

# Health Care Regulation Policy Committee

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

# Revised



# The Florida House of Representatives

### **Health Care Regulation Policy Committee**

#### AGENDA

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

Revised Uniform Anatomical Gift Act

**SPONSOR(S):** Schwartz

**TIED BILLS:** 

IDEN./SIM. BILLS: SB 492

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	***************************************	Holt X	Calamas 🕊
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

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

STORAGE NAME:

2/17/2009

h0209.HCR.doc

DATE:

#### **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 actually 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>

STORAGE NAME:

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

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

<sup>&</sup>lt;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>&</sup>lt;sup>4</sup> Section 756.516, F.S.

<sup>&</sup>lt;sup>5</sup> Section 765.513, F.S.

<sup>&</sup>lt;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: <a href="http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=633">http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=633</a> (last visited on March 3, 2009).

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

<sup>&</sup>lt;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).

- 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.1

#### 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,

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<sup>&</sup>lt;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 decent, 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 form 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:

STORAGE NAME: DATE:

#### 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

STORAGE NAME: DATE:

### HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES Amendment No. 1 (for drafter's use only)

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		Bill No. HB 2		
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	MANAGEMENTALISMENT			
		-		
Council/Committee heari	ing bill: Health Care Re	gulation Policy		
Committee				
Representative(s) Schwartz offered the following:				

#### Amendment (with title amendment)

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Remove everything after the enacting clause and insert: Section 1. Section 765.511, Florida Statutes, is amended to read:

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

- (1) "Agency" means the Agency for Health Care Administration.
- (2) "Anatomical gift" or "gift" means a donation of all or part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education.
- (3) (1) "Bank" or "storage facility" means a facility licensed, accredited, or approved under the laws of any state for storage of human bodies or body parts thereof.
- (4) "Death" means the absence of life as determined, in accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, including the brain stem.
  - (5) "Decedent" means a deceased individual whose body or

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

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- body parts may be, or are, the source of an anatomical gift. (6) "Department" means the Department of Highway Safety
- and Motor Vehicles.
- (7) "Disinterested witness" means a witness other than a person listed in s. 765.512(3) or other family member.
- (8) "Document of gift" means any of the documents or mechanisms used in making an anatomical gift under s. 765.514.
- (9) (3) "Donor" means an individual who makes an anatomical a gift of all or part of his or her body.
- (10) "Donor registry" means a database that contains records of anatomical gifts and amendments to, or revocations of, such gifts.
- (11) "Eye bank" means an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue.
- (12) "Guardian" means a person appointed pursuant to chapter 744. The term does not include a guardian ad litem.
- (13) (4) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state and includes a hospital operated by the United States Government or a state, or a subdivision thereof, although not required to be licensed under state laws.
- (14) "Identification card" means an official identification card issued by a governmental entity, state agency, or subdivision thereof.
- (15) "Organ procurement organization" means an entity that is designated as an organ procurement organization by the Secretary of the United States Department of Health and Human Services and that engages in the retrieval, screening, testing, processing, storage, or distribution of human organs.
  - (16) "Part of the body" or "body part" means an organ,

eye, or tissue of a human being. The term does not include the

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

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

- "Procurement" means any retrieval, recovery, (18)processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education.
- "Procurement organization" means an organ procurement (19)organization, eye bank, or tissue bank.
- "Reasonably available" means able to be contacted by a procurement organization in a timely manner without undue effort, and willing and able to act in a manner consistent with existing medical protocols necessary for the making of an anatomical gift.
- (21) "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- (22) "Sign" or "signed" means, with the present intent to authenticate or adopt a record, to execute or adopt a tangible symbol, or attach to or logically associate an electronic symbol, sound, or process with the record.
- "Tissue bank" means an entity that is accredited by (23)the American Association of Tissue Banks or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human tissue.

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

765.512 Persons who may make an anatomical gift.--

Any person who may make a will may make an anatomical gift give all or part of his or her body for any purpose specified in s. 765.513. The gift is effective upon the death of methods listed in s. 765.514(1), and in the absence of actual

notice of contrary indications by the decedent, the document or

If the decedent makes an anatomical gift by one of the

anatomical gift after the donor's death.

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96 entry in the donor organ and tissue registry is legally sufficient evidence of the decedent's informed consent to donate 98 an anatomical gift.

the donor.

(a)

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

- (4) A donee may not accept an anatomical gift if the donee has actual notice of contrary indications by the donor or actual notice that an anatomical a gift by a member of a class is opposed by a member of a prior class.
- The person authorized by subsection (3) may make the anatomical gift after the decedent's death or immediately before the decedent's death.
- An anatomical A gift of all or part of a body authorizes:
- Any examination necessary to assure medical acceptability of the gift for the purposes intended.
- The decedent's medical provider, family, or a third party to furnish medical records requested concerning the decedent's medical and social history.
- (7) Once the anatomical gift has been made, the rights of the donee are paramount to the rights of others, except as provided by s. 765.517.

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

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

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stated: (a) (1) Any procurement organization or accredited hospital, surgeon, or physician for medical or dental school, college, or university for education, or research, advancement

anatomical gifts of bodies or parts of them for the purposes

(1) The following persons or entities may become donees of

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

of medical or dental science, therapy, or transplantation.

- (3) Any bank or storage facility for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation.
- (b) (4) Any individual specified by name for therapy or transplantation needed by him or her.
- (2) If multiple purposes are set forth in the document of gift but are not set forth in any priority order, the anatomical gift shall be used first for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.
- (3) However, The Legislature declares that the public policy of this state prohibits restrictions on the possible recipients of an anatomical gift on the basis of race, color, religion, gender sex, national origin, age, physical disability handicap, health status, marital status, or economic status, and such restrictions are hereby declared void and unenforceable.
- Section 4. Section 765.514, Florida Statutes, is amended to read:
  - 765.514 Manner of making anatomical gifts.--
- A person may make an anatomical a gift of all or part of his or her body under s. 765.512(1) by:
  - Signing an organ and tissue donor card. (a)
- Registering online with the <del>organ and tissue</del> donor (b) registry.

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- (c) Signifying an intent to donate on his or her driver's license or identification card issued by the <a href="mailto:department of Highway Safety and Motor Vehicles">department Department of Highway Safety and Motor Vehicles</a>. Revocation, suspension, expiration, or cancellation of the driver's license or identification card does not invalidate the gift.
- (d) Expressing a wish to donate in a living will or other advance directive.
- (e) Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift. The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or if it is declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith.
- (f) Expressing a wish to donate in a document other than a will. The document must be signed by the donor in the presence of two witnesses who shall sign the document in the donor's presence. If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must sign the document in the donor's presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid. The following form of written document is sufficient for any person to make an anatomical gift give all or part of his or her body for the purposes of this part:

#### UNIFORM DONOR CARD

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

#### I give:

- (a) .... any needed organs, tissues, or eyes;
- (b) .... only the following organs, tissues, or eyes

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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 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 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

withdraws the gift, the records of the department Department of

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

- (2) If <u>an anatomical</u> a gift is made by the donor to a specified donee, the document <u>of gift</u>, other than a will, may be delivered to the donee to expedite the appropriate procedures immediately after death, but delivery is not necessary to the validity of the gift. <u>The Such</u> document <u>of gift</u> may be deposited in any hospital, bank, storage facility, or registry office that accepts such documents for safekeeping or to facilitate the donation of organs and tissue after death.
- (3) At the request of any interested party upon or after the donor's death, the person in possession shall produce the document of gift for examination.

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

765.5155 Organ and tissue Donor registry; education program.--

- (1) The Legislature finds that:
- (a) There is a shortage of organ and tissue donors in this state willing to provide the organs and tissue that could save lives or enhance the quality of life for many persons.
- (b) There is a need to encourage the various minority populations of this state to donate organs and tissue.
- (c) A statewide organ and tissue donor registry having an online donor registration process coupled with an enhanced program of donor education will lead to an increase in the number of organ and tissue donors registered in this state, thus affording more persons who are awaiting organ or tissue transplants the opportunity for a full and productive life.
- (2) The agency for Health Care Administration and the department of Highway Safety and Motor Vehicles shall jointly contract for the operation of a an organ and tissue

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

- (3) The contractor shall be responsible for:
- (a) The development, implementation, and maintenance of an interactive web-based organ and tissue donor registry that, through electronic means, allows for online organ donor registration and the recording of organ and tissue donation records submitted through the driver's license identification program or through other sources.
- 1. The registry must be maintained in a manner that allows, through electronic and telephonic methods, immediate access to organ and tissue donation records 24 hours a day, 7 days a week.
- 2. Access to the registry must be through coded and secure means to protect the integrity of the data in the registry.
- (b) A continuing program to educate and inform medical professionals, law enforcement agencies and officers, other state and local government employees, high school students, minorities, and the public about the laws of this state relating to anatomical gifts and the need for anatomical gifts.
- 1. Existing community resources, when available, must be used to support the program and volunteers may assist the program to the maximum extent possible.
- 2. The contractor shall coordinate with the head of a state agency or other political subdivision of the state, or his or her designee, to establish convenient times, dates, and

year. The report must include:

locations for educating that entity's employees.

- (c) Preparing and submitting an annual written report to the agency for Health Care Administration by December 31 of each
- 1. The number of donors on the registry and an analysis of the registration rates by location and method of donation;
- 2. The characteristics of donors as determined from registry information submitted directly by the donors or by the Department of Highway Safety and Motor Vehicles;
- 3. The annual dollar amount of voluntary contributions received by the contractor;
- 4. A description of the educational campaigns and initiatives implemented during the year and an evaluation of their effectiveness in increasing enrollment on the registry; and
- 5. An analysis of Florida's registry compared with other states' donor registries.
- (4) Costs for the <del>organ and tissue</del> donor registry and education program shall be paid by the agency <del>for Health Care</del> Administration from the funds deposited into the Health Care Trust Fund pursuant to ss. 320.08047 and 322.08, which are designated for maintaining the <del>organ and tissue</del> donor registry and education program. In addition, the contractor may receive and use voluntary contributions to help support the registry and provide education.
- (5) The organ and tissue donor registry established by this section is designated as the "Joshua Abbott Organ and Tissue Registry."
- Section 7. Section 765.51551, Florida Statutes, is amended to read
- 765.51551 Organ and tissue Donor registry; public records exemption.--
- (1) Information held in the <del>organ and tissue</del> donor registry which identifies a donor is confidential and exempt

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- from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
  - (2) Such information may be disclosed to the following:
  - (a) Organ, tissue, and eye Procurement organizations that have been certified by the agency for Health Care Administration for the purpose of ascertaining or effectuating the existence of a gift under s. 765.522.
  - (b) Persons engaged in bona fide research if the person agrees to:
  - 1. Submit a research plan to the agency that specifies the exact nature of the information requested and the intended use of the information;
  - 2. Maintain the confidentiality of the records or information if personal identifying information is made available to the researcher;
  - 3. Destroy any confidential records or information obtained after the research is concluded; and
  - 4. Not directly or indirectly contact, for any purpose, any donor or donee.
  - (3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2013, unless reviewed and saved from repeal through reenactment by the Legislature.
  - Section 8. Section 765.516, Florida Statutes, is amended to read:
  - 765.516 <u>Donor</u> amendment <del>of the terms of</del> or <del>the</del> revocation of <u>anatomical</u> the gift.--
  - (1) A donor may amend the terms of or revoke an anatomical gift by:
  - (a) The execution and delivery to the donee of a signed statement witnessed by at least two adults, at least one of whom is a disinterested witness.
  - (b) An oral statement that is made in the presence of two persons, one of whom is must not be a family member, and

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communicated to the donor's family or attorney or to the donee.

