymphoma Society

National Board of Directors/Representatives since 1986  
Former-Secretary/Treasurer of National Board  
Former-Executive Committee member  
Chairman of more than 5 different committees of National Board  
Past President of Central Florida Chapter  
Recipient of National Leadership Award  
Recipient of the deVilliers Society Award

### Former Positions in Political and Community services

Mayor of Lake Mary, Florida  
President of Tri-County League of Cities  
Chairman of Florida Quality Cities Task Force (League of Cities)  
Seminole County Republican Executive Committee  
Chairman-Central Florida Pvt Industry Council/WorkForce  
President/Chairman Seminole County United Way  
President Lake Mary Chamber/Seminole County Chamber  
Board Member Greater Orlando Chamber  
Florida Hospital Board  
18<sup>th</sup> Judicial District Grievance Committee  
18<sup>th</sup> Judicial Circuit Nominating Committee  
18<sup>th</sup> Judicial Mediator for County Courts  
Orlando - Jefferson Award  
Presidential Citation from Ronald Reagan







**The Leukemia &  
Lymphoma Society**<sup>®</sup>  
*Fighting Blood Cancers*

# **Importance of Patient Access to Cancer Clinical Trials**

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Zina D. Cary  
National Director, State Affairs  
Office of Public Policy  
The Leukemia & Lymphoma Society

# **LLS Strategic Plan to Increase Patient Access to Cancer Clinical Trials**

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- ❑ Office of Public Policy (OPP) following lead of LLS' strategic plan, to increase adult access to cancer clinical trials.
  - ❑ OPP addressing adult access barriers to clinical trials at state & federal levels.
  - ❑ LLS engaged in more than half dozen state legislatures.
-

# **Who Sponsors Cancer Clinical Trials?**

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- National Institutes of Health (NIH)
  - U.S. Food & Drug Administration (FDA)
  - U.S. Department of Veterans Affairs (VA)
  - U.S. Department of Defense (DoD)
  - Pharmaceutical & Biotechnology Industry
-

# Why Access to Cancer Clinical Trials Matters

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- ❑ Cutting-edge treatments for blood & other cancers discovered through clinical trials- **Gleevac miracle breakthrough for CML patients, via clinical trials!**
  - ❑ Participation of pediatric cancer patients greatly increased over last 25 years to more than 60%.
  - ❑ Survival rate among children, with some cancers, nearly 90%.
  - ❑ Only 3% -- 5% of adults participate in cancer clinical trials.
-

## **Barriers to Cancer Clinical Trials**

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- Lack of means to afford “routine patient costs” involved in clinical trials; these include nursing, in-patient services, lab work & other tests.
  - Lack of transportation.
  - Lack of patient & family/care giver education.
  - Lack of physician/provider education.
-

# **Downsides to Barriers to Cancer Clinical Trials**

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- Fewer breakthroughs in new treatments & therapies; also slows pace of reaching ultimate goal of finding a cure.
  - Patients not receiving best possible care/treatments.
  - Deters young, promising scientists from entering field of clinical research.
-

# States Who Have Successfully Addressed Barrier Issues

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- 24 states, & the District of Columbia, currently provide coverage for “routine care” in clinical trials.
  - Included are California, Georgia, Maryland, New Jersey, Michigan, Ohio, Wisconsin, Vermont, Virginia & Wyoming.
-

## **States Tackling Barrier Issues**

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- Alaska, Colorado, Indiana, Iowa, Kentucky, Nebraska, New York, Oklahoma, Oregon, Pennsylvania, Texas
  
  - LLS thanks House Health Committee for taking closer, thoughtful look at issue.
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# Resources

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The Leukemia & Lymphoma Society (LLS)

[www.lls.org](http://www.lls.org)

National Cancer Institute (NCI)

[www.cancer.gov/clinicaltrials](http://www.cancer.gov/clinicaltrials)

American Society of Clinical Oncology (ASCO)

[www.asco.org/portal/site/ASCO](http://www.asco.org/portal/site/ASCO)

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# ***Cancer Clinical Trials***

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**Claudio Anasetti, M.D.**

**Chair, Department of Blood and Marrow Transplantation  
Moffitt Cancer Center, Tampa FL**

**President,  
American Society of Blood and Marrow Transplantation**



# Importance of Clinical Trials to Cancer Patients

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- Life-threatening diseases
- Each type of cancer is rare
- Treatment may:
  - decrease symptoms
  - prolong life
  - produce cure
- Treatment is toxic
- Benefits must offset toxic effects

# Clinical Research at Moffitt Cancer Center

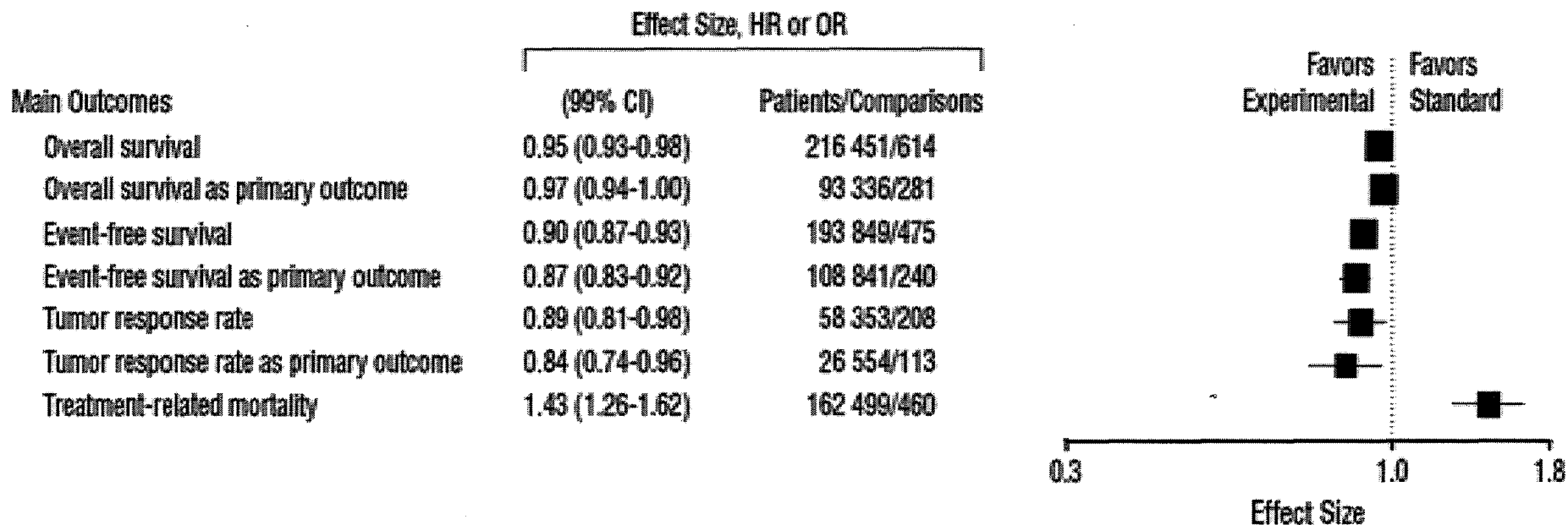
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- Florida's largest clinical cancer research unit
- More than 200 Moffitt clinical trials now underway
- 1,462 patients enrolled in Moffitt clinical trials in 2008
- Several Moffitt clinical trials being conducted at affiliate hospitals throughout Florida

