LEGISLATIVE ACTION

Senate	•	House
Comm: FAV		
02/18/2009		
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The Committee on Health Regulation (Sobel) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

11

and insert:

read:

(2) "Anatomical gift" or "gift" means a donation of all or

(1) "Agency" means the Agency for Health Care

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

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

Administration.

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12 part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education. 13

14 (3) (1) "Bank" or "storage facility" means a facility 15 licensed, accredited, or approved under the laws of any state 16 for storage of human bodies or body parts thereof.

17 (4) (4) (2) "Death" means the absence of life as determined, in accordance with currently accepted medical standards, by the 18 irreversible cessation of all respiration and circulatory 19 20 function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, 21 22 including the brain stem.

23 (5) "Decedent" means a deceased individual whose body or body parts may be, or are, the source of an anatomical gift. 24

25 (6) "Disinterested witness" means a witness other than a 26 person listed in s. 765.512(3) or other family member.

(7) "Document of gift" means any of the documents or 28 mechanisms used in making an anatomical gift under s. 765.514.

29 (8) (3) (3) "Donor" means an individual who makes an anatomical 30 a gift of all or part of his or her body.

(9) "Donor registry" means a database that contains records 31 32 of anatomical gifts and amendments to, or revocations of, such 33 gifts.

(10) "Eye bank" means an entity that is accredited by the 34 35 Eye Bank Association of America or otherwise regulated under 36 federal or state law to engage in the retrieval, screening, 37 testing, processing, storage, or distribution of human eye 38 tissue.

39 (11) "Guardian" means a person appointed pursuant to chapter 744. The term does not include a guardian ad litem. 40

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41	(12) (4) "Hospital" means a hospital licensed, accredited,
42	or approved under the laws of any state and includes a hospital
43	operated by the United States Government or a state, or a
44	subdivision thereof, although not required to be licensed under
45	state laws.
46	(13) "Identification card" means an official identification
47	card issued by a governmental entity, state agency, or
48	subdivision thereof.
49	(14) "Organ procurement organization" means an entity that
50	is designated as an organ procurement organization by the
51	Secretary of the United States Department of Health and Human
52	Services and that engages in the retrieval, screening, testing,
53	processing, storage, or distribution of human organs.
54	(15) "Part of the body" or "body part" means an organ, eye,
55	or tissue of a human being. The term does not include the whole
56	body.
57	<u>(16)</u> "Physician" or "surgeon" means a physician or
58	surgeon licensed to practice under chapter 458 or chapter 459 or
59	similar laws of any state. "Surgeon" includes dental or oral
60	surgeon.
61	(17) "Procurement" means any retrieval, recovery,
62	processing, storage, or distribution of human organs or tissues
63	for transplantation, therapy, research, or education.
64	(18) "Procurement organization" means an organ procurement
65	organization, eye bank, or tissue bank.
66	(19) "Reasonably available" means able to be contacted by a
67	procurement organization in a timely manner without undue
68	effort, and willing and able to act in a manner consistent with
69	existing medical protocols necessary for the making of an