An oral statement is effective only if the procurement

organization, transplant hospital, or physician or technician

has actual notice of the oral amendment or revocation before an

incision is made to the decedent's body or an invasive procedure

to prepare the recipient has begun.

- (c) A statement <u>made</u> during a terminal illness or injury addressed to an attending physician, who must communicate the revocation of the gift to the procurement organization <del>that is certified by the state</del>.
- (d) A signed document found on or about the donor's person.
- (e) Removing his or her name from the <del>organ and tissue</del> donor registry.
- (f) A later-executed document of gift which amends or revokes a previous anatomical gift or portion of an anatomical gift, either expressly or by inconsistency.
- (g) By the destruction or cancellation of the document of gift or the destruction or cancellation of that portion of the document of gift used to make the gift with the intent to revoke the gift.
- (2) Any <u>anatomical</u> gift made by a will may also be amended or revoked in the manner provided for <u>the</u> amendment or revocation of wills or as provided in <u>paragraph (1)(a)</u> subsection (1).

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

765.517 Rights and duties at death. --

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

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

- The time of death shall be determined by a physician who attends the donor at the donor's death or, if there is no such physician, the physician who certifies the death. After death, those physicians or the donor's primary care and in the absence of other qualified personnel, this physician may participate in, but may shall not obstruct, the procedures to preserve the donor's organs or tissues and may shall not be paid or reimbursed for such participation by, nor be associated with or employed by, a, an organ procurement organization, tissue bank, or eye bank. These physicians may This physician shall not participate in the procedures for removing or transplanting a part. However, this subsection does not prevent a physician from serving in a voluntary capacity on the board of directors of a procurement organization or participating on any board, council, commission, or similar body related to the organ and tissue procurement system.
- (3) The organ procurement organizations organization, tissue bank, or eye bank, or hospital medical professionals under the direction thereof, may perform any and all tests to evaluate the deceased as a potential donor and any invasive procedures on the deceased body in order to preserve the potential donor's organs. These procedures do not include the surgical removal of an organ or penetrating any body cavity, specifically for the purpose of donation, until:
- (a) It has been verified that the deceased's consent to donate appears in the <del>organ and tissue</del> donor registry or a properly executed <del>donor card or</del> document of gift is located; or

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- (b) If a properly executed donor card or document of gift cannot be located or the deceased's consent is not listed in the organ and tissue donor registry, a person specified in s. 765.512(2) or (3) has been located, has been notified of the death, and has granted legal permission for the donation.
- (4) All reasonable additional expenses incurred in the procedures to preserve the donor's organs or tissues shall be reimbursed by the organ procurement organization, tissue bank, or eye bank.
- (5) A person who acts in good faith and without negligence in accord with the terms of this part or under the anatomical gift laws of this state or another state or a foreign country, or attempts to do so, is not liable for damages in any civil action, is not or subject to prosecution for his or her acts in any criminal proceeding, and may not be subject to any civil action for damages, may not be subject to any criminal proceeding, and may not be subject to any criminal proceeding, and may not be subject to discipline, penalty, or liability in any administrative proceeding.
- (6) The provisions of this part are subject to the laws of this state prescribing powers and duties with respect to autopsies.
- (7) The person making an anatomical gift and the donor's estate are not liable for any injury or damages that result from the making or use of the gift.
- (8) In determining whether an anatomical gift has been made, amended, or revoked under this part, a person may rely upon the representation of an individual listed in s. 765.512, relating to the individual's relationship to the donor or prospective donor, unless the person knows that the representation is untrue.

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

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

- 463 The agency for Health Care Administration and the 464 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 gift donate the individual's organs, tissues, or eyes. A 477 478 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.
  - (2) The Department of Highway Safety and Motor Vehicles, after consultation with and concurrence by the agency for Health Care Administration, shall adopt rules to implement the provisions of this section according to the provisions of chapter 120.

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Funds expended by the agency for Health Care

Administration to carry out the intent of this section may shall

(3)

not be taken from any funds appropriated for patient care.

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

765.522 Duty of certain hospital administrators; liability of hospital administrators and, organ procurement organizations, eve banks, and tissue banks.--

- (1) When used in this section, "hospital" means any establishment licensed under chapter 395 except psychiatric and rehabilitation hospitals.
- (1)(2) If Where, based on accepted medical standards, a hospital patient is a suitable candidate for organ or tissue donation, the hospital administrator or the hospital administrator's designee shall, at or near the time of death, notify the appropriate procurement organization organ, eye, or tissue recovery program, which shall access the organ and tissue donor registry created by s. 765.5155 or any other donor registry to ascertain the existence of an entry in the registry which that has not been revoked, a donor card, or a document of gift executed by the decedent. In the absence of an entry in the donor registry, a document of gift donor card, organ donation sticker or organ donation imprint on a driver's license, or other properly executed document, the procurement organization organ, eye, or tissue recovery program shall request:
- (a) The patient's health care surrogate, as authorized in s. 765.512(2); or
- (b) If the patient does not have a surrogate, or the surrogate is not reasonably available, any of the persons specified in s. 765.512(3), in the order and manner listed,

to consent to the <u>anatomical</u> gift of all or any part of the decedent's body for any purpose specified in this part. Except as provided in s. 765.512, in the absence of actual notice of

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

- (3) A document of gift is valid if made pursuant to a request required by this section shall be executed in accordance with this part or the laws of the state or country where it was executed and where the person making the anatomical gift was domiciled, has a place of residence, or was a citizen at the time the document of gift was executed pursuant to s. 765.514.
- The agency for Health Care Administration shall establish rules and guidelines concerning the education of individuals who may be designated to perform the request and the procedures to be used in making the request. The agency is authorized to adopt rules concerning the documentation of the request, where such request is made.
- (5) If a document of gift is valid under this section, the laws of this state govern the interpretation of the document of gift.
- (6) A document of gift or amendment of an anatomical gift is presumed to be valid unless it was not validly executed or was revoked.
- (7) There shall be no civil or criminal liability against any organ procurement organization, eye bank, or tissue  $\frac{bank}{c}$  certified under s.  $765.542_{T}$  or against any hospital or hospital administrator or designee who complies, when complying with the provisions of this part and agency the rules of the agency for Health Care Administration or if when, in the exercise of reasonable care, a request for organ donation is inappropriate and the gift is not made according to this part and agency the rules of the agency for Health Care Administration.
- (8) (8) (6) The hospital administrator or a designee shall, at or near the time of death of a potential <del>organ</del> donor, directly notify the affiliated organ procurement organization designated

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

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

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

- (1) There is hereby created within the agency for Health Care Administration A statewide technical Organ Transplant Advisory Council is created within the agency, consisting of twelve members who are physicians licensed under chapter 458 or chapter 459, to represent the interests of the public and the clients of the Department of Health or the agency. The members shall be physicians licensed according to chapter 458 or chapter 459. A person employed by the agency may not be appointed as a member of the council.
- (5) Members of the council shall receive no compensation, but shall be reimbursed for per diem and travel expenses by the agency for Health Care Administration in accordance with the provisions of s. 112.061 while engaged in the performance of their duties.
- (6) The responsibilities of the council shall be to recommend to the agency for Health Care Administration

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

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

765.541 Certification of <u>procurement</u> organizations <del>engaged</del> in the practice of cadaveric organ and tissue procurement.—The agency for Health Care Administration shall:

- (1) Establish a program for the certification of organizations, <u>corporations</u> agencies, or other entities engaged in the procurement of organs, tissues, and eyes for transplantation.
- (2) Adopt rules that set forth appropriate standards and guidelines for the program in accordance with ss. 765.541-765.546 and part II of chapter 408. These standards and guidelines must be substantially based on the existing laws of the Federal Government and this state and the existing standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the Eye Bank Association of America (EBAA). In addition, the agency for Health Care Administration shall, before adopting these standards and guidelines, seek input from all organ procurement organizations, tissue banks, and eye banks based in this state. +
- (3) Collect, keep, and make available to the Governor and the Legislature information regarding the numbers and disposition of organs, and tissues, and eyes procured by each certified procurement organization. entity;
  - (4) Monitor procurement organizations participating

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facilities and agencies for program compliance.; and

Provide for the administration of the Organ and Tissue Procurement and Transplantation Advisory Board.

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

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

- The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 765.541-765.546 and part II of chapter 408 and to entities licensed or certified by or applying for such licensure or certification from the agency for Health Care Administration pursuant to ss. 765.541-765.546. A person An organization, agency, or other entity may not engage in the practice of organ procurement in this state without being designated as an organ procurement organization by the secretary of the United States Department of Health and Human Services and being appropriately certified by the agency for Health Care Administration. As used in this subsection, the term "procurement" includes the retrieval, processing, or distribution of human organs. A physician or organ procurement organization based outside this state is exempt from these certification requirements if:
- The organs are procured for an out-of-state patient who is listed on, or referred through, the United Network for Organ Sharing System; and
- The organs are procured through an agreement of an organ procurement organization certified by the state.
- A person An organization, agency, or other entity may not engage in tissue procurement in this state unless it is appropriately certified as a tissue bank by the agency for Health Care Administration. As used in this subsection, the term "procurement" includes any retrieval, processing, storage, or distribution of human tissue for transplantation.
  - (3) A person An organization, agency, or other entity may

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

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

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

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

(3) The board shall:

- (a) Assist the agency for Health Care Administration in the development of necessary professional qualifications, including, but not limited to, the education, training, and performance of persons engaged in the various facets of organ and tissue procurement, processing, preservation, and distribution for transplantation;
- (b) Assist the agency for Health Care Administration in monitoring the appropriate and legitimate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;
  - (c) Provide assistance to the Florida Medical Examiners

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

(d) Develop with and recommend to the agency for Health

- (d) Develop with and recommend to the agency for Health Care Administration the necessary procedures and protocols required to assure that all residents of this state have reasonable access to available organ and tissue transplantation therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is will be able to fulfill their organ and tissue requirements within the limits of the available supply and according to the severity of their medical condition and need; and
- (e) Develop with and recommend to the agency for Health Care Administration any changes to the laws of this state or administrative rules or procedures required to ensure assure that the statewide organ and tissue procurement and transplantation system is will be able to function smoothly, effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents of this state that no person or entity profits from the altruistic voluntary donation of organs or tissues.