# IMPROVED SURVIVAL OF PATIENTS

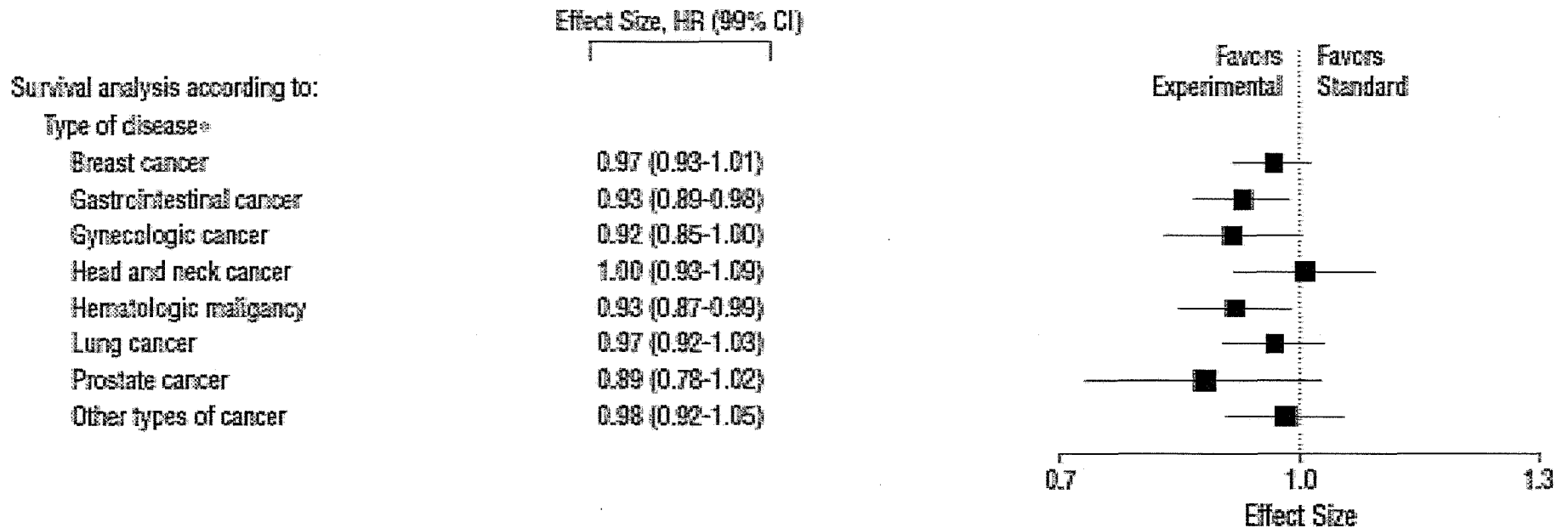
*Randomized Clinical Trials – Nat'l Cancer Institute*

*1955 - 2006*



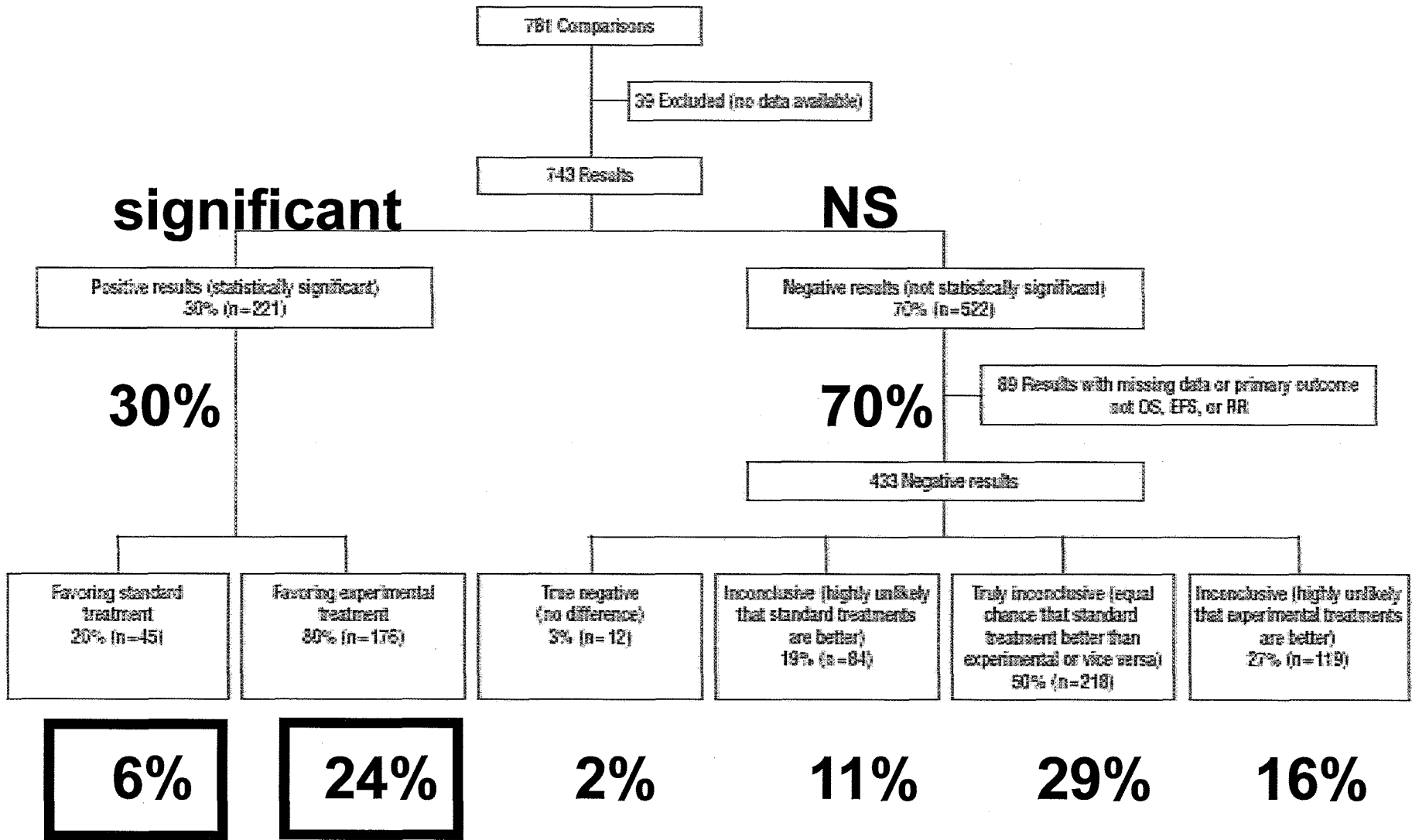
*Ben Djulbegovic et al, Arch Intern Med. 2008; 168:632-642*