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70	anatomical gift.
71	(20) "Record" means information that is inscribed on a
72	tangible medium or that is stored in an electronic or other
73	medium and is retrievable in perceivable form.
74	(21) "Sign" or "signed" means, with the present intent to
75	authenticate or adopt a record, to execute or adopt a tangible
76	symbol, or attach to or logically associate an electronic
77	symbol, sound, or process with the record.
78	(22) "Tissue bank" means an entity that is accredited by
79	the American Association of Tissue Banks or otherwise regulated
80	under federal or state law to engage in the retrieval,
81	screening, testing, processing, storage, or distribution of
82	human tissue.
83	Section 2. Subsections (1), (4), (5), (6), and (7) of
84	section 765.512, Florida Statutes, are amended to read:
85	765.512 Persons who may make an anatomical gift
86	(1) Any person who may make a will may <u>make an anatomical</u>
87	gift give all or part of his or her body for any purpose
88	specified in s. 765.513. The gift is effective upon the death of
89	the donor.
90	(a) If the decedent makes an anatomical gift by one of the
91	methods listed in s. 765.514(1), and in the absence of actual
92	notice of contrary indications by the decedent, the document or
93	entry in the <u>donor</u> organ and tissue registry is legally
94	sufficient evidence of the decedent's informed consent to donate
95	an anatomical gift.
96	(b) An anatomical gift made by a qualified donor and not
97	revoked by the donor, as provided in s. 765.516, is irrevocable
98	after the donor's death. A family member, guardian,
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99 representative ad litem, or health care surrogate may not modify, deny, or prevent a donor's wish or intent to make an 100 101 anatomical gift after the donor's death. 102 (4) A donee may not accept an anatomical gift if the donee 103 has actual notice of contrary indications by the donor or actual 104 notice that an anatomical $\frac{1}{2}$ gift by a member of a class is 105 opposed by a member of a prior class. 106 (5) The person authorized by subsection (3) may make the 107 anatomical gift after the decedent's death or immediately before 108 the decedent's death. 109 (6) An anatomical A gift of all or part of a body 110 authorizes: (a) Any examination necessary to assure medical 111 112 acceptability of the gift for the purposes intended. 113 (b) The decedent's medical provider, family, or a third 114 party to furnish medical records requested concerning the 115 decedent's medical and social history. (7) Once the anatomical gift has been made, the rights of 116 117 the donee are paramount to the rights of others, except as 118 provided by s. 765.517. 119 Section 3. Section 765.513, Florida Statutes, is amended to 120 read: 121 765.513 Persons and entities that may become Donees; 122 purposes for which anatomical gifts may be made.-123 (1) The following persons or entities may become donees of 124 anatomical gifts of bodies or parts of them for the purposes 125 stated: 126 (a) (1) Any procurement organization or accredited hospital, 127 surgeon, or physician for medical or dental school, college, or

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128 <u>university for</u> education, or research, advancement of medical or 129 <u>dental science</u>, therapy, or transplantation.

130 (2) Any accredited medical or dental school, college, or 131 university for education, research, advancement of medical or 132 dental science, or therapy.

133 (3) Any bank or storage facility for medical or dental 134 education, research, advancement of medical or dental science, 135 therapy, or transplantation.

136 (b) (4) Any individual specified by name for therapy or 137 transplantation needed by him or her.

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

<u>(3)</u> 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, <u>gender sex</u>, national origin, age, physical <u>disability</u>
handicap, health status, marital status, or economic status, and
such restrictions are <u>hereby declared</u> void and unenforceable.

149 Section 4. Section 765.514, Florida Statutes, is amended to 150 read:

765.514 Manner of making anatomical gifts.-

(1) A person may make <u>an anatomical</u> a gift of all or part
of his or her body under s. 765.512(1) by:

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(a) Signing an organ and tissue donor card.

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

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(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 otheradvance 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.

170 (f) Expressing a wish to donate in a document other than a 171 will. The document must be signed by the donor in the presence 172 of two witnesses who shall sign the document in the donor's 173 presence. If the donor cannot sign, the document may be signed 174 for him or her at the donor's direction and in his or her 175 presence and the presence of two witnesses who must sign the 176 document in the donor's presence. Delivery of the document of 177 gift during the donor's lifetime is not necessary to make the 178 gift valid. The following form of written document is sufficient 179 for any person to make an anatomical gift give all or part of 180 his or her body for the purposes of this part: 181 UNIFORM DONOR CARD

183 The undersigned hereby makes this anatomical gift, if medically 184 acceptable, to take effect on death. The words and marks below 185 indicate my desires:

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186	I give:
187	(a) any needed organs, tissues, or eyes;
188	(b) only the following organs, tissues, or eyes
189	[Specify the organs, tissues, or eyes]
190	for the purpose of transplantation, therapy, medical research,
191	or education;
192	(c) my body for anatomical study if needed.
193	Limitations or special wishes, if any:
194	(If applicable, list specific donee;this must be arranged in
195	advance with the donee.)
196	
197	Signed by the donor and the following witnesses in the presence
198	of each other:
199	
200	(Signature of donor) (Date of birth of donor)
201	(Date signed)(City and State)
202	
203	(Witness)(Witness)
204	(Address) (Address)
205	(2) The <u>anatomical</u> gift may be made to a donee listed in s.
206	765.513, and the donee may be specified by name.
207	(3) Any <u>anatomical</u> gift by a health care surrogate
208	designated by the decedent pursuant to part II of this chapter
209	or a member of a class designated in s. 765.512(3) must be made
210	by a document signed by that person or made by that person's
211	witnessed telephonic discussion, telegraphic message, or other
212	recorded message.
213	Section 5. Section 765.515, Florida Statutes, is amended to
214	read:

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765.515 Delivery of donor document.-

216 (1) If an anatomical a gift is made pursuant to s. 765.521, the completed donor registration card shall be delivered to the 217 218 Department of Highway Safety and Motor Vehicles and the department must communicate the donor's intent to the organ and 219 220 tissue donor registry, but delivery is not necessary to the 221 validity of the gift. If the donor withdraws the gift, the 222 records of the Department of Highway Safety and Motor Vehicles 223 must be updated to reflect such withdrawal and the department 224 must communicate the withdrawal to the organ and tissue donor 225 registry for the purpose of updating the registry.

226 (2) If an anatomical a gift is made by the donor to a 227 specified donee, the document of gift, other than a will, may be 228 delivered to the donee to expedite the appropriate procedures 229 immediately after death, but delivery is not necessary to the 230 validity of the gift. The Such document of gift may be deposited 231 in any hospital, bank, storage facility, or registry office that 232 accepts such documents for safekeeping or to facilitate the 233 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.

237 Section 6. Section 765.5155, Florida Statutes, is amended 238 to read:

239 765.5155 Organ and tissue Donor registry; education 240 program.-

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(1) The Legislature finds that:

(a) There is a shortage of organ and tissue donors in thisstate willing to provide the organs and tissue that could save

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244 lives or enhance the quality of life for many persons.
245 (b) There is a need to encourage the various minority
246 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.

253 (2) The agency for Health Care Administration and the 254 Department of Highway Safety and Motor Vehicles shall jointly 255 contract for the operation of a an organ and tissue donor 256 registry and education program. The contractor shall be procured 257 by competitive solicitation pursuant to chapter 287, 258 notwithstanding any exemption in s. 287.057(5)(f). When awarding the contract, priority shall be given to existing nonprofit 259 260 groups that are based within the state, have expertise working 261 with organ and tissue procurement organizations, have expertise 262 in conducting statewide organ and tissue donor public education 263 campaigns, and represent the needs of the organ and tissue 264 donation community in the state.

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(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.

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1. The registry must be maintained in a manner that allows,



273 through electronic and telephonic methods, immediate access to 274 organ and tissue donation records 24 hours a day, 7 days a week.

275 2. Access to the registry must be through coded and secure 276 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.

285 2. The contractor shall coordinate with the head of a state 286 agency or other political subdivision of the state, or his or 287 her designee, to establish convenient times, dates, and 288 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:

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

294 2. The characteristics of donors as determined from 295 registry information submitted directly by the donors or by the 296 Department of Highway Safety and Motor Vehicles;

297 3. The annual dollar amount of voluntary contributions298 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;

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302 and 303 5. An analysis of Florida's registry compared with other states' donor registries. 304 305 (4) Costs for the organ and tissue donor registry and 306 education program shall be paid by the agency for Health Care 307 Administration from the funds deposited into the Health Care 308 Trust Fund pursuant to ss. 320.08047 and 322.08, which are 309 designated for maintaining the organ and tissue donor registry 310 and education program. In addition, the contractor may receive 311 and use voluntary contributions to help support the registry and 312 provide education. 313 (5) The organ and tissue donor registry established by this 314 section is designated as the "Joshua Abbott Organ and Tissue 315 Registry." 316 Section 7. Section 765.51551, Florida Statutes, is amended 317 to read 318 765.51551 Organ and tissue Donor registry; public records 319 exemption.-320 (1) Information held in the organ and tissue donor registry which identifies a donor is confidential and exempt from s. 321 322 119.07(1) and s. 24(a), Art. I of the State Constitution. 323 (2) Such information may be disclosed to the following: 324 (a) Organ, tissue, and eye Procurement organizations that 325 have been certified by the agency for Health Care Administration 326 for the purpose of ascertaining or effectuating the existence of 327 a gift under s. 765.522. 328 (b) Persons engaged in bona fide research if the person 329 agrees to: 330 1. Submit a research plan to the agency that specifies the