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

- 765.544 Fees; organ and tissue donor education and procurement.--
- (1) In accordance with s. 408.805, an applicant or a certificateholder shall pay a fee for each application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be as follows:
- (a) An initial application fee of \$1,000 from organ procurement organizations and tissue banks and \$500 from eye banks.
  - (b) Annual fees to be used, in the following order of

 priority, for the certification program, the advisory board, maintenance of the <del>organ and tissue</del> donor registry, and the organ and tissue donor education program <del>in the following</del> <del>amounts</del>, which may not exceed \$35,000 per organization:

- 1. Each general organ procurement organization shall pay the greater of \$1,000 or 0.25 percent of its total revenues produced from procurement activity in this state by the certificateholder during its most recently completed fiscal year or operational year.
- 2. Each bone and tissue procurement <u>organization</u> agency or bone and tissue bank shall pay the greater of \$1,000 or 0.25 percent of its total revenues from procurement and processing activity in this state by the certificateholder during its most recently completed fiscal <del>year</del> or operational year.
- 3. Each eye bank shall pay the greater of \$500 or 0.25 percent of its total revenues produced from procurement activity in this state by the certificateholder during its most recently completed fiscal year or operational year.
- (2) The agency for Health Care Administration shall specify by rule the administrative penalties for the purpose of ensuring adherence to the standards of quality and practice required by this chapter, part II of chapter 408, and applicable rules of the agency for continued certification.
- (3)(a) Proceeds from fees, administrative penalties, and surcharges collected pursuant to this section must be deposited into the Health Care Trust Fund.
- (b) Moneys deposited in the trust fund pursuant to this section must be used exclusively for the implementation, administration, and operation of the certification program and the advisory board, for maintaining the organ and tissue donor registry, and for organ and tissue donor education.
- (4) As used in this section, the term "procurement activity in this state" includes the bringing into this state

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

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

Physician supervision of cadaveric organ and tissue procurement coordinators. -- Organ Procurement organizations, tissue banks, and eye banks may employ coordinators, who are registered nurses, physician's assistants, or other medically trained personnel who meet the relevant standards for organ procurement organizations, tissue banks, or eye banks as adopted by the agency for Health Care Administration under s. 765.541, to assist in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research. A coordinator who assists in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research must do so under the direction and supervision of a licensed physician medical director pursuant to rules and guidelines to be adopted by the agency for Health Care Administration. With the exception of organ procurement surgery, this supervision may be indirect supervision. For purposes of this section, the term "indirect supervision" means that the medical director is responsible for the medical actions of the coordinator, that the coordinator is operating under protocols expressly approved by the medical director, and that the medical director or his or her physician designee is always available, in person or by telephone, to provide medical direction, consultation, and advice in cases of organ, tissue, and eye donation and procurement. Although indirect supervision is authorized under this section, direct physician supervision is to be encouraged when appropriate. Section 18. Section 765.547, Florida Statutes, is created

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to read:

765.547 Cooperation between medical examiner and procurement organization.--

- (1) A medical examiner and procurement organization shall cooperate with each other in order to maximize opportunities to recover anatomical gifts for the purpose of transplantation, therapy, research, or education.
- (2) The Florida Medical Examiners Commission shall adopt rules establishing cooperative responsibilities between medical examiners and procurement organizations to facilitate and expedite completion of the medical examiner's responsibilities under chapter 406 in a manner that will maximize opportunities to recover anatomical gifts.
- (3) This part does not supersede any part of chapter 406 relating to medical examiners and the disposition of dead bodies.
- Section 19. Subsection (30) of section 408.802, Florida Statutes, is amended to read:
- 408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:
- (30) Organ, and tissue, and eye procurement organizations agencies, as provided under part V of chapter 765.
- Section 20. Subsection (29) of section 408.820, Florida Statutes, is amended to read:
- 408.820 Exemptions.--Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:
- (29) Organ, and tissue, and eye procurement organizations agencies, as provided under part V of chapter 765, are exempt from s. 408.810(5)-(10).
  - Section 21. This act shall take effect July 1, 2009.

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TITLE AMENDMENT

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

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

date.

A bill to be entitled

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An act relating to the Revised Uniform Anatomical Gift Act; creating s. 765.5101, F.S.; providing a short title; creating s. 765.5102, F.S.; providing definitions; creating s. 765.5103, F.S.; providing that the revised act applies to an anatomical gift or amendment to, revocation of, or refusal to make an anatomical gift, whenever made; creating s. 765.5104, F.S.; specifying who may make an anatomical gift before the donor's death; creating s. 765.5105, F.S.; providing the manner of making an anatomical gift before the donor's death; creating s. 765.5106, F.S.; providing for amending or revoking an anatomical gift before the donor's death; creating s. 765.5107, F.S.; specifying the manner of refusal to make an anatomical gift; providing the effect of such a refusal; creating s. 765.5108, F.S.; providing for the preclusive effect of an anatomical gift, amendment, or revocation in certain circumstances; providing exceptions; creating s. 765.5109, F.S.; specifying who may make an anatomical gift of a decedent's body or part; creating s. 765.5110, F.S.; specifying the manner of making, amending, or revoking an anatomical gift of a decedent's body or part; creating s. 765.5111, F.S.; specifying persons that may receive an anatomical gift; providing for the purpose of an anatomical gift; providing that a person may not accept an anatomical gift if the person knows that the gift was not effectively made under specified provisions or if the person knows that the decedent made a refusal

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that was not revoked; creating s. 765.5112, F.S.; requiring specified persons to make a reasonable search of an individual who the person reasonably believes is dead or near death for a document of gift or other information identifying the individual as a donor or as an individual who made a refusal; providing duties if a document of gift or a refusal to make an anatomical gift is located; providing immunity from criminal or civil liability for failure to discharge specified duties; creating s. 765.5113, F.S.; providing that delivery of a document of gift is not a requirement for its effectiveness; requiring a person in possession of a document of gift or a refusal to make an anatomical gift with respect to the individual to allow examination and copying of the document; creating s. 765.5114, F.S.; specifying rights and duties of procurement organizations when an individual has been referred to them; allowing the person to whom a part passes under specified provisions to conduct any reasonable examination necessary to ensure the medical suitability of the body or part for its intended purpose unless otherwise prohibited; requiring a procurement organization, upon the death of a minor who was a donor or who had refused, to conduct a reasonable search for the parents of the minor and provide them with an opportunity to revoke or amend the gift or revoke the refusal; providing that the rights of the person to whom a part passes under a specified provision are superior to the rights of all others with respect to the part; prohibiting

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

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the effect of an anatomical gift on an advance healthcare directive; creating s. 765.5122, F.S.; requiring cooperation between medical examiners and procurement organizations; creating s. 765.5123, F.S.; providing for facilitation of anatomical gifts from decedents whose bodies are under the jurisdiction of medical examiners; requiring persons with information requested by a medical examiner conducting a medicolegal examination about a donor or prospective donor whose body is under the examiner's jurisdiction to provide that information as expeditiously as possible; requiring a medical examiner and procurement organization to cooperate in the timely removal of a part when recovery of the part will not interfere with the examination; requiring consultation between a medical examiner and a procurement organization when the medical examiner believes that recovery of the part could interfere with the postmortem investigation into the decedent's cause or manner of death; requiring a medical examiner who intends to deny recovery to attend, if requested, the removal procedure for the part before making a final determination not to allow recovery of the part; requiring a medical examiner denying recovery to make specified recorded findings; requiring a procurement organization in certain circumstances, upon request, to provide the medical examiner with a records concerning a part assist in the postmortem examination; requiring a procurement organization to reimburse a medical examiner for additional costs incurred by the examiner who is

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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:

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Section 765.5101, Florida Statutes, is created to read:

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

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140	Section 2. Section 765.5102, Florida Statutes, is created
141	to read:
142	765.5102 DefinitionsAs 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

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

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- (7) "Donor" means an individual whose body or part is the subject of an anatomical gift.
- (8) "Donor registry" means a database that contains records of anatomical gifts and amendments to or revocations of anatomical gifts.
- (9) "Driver's license" means a license or permit issued by the Department of Highway Safety and Motor Vehicles to operate a vehicle, whether or not conditions are attached to the license or permit.
- (10) "Eye bank" means a person licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of human eyes or portions of human eyes.
- (11) "Guardian" means a person appointed by a court to make decisions regarding the support, care, education, health, or welfare of an individual. The term does not include a quardian ad litem.
- (12) "Hospital" means a facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state.
- (13) "Identification card" means an identification card issued by the Department of Highway Safety and Motor Vehicles.
  - (14) "Know" means to have actual knowledge.
- (15) "Organ procurement organization" means a person designated by the Secretary of the United States Department of Health and Human Services as an organ procurement organization.

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

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- (17) "Part" means an organ, an eye, or tissue of a human being. The term does not include the whole body.
- (18) "Person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, public corporation, government or governmental subdivision, agency, or instrumentality or any other legal or commercial entity.
- (19) "Physician" means an individual authorized to practice medicine or osteopathy under the law of any state.
- (20) "Procurement organization" means an eye bank, organ procurement organization, or tissue bank.
- (21) "Prospective donor" means an individual who is dead or near death and who has been determined by a procurement organization to have a part that could be medically suitable for transplantation, therapy, research, or education. The term does not include an individual who has made a refusal.
- (22) "Reasonably available" means able to be contacted by a procurement organization without undue effort and willing and able to act in a timely manner consistent with existing medical criteria necessary for the making of an anatomical gift.
- (23) "Recipient" means an individual into whose body a decedent's part has been or is intended to be transplanted.
- (24) "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

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	(25)	"Refusal	." mea	ns a :	record	l cre	eated	under	s.	765.5	<u>5107</u>
<u>that</u>	expres	ssly stat	es an	inte	nt to	bar	other	perso	ns	from	making
an a	natomio	cal gift	of an	indi	<u> zidual</u>	's b	ody o	r part	-		

- (26) "Sign" means, with the present intent to authenticate or adopt a record:
  - (a) To execute or adopt a tangible symbol; or

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- (b) To attach to or logically associate with the record an electronic symbol, sound, or process.
- (27) "State" means a state of the United States, the

  District of Columbia, Puerto Rico, the United States Virgin

  Islands, or any territory or insular possession subject to the jurisdiction of the United States.
- (28) "Technician" means an individual determined to be qualified to remove or process parts by an appropriate organization that is licensed, accredited, or regulated under federal or state law. The term includes an enucleator.
- (29) "Tissue" means a portion of the human body other than an organ or an eye. The term does not include blood unless the blood is donated for the purpose of research or education.
- (30) "Tissue bank" means a person licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue.
- (31) "Transplant hospital" means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.
- Section 3. Section 765.5103, Florida Statutes, is created to read:

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250	765.5103 ApplicabilitySections 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:

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

(b) In a will;

- (c) During a terminal illness or injury of the donor, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness; or
  - (d) As provided in subsection (2).
- anatomical gift under s. 765.5104 may make a gift by a donor card or other record signed by the donor or other person making the gift or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry. If the donor or other person is physically unable to sign a record, the record may be signed by another individual at the direction of the donor or other person and must:
- (a) Be witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person.
- (b) State that it has been signed and witnessed as provided in paragraph (a).
- (3) Revocation, suspension, expiration, or cancellation of a driver's license or identification card upon which an anatomical gift is indicated does not invalidate the gift.
- (4) An anatomical gift made by will takes effect upon the donor's death whether or not the will is probated. Invalidation

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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

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

- (4) A donor may amend or revoke an anatomical gift that was not made in a will by any form of communication during a terminal illness or injury addressed to at least two adults, at least one of whom is a disinterested witness.
- (5) A donor who makes an anatomical gift in a will may amend or revoke the gift in the manner provided for amendment or revocation of wills or as provided in subsection (1).
- Section 7. Section 765.5107, Florida Statutes, is created to read:
- 765.5107 Refusal to make an anatomical gift; effect of refusal.--
- (1) An individual may refuse to make an anatomical gift of the individual's body or part by:
  - (a) A record signed by:
  - 1. The individual; or

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- 2. Subject to subsection (2), another individual acting at the direction of the individual if the individual is physically unable to sign;
- (b) The individual's will, whether or not the will is admitted to probate or invalidated after the individual's death; or
- (c) Any form of communication made by the individual during the individual's terminal illness or injury addressed to at least two adults, at least one of whom is a disinterested witness.