# Treatment Success by Cancer Site



*Ben Djulbegovic et al, Arch Intern Med. 2008; 168:632-642*

# Probability of Clinical Trial Outcome

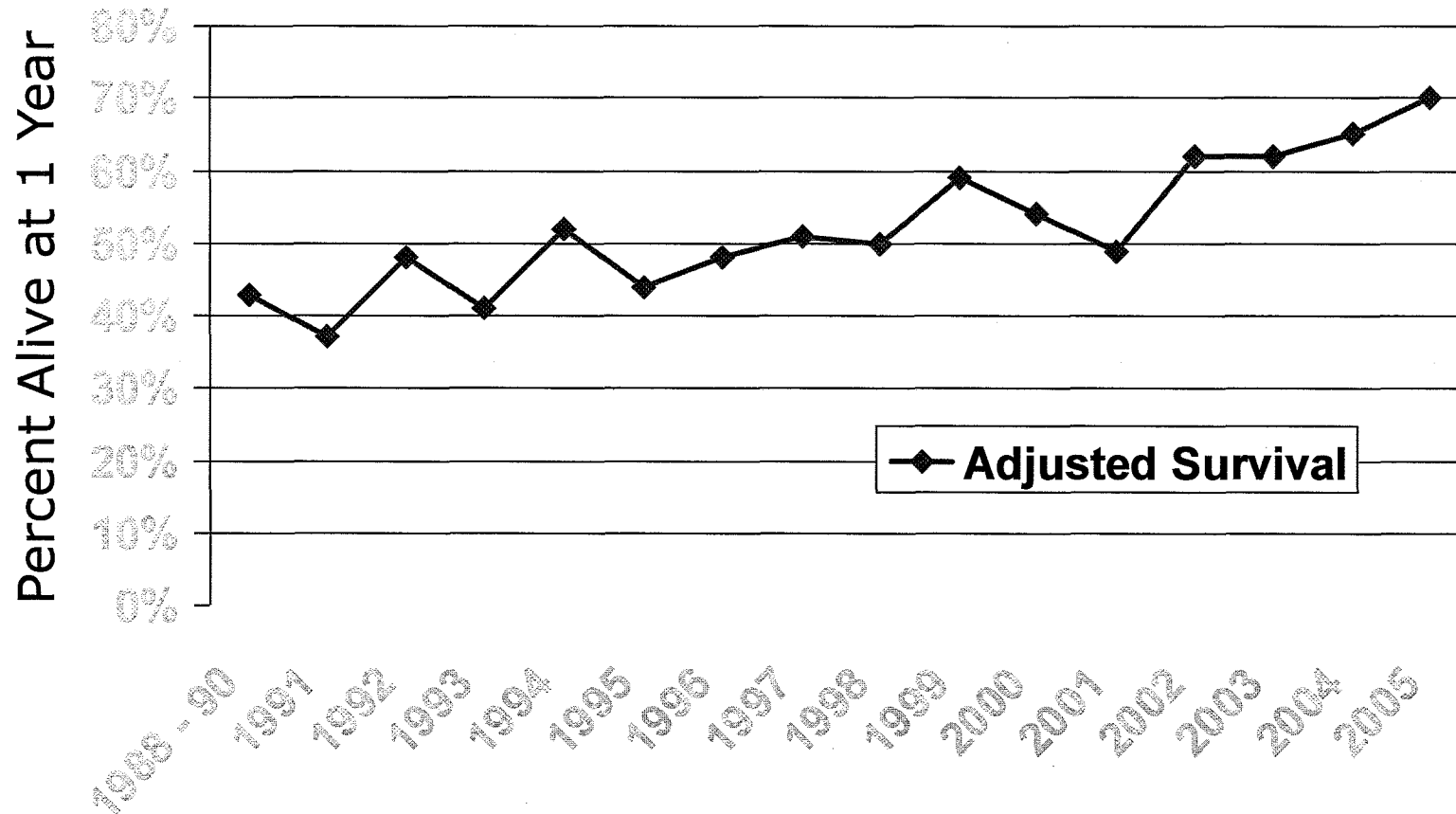


Ben Djulbegovic et al, Arch Intern Med. 2008; 168:632-642



# CLINICAL TRIALS ARE IMPROVING SURVIVAL RATES

Adjusted 1-year Survivals over Time:  
PART Analysis – 1988 - 2005



Courtesy of Dr. Dennis Confer





**Workshop on  
Prescription Drug  
Distribution Reg.**





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# Health Care Regulation Policy Committee

Tuesday, March 10, 2009  
2:45 PM – 5:00 PM  
Webster Hall (212 Knott Building)

# Revised

Larry Cretul  
Speaker

Jimmy Patronis  
Chair

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

Bill No. **HB 209**

COUNCIL/COMMITTEE ACTION

ADOPTED \_\_\_\_\_ (Y/N)  
ADOPTED AS AMENDED \_\_\_\_\_ (Y/N)  
ADOPTED W/O OBJECTION \_\_\_\_\_ (Y/N)  
FAILED TO ADOPT \_\_\_\_\_ (Y/N)  
WITHDRAWN \_\_\_\_\_ (Y/N)  
OTHER \_\_\_\_\_

1 Council/Committee hearing bill: Health Care Regulation Policy  
2 Committee

3 Representative(s) Schwartz offered the following:  
4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 765.511, Florida Statutes, is amended  
8 to read:

9 765.511 Definitions.--As used in this part, the term:

10 (1) "Agency" means the Agency for Health Care  
11 Administration.

12 (2) "Anatomical gift" or "gift" means a donation of all or  
13 part of a human body to take effect after the donor's death and  
14 to be used for transplantation, therapy, research, or education.

15 (3) ~~(1)~~ "Bank" or "storage facility" means a facility  
16 licensed, accredited, or approved under the laws of any state  
17 for storage of human bodies or body parts thereof.

18 (4) ~~(2)~~ "Death" means the absence of life as determined, in  
19 accordance with currently accepted medical standards, by the  
20 irreversible cessation of all respiration and circulatory  
21 function, or as determined, in accordance with s. 382.009, by  
22 the irreversible cessation of the functions of the entire brain,  
23 including the brain stem.

24 (5) "Decedent" means a deceased individual whose body or

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

25 body parts may be, or are, the source of an anatomical gift.

26 (6) "Department" means the Department of Highway Safety  
27 and Motor Vehicles.

28 (7) "Disinterested witness" means a witness other than a  
29 person listed in s. 765.512(3) or other family member.

30 (8) "Document of gift" means any of the documents or  
31 mechanisms used in making an anatomical gift under s. 765.514.

32 (9)-(3) "Donor" means an individual who makes an anatomical  
33 a gift of all or part of his or her body.

34 (10) "Donor registry" means a database that contains  
35 records of anatomical gifts and amendments to, or revocations  
36 of, such gifts.

37 (11) "Eye bank" means an entity that is accredited by the  
38 Eye Bank Association of America or otherwise regulated under  
39 federal or state law to engage in the retrieval, screening,  
40 testing, processing, storage, or distribution of human eye  
41 tissue.

42 (12) "Guardian" means a person appointed pursuant to  
43 chapter 744. The term does not include a guardian ad litem.

44 (13)-(4) "Hospital" means a hospital licensed, accredited,  
45 or approved under the laws of any state and includes a hospital  
46 operated by the United States Government or a state, or a  
47 subdivision thereof, although not required to be licensed under  
48 state laws.

49 (14) "Identification card" means an official  
50 identification card issued by a governmental entity, state  
51 agency, or subdivision thereof.

52 (15) "Organ procurement organization" means an entity that  
53 is designated as an organ procurement organization by the  
54 Secretary of the United States Department of Health and Human  
55 Services and that engages in the retrieval, screening, testing,  
56 processing, storage, or distribution of human organs.

57 (16) "Part of the body" or "body part" means an organ,

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

58 eye, or tissue of a human being. The term does not include the  
59 whole body.

60 (17)~~(5)~~ "Physician" or "surgeon" means a physician or  
61 surgeon licensed to practice under chapter 458 or chapter 459 or  
62 similar laws of any state. "Surgeon" includes dental or oral  
63 surgeon.

64 (18) "Procurement" means any retrieval, recovery,  
65 processing, storage, or distribution of human organs or tissues  
66 for transplantation, therapy, research, or education.

67 (19) "Procurement organization" means an organ procurement  
68 organization, eye bank, or tissue bank.

69 (20) "Reasonably available" means able to be contacted by  
70 a procurement organization in a timely manner without undue  
71 effort, and willing and able to act in a manner consistent with  
72 existing medical protocols necessary for the making of an  
73 anatomical gift.

74 (21) "Record" means information that is inscribed on a  
75 tangible medium or that is stored in an electronic or other  
76 medium and is retrievable in perceivable form.

77 (22) "Sign" or "signed" means, with the present intent to  
78 authenticate or adopt a record, to execute or adopt a tangible  
79 symbol, or attach to or logically associate an electronic  
80 symbol, sound, or process with the record.

81 (23) "Tissue bank" means an entity that is accredited by  
82 the American Association of Tissue Banks or otherwise regulated  
83 under federal or state law to engage in the retrieval,  
84 screening, testing, processing, storage, or distribution of  
85 human tissue.

86 Section 2. Subsections (1), (4), (5), (6), and (7) of  
87 section 765.512, Florida Statutes, are amended to read:

88 765.512 Persons who may make an anatomical gift.--

89 (1) Any person who may make a will may make an anatomical  
90 gift ~~give all or part of his or her body for any purpose~~  
91 ~~specified in s. 765.513. The gift is effective upon the death of~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

92 ~~the donor.~~

93 (a) If the decedent makes an anatomical gift by one of the  
94 methods listed in s. 765.514(1), and in the absence of actual  
95 notice of contrary indications by the decedent, the document or  
96 entry in the donor organ and tissue registry is legally  
97 sufficient evidence of the decedent's informed consent to donate  
98 an anatomical gift.

99 (b) An anatomical gift made by a qualified donor and not  
100 revoked by the donor, as provided in s. 765.516, is irrevocable  
101 after the donor's death. A family member, guardian,  
102 representative ad litem, or health care surrogate may not  
103 modify, deny, or prevent a donor's wish or intent to make an  
104 anatomical gift after the donor's death.

105 (4) A donee may not accept an anatomical gift if the donee  
106 has actual notice of contrary indications by the donor or actual  
107 notice that an anatomical a gift by a member of a class is  
108 opposed by a member of a prior class.

109 (5) The person authorized by subsection (3) may make the  
110 anatomical gift after the decedent's death or immediately before  
111 the decedent's death.

112 (6) An anatomical A gift of ~~all or part of a body~~  
113 authorizes:

114 (a) Any examination necessary to assure medical  
115 acceptability of the gift for the purposes intended.

