

Committee Substitute for
Committee Substitute for Senate Bill No. 766

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:

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)(4) “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)(2) “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.

(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 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.

(18) “Procurement” means any retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education.

(19) “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.

(23) “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.

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.—

(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 the donor.~~

(a) 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.

(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 anatomical gift after the donor’s death.

(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.

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

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

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

(b) 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.—~~

(1) The following persons or entities may become donees of anatomical gifts of bodies or parts of them for the purposes 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 of medical or dental science, therapy, or transplantation.~~

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

~~(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.—

(1) A person may make an anatomical a 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 ~~organ and tissue~~ donor registry.

(c) Signifying an intent to donate on his or her driver's license or identification card issued by the Department of Highway Safety and Motor Vehicles. 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
 ...[Specify the organs, tissues, or eyes]...

for the purpose of transplantation, therapy, medical research, or education;

- (c) my body for anatomical study if needed. Limitations or special wishes, if any:
 ...(If applicable, list specific donee;
 this must be arranged in advance with the donee.)...

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

...(Signature of donor)...	...(Date of birth of donor)...
...(Date signed)...	...(City and State)...
...(Witness)...	...(Witness)...
...(Address)...	...(Address)...

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

(3) Any anatomical gift by a health care surrogate 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 by a document signed by that person or made by that person’s witnessed telephonic discussion, telegraphic message, or other recorded message.

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

765.515 Delivery of donor document.—

(1) If an anatomical a gift is made pursuant to s. 765.521, the completed donor registration card shall be delivered to the Department of Highway Safety and Motor Vehicles and the department must communicate the donor's intent to the ~~organ and tissue~~ donor registry, but delivery is not necessary to the validity of the gift. If the donor withdraws the gift, the records of the 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 an anatomical a gift is made by the donor to a specified donee, the document of gift, 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. ~~The Such~~ document of gift 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 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 ~~organ and tissue~~ 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 Donor 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 made during a terminal illness or injury addressed to an attending physician, who must communicate the revocation of the gift to the procurement organization ~~that is certified by the state.~~

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

(e) Removing his or her name from the ~~organ and tissue~~ 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 anatomical gift made by a will may also be amended or revoked in the manner provided for the amendment or revocation of wills or as provided in paragraph (1)(a) subsection (1).

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

765.517 Rights and duties at death.—

(1) The donee, pursuant to as specified under the provisions of s. 765.515(2), may accept or reject an anatomical the gift. If the donee accepts a gift ~~of the entire body or a part of the body to be used for research or education 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.

(2) 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 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 ~~organ and tissue donor registry~~ or a properly executed ~~donor card or document of gift~~ is located; or

(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 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 is ~~not liable for damages in any civil action or subject to prosecution for his or her acts in any criminal 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 of Highway Safety and Motor Vehicles shall develop and implement a program encouraging and allowing persons to make anatomical gifts as a part of the process of issuing identification cards and issuing and renewing driver licenses. The donor registration card distributed by the Department of Highway Safety and Motor Vehicles shall include the information required by the uniform donor card under s. 765.514 and such additional information as determined necessary 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

make an anatomical gift donate the individual's organs, tissues, or eyes. A notation on an individual's driver license or identification card that the individual intends to make an anatomical gift 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.

(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 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 anatomical 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 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.

(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 procurement organizations; agency responsibilities engaged 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, corporations ~~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 facilities and agencies for program compliance.;

(5) 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 Requirements to engage in organ, tissue, or eye ~~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) 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 as-~~sure~~ 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 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 ~~organ and tissue~~ donor registry, and the 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.

2. 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.

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:

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 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 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.

Approved by the Governor June 24, 2009.

Filed in Office Secretary of State June 24, 2009.