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550	(2) A record signed pursuant to supparagraph (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:
882	765.5108 Preclusive effect of an anatomical gift,
383	amendment, or revocation
384	(1) Except as otherwise provided in subsection (7) and
885	subject to subsection (6), in the absence of an express,

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

- (2) A donor's revocation of an anatomical gift of the donor's body or part under s. 765.5106 is not a refusal and does not bar another person specified in s. 765.5104 or s. 765.5109 from making an anatomical gift of the donor's body or part under s. 765.5105 or s. 765.5110.
- (3) If a person other than the donor makes an unrevoked anatomical gift of the donor's body or part under s. 765.5105 or an amendment to an anatomical gift of the donor's body or part under s. 765.5106, another person may not make, amend, or revoke the gift of the donor's body or part under s. 765.5110.
- (4) A revocation of an anatomical gift of a donor's body or part under s. 765.5106 by a person other than the donor does not bar another person from making an anatomical gift of the body or part under s. 765.5105 or s. 765.5110.
- (5) In the absence of an express, contrary indication by the donor or other person authorized to make an anatomical gift under s. 765.5104, an anatomical gift of a part is neither a refusal to give another part nor a limitation on the making of an anatomical gift of another part at a later time by the donor or another person.
- (6) In the absence of an express, contrary indication by the donor or other person authorized to make an anatomical gift

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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
124	minor's refusal.
125	Section 9. Section 765.5109, Florida Statutes, is created
126	to read:
127	765.5109 Who may make an anatomical gift of a decedent's
128	body or part
129	(1) Subject to subsections (2) and (3) and unless barred
130	by s. $765.5107$ or s. $765.5108$ , an anatomical gift of a
131	decedent's body or part for purpose of transplantation, therapy,
132	research, or education may be made by any member of the
133	following classes of persons who is reasonably available, in the
134	order of priority listed:
135	(a) An agent of the decedent at the time of death who
136	could have made an anatomical gift under s. 765.5104(2)
137	immediately before the decedent's death.
138	(b) The spouse of the decedent.
139	(c) Adult children of the decedent.
140	(d) Parents of the decedent.
41	(e) Adult siblings of the decedent.

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CODING: Words  $\underline{\text{stricken}}$  are deletions; words  $\underline{\text{underlined}}$  are additions.

(f) Adult grandchildren of the decedent.

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- (g) Grandparents of the decedent.
- (h) An adult who exhibited special care and concern for the decedent.
  - (i) The persons who were acting as the guardians of the person of the decedent at the time of death.
  - (j) Any other person having the authority to dispose of the decedent's body.
  - (2) If there is more than one member of a class listed in paragraphs (1)(a), (c), (d), (e), (f), (g), or (i) who is entitled to make an anatomical gift, an anatomical gift may be made by a member of the class unless that member or a person to whom the gift may pass under s. 765.5111 knows of an objection by another member of the class. If an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available.
  - (3) A person may not make an anatomical gift if, at the time of the decedent's death, a person in a prior class under subsection (1) is reasonably available to make or to object to the making of an anatomical gift.
  - (4) A health care surrogate designated by the decedent pursuant to part II of this chapter may give all or any part of the decedent's body for any purpose specified in s. 765.5111 absent actual notice of contrary indications by the decedent.
- Section 10. Section 765.5110, Florida Statutes, is created to read:
- 468 765.5110 Manner of making, amending, or revoking an anatomical gift of a decedent's body or part.--

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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;

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(1) An anatomical gift may be made to the following

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persons named in the document of gift:

purpose of an anatomical gift. --

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

- (b) Subject to subsection (2), an individual designated by the person making the anatomical gift if the individual is the recipient of the part.
  - (c) An eye bank or tissue bank.

- (2) If an anatomical gift to an individual under paragraph (1)(b) cannot be transplanted into that individual, the part passes in accordance with subsection (7) in the absence of an express, contrary indication by the person making the anatomical gift.
- (3) If an anatomical gift of one or more specific parts or all parts is made in a document of gift that does not name a person described in subsection (1) but identifies the purpose for which an anatomical gift may be used, the following rules apply:
- (a) If the part is an eye and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate eye bank.
- (b) If the part is tissue and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate tissue bank.
- (c) If the part is an organ and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate organ procurement organization as custodian of the organ.

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

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- (4) For the purpose of subsection (3), if there is more than one purpose of an anatomical gift set forth in the document of gift but the purposes are not set forth in any priority, the gift must be used for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.
- (5) If an anatomical gift of one or more specific parts is made in a document of gift that does not name a person described in subsection (1) and does not identify the purpose of the gift, the gift may be used only for transplantation or therapy, and the gift passes in accordance with subsection (7).
- (6) If a document of gift specifies only a general intent to make an anatomical gift by words such as "donor," "organ donor," or "body donor," or by a symbol or statement of similar import, the gift may be used only for transplantation or therapy, and the gift passes in accordance with subsection (7).
- (7) For purposes of subsections (2), (5), and (6), the following rules apply:
- (a) If the part is an eye, the gift passes to the appropriate eye bank.
  - (b) If the part is tissue, the gift passes to the appropriate tissue bank.
- (c) If the part is an organ, the gift passes to the
  appropriate organ procurement organization as custodian of the
  organ.

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

- (9) If an anatomical gift does not pass pursuant to subsections (1)-(8) or the decedent's body or part is not used for transplantation, therapy, research, or education, custody of the body or part passes to the person under obligation to dispose of the body or part.
- (10) A person may not accept an anatomical gift if the person knows that the gift was not effectively made under s. 765.5105 or s. 765.5110 or if the person knows that the decedent made a refusal under s. 765.5107 that was not revoked. For purposes of the subsection, if a person knows that an anatomical gift was made on a document of gift, the person is deemed to know of any amendment or revocation of the gift or any refusal to make an anatomical gift on the same document of gift.
- (11) Except as otherwise provided in paragraph (1)(b), nothing in ss. 765.5101-765.5125 affects the allocation of organs for transplantation or therapy.

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

## 765.5112 Search and notification. --

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

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

- (b) If no other source of the information is immediately available, a hospital, as soon as practical after the individual's arrival at the hospital.
- (2) If a document of gift or a refusal to make an anatomical gift is located by the search required by paragraph (1)(a) and the individual or deceased individual to whom it relates is taken to a hospital, the person responsible for conducting the search shall send the document of gift or refusal to the hospital.
- (3) A person is not subject to criminal or civil liability for failing to discharge the duties imposed by this section but may be subject to administrative sanctions.
- Section 13. Section 765.5113, Florida Statutes, is created to read:
- 765.5113 Delivery of a document of gift not required; right to examine.--
- (1) A document of gift need not be delivered during the donor's lifetime to be effective.
- (2) Upon or after an individual's death, a person in possession of a document of gift or a refusal to make an anatomical gift with respect to the individual shall allow examination and copying of the document of gift or refusal by a person authorized to make or object to the making of an anatomical gift with respect to the individual or by a person to whom the gift could pass under s. 765.5111.

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

- 765.5114 Rights and duties of procurement organizations and others.--
- (1) When a hospital refers an individual at or near death to a procurement organization, the organization shall make a reasonable search of the records of the statewide organ and tissue donor registry and any donor registry that the organization knows exists for the geographical area in which the individual resides to ascertain whether the individual has made an anatomical gift.
- (2) A procurement organization must be allowed reasonable access to information in the records of the statewide organ and tissue donor registry to ascertain whether an individual at or near death is a donor.
- (3) When a hospital refers an individual at or near death to a procurement organization, the organization may conduct any reasonable examination necessary to ensure the medical suitability of a part that is or could be the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor. During the examination period, measures necessary to ensure the medical suitability of the part may not be withdrawn unless the hospital or procurement organization knows that the individual expressed a contrary intent.
- (4) Unless prohibited by law other than ss. 765.5101765.5125, at any time after a donor's death, the person to whom a part passes under s. 765.5111 may conduct any reasonable

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

- (5) Unless prohibited by law other than ss. 765.5101-765.5125, an examination under subsection (3) or subsection (4) may include an examination of all medical and dental records of the donor or prospective donor.
- (6) Upon the death of a minor who was a donor or had signed a refusal, unless a procurement organization knows the minor is emancipated, the procurement organization shall conduct a reasonable search for the parents of the minor and provide the parents with an opportunity to revoke or amend the anatomical gift or revoke the refusal.
- (7) Upon referral by a hospital under subsection (1), a procurement organization shall make a reasonable search for any person listed in s. 765.5109 having priority to make an anatomical gift on behalf of a prospective donor. If a procurement organization receives information that an anatomical gift to any other person was made, amended, or revoked, it shall promptly advise the other person of all relevant information.
- (8) Subject to s. 765.5111(9) and s. 765.5123, the rights of the person to whom a part passes under s. 765.5111 are superior to the rights of all others with respect to the part. The person may accept or reject an anatomical gift in whole or in part. Subject to the terms of the document of gift and ss. 765.5101-765.5125, a person who accepts an anatomical gift of an entire body may allow embalming, burial, or cremation, and use of remains in a funeral service. If the gift is of a part, the person to whom the part passes under s. 765.5111, upon the death

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565	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
570	or transplanting a part from the decedent.
671	(10) A physician or technician may remove a donated part
572	from the body of a donor that the physician or technician is
573	qualified to remove.
574	Section 15. Section 765.5115, Florida Statutes, is created
575	to read:
576	765.5115 Coordination of procurement and use Each
577	hospital in this state shall enter into agreements or
578	affiliations with procurement organizations for coordination of
579	procurement and use of anatomical gifts.
80	Section 16. Section 765.5117, Florida Statutes, is created
581	to read:
82	765.5117 Prohibited actsA person who, in order to
583	obtain financial gain, intentionally falsifies, forges,
584	conceals, defaces, or obliterates a document of gift, an
85	amendment or revocation of a document of gift, or a refusal
586	commits a felony of the third degree, punishable as provided in
587	s. 775.082, s. 775.083, or s. 775.084.
88	Section 17. Section 765.5118, Florida Statutes, is created
89	to read:
590	765.5118 Immunity
591	(1) A person who acts in accordance with ss. 765.5101-
592	765.5125 or with the applicable anatomical gift law of another

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HB 209

state, or attempts in good faith to do so, is not liable for

such an act in a civil action, criminal prosecution, or

administrative proceeding.