116 (b) The decedent's medical provider, family, or a third  
117 party to furnish medical records requested concerning the  
118 decedent's medical and social history.

119 (7) Once the anatomical gift has been made, the rights of  
120 the donee are paramount to the rights of others, except as  
121 provided by s. 765.517.

122 Section 3. Section 765.513, Florida Statutes, is amended  
123 to read:

124 765.513 ~~Persons and entities that may become~~ Donees;  
125 purposes for which anatomical gifts may be made.--

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

126        (1) The following persons or entities may become donees of  
127 anatomical gifts of bodies or parts of them for the purposes  
128 stated:

129        ~~(a)(1)~~ Any procurement organization or accredited  
130 ~~hospital, surgeon, or physician for~~ medical or dental school,  
131 college, or university for education, ~~or~~ research, advancement  
132 ~~of medical or dental science,~~ therapy, or transplantation.

133        ~~(2)~~ Any ~~accredited medical or dental school, college, or~~  
134 ~~university for~~ education, ~~research, advancement of medical or~~  
135 ~~dental science, or therapy.~~

136        ~~(3)~~ Any ~~bank or storage facility for~~ medical or dental  
137 ~~education, research, advancement of medical or dental science,~~  
138 ~~therapy, or transplantation.~~

139        ~~(b)(4)~~ Any individual specified by name for therapy or  
140 transplantation needed by him or her.

141        (2) If multiple purposes are set forth in the document of  
142 gift but are not set forth in any priority order, the anatomical  
143 gift shall be used first for transplantation or therapy, if  
144 suitable. If the gift cannot be used for transplantation or  
145 therapy, the gift may be used for research or education.

146        (3) ~~However,~~ The Legislature declares that the public  
147 policy of this state prohibits restrictions on the possible  
148 recipients of an anatomical gift on the basis of race, color,  
149 religion, gender ~~sex~~, national origin, age, physical disability  
150 handicap, health status, marital status, or economic status, and  
151 such restrictions are ~~hereby declared~~ void and unenforceable.

152        Section 4. Section 765.514, Florida Statutes, is amended  
153 to read:

154        765.514 Manner of making anatomical gifts.--

155        (1) A person may make an anatomical ~~a~~ gift of all or part  
156 of his or her body under s. 765.512(1) by:

157        (a) Signing an organ and tissue donor card.

158        (b) Registering online with the ~~organ and tissue~~ donor  
159 registry.



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

160 (c) Signifying an intent to donate on his or her driver's  
161 license or identification card issued by the  
162 ~~department~~~~Department of Highway Safety and Motor Vehicles.~~  
163 Revocation, suspension, expiration, or cancellation of the  
164 driver's license or identification card does not invalidate the  
165 gift.

166 (d) Expressing a wish to donate in a living will or other  
167 advance directive.

168 (e) Executing a will that includes a provision indicating  
169 that the testator wishes to make an anatomical gift. The gift  
170 becomes effective upon the death of the testator without waiting  
171 for probate. If the will is not probated or if it is declared  
172 invalid for testamentary purposes, the gift is nevertheless  
173 valid to the extent that it has been acted upon in good faith.

174 (f) Expressing a wish to donate in a document other than a  
175 will. The document must be signed by the donor in the presence  
176 of two witnesses who shall sign the document in the donor's  
177 presence. If the donor cannot sign, the document may be signed  
178 for him or her at the donor's direction and in his or her  
179 presence and the presence of two witnesses who must sign the  
180 document in the donor's presence. Delivery of the document of  
181 gift during the donor's lifetime is not necessary to make the  
182 gift valid. The following form of written document is sufficient  
183 for any person to make an anatomical gift ~~give all or part of~~  
184 ~~his or her body~~ for the purposes of this part:

185 UNIFORM DONOR CARD

186  
187 The undersigned hereby makes this anatomical gift, if medically  
188 acceptable, to take effect on death. The words and marks below  
189 indicate my desires:

190 I give:

191 (a) .... any needed organs, tissues, or eyes;

192 (b) .... only the following organs, tissues, or eyes

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

193           ...[Specify the organs, tissues, or eyes]...  
194 for the purpose of transplantation, therapy, medical research,  
195 or education;

196           (c) .... my body for anatomical study if needed.

197 Limitations or special wishes, if any:

198       ...(If applicable, list specific donee; this must be arranged in  
199           advance with the donee.)...

200

201 Signed by the donor and the following witnesses in the presence  
202 of each other:

203

204       ...(Signature of donor)...                   ...(Date of birth of donor)...

205       ...(Date signed)...                               ...(City and State)...

206

207       ...(Witness)...                                       ...(Witness)...

208       ...(Address)...                                       ...(Address)...

209           (2) The anatomical gift may be made to a donee listed in  
210 s. 765.513, and the donee may be specified by name.

211           (3) Any anatomical gift by a health care surrogate  
212 designated by the decedent pursuant to part II of this chapter  
213 or a member of a class designated in s. 765.512(3) must be made  
214 by a document signed by that person or made by that person's  
215 witnessed telephonic discussion, telegraphic message, or other  
216 recorded message.

217           Section 5. Section 765.515, Florida Statutes, is amended  
218 to read:

219           765.515 Delivery of donor document.--

220           (1) If an anatomical a gift is made pursuant to s.  
221 765.521, the completed donor registration card shall be  
222 delivered to the department~~Department of Highway Safety and~~  
223 ~~Motor Vehicles~~ and the department must communicate the donor's  
224 intent to the ~~organ and tissue~~ donor registry, but delivery is  
225 not necessary to the validity of the gift. If the donor  
226 withdraws the gift, the records of the department~~Department of~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

227 ~~Highway Safety and Motor Vehicles~~ must be updated to reflect  
228 such withdrawal and the department must communicate the  
229 withdrawal to the ~~organ and tissue~~ donor registry for the  
230 purpose of updating the registry.

231 (2) If an anatomical a gift is made by the donor to a  
232 specified donee, the document of gift, other than a will, may be  
233 delivered to the donee to expedite the appropriate procedures  
234 immediately after death, but delivery is not necessary to the  
235 validity of the gift. ~~The Such~~ document of gift may be deposited  
236 in any hospital, bank, storage facility, or registry office that  
237 accepts such documents for safekeeping or to facilitate the  
238 donation of organs and tissue after death.

239 (3) At the request of any interested party upon or after  
240 the donor's death, the person in possession shall produce the  
241 document of gift for examination.

242 Section 6. Section 765.5155, Florida Statutes, is amended  
243 to read:

244 765.5155 ~~Organ and tissue~~ Donor registry; education  
245 program.--

246 (1) The Legislature finds that:

247 (a) There is a shortage of organ and tissue donors in this  
248 state willing to provide the organs and tissue that could save  
249 lives or enhance the quality of life for many persons.

250 (b) There is a need to encourage the various minority  
251 populations of this state to donate organs and tissue.

252 (c) A statewide ~~organ and tissue~~ donor registry having an  
253 online donor registration process coupled with an enhanced  
254 program of donor education will lead to an increase in the  
255 number of organ and tissue donors registered in this state, thus  
256 affording more persons who are awaiting organ or tissue  
257 transplants the opportunity for a full and productive life.

258 (2) The agency ~~for Health Care Administration~~ and the  
259 ~~department~~Department of Highway Safety and Motor Vehicles shall  
260 jointly contract for the operation of a ~~an organ and tissue~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

261 donor registry and education program. The contractor shall be  
262 procured by competitive solicitation pursuant to chapter 287,  
263 notwithstanding any exemption in s. 287.057(5)(f). When awarding  
264 the contract, priority shall be given to existing nonprofit  
265 groups that are based within the state, have expertise working  
266 with ~~organ and tissue~~ procurement organizations, have expertise  
267 in conducting statewide organ and tissue donor public education  
268 campaigns, and represent the needs of the organ and tissue  
269 donation community in the state.

270 (3) The contractor shall be responsible for:

271 (a) The development, implementation, and maintenance of an  
272 interactive web-based ~~organ and tissue~~ donor registry that,  
273 through electronic means, allows for online organ donor  
274 registration and the recording of organ and tissue donation  
275 records submitted through the driver's license identification  
276 program or through other sources.

277 1. The registry must be maintained in a manner that  
278 allows, through electronic and telephonic methods, immediate  
279 access to organ and tissue donation records 24 hours a day, 7  
280 days a week.

281 2. Access to the registry must be through coded and secure  
282 means to protect the integrity of the data in the registry.

283 (b) A continuing program to educate and inform medical  
284 professionals, law enforcement agencies and officers, other  
285 state and local government employees, high school students,  
286 minorities, and the public about the laws of this state relating  
287 to anatomical gifts and the need for anatomical gifts.

288 1. Existing community resources, when available, must be  
289 used to support the program and volunteers may assist the  
290 program to the maximum extent possible.

291 2. The contractor shall coordinate with the head of a  
292 state agency or other political subdivision of the state, or his  
293 or her designee, to establish convenient times, dates, and

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

294 locations for educating that entity's employees.

295 (c) Preparing and submitting an annual written report to  
296 the agency ~~for Health Care Administration~~ by December 31 of each  
297 year. The report must include:

298 1. The number of donors on the registry and an analysis of  
299 the registration rates by location and method of donation;

300 2. The characteristics of donors as determined from  
301 registry information submitted directly by the donors or by the  
302 Department of Highway Safety and Motor Vehicles;

303 3. The annual dollar amount of voluntary contributions  
304 received by the contractor;

305 4. A description of the educational campaigns and  
306 initiatives implemented during the year and an evaluation of  
307 their effectiveness in increasing enrollment on the registry;  
308 and

309 5. An analysis of Florida's registry compared with other  
310 states' donor registries.

311 (4) Costs for the ~~organ and tissue~~ donor registry and  
312 education program shall be paid by the agency ~~for Health Care~~  
313 ~~Administration~~ from the funds deposited into the Health Care  
314 Trust Fund pursuant to ss. 320.08047 and 322.08, which are  
315 designated for maintaining the ~~organ and tissue~~ donor registry  
316 and education program. In addition, the contractor may receive  
317 and use voluntary contributions to help support the registry and  
318 provide education.

319 (5) The ~~organ and tissue~~ donor registry established by  
320 this section is designated as the "Joshua Abbott Organ and  
321 Tissue Registry."

322 Section 7. Section 765.51551, Florida Statutes, is amended  
323 to read

324 765.51551 ~~Organ and tissue~~ Donor registry; public records  
325 exemption.--

326 (1) Information held in the ~~organ and tissue~~ donor  
327 registry which identifies a donor is confidential and exempt

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

328 from s. 119.07(1) and s. 24(a), Art. I of the State  
329 Constitution.

330 (2) Such information may be disclosed to the following:

331 (a) ~~Organ, tissue, and eye~~ Procurement organizations that  
332 have been certified by the agency ~~for Health Care Administration~~  
333 for the purpose of ascertaining or effectuating the existence of  
334 a gift under s. 765.522.

335 (b) Persons engaged in bona fide research if the person  
336 agrees to:

337 1. Submit a research plan to the agency that specifies the  
338 exact nature of the information requested and the intended use  
339 of the information;

340 2. Maintain the confidentiality of the records or  
341 information if personal identifying information is made  
342 available to the researcher;

343 3. Destroy any confidential records or information  
344 obtained after the research is concluded; and

345 4. Not directly or indirectly contact, for any purpose,  
346 any donor or donee.

347 (3) This section is subject to the Open Government Sunset  
348 Review Act in accordance with s. 119.15 and shall stand repealed  
349 on October 2, 2013, unless reviewed and saved from repeal  
350 through reenactment by the Legislature.

351 Section 8. Section 765.516, Florida Statutes, is amended  
352 to read:

353 765.516 Donor ~~amendment of the terms of or the revocation~~  
354 ~~of anatomical the gift.--~~

355 (1) A donor may amend the terms of or revoke an anatomical  
356 gift by:

357 (a) The execution and delivery to the donee of a signed  
358 statement witnessed by at least two adults, at least one of whom  
359 is a disinterested witness.

360 (b) An oral statement that is made in the presence of two  
361 persons, one of whom is ~~must~~ ~~be~~ a family member, and

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

362 communicated to the donor's family or attorney or to the donee.  
363 An oral statement is effective only if the procurement  
364 organization, transplant hospital, or physician or technician  
365 has actual notice of the oral amendment or revocation before an  
366 incision is made to the decedent's body or an invasive procedure  
367 to prepare the recipient has begun.

368 (c) A statement made during a terminal illness or injury  
369 addressed to an attending physician, who must communicate the  
370 revocation of the gift to the procurement organization ~~that is~~  
371 ~~certified by the state.~~

372 (d) A signed document found on or about the donor's  
373 person.

374 (e) Removing his or her name from the ~~organ and tissue~~  
375 donor registry.

376 (f) A later-executed document of gift which amends or  
377 revokes a previous anatomical gift or portion of an anatomical  
378 gift, either expressly or by inconsistency.

379 (g) By the destruction or cancellation of the document of  
380 gift or the destruction or cancellation of that portion of the  
381 document of gift used to make the gift with the intent to revoke  
382 the gift.

383 (2) Any anatomical gift made by a will may also be amended  
384 or revoked in the manner provided for the amendment or  
385 revocation of wills or as provided in paragraph (1)(a)  
386 ~~subsection (1).~~

387 Section 9. Section 765.517, Florida Statutes, is amended  
388 to read:

389 765.517 Rights and duties at death.--

390 (1) The donee, pursuant to ~~as specified under the~~  
391 ~~provisions of s. 765.515(2),~~ may accept or reject an anatomical  
392 the gift. If the donee accepts a gift ~~of the entire body or a~~  
393 ~~part of the body~~ to be used for research or education ~~scientific~~  
394 purposes ~~other than a transplant,~~ the donee may authorize  
395 embalming and the use of the body in funeral services, subject

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

396 to the terms of the gift. If the gift is of a part of the body,  
397 the donee shall cause the part to be removed without unnecessary  
398 mutilation upon the death of the donor and before or after  
399 embalming. After removal of the body part, custody of the  
400 remainder of the body vests in the surviving spouse, next of  
401 kin, or other persons under obligation to dispose of the body.

402 (2) The time of death shall be determined by a physician  
403 who attends the donor at the donor's death or, if there is no  
404 such physician, the physician who certifies the death. After  
405 death, those physicians or the donor's primary care and in the  
406 ~~absence of other qualified personnel, this~~ physician may  
407 participate in, but may shall not obstruct, the procedures to  
408 preserve the donor's organs or tissues and may shall not be paid  
409 or reimbursed for such participation by, nor be associated with  
410 or employed by, a, an organ procurement organization, tissue  
411 ~~bank, or eye bank.~~ These physicians may ~~This physician shall~~ not  
412 participate in the procedures for removing or transplanting a  
413 part. However, this subsection does not prevent a physician from  
414 serving in a voluntary capacity on the board of directors of a  
415 procurement organization or participating on any board, council,  
416 commission, or similar body related to the organ and tissue  
417 procurement system.

418 (3) The ~~organ~~ procurement organizations organization,  
419 ~~tissue bank, or eye bank,~~ or hospital medical professionals  
420 under the direction thereof, may perform any and all tests to  
421 evaluate the deceased as a potential donor and any invasive  
422 procedures on the deceased body in order to preserve the  
423 potential donor's organs. These procedures do not include the  
424 surgical removal of an organ or penetrating any body cavity,  
425 specifically for the purpose of donation, until:

426 (a) It has been verified that the deceased's consent to  
427 donate appears in the ~~organ and tissue~~ donor registry or a  
428 properly executed ~~donor card or document~~ of gift is located; or



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

429 (b) If a properly executed ~~donor card or~~ document of gift  
430 cannot be located or the deceased's consent is not listed in the  
431 ~~organ and tissue~~ donor registry, a person specified in s.  
432 765.512(2) or (3) has been located, has been notified of the  
433 death, and has granted legal permission for the donation.

434 (4) All reasonable additional expenses incurred in the  
435 procedures to preserve the donor's organs or tissues shall be  
436 reimbursed by the ~~organ~~ procurement organization, ~~tissue bank,~~  
437 ~~or eye bank.~~

438 (5) A person who acts in good faith and without negligence  
439 in accord with the terms of this part or under the anatomical  
440 gift laws of this state or another state or a foreign country,  
441 or attempts to do so, may not be subject to any civil action for  
442 damages, may not be subject to any criminal proceeding, and may  
443 not be subject to discipline, penalty, or liability in any  
444 administrative proceeding.