- (2) Neither the person making an anatomical gift nor the donor's estate is liable for any injury or damage that results from the making or use of the gift.
- (3) In determining whether an anatomical gift has been made, amended, or revoked under ss. 765.5101-765.5125, a person may rely upon representations of an individual listed in s. 765.5109(1)(b), (c), (d), (e), (f), (g), or (h) relating to the individual's relationship to the donor or prospective donor unless the person knows that the representation is untrue.

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

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

- (1) A document of gift is valid if executed in accordance with:
  - (a) Sections 765.5101-765.5125;
- (b) The laws of the state or country where it was executed; or
- (c) The laws of the state or country where the person making the anatomical gift was domiciled, has a place of residence, or was a national at the time the document of gift was executed.
- (2) If a document of gift is valid under this section, the law of this state governs the interpretation of the document of gift.

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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

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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

- (1) A medical examiner shall cooperate with procurement organizations to maximize the opportunity to recover anatomical gifts for the purpose of transplantation, therapy, research, or education.
- (2) If a medical examiner receives notice from a procurement organization that an anatomical gift might be available or was made with respect to a decedent whose body is

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

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

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

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

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

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

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- examination by reviewing all medical records, laboratory test results, X rays, other diagnostic results, and other information that any person possesses about a donor or prospective donor whose body is under the jurisdiction of the medical examiner which the medical examiner determines may be relevant to the investigation.
- (3) A person who has any information requested by a medical examiner pursuant to subsection (2) shall provide that information as expeditiously as possible to allow the medical examiner to conduct the medicolegal investigation within a period compatible with the preservation of parts for the purpose of transplantation, therapy, research, or education.
- (4) If an anatomical gift has been or might be made of a part of a decedent whose body is under the jurisdiction of the medical examiner and a postmortem examination is not required, or the medical examiner determines that a postmortem examination is required but that the recovery of the part that is the subject of an anatomical gift will not interfere with the examination, the medical examiner and procurement organization shall cooperate in the timely removal of the part from the decedent for the purpose of transplantation, therapy, research, or education.

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under the jurisdiction of the medical examiner has been or might be made, but the medical examiner initially believes that the recovery of the part could interfere with the postmortem investigation into the decedent's cause or manner of death, the medical examiner shall consult with the procurement organization or physician or technician designated by the procurement organization, the medical examiner may allow the recovery.

- determining the decedent's cause or manner of death, may deny recovery by the procurement organization.
- (7) If the medical examiner or designee denies recovery under subsection (6), the medical examiner or designee shall:
- (a) Explain in a record the specific reasons for not allowing recovery of the part.
- 859 (b) Include the specific reasons in the records of the 860 medical examiner.

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

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- (8) If the medical examiner or designee allows recovery of a part under subsection (4), subsection (5), or subsection (6), the procurement organization shall, upon request, cause the physician or technician who removes the part to provide the medical examiner with a record describing the condition of the part, a biopsy, a photograph, and any other information and observations that would assist in the postmortem examination.
- (9) If a medical examiner or designee is required to be present at a removal procedure under subsection (6), upon request the procurement organization requesting the recovery of the part shall reimburse the medical examiner or designee for the additional costs incurred in complying with subsection (6).

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

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

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

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

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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. <u>Sections 765.510, 765.511, 765.512, 765.513,</u>
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. $\frac{765.5105}{765.514}$ , 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 $ au$
912	The donor registration card distributed by the Department of
913	Highway Safety and Motor Vehicles shall include the information

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and such additional information as determined necessary

required by the uniform donor card under s. 765.5105(1)(a)

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

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

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

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

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

- (a) The patient's health care surrogate, as authorized in s. 765.5109(4)  $\frac{765.512(2)}{765.512(2)}$ ; or
- (b) If the patient does not have a surrogate, or the surrogate is not reasonably available, any of the persons specified in s.  $\frac{765.5109(1)}{765.512(3)}$ , in the order and manner listed,

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

(3) A gift made pursuant to a request required by this section shall be executed pursuant to s. <u>765.5110</u> <del>765.514</del>. Section 30. This act shall take effect October 1, 2009.

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#### 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 CEC
3) Health & Family Services Policy Council	Manager Commission of the Comm		
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.

This document does not reflect the Intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0573b.HCR.doc

DATE:

3/9/2009

#### **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:

#### **Current Situation:**

<u>Background</u>: 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>

s. 154.207(7), F.S.

STORAGE NAME:

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

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

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

<u>Purpose of the Authority</u>: 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 qequip 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>7</sup> s. 154.209, F.S. **STORAGE NAME**:

DATE:

<sup>&</sup>lt;sup>6</sup> s. 154.247, F.S.

- Participate in and issue bonds and other forms of indebtedness for the purpose of establishing and m 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.

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.

License and resident data received from the Department of Financial Services, August 2008.

s. 154.223, F.S.

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

STORAGE NAME: DATE:

h0573b.HCR.doc 3/9/2009 PAGE: 6

#### 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:			
4				
5	Amendment (with directory and title amendments)			
6	Remove line(s) 23-28 and insert:			
7	(e) Services for the mentally ill under chapter 394;			
8	(f) Assisted living services in accordance with chapter			
9	429; or			
10	(g) Hospice services in accordance with chapter 400.			
11				
12	Health facility also includes any private corporation organized			
13	not for profit which offers independent living facilities and			
14	services as part of a retirement community that provides nursing			
15	home care services or assisted living services on the same			
16	campus. hospital or nursing home care services in accordance			
17	with chapter 395 or chapter 400 or life care services in			
18	accordance with chapter 651, and also includes facilities			
19	licensed under chapter 393 and 394.			
20				
21				

#### HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES Amendment No. 1 (for drafter's use only)

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TITLE AMENDMENT

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.

CS/HB 573 2009

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	
LO	Section 1. Subsection (8) of section 154.205, Florida
L1	Statutes, is amended to read:
L2	154.205 DefinitionsThe following terms, whenever used
L3	in this part, shall have the following meanings unless a
L4	different meaning clearly appears from the context:
1.5	(8) "Health facility" means any private corporation
L 6	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	<u>400;</u>
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.

Page 1 of 2

CODING: Words stricken are deletions; words underlined are additions.

CS/HB 573 2009

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

29

Page 2 of 2

CODING: Words stricken are deletions; words underlined are additions.

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.

Mark D. Potter, Ph D. 94 S. Chantsong Circle The Woodlands, TX 77382 mark.potter@bms.com Phone (work): (281) 419-1525 FAX (281) 419-1302

#### **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**

Amercian 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.

Klebig ML, Wall MD, **Potter** MD, Rowe EL, Carpenter DA, Rinchik EM. Mutations in the clatharin-assembly gene Picalm are responsible for the hematopoietic and iron metabolism abnormalities in fit1 mice. *PNAS* 100, 8360-65, 2003.

van Rompaey, L, **Potter**, M, Grosveld, G: Tel induces a G1 arrest and suppresses Rasinduced transformation. *Oncogene* 19, 5244-5250, 2000.

Buijs, A, van Rompaey, L, Molijn, A, Davis, N, Vertegaal, A, **Potter**, M, Adams, C, van Baal, S, Zwarthoff, E, Roussel, M, Grosveld, G: The MN1-TEL fusion protein, encoded by the translocation (12;22)(p13;q11) in myeloid leukemia, is a transcription factor with transforming activity. *Mol. Cell. Biology* 20, 9281-9293, 2000.

**Potter**, MD, Buijs, A, Kreider, B, Grosveld, G: Identification and characterization of a new human ETS-family transcription factor, TEL2, that is expressed in hematopoietic tissues and can associate with TEL1/ETV6. *BLOOD* 95, 3341-48, 2000.

Potter, MD, Bernstein, A, Lee, J: Thymocyte apoptosis in the wasted (wst) mouse. Cellular Immunology 188, 111-17, 1998.

Bernstein, A, Correll, P, Paulson, R, Potter, M: In vitro and in vivo approaches to the molecular understanding of mouse hematopoiesis. In Towards a molecular

understanding of development, Lonai, P, editor. Switzerland, Harwood Academic Publishers, 101-47, 1996.

**Potter**, MD, Klebig, ML, Rinchik, EM: Genetic and physical mapping the *fitness 1 (fit1)* locus within the *Fes-Hbb* region of mouse chromosome 7. *Mammalian Genome* 6: 70-5, 1995.

Holdener-Kenney, BC, Thomas, JW, **Potter**, MD, Rinchik, EM, Sharan, SK, Schumacher, A, Magnuson, T: Physical localization of *eed*: A region of mouse chromosome 7 required for gastrulation. *Genomics* 27: 447-56, 1995.

Rinchik, EM, Tonjes, RR, Paul, D, **Potter**, MD: Molecular analysis of radiation-induced *albino* (c)-locus mutations that cause death of preimplantation stages of development. Genetics 135: 1107-16, 1994.

**Potter**, MD, Rinchik, EM: Deletion mapping of the *chocolate* (*cht*) locus within the *Fes-Hbb* region of mouse chromosome 7. Mammalian Genome 4: 46-8, 1993.

Porter, MA, **Potter**, MD, Hartman, FC: Affinity labeling of spinach phosphoribulokinase subsequent to s-methylation at cys16. *Journal Protein Chemisty* 9: 445-51, 1990.

#### Abstracts:

Schultz, A, **Potter**, MD, Johnson, DK, Schaeffer, DO: Characterization of hematologic and serum chemistry in *fitness 1* mutant mice. American Veterinary Association Meeting, August 1995.

**Potter**, MD, Carpenter, DA, Stubbs, LJ, Johnson, DK, Popp, D, Popp, RA, Shinpock, S, Wilkinson, J, Long, C, Holdener-Kenney, B, Magnuson, T, Rinchik, EM: Positional cloning of a mutant locus specifying *in utero* growth retardation, reduced viability, and abnormal hematopoiesis. EMBL Mouse Genetics Meeting, Heidelberg, Germany, August 1993. (Ten minute oral presentation).

**Potter**, MD, Carpenter, DA, Holdener-Kenney, B, Magnuson, T, Rinchik, EM: A positional cloning strategy for the molecular identification of a mutant locus specifying growth retardation and reduced fitness. Second Biennial Mammalian Developmental Genetics Workshop, Bar Harbor, ME. September 1991.

Rinchik, EM, Klebig, ML, **Potter**, MD, Taylor, LD, Houser, KJ, Long, CF, Johnson, DK, Machanoff, R, Carpenter, DA: Strategies for functional and physical mapping of mouse chromosome 7. Fourth International Workshop on Mouse Genome Mapping, Annapolis, MD. November 1990.

#### 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**

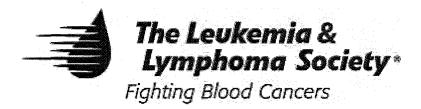
Richard A. Fess, Florida Insurance and Real Estate Broker Lake Mary, Florida resident Married to Julie Fess, 4 children US Army Veteran

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 Cites
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



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

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

- 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?**

- □ 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

- 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**

- Lack of means to afford "routine patient costs" involved in clinical trials; these include nursing, inpatient 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**

- 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

- □ 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**

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

## Resources

The Leukemia & Lymphoma Society (LLS) www.lls.org

National Cancer Institute (NCI) <a href="https://www.cancer.gov/clinicaltrials">www.cancer.gov/clinicaltrials</a>

American Society of Clinical Oncology (ASCO) <a href="https://www.asco.org/portal/site/ASCO">www.asco.org/portal/site/ASCO</a>

## Cancer Clinical Trials

## 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

- 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



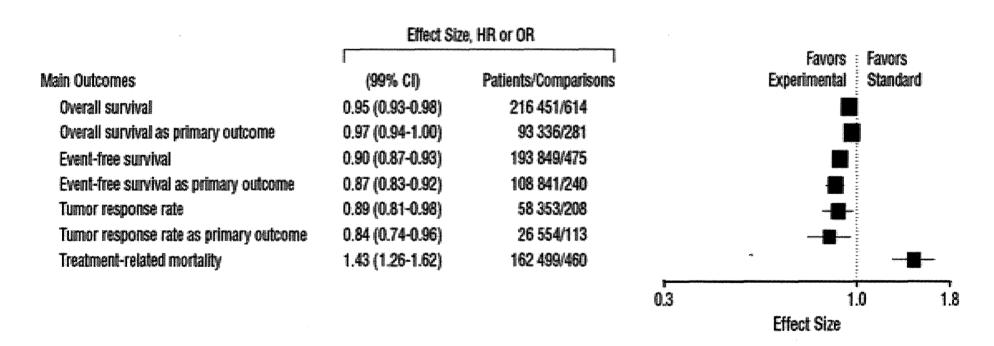
# **Clinical Research at Moffitt Cancer Center**

- 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

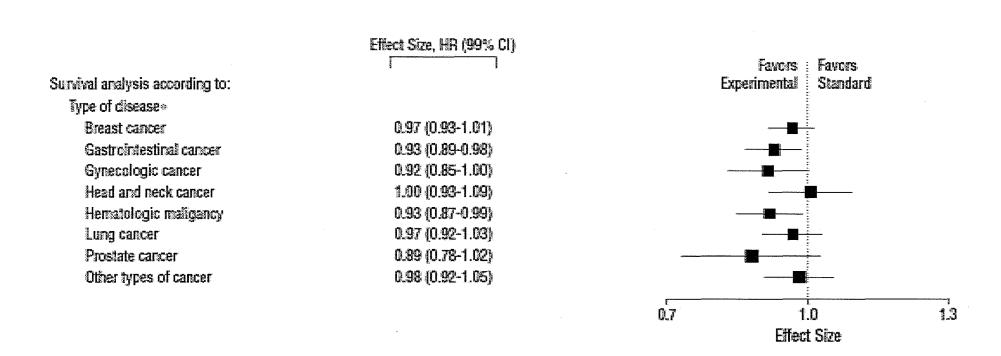
Randomized Clinical Trials – Nat'l Cancer Institute 1955 - 2006



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



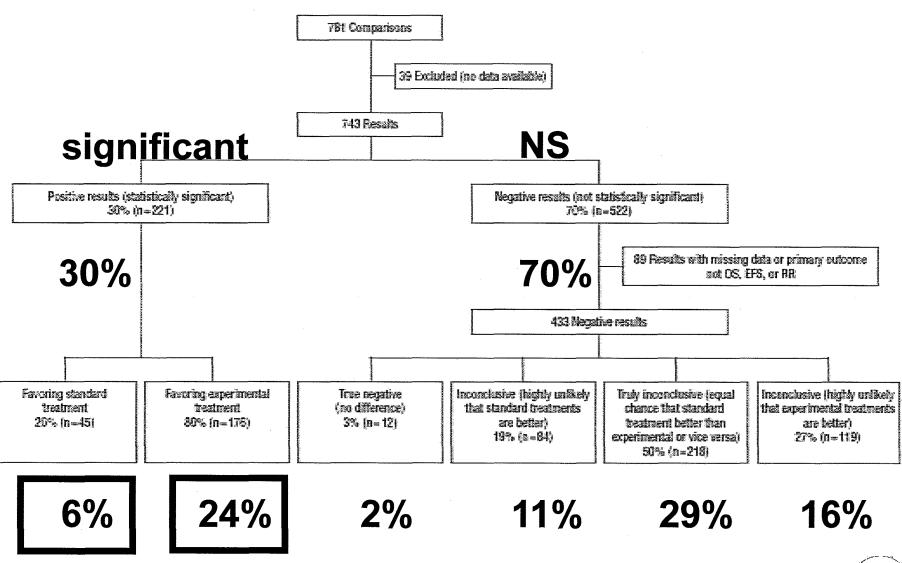
## **Treatment Success by Cancer Site**



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



## **Probability of Clinical Trial Outcome**

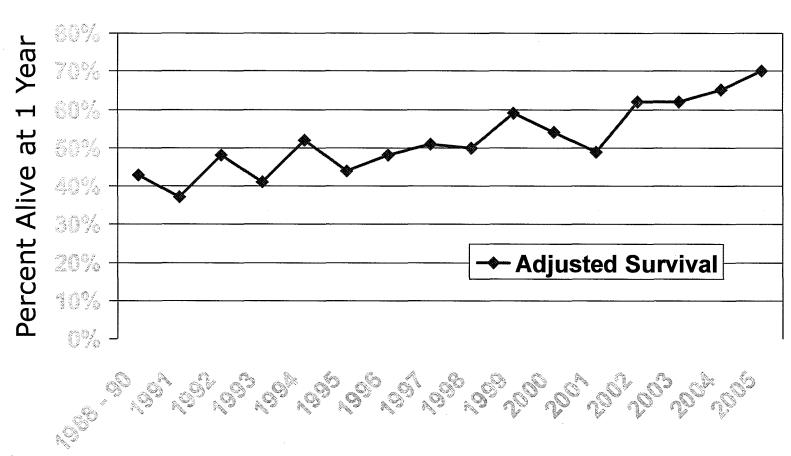


Ben Djulbegovic et al, Arch Intern Med. 2008; 168:632-642



### **CLINICAL TRIALS ARE IMPROVING SURVIVAL RATES**

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





**Courtesy of Dr. Dennis Confer** 



## Health Care Regulation Policy Committee

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

## Revised

#### 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 \_\_\_\_\_

Council/Committee hearing bill: Health Care Regulation Policy Committee

Representative(s) Schwartz offered the following:

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#### Amendment (with title amendment)

Remove everything after the enacting clause and insert:

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

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

- (1) "Agency" means the Agency for Health Care Administration.
- (2) "Anatomical gift" or "gift" means a donation of all or part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education.
- (3)(1) "Bank" or "storage facility" means a facility licensed, accredited, or approved under the laws of any state for storage of human bodies or body parts thereof.
- $\underline{(4)}$  "Death" means the absence of life as determined, in accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, including the brain stem.
  - (5) "Decedent" means a deceased individual whose body or

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

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

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person listed in s. 765.512(3) or other family member. (8) "Document of gift" means any of the documents or mechanisms used in making an anatomical gift under s. 765.514.

(7) "Disinterested witness" means a witness other than a

- (9) (3) "Donor" means an individual who makes an anatomical a gift of all or part of his or her body.
- (10) "Donor registry" means a database that contains records of anatomical gifts and amendments to, or revocations of, such gifts.
- (11) "Eye bank" means an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue.
- (12) "Guardian" means a person appointed pursuant to chapter 744. The term does not include a guardian ad litem.
- (13) (4) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state and includes a hospital operated by the United States Government or a state, or a subdivision thereof, although not required to be licensed under state laws.
- (14) "Identification card" means an official identification card issued by a governmental entity, state agency, or subdivision thereof.
- (15) "Organ procurement organization" means an entity that is designated as an organ procurement organization by the Secretary of the United States Department of Health and Human Services and that engages in the retrieval, screening, testing, processing, storage, or distribution of human organs.
  - (16) "Part of the body" or "body part" means an organ,

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- eye, or tissue of a human being. The term does not include the whole body.
- (17) (5) "Physician" or "surgeon" means a physician or surgeon licensed to practice under chapter 458 or chapter 459 or similar laws of any state. "Surgeon" includes dental or oral surgeon.
- "Procurement" means any retrieval, recovery, (18)processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education.
- "Procurement organization" means an organ procurement organization, eye bank, or tissue bank.
- (20) "Reasonably available" means able to be contacted by a procurement organization in a timely manner without undue effort, and willing and able to act in a manner consistent with existing medical protocols necessary for the making of an anatomical gift.
- (21) "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- (22) "Sign" or "signed" means, with the present intent to authenticate or adopt a record, to execute or adopt a tangible symbol, or attach to or logically associate an electronic symbol, sound, or process with the record.
- "Tissue bank" means an entity that is accredited by the American Association of Tissue Banks or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human tissue.
- Subsections (1), (4), (5), (6), and (7) of Section 2. section 765.512, Florida Statutes, are amended to read:
  - 765.512 Persons who may make an anatomical gift.--
- (1) Any person who may make a will may make an anatomical gift give all or part of his or her body for any purpose specified in s. 765.513. The gift is effective upon the death of

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the donor.

- If the decedent makes an anatomical gift by one of the methods listed in s. 765.514(1), and in the absence of actual notice of contrary indications by the decedent, the document or entry in the donor organ and tissue registry is legally sufficient evidence of the decedent's informed consent to donate an anatomical gift.
- An anatomical gift made by a qualified donor and not revoked by the donor, as provided in s. 765.516, is irrevocable after the donor's death. A family member, quardian, representative ad litem, or health care surrogate may not modify, deny, or prevent a donor's wish or intent to make an anatomical gift after the donor's death.
- A donee may not accept an anatomical gift if the donee has actual notice of contrary indications by the donor or actual notice that an anatomical a gift by a member of a class is opposed by a member of a prior class.
- The person authorized by subsection (3) may make the anatomical gift after the decedent's death or immediately before the decedent's death.
- An anatomical A gift of all or part of a body authorizes:
- Any examination necessary to assure medical acceptability of the gift for the purposes intended.
- The decedent's medical provider, family, or a third party to furnish medical records requested concerning the decedent's medical and social history.
- Once the anatomical gift has been made, the rights of the donee are paramount to the rights of others, except as provided by s. 765.517.
- Section 3. Section 765.513, Florida Statutes, is amended to read:
- 765.513 Persons and entities that may become Donees; purposes for which anatomical gifts may be made .--

stated:

(a) (1) Any procurement organization or accredited hospital, surgeon, or physician for medical or dental school, college, or university for education, or research, advancement

anatomical gifts of bodies or parts of them for the purposes

The following persons or entities may become donees of

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

of medical or dental science, therapy, or transplantation.