445 (6) The provisions of this part are subject to the laws of  
446 this state prescribing powers and duties with respect to  
447 autopsies.

448 (7) The person making an anatomical gift and the donor's  
449 estate are not liable for any injury or damages that result from  
450 the making or use of the gift.

451 (8) In determining whether an anatomical gift has been  
452 made, amended, or revoked under this part, a person may rely  
453 upon the representation of an individual listed in s. 765.512,  
454 relating to the individual's relationship to the donor or  
455 prospective donor, unless the person knows that the  
456 representation is untrue.

457 Section 10. Section 765.521, Florida Statutes, is amended  
458 to read:

459 765.521 Donations as part of driver license or  
460 identification card process.--

461 (1) The agency ~~for Health Care Administration~~ and the  
462 ~~department~~Department of Highway Safety and Motor Vehicles shall

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

463 develop and implement a program encouraging and allowing persons  
464 to make anatomical gifts as a part of the process of issuing  
465 identification cards and issuing and renewing driver licenses.  
466 The donor registration card distributed by the  
467 ~~department~~Department of Highway Safety and Motor Vehicles shall  
468 include the information required by the uniform donor card under  
469 s. 765.514 and such additional information as determined  
470 necessary by the department. The department shall also develop  
471 and implement a program to identify donors, which includes  
472 notations on identification cards, driver licenses, and driver  
473 records or such other methods as the department develops to  
474 clearly indicate the individual's intent to make an anatomical  
475 gift ~~donate the individual's organs, tissues, or eyes~~. A  
476 notation on an individual's driver license or identification  
477 card that the individual intends to make an anatomical gift  
478 ~~donate organs, tissues, or eyes~~ satisfies all requirements for  
479 consent to organ or tissue donation. The agency ~~for Health Care~~  
480 ~~Administration~~ shall provide the necessary supplies and forms  
481 from funds appropriated from general revenue or contributions  
482 from interested voluntary, nonprofit organizations. The  
483 department shall provide the necessary recordkeeping system from  
484 funds appropriated from general revenue. The  
485 ~~department~~Department of Highway Safety and Motor Vehicles and  
486 the agency ~~for Health Care Administration~~ shall incur no  
487 liability in connection with the performance of any acts  
488 authorized herein.

489 (2) The Department of Highway Safety and Motor Vehicles,  
490 after consultation with and concurrence by the agency ~~for Health~~  
491 ~~Care Administration~~, shall adopt rules to implement the  
492 provisions of this section according to the provisions of  
493 chapter 120.

494 (3) Funds expended by the agency ~~for Health Care~~  
495 ~~Administration~~ to carry out the intent of this section may ~~shall~~

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

496 not be taken from ~~any~~ funds appropriated for patient care.

497 Section 11. Section 765.522, Florida Statutes, is amended  
498 to read:

499 765.522 Duty of ~~certain~~ hospital administrators; liability  
500 of hospital administrators and, ~~organ~~ procurement organizations,  
501 ~~eye banks, and tissue banks.--~~

502 ~~(1) When used in this section, "hospital" means any~~  
503 ~~establishment licensed under chapter 395 except psychiatric and~~  
504 ~~rehabilitation hospitals.~~

505 ~~(1)(2)~~ If ~~Where~~, based on accepted medical standards, a  
506 hospital patient is a suitable candidate for organ or tissue  
507 donation, the hospital administrator or the hospital  
508 administrator's designee shall, at or near the time of death,  
509 notify the appropriate procurement organization ~~organ, eye, or~~  
510 ~~tissue recovery program~~, which shall access the ~~organ and tissue~~  
511 donor registry created by s. 765.5155 or any other donor  
512 registry to ascertain the existence of an entry in the registry  
513 which ~~that~~ has not been revoked, ~~a donor card~~, or a document of of  
514 gift executed by the decedent. In the absence of an entry in the  
515 donor registry, a document of gift ~~donor card, organ donation~~  
516 ~~sticker or organ donation imprint on a driver's license~~, or  
517 other properly executed document, the procurement organization  
518 ~~organ, eye, or tissue recovery program~~ shall request:

519 (a) The patient's health care surrogate, as authorized in  
520 s. 765.512(2); or

521 (b) If the patient does not have a surrogate, or the  
522 surrogate is not reasonably available, any of the persons  
523 specified in s. 765.512(3), in the order and manner listed,  
524

525 to consent to the anatomical gift ~~of all or any part~~ of the  
526 decedent's body for any purpose specified in this part. Except  
527 as provided in s. 765.512, in the absence of actual notice of  
528 opposition, consent need only be obtained from the person or  
529 persons in the highest priority class reasonably available.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

530 (3) A document of gift is valid if made pursuant to a  
531 request required by this section shall be executed in accordance  
532 with this part or the laws of the state or country where it was  
533 executed and where the person making the anatomical gift was  
534 domiciled, has a place of residence, or was a citizen at the  
535 time the document of gift was executed pursuant to s. 765.514.

536 (4) The agency for Health Care Administration shall  
537 establish rules and guidelines concerning the education of  
538 individuals who may be designated to perform the request and the  
539 procedures to be used in making the request. The agency is  
540 authorized to adopt rules concerning the documentation of the  
541 request, where such request is made.

542 (5) If a document of gift is valid under this section, the  
543 laws of this state govern the interpretation of the document of  
544 gift.

545 (6) A document of gift or amendment of an anatomical gift  
546 is presumed to be valid unless it was not validly executed or  
547 was revoked.

548 (7)(5) There shall be no civil or criminal liability  
549 against any ~~organ~~ procurement organization, ~~eye bank, or tissue~~  
550 ~~bank~~ certified under s. 765.542, or against any hospital or  
551 hospital administrator or designee who complies, when complying  
552 with the provisions of this part and agency the rules of the  
553 agency for Health Care Administration or if when, in the  
554 exercise of reasonable care, a request for organ donation is  
555 inappropriate and the gift is not made according to this part  
556 and agency the rules of the agency for Health Care  
557 Administration.

558 (8)(6) The hospital administrator or a designee shall, at  
559 or near the time of death of a potential ~~organ~~ donor, directly  
560 notify the affiliated organ procurement organization ~~designated~~  
561 ~~by the United States Department of Health and Human Services of~~  
562 the potential organ donor. The This organ procurement

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

563 organization must offer any organ from such a donor first to  
564 patients on a Florida-based local or state organ sharing  
565 transplant list. For the purpose of this subsection, the term  
566 "transplant list" includes certain categories of national or  
567 regional organ sharing for patients of exceptional need or  
568 exceptional match, as approved or mandated by the Organ  
569 Procurement and Transplantation Network, or its agent. This  
570 notification may not be made to a tissue bank or eye bank in  
571 lieu of the organ procurement organization unless the tissue  
572 bank or eye bank is also designated as an organ procurement  
573 organization by the United States Department of Health and Human  
574 Services.

575 Section 12. Subsections (1), (5), and (6) of section  
576 765.53, Florida Statutes, are amended to read:

577 765.53 Organ Transplant Advisory Council; membership;  
578 responsibilities.--

579 (1) ~~There is hereby created within the agency for Health~~  
580 ~~Care Administration~~ A statewide technical Organ Transplant  
581 Advisory Council is created within the agency, consisting of  
582 twelve members who are physicians licensed under chapter 458 or  
583 chapter 459, to represent the interests of the public and the  
584 clients of the Department of Health or the agency. ~~The members~~  
585 ~~shall be physicians licensed according to chapter 458 or chapter~~  
586 ~~459.~~ A person employed by the agency may not be appointed as a  
587 member of the council.

588 (5) Members of the council shall receive no compensation,  
589 but shall be reimbursed for per diem and travel expenses by the  
590 agency ~~for Health Care Administration~~ in accordance with the  
591 ~~provisions of~~ s. 112.061 while engaged in the performance of  
592 their duties.

593 (6) The responsibilities of the council shall be to  
594 recommend to the agency ~~for Health Care Administration~~  
595 indications for adult and pediatric organ transplants. The  
596 council shall also formulate guidelines and standards for organ

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

597 transplants and for the development of End Stage Organ Disease  
598 and Tissue/Organ Transplant programs. The recommendations,  
599 guidelines, and standards developed by the council are  
600 applicable only to those health programs funded through the  
601 agency ~~for Health Care Administration.~~

602 Section 13. Section 765.541, Florida Statutes, is amended  
603 to read:

604 765.541 Certification of procurement organizations ~~engaged~~  
605 ~~in the practice of cadaveric organ and tissue procurement.~~--The  
606 agency ~~for Health Care Administration~~ shall:

607 (1) Establish a program for the certification of  
608 organizations, corporations ~~agencies~~, or other entities engaged  
609 in the procurement of organs, tissues, and eyes for  
610 transplantation.†

611 (2) Adopt rules that set forth appropriate standards and  
612 guidelines for the program in accordance with ss. 765.541-  
613 765.546 and part II of chapter 408. These standards and  
614 guidelines must be substantially based on the existing laws of  
615 the Federal Government and this state and the existing standards  
616 and guidelines of the United Network for Organ Sharing (UNOS),  
617 the American Association of Tissue Banks (AATB), the South-  
618 Eastern Organ Procurement Foundation (SEOPF), the North American  
619 Transplant Coordinators Organization (NATCO), and the Eye Bank  
620 Association of America (EBAA). In addition, the agency ~~for~~  
621 ~~Health Care Administration~~ shall, before adopting these  
622 standards and guidelines, seek input from all ~~organ~~ procurement  
623 organizations, ~~tissue banks, and eye banks~~ based in this state.†

624 (3) Collect, keep, and make available to the Governor and  
625 the Legislature information regarding the numbers and  
626 disposition of organs, and tissues, and eyes procured by each  
627 certified procurement organization. ~~entity.~~†

628 (4) Monitor procurement organizations ~~participating~~  
629 ~~facilities and agencies~~ for program compliance.† and

630 (5) Provide for the administration of the Organ and Tissue

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

631 Procurement and Transplantation Advisory Board.

632 Section 14. Section 765.542, Florida Statutes, is amended  
633 to read:

634 765.542 Certification of ~~organ~~ procurement organizations,  
635 ~~tissue banks, and eye banks.--~~

636 (1) The requirements of part II of chapter 408 apply to  
637 the provision of services that require licensure pursuant to ss.  
638 765.541-765.546 and part II of chapter 408 and to entities  
639 licensed or certified by or applying for such licensure or  
640 certification from the agency ~~for Health Care Administration~~  
641 pursuant to ss. 765.541-765.546. A person ~~An organization,~~  
642 ~~agency, or other entity~~ may not engage in the practice of organ  
643 procurement in this state without being designated as an organ  
644 procurement organization by the secretary of the United States  
645 Department of Health and Human Services and being appropriately  
646 certified by the agency ~~for Health Care Administration~~. As used  
647 ~~in this subsection, the term "procurement" includes the~~  
648 ~~retrieval, processing, or distribution of human organs.~~ A  
649 physician or organ procurement organization based outside this  
650 state is exempt from these certification requirements if:

651 (a) The organs are procured for an out-of-state patient  
652 who is listed on, or referred through, the United Network for  
653 Organ Sharing System; and

654 (b) The organs are procured through an agreement of an  
655 organ procurement organization certified by the state.

656 (2) A person ~~An organization, agency, or other entity~~ may  
657 not engage in tissue procurement in this state unless it is  
658 appropriately certified as a tissue bank by the agency ~~for~~  
659 ~~Health Care Administration~~. As used in this subsection, the term  
660 ~~"procurement" includes any retrieval, processing, storage, or~~  
661 ~~distribution of human tissue for transplantation.~~

662 (3) A person ~~An organization, agency, or other entity~~ may  
663 not engage in the practice of eye procurement in this state  
664 without being appropriately certified as an eye bank by the

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

665 agency ~~for Health Care Administration. As used in this~~  
666 ~~subsection, the term "procurement" includes the retrieval,~~  
667 ~~processing, or distribution of human eye tissue. Funeral~~  
668 directors or direct disposers who ~~that~~ retrieve eye tissue for  
669 an eye bank certified under this subsection are exempt from the  
670 certification requirements under this subsection.

671 (4) A limited certificate may be issued to a tissue bank  
672 or eye bank, certifying only those components of procurement  
673 which the bank has chosen to perform. The agency ~~for Health Care~~  
674 ~~Administration~~ may issue a limited certificate if it determines  
675 that the tissue bank or eye bank is adequately staffed and  
676 equipped to operate in conformity with the rules adopted under  
677 this section.

678 Section 15. Subsection (3) of section 765.543, Florida  
679 Statutes, is amended to read:

680 765.543 Organ and Tissue Procurement and Transplantation  
681 Advisory Board; creation; duties.--

682 (3) The board shall:

683 (a) Assist the agency ~~for Health Care Administration~~ in  
684 the development of necessary professional qualifications,  
685 including, but not limited to, the education, training, and  
686 performance of persons engaged in the various facets of organ  
687 and tissue procurement, processing, preservation, and  
688 distribution for transplantation;

689 (b) Assist the agency ~~for Health Care Administration~~ in  
690 monitoring the appropriate and legitimate expenses associated  
691 with organ and tissue procurement, processing, and distribution  
692 for transplantation and developing methodologies to assure the  
693 uniform statewide reporting of data to facilitate the accurate  
694 and timely evaluation of the organ and tissue procurement and  
695 transplantation system;

696 (c) Provide assistance to the Florida Medical Examiners  
697 Commission in the development of appropriate procedures and  
698 protocols to ensure the ~~assure~~ continued improvement in the



HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

699 approval and release of potential ~~organ and tissue~~ donors by the  
700 district medical examiners and associate medical examiners;

701 (d) Develop with and recommend to the agency ~~for Health~~  
702 ~~Care Administration~~ the necessary procedures and protocols  
703 required to assure that all residents of this state have  
704 reasonable access to available organ and tissue transplantation  
705 therapy and that residents of this state can be reasonably  
706 assured that the statewide procurement transplantation system is  
707 ~~will be~~ able to fulfill their organ and tissue requirements  
708 within the limits of the available supply and according to the  
709 severity of their medical condition and need; and

710 (e) Develop with and recommend to the agency ~~for Health~~  
711 ~~Care Administration~~ any changes to the laws of this state or  
712 administrative rules or procedures ~~required~~ to ensure assure  
713 that the statewide organ and tissue procurement and  
714 transplantation system is ~~will be~~ able to function smoothly,  
715 effectively, and efficiently, in accordance with the Federal  
716 Anatomical Gift Act and in a manner that assures the residents  
717 of this state that no person or entity profits from the  
718 altruistic voluntary donation of organs or tissues.

719 Section 16. Section 765.544, Florida Statutes, is amended  
720 to read

721 765.544 Fees; organ and tissue donor education and  
722 procurement.--

723 (1) In accordance with s. 408.805, an applicant or a  
724 certificateholder shall pay a fee for each application submitted  
725 under this part, part II of chapter 408, and applicable rules.  
726 The amount of the fee shall be as follows:

727 (a) An initial application fee of \$1,000 from organ  
728 procurement organizations and tissue banks and \$500 from eye  
729 banks.

730 (b) Annual fees to be used, in the following order of  
731 priority, for the certification program, the advisory board,  
732 maintenance of the ~~organ and tissue~~ donor registry, and the

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

733 organ and tissue donor education program ~~in the following~~  
734 ~~amounts~~, which may not exceed \$35,000 per organization:

735 1. Each ~~general~~ organ procurement organization shall pay  
736 the greater of \$1,000 or 0.25 percent of its total revenues  
737 produced from procurement activity in this state by the  
738 certificateholder during its most recently completed fiscal year  
739 or operational year.

740 2. Each ~~bone and tissue procurement organization agency or~~  
741 ~~bone and tissue bank~~ shall pay the greater of \$1,000 or 0.25  
742 percent of its total revenues from procurement and processing  
743 activity in this state by the certificateholder during its most  
744 recently completed fiscal year or operational year.

745 3. Each eye bank shall pay the greater of \$500 or 0.25  
746 percent of its total revenues produced from procurement activity  
747 in this state by the certificateholder during its most recently  
748 completed fiscal year or operational year.

749 (2) The agency ~~for Health Care Administration~~ shall  
750 specify by rule the administrative penalties for the purpose of  
751 ensuring adherence to the standards of quality and practice  
752 required by this chapter, part II of chapter 408, and applicable  
753 rules of the agency for continued certification.