- (3) Any bank or storage facility for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation.
- $\underline{\text{(b)}}$  Any individual specified by name for therapy or transplantation needed by him or her.
- (2) If multiple purposes are set forth in the document of gift but are not set forth in any priority order, the anatomical gift shall be used first for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.
- (3) However, The Legislature declares that the public policy of this state prohibits restrictions on the possible recipients of an anatomical gift on the basis of race, color, religion, gender sex, national origin, age, physical disability handicap, health status, marital status, or economic status, and such restrictions are hereby declared void and unenforceable.
- Section 4. Section 765.514, Florida Statutes, is amended to read:
  - 765.514 Manner of making anatomical gifts.--
- (1) A person may make <u>an anatomical</u>  $\frac{1}{2}$  gift of all or part of his or her body under s. 765.512(1) by:
  - (a) Signing an organ and tissue donor card.
- (b) Registering online with the <del>organ and tissue</del> donor registry.

- (c) Signifying an intent to donate on his or her driver's license or identification card issued by the department Department of Highway Safety and Motor Vehicles.

  Revocation, suspension, expiration, or cancellation of the driver's license or identification card does not invalidate the gift.
- (d) Expressing a wish to donate in a living will or other advance directive.
- '(e) Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift. The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or if it is declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith.
- (f) Expressing a wish to donate in a document other than a will. The document must be signed by the donor in the presence of two witnesses who shall sign the document in the donor's presence. If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must sign the document in the donor's presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid. The following form of written document is sufficient for any person to make an anatomical gift give all or part of his or her body for the purposes of this part:

#### UNIFORM DONOR CARD

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

I give:

- (a) .... any needed organs, tissues, or eyes;
- (b) .... only the following organs, tissues, or eyes

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                 ...[Specify the organs, tissues, or eyes]...
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     for the purpose of transplantation, therapy, medical research,
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     or education;
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           (c) .... my body for anatomical study if needed.
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     Limitations or special wishes, if any:
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       ...(If applicable, list specific donee; this must be arranged in
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                         advance with the donee.)...
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     Signed by the donor and the following witnesses in the presence
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     of each other:
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     ... (Signature of donor)... ... (Date of birth of donor)...
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     ... (Date signed) ...
                                                  ... (City and State) ...
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     ...(Witness)...
                                                         ...(Witness)...
      ...(Address)...
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                                                         ... (Address) ...
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                The anatomical gift may be made to a donee listed in
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     s. 765.513, and the donee may be specified by name.
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                Any anatomical gift by a health care surrogate
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     designated by the decedent pursuant to part II of this chapter
     or a member of a class designated in s. 765.512(3) must be made
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     by a document signed by that person or made by that person's
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     witnessed telephonic discussion, telegraphic message, or other
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     recorded message.
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          Section 5. Section 765.515, Florida Statutes, is amended
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     to read:
          765.515 Delivery of donor document.--
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                If an anatomical a gift is made pursuant to s.
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     765.521, the completed donor registration card shall be
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     delivered to the department Department of Highway Safety and
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     Motor Vehicles and the department must communicate the donor's
     intent to the <del>organ and tissue</del> donor registry, but delivery is
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withdraws the gift, the records of the department Department of

not necessary to the validity of the gift. If the donor

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Highway Safety and Motor Vehicles must be updated to reflect

such withdrawal and the department must communicate the

withdrawal to the organ and tissue donor registry for the

purpose of updating the registry.

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

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

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

765.5155 Organ and tissue Donor registry; education program.--

- (1) The Legislature finds that:
- (a) There is a shortage of organ and tissue donors in this state willing to provide the organs and tissue that could save lives or enhance the quality of life for many persons.
- (b) There is a need to encourage the various minority populations of this state to donate organs and tissue.
- (c) A statewide organ and tissue donor registry having an online donor registration process coupled with an enhanced program of donor education will lead to an increase in the number of organ and tissue donors registered in this state, thus affording more persons who are awaiting organ or tissue transplants the opportunity for a full and productive life.
- (2) The agency for Health Care Administration and the department Department of Highway Safety and Motor Vehicles shall jointly contract for the operation of a an organ and tissue

donor registry and education program. The contractor shall be

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

- The contractor shall be responsible for:
- The development, implementation, and maintenance of an interactive web-based organ and tissue donor registry that, through electronic means, allows for online organ donor registration and the recording of organ and tissue donation records submitted through the driver's license identification program or through other sources.
- The registry must be maintained in a manner that allows, through electronic and telephonic methods, immediate access to organ and tissue donation records 24 hours a day, 7 days a week.
- Access to the registry must be through coded and secure means to protect the integrity of the data in the registry.
- A continuing program to educate and inform medical professionals, law enforcement agencies and officers, other state and local government employees, high school students, minorities, and the public about the laws of this state relating to anatomical gifts and the need for anatomical gifts.
- Existing community resources, when available, must be used to support the program and volunteers may assist the program to the maximum extent possible.
- 2. The contractor shall coordinate with the head of a state agency or other political subdivision of the state, or his or her designee, to establish convenient times, dates, and

294 locations for educating that entity's employees.

- (c) Preparing and submitting an annual written report to the agency for Health Care Administration by December 31 of each year. The report must include:
- 1. The number of donors on the registry and an analysis of the registration rates by location and method of donation;
- 2. The characteristics of donors as determined from registry information submitted directly by the donors or by the Department of Highway Safety and Motor Vehicles;
- 3. The annual dollar amount of voluntary contributions received by the contractor;
- 4. A description of the educational campaigns and initiatives implemented during the year and an evaluation of their effectiveness in increasing enrollment on the registry; and
- 5. An analysis of Florida's registry compared with other states' donor registries.
- (4) Costs for the organ and tissue donor registry and education program shall be paid by the agency for Health Care Administration from the funds deposited into the Health Care Trust Fund pursuant to ss. 320.08047 and 322.08, which are designated for maintaining the organ and tissue donor registry and education program. In addition, the contractor may receive and use voluntary contributions to help support the registry and provide education.
- (5) The organ and tissue donor registry established by this section is designated as the "Joshua Abbott Organ and Tissue Registry."

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

- 765.51551 Organ and tissue Donor registry; public records exemption.--
- (1) Information held in the <del>organ and tissue</del> donor registry which identifies a donor is confidential and exempt

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

- (2) Such information may be disclosed to the following:
- (a) Organ, tissue, and eye Procurement organizations that have been certified by the agency for Health Care Administration for the purpose of ascertaining or effectuating the existence of a gift under s. 765.522.
- (b) Persons engaged in bona fide research if the person agrees to:
- 1. Submit a research plan to the agency that specifies the exact nature of the information requested and the intended use of the information;
- 2. Maintain the confidentiality of the records or information if personal identifying information is made available to the researcher;
- 3. Destroy any confidential records or information obtained after the research is concluded; and
- 4. Not directly or indirectly contact, for any purpose, any donor or donee.
- (3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2013, unless reviewed and saved from repeal through reenactment by the Legislature.

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

- 765.516 <u>Donor</u> amendment of the terms of or the revocation of anatomical the gift.--
- (1) A donor may amend the terms of or revoke an anatomical gift by:
- (a) The execution and delivery to the donee of a signed statement witnessed by at least two adults, at least one of whom is a disinterested witness.
- (b) An oral statement that is made in the presence of two persons, one of whom is must not be a family member, and

communicated to the donor's family or attorney or to the donee.

An oral statement is effective only if the procurement

organization, transplant hospital, or physician or technician

has actual notice of the oral amendment or revocation before an

incision is made to the decedent's body or an invasive procedure

to prepare the recipient has begun.

- (c) A statement <u>made</u> during a terminal illness or injury addressed to an attending physician, who must communicate the revocation of the gift to the procurement organization <del>that is certified by the state</del>.
- (d) A signed document found on or about the donor's person.
- (e) Removing his or her name from the <del>organ and tissue</del> donor registry.
- (f) A later-executed document of gift which amends or revokes a previous anatomical gift or portion of an anatomical gift, either expressly or by inconsistency.
- (g) By the destruction or cancellation of the document of gift or the destruction or cancellation of that portion of the document of gift used to make the gift with the intent to revoke the gift.
- (2) Any <u>anatomical</u> gift made by a will may also be amended or revoked in the manner provided for <u>the</u> amendment or revocation of wills or as provided in <u>paragraph (1)(a)</u> subsection (1).

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

765.517 Rights and duties at death.--

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

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

- The time of death shall be determined by a physician who attends the donor at the donor's death or, if there is no such physician, the physician who certifies the death. After death, those physicians or the donor's primary care and in the absence of other qualified personnel, this physician may participate in, but may shall not obstruct, the procedures to preserve the donor's organs or tissues and may shall not be paid or reimbursed for such participation by, nor be associated with or employed by, a, an organ procurement organization, tissue bank, or eye bank. These physicians may This physician shall not participate in the procedures for removing or transplanting a part. However, this subsection does not prevent a physician from serving in a voluntary capacity on the board of directors of a procurement organization or participating on any board, council, commission, or similar body related to the organ and tissue procurement system.
- (3) The organ procurement organizations organization, tissue bank, or eye bank, or hospital medical professionals under the direction thereof, may perform any and all tests to evaluate the deceased as a potential donor and any invasive procedures on the deceased body in order to preserve the potential donor's organs. These procedures do not include the surgical removal of an organ or penetrating any body cavity, specifically for the purpose of donation, until:
- (a) It has been verified that the deceased's consent to donate appears in the <del>organ and tissue</del> donor registry or a properly executed <del>donor card or</del> document of gift is located; or

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- (b) If a properly executed donor card or document of gift cannot be located or the deceased's consent is not listed in the organ and tissue donor registry, a person specified in s. 765.512(2) or (3) has been located, has been notified of the death, and has granted legal permission for the donation.
- (4) All reasonable additional expenses incurred in the procedures to preserve the donor's organs or tissues shall be reimbursed by the organ procurement organization, tissue bank, or eye bank.
- (5) A person who acts in good faith and without negligence in accord with the terms of this part or under the anatomical gift laws of this state or another state or a foreign country, or attempts to do so, may not be subject to any civil action for damages, may not be subject to any criminal proceeding, and may not be subject to discipline, penalty, or liability in any administrative proceeding.
- (6) The provisions of this part are subject to the laws of this state prescribing powers and duties with respect to autopsies.
- (7) The person making an anatomical gift and the donor's estate are not liable for any injury or damages that result from the making or use of the gift.
- (8) In determining whether an anatomical gift has been made, amended, or revoked under this part, a person may rely upon the representation of an individual listed in s. 765.512, relating to the individual's relationship to the donor or prospective donor, unless the person knows that the representation is untrue.

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

- 765.521 Donations as part of driver license or identification card process.--
- (1) The agency for Health Care Administration and the department Department of Highway Safety and Motor Vehicles shall

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.

- (2) The Department of Highway Safety and Motor Vehicles, after consultation with and concurrence by the agency for Health Care Administration, shall adopt rules to implement the provisions of this section according to the provisions of chapter 120.
- (3) Funds expended by the agency for Health Care

  Administration to carry out the intent of this section may shall

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not be taken from any funds appropriated for patient care.