754 (3) (a) Proceeds from fees, administrative penalties, and  
755 surcharges collected pursuant to this section must be deposited  
756 into the Health Care Trust Fund.

757 (b) Moneys deposited in the trust fund pursuant to this  
758 section must be used exclusively for the implementation,  
759 administration, and operation of the certification program and  
760 the advisory board, for maintaining the ~~organ and tissue donor~~  
761 registry, and for organ and tissue donor education.

762 (4) As used in this section, the term "procurement  
763 activity in this state" includes the bringing into this state  
764 for processing, storage, distribution, or transplantation of  
765 organs or tissues that are initially procured in another state

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

766 or country.

767 Section 17. Section 765.545, Florida Statutes, is amended  
768 to read:

769 765.545 Physician supervision of cadaveric organ and  
770 tissue procurement coordinators.--~~Organ Procurement~~  
771 ~~organizations, tissue banks, and eye banks~~ may employ  
772 coordinators, who are registered nurses, physician's assistants,  
773 or other medically trained personnel who meet the relevant  
774 standards for ~~organ procurement organizations, tissue banks, or~~  
775 ~~eye banks~~ as adopted by the agency for ~~Health Care~~  
776 ~~Administration~~ under s. 765.541, to assist in the medical  
777 management of organ donors or in the surgical procurement of  
778 cadaveric organs, tissues, or eyes for transplantation or  
779 research. A coordinator who assists in the medical management of  
780 organ donors or in the surgical procurement of cadaveric organs,  
781 tissues, or eyes for transplantation or research must do so  
782 under the direction and supervision of a ~~licensed~~ physician  
783 medical director pursuant to rules and guidelines ~~to be~~ adopted  
784 by the agency for ~~Health Care Administration~~. With the exception  
785 of organ procurement surgery, this supervision may be indirect  
786 supervision. For purposes of this section, the term "indirect  
787 supervision" means that the medical director is responsible for  
788 the medical actions of the coordinator, that the coordinator is  
789 operating under protocols expressly approved by the medical  
790 director, and that the medical director or his or her physician  
791 designee is always available, in person or by telephone, to  
792 provide medical direction, consultation, and advice in cases of  
793 organ, tissue, and eye donation and procurement. Although  
794 indirect supervision is authorized under this section, direct  
795 physician supervision is to be encouraged when appropriate.

796 Section 18. Section 765.547, Florida Statutes, is created  
797 to read:

798 765.547 Cooperation between medical examiner and  
799 procurement organization.--

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

800           (1) A medical examiner and procurement organization shall  
801 cooperate with each other in order to maximize opportunities to  
802 recover anatomical gifts for the purpose of transplantation,  
803 therapy, research, or education.

804           (2) The Florida Medical Examiners Commission shall adopt  
805 rules establishing cooperative responsibilities between medical  
806 examiners and procurement organizations to facilitate and  
807 expedite completion of the medical examiner's responsibilities  
808 under chapter 406 in a manner that will maximize opportunities  
809 to recover anatomical gifts.

810           (3) This part does not supersede any part of chapter 406  
811 relating to medical examiners and the disposition of dead  
812 bodies.

813           Section 19. Subsection (30) of section 408.802, Florida  
814 Statutes, is amended to read:

815           408.802 Applicability.--The provisions of this part apply  
816 to the provision of services that require licensure as defined  
817 in this part and to the following entities licensed, registered,  
818 or certified by the agency, as described in chapters 112, 383,  
819 390, 394, 395, 400, 429, 440, 483, and 765:

820           (30) Organ, and tissue, and eye procurement organizations  
821 agencies, as provided under part V of chapter 765.

822           Section 20. Subsection (29) of section 408.820, Florida  
823 Statutes, is amended to read:

824           408.820 Exemptions.--Except as prescribed in authorizing  
825 statutes, the following exemptions shall apply to specified  
826 requirements of this part:

827           (29) Organ, and tissue, and eye procurement organizations  
828 agencies, as provided under part V of chapter 765, are exempt  
829 from s. 408.810(5)-(10).

830           Section 21. This act shall take effect July 1, 2009.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 1 (for drafter's use only)

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**T I T L E   A M E N D M E N T**

Remove the entire title and insert:

A bill to be entitled  
An act relating to anatomical gifts; amending s. 765.511,  
F.S.; providing additional definitions; amending s.  
765.512, F.S.; conforming terms; amending s. 765.513,  
F.S.; revising the list of donees that may accept  
anatomical gifts and the purposes for which such gifts may  
be used; amending ss. 765.514, 765.515, 765.5155, and  
765.51551, F.S.; conforming terms; amending s. 765.516,  
F.S.; revising provisions relating to a donor's amendment  
or revocation of an anatomical gift; amending s. 765.517,  
F.S.; revising provisions relating to a donee's use of an  
anatomical gift at the time of the donor's death;  
providing liability protection for the person making a  
gift and for the donor's estate; amending s. 765.521,  
F.S.; conforming terms; amending s. 765.522, F.S.;  
providing that the laws of this state govern the  
interpretation of a valid document of gift, and that a  
document of gift is presumed to be valid; amending ss.  
765.53, 765.541, 765.542, 765.543, 765.544, and 765.545,  
F.S.; conforming terms; creating s. 765.547, F.S.;  
requiring medical examiners and procurement organizations  
to cooperate and maximize opportunities for organ  
donations; authorizing the Florida Medical Examiners  
Commission to adopt rules; amending ss. 408.802 and  
408.820, F.S.; conforming terms; providing an effective  
date.

Be It Enacted by the Legislature of the State of Florida:



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# **ADDENDUM**

## **HEALTH CARE REGULATION POLICY COMMITTEE**

**Tuesday, March 10, 2009**

**2:45 PM – 5:00 PM**

**Webster Hall (212 Knott Building)**

## Prescription Drug Distribution Regulation

### Overview

- The distribution of prescription drugs in Florida is regulated by the Department of Health, under Chapter 499, F.S. The regulations have several parts, including:
  - **Licensure** of entities in the distribution chain, like prescription drug manufacturers and wholesale distributors. Florida has 20 different permits.
  - **Documentation** requirements to track the distribution of prescription drugs from manufacturer through to the end user, such as “**pedigree papers**”.
  - **Criminal prohibitions** for distributing contraband prescription drugs.
- Some of Florida’s regulations are required by the federal Prescription Drug Marketing Act (1988), which required states to regulate wholesale distributors.

### Grand Jury Report

- In 2002, at the request of Governor Jeb Bush, the Florida Supreme Court convened a grand jury to report on drug distribution abuses. It made several findings:
  - **1<sup>st</sup> Tier Wholesalers:** The three largest national wholesale distributors, which obtain the vast majority of their stock – as much as 100% - directly from the manufacturer. This is known as the “**primary market**”.
  - **2<sup>nd</sup> Tier Wholesalers:** Hundreds of smaller wholesale distributors which obtain the vast majority of their stock from 1<sup>st</sup> Tier Wholesalers. This is the “**secondary market**”, in which prescription drugs may move “up, down, and sideways through the distribution system[, creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system.”
  - The secondary market has generally been the point of introduction of counterfeit or adulterated drugs.
  - Drug manufacturers were not at fault.

## Recent Changes

- Florida's regulations have strengthened significantly in the past 6 years. These changes produced:
  - A significantly stronger wholesale distributor permit, requiring a bond and extensive background information.
  - More thorough distribution documentation, including application of the pedigree paper to most wholesale distributions.
  - Enhanced criminal penalties for distribution of contraband drugs.
  - Stronger DOH enforcement authority.
- **Direct Purchase Pedigree.** The 2006 Legislature recognized some transactions are safer than others. It created a less strict pedigree paper for where the wholesale distributor purchases the prescription drug directly from the manufacturer and distributes the prescription drug directly to an end user.
- **Health Care Clinic Establishment Permit.** The 2008 Legislature created a new permit to authorize physician clinics to purchase prescription drugs in the name of the clinic.
- **"Manufacturer" Definition.** The 2008 Legislature recognized that licensing certain manufacturers' distributors as wholesale distributors is unnecessary to ensure safety. It expanded the definition of "manufacturer" to recognize these distributors that are legitimately involved in the manufacturing process.



## Pedigree Papers under Florida Law