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

- 765.522 Duty of certain hospital administrators; liability of hospital administrators and, organ procurement organizations, eye banks, and tissue banks.--
- (1) When used in this section, "hospital" means any establishment licensed under chapter 395 except psychiatric and rehabilitation hospitals.
- (1)(2) If Where, based on accepted medical standards, a hospital patient is a suitable candidate for organ or tissue donation, the hospital administrator or the hospital administrator's designee shall, at or near the time of death, notify the appropriate procurement organization organ, eye, or tissue recovery program, which shall access the organ and tissue donor registry created by s. 765.5155 or any other donor registry to ascertain the existence of an entry in the registry which that has not been revoked, a donor card, or a document of gift executed by the decedent. In the absence of an entry in the donor registry, a document of gift donor card, organ donation sticker or organ donation imprint on a driver's license, or other properly executed document, the procurement organization organ, eye, or tissue recovery program shall request:
- (a) The patient's health care surrogate, as authorized in s. 765.512(2); or
- (b) If the patient does not have a surrogate, or the surrogate is not reasonably available, any of the persons specified in s. 765.512(3), in the order and manner listed,

to consent to the <u>anatomical</u> gift of all or any part of the decedent's body for any purpose specified in this part. Except as provided in s. 765.512, in the absence of actual notice of opposition, consent need only be obtained from the person or persons in the highest priority class reasonably available.

- (3) A <u>document of gift is valid if made pursuant to a request required by this section shall be executed in accordance with this part or the laws of the state or country where it was executed and where the person making the anatomical gift was domiciled, has a place of residence, or was a citizen at the time the document of gift was executed pursuant to s. 765.514.</u>
- (4) The agency for Health Care Administration shall establish rules and guidelines concerning the education of individuals who may be designated to perform the request and the procedures to be used in making the request. The agency is authorized to adopt rules concerning the documentation of the request, where such request is made.
- (5) If a document of gift is valid under this section, the laws of this state govern the interpretation of the document of gift.
- (6) A document of gift or amendment of an anatomical gift is presumed to be valid unless it was not validly executed or was revoked.
- (7)(5) There shall be no civil or criminal liability against any organ procurement organization, eye bank, or tissue bank certified under s. 765.542, or against any hospital or hospital administrator or designee who complies, when complying with the provisions of this part and agency the rules of the agency for Health Care Administration or if when, in the exercise of reasonable care, a request for organ donation is inappropriate and the gift is not made according to this part and agency the rules of the agency for Health Care Administration.
- (8)(6) The hospital administrator or a designee shall, at or near the time of death of a potential organ donor, directly notify the affiliated organ procurement organization designated by the United States Department of Health and Human Services of the potential organ donor. The This organ procurement

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

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

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

- (1) There is hereby created within the agency for Health Care Administration A statewide technical Organ Transplant Advisory Council is created within the agency, consisting of twelve members who are physicians licensed under chapter 458 or chapter 459, to represent the interests of the public and the clients of the Department of Health or the agency. The members shall be physicians licensed according to chapter 458 or chapter 459. A person employed by the agency may not be appointed as a member of the council.
- (5) Members of the council shall receive no compensation, but shall be reimbursed for per diem and travel expenses by the agency for Health Care Administration in accordance with the provisions of s. 112.061 while engaged in the performance of their duties.
- (6) The responsibilities of the council shall be to recommend to the agency for Health Care Administration indications for adult and pediatric organ transplants. The council shall also formulate guidelines and standards for organ

transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The recommendations, guidelines, and standards developed by the council are applicable only to those health programs funded through the agency for Health Care Administration.

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

- 765.541 Certification of <u>procurement</u> organizations <del>engaged</del> in the practice of cadaveric organ and tissue procurement. -- The agency for Health Care Administration shall:
- (1) Establish a program for the certification of organizations, <u>corporations</u> agencies, or other entities engaged in the procurement of organs, tissues, and eyes for transplantation.
- (2) Adopt rules that set forth appropriate standards and guidelines for the program in accordance with ss. 765.541-765.546 and part II of chapter 408. These standards and guidelines must be substantially based on the existing laws of the Federal Government and this state and the existing standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the Eye Bank Association of America (EBAA). In addition, the agency for Health Care Administration shall, before adopting these standards and guidelines, seek input from all organ procurement organizations, tissue banks, and eye banks based in this state.7
- (3) Collect, keep, and make available to the Governor and the Legislature information regarding the numbers and disposition of organs, and tissues, and eyes procured by each certified procurement organization. entity;
- (4) Monitor <u>procurement organizations</u> <del>participating</del> <del>facilities and agencies</del> for program compliance.; and
  - (5) Provide for the administration of the Organ and Tissue

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Procurement and Transplantation Advisory Board.

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

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

- (1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 765.541-765.546 and part II of chapter 408 and to entities licensed or certified by or applying for such licensure or certification from the agency for Health Care Administration pursuant to ss. 765.541-765.546. A person An organization, agency, or other entity may not engage in the practice of organ procurement in this state without being designated as an organ procurement organization by the secretary of the United States Department of Health and Human Services and being appropriately certified by the agency for Health Care Administration. As used in this subsection, the term "procurement" includes the retrieval, processing, or distribution of human organs. A physician or organ procurement organization based outside this state is exempt from these certification requirements if:
- (a) The organs are procured for an out-of-state patient who is listed on, or referred through, the United Network for Organ Sharing System; and
- (b) The organs are procured through an agreement of an organ procurement organization certified by the state.
- (2) A person An organization, agency, or other entity may not engage in tissue procurement in this state unless it is appropriately certified as a tissue bank by the agency for Health Care Administration. As used in this subsection, the term "procurement" includes any retrieval, processing, storage, or distribution of human tissue for transplantation.
- (3) <u>A person</u> An organization, agency, or other entity may not engage in the practice of eye procurement in this state without being appropriately certified as an eye bank by the

agency for Health Care Administration. As used in this subsection, the term "procurement" includes the retrieval, processing, or distribution of human eye tissue. Funeral directors or direct disposers who that retrieve eye tissue for an eye bank certified under this subsection are exempt from the certification requirements under this subsection.

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

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

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

(3) The board shall:

- (a) Assist the agency for Health Care Administration in the development of necessary professional qualifications, including, but not limited to, the education, training, and performance of persons engaged in the various facets of organ and tissue procurement, processing, preservation, and distribution for transplantation;
- (b) Assist the agency for Health Care Administration in monitoring the appropriate and legitimate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;
- (c) Provide assistance to the Florida Medical Examiners Commission in the development of appropriate procedures and protocols to ensure the assure continued improvement in the

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approval and release of potential organ and tissue donors by the

severity of their medical condition and need; and

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district medical examiners and associate medical examiners; Develop with and recommend to the agency for Health Care Administration the necessary procedures and protocols required to assure that all residents of this state have

- reasonable access to available organ and tissue transplantation therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is will be able to fulfill their organ and tissue requirements within the limits of the available supply and according to the
- Develop with and recommend to the agency for Health Care Administration any changes to the laws of this state or administrative rules or procedures required to ensure assure that the statewide organ and tissue procurement and transplantation system is will be able to function smoothly, effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents of this state that no person or entity profits from the altruistic voluntary donation of organs or tissues.

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

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

- In accordance with s. 408.805, an applicant or a certificateholder shall pay a fee for each application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be as follows:
- An initial application fee of \$1,000 from organ procurement organizations and tissue banks and \$500 from eye banks.
- Annual fees to be used, in the following order of priority, for the certification program, the advisory board, maintenance of the organ and tissue donor registry, and the

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organ and tissue donor education program in the following amounts, which may not exceed \$35,000 per organization:

- 1. Each general organ procurement organization shall pay the greater of \$1,000 or 0.25 percent of its total revenues produced from procurement activity in this state by the certificateholder during its most recently completed fiscal year or operational year.
- Each bone and tissue procurement organization agency or bone and tissue bank shall pay the greater of \$1,000 or 0.25 percent of its total revenues from procurement and processing activity in this state by the certificateholder during its most recently completed fiscal year or operational year.
- Each eye bank shall pay the greater of \$500 or 0.25 percent of its total revenues produced from procurement activity in this state by the certificateholder during its most recently completed fiscal year or operational year.
- (2) The agency for Health Care Administration shall specify by rule the administrative penalties for the purpose of ensuring adherence to the standards of quality and practice required by this chapter, part II of chapter 408, and applicable rules of the agency for continued certification.
- Proceeds from fees, administrative penalties, and surcharges collected pursuant to this section must be deposited into the Health Care Trust Fund.
- Moneys deposited in the trust fund pursuant to this section must be used exclusively for the implementation, administration, and operation of the certification program and the advisory board, for maintaining the organ and tissue donor registry, and for organ and tissue donor education.
- As used in this section, the term "procurement activity in this state" includes the bringing into this state for processing, storage, distribution, or transplantation of organs or tissues that are initially procured in another state

### HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES Amendment No. 1 (for drafter's use only)

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to read:

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

765.545 Physician supervision of cadaveric organ and tissue procurement coordinators. -- Organ Procurement organizations, tissue banks, and eye banks may employ coordinators, who are registered nurses, physician's assistants, or other medically trained personnel who meet the relevant standards for organ procurement organizations, tissue banks, or eve banks as adopted by the agency for Health Care Administration under s. 765.541, to assist in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research. A coordinator who assists in the medical management of organ donors or in the surgical procurement of cadaveric organs, tissues, or eyes for transplantation or research must do so under the direction and supervision of a licensed physician medical director pursuant to rules and quidelines to be adopted by the agency for Health Care Administration. With the exception of organ procurement surgery, this supervision may be indirect supervision. For purposes of this section, the term "indirect supervision" means that the medical director is responsible for the medical actions of the coordinator, that the coordinator is operating under protocols expressly approved by the medical director, and that the medical director or his or her physician designee is always available, in person or by telephone, to provide medical direction, consultation, and advice in cases of organ, tissue, and eye donation and procurement. Although indirect supervision is authorized under this section, direct physician supervision is to be encouraged when appropriate. Section 18. Section 765.547, Florida Statutes, is created

765.547 Cooperation between medical examiner and procurement organization.--

- (1) A medical examiner and procurement organization shall cooperate with each other in order to maximize opportunities to recover anatomical gifts for the purpose of transplantation, therapy, research, or education.
- (2) The Florida Medical Examiners Commission shall adopt rules establishing cooperative responsibilities between medical examiners and procurement organizations to facilitate and expedite completion of the medical examiner's responsibilities under chapter 406 in a manner that will maximize opportunities to recover anatomical gifts.
- (3) This part does not supersede any part of chapter 406 relating to medical examiners and the disposition of dead bodies.
- Section 19. Subsection (30) of section 408.802, Florida Statutes, is amended to read:
- 408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:
- (30) Organ, and tissue, and eye procurement organizations agencies, as provided under part V of chapter 765.
- Section 20. Subsection (29) of section 408.820, Florida Statutes, is amended to read:
- 408.820 Exemptions.--Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:
- (29) Organ, and tissue, and eye procurement organizations agencies, as provided under part V of chapter 765, are exempt from s. 408.810(5)-(10).
  - Section 21. This act shall take effect July 1, 2009.

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

#### 835 TITLE AMENDMENT

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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