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331	exact nature of the information requested and the intended use
332	of the information;
333	2. Maintain the confidentiality of the records or
334	information if personal identifying information is made
335	available to the researcher;
336	3. Destroy any confidential records or information obtained
337	after the research is concluded; and
338	4. Not directly or indirectly contact, for any purpose, any
339	donor or donee.
340	(3) This section is subject to the Open Government Sunset
341	Review Act in accordance with s. 119.15 and shall stand repealed
342	on October 2, 2013, unless reviewed and saved from repeal
343	through reenactment by the Legislature.
344	Section 8. Section 765.516, Florida Statutes, is amended to
345	read:
346	765.516 Donor amendment of the terms of or the revocation
347	of <u>anatomical</u> the gift
348	(1) A donor may amend the terms of or revoke an anatomical
349	gift by:
350	(a) The execution and delivery to the donee of a signed
351	statement witnessed by at least two adults, at least one of whom
352	is a disinterested witness.
353	(b) An oral statement that is made in the presence of two
354	persons, one of whom <u>is</u> must not be a family member, and
355	communicated to the donor's family or attorney or to the donee.
356	An oral statement is effective only if the procurement
357	organization, transplant hospital, or physician or technician
358	has actual notice of the oral amendment or revocation before an
359	incision is made to the decedent's body or an invasive procedure
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360	to prepare the recipient has begun.
361	(c) A statement <u>made</u> during a terminal illness or injury
362	addressed to an attending physician, who must communicate the
363	revocation of the gift to the procurement organization that is
364	certified by the state.
365	(d) A signed document found on or about the donor's person.
366	(e) Removing his or her name from the organ and tissue
367	donor registry.
368	(f) A later-executed document of gift which amends or
369	revokes a previous anatomical gift or portion of an anatomical
370	gift, either expressly or by inconsistency.
371	(g) By the destruction or cancellation of the document of
372	gift or the destruction or cancellation of that portion of the
373	document of gift used to make the gift with the intent to revoke
374	the gift.
375	(2) Any <u>anatomical</u> gift made by a will may also be amended
376	or revoked in the manner provided for the amendment or
377	revocation of wills or as provided in paragraph (1)(a)
378	subsection (1).
379	Section 9. Section 765.517, Florida Statutes, is amended to
380	read:
381	765.517 Rights and duties at death
382	(1) The donee, pursuant to as specified under the
383	provisions of s. 765.515(2), may accept or reject <u>an anatomical</u>
384	the gift. If the donee accepts a gift of the entire body or a
385	part of the body to be used for <u>research or education</u> scientific
386	purposes other than a transplant , the donee may authorize
387	embalming and the use of the body in funeral services, subject
388	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 <u>body</u> 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.

394 (2) The time of death shall be determined by a physician 395 who attends the donor at the donor's death or, if there is no 396 such physician, the physician who certifies the death. After 397 death, those physicians or the donor's primary care and in the 398 absence of other qualified personnel, this physician may 399 participate in, but may shall not obstruct, the procedures to 400 preserve the donor's organs or tissues and may shall not be paid 401 or reimbursed for such participation by, nor be associated with 402 or employed by, a, an organ procurement organization, tissue 403 bank, or eye bank. These physicians may This physician shall not participate in the procedures for removing or transplanting a 404 405 part. However, this subsection does not prevent a physician from 406 serving in a voluntary capacity on the board of directors of a 407 procurement organization or participating on any board, council, 408 commission, or similar body related to the organ and tissue 409 procurement system.

410 (3) The organ procurement organizations organization, 411 tissue bank, or eye bank, or hospital medical professionals 412 under the direction thereof, may perform any and all tests to 413 evaluate the deceased as a potential donor and any invasive 414 procedures on the deceased body in order to preserve the 415 potential donor's organs. These procedures do not include the surgical removal of an organ or penetrating any body cavity, 416 417 specifically for the purpose of donation, until:

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(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 in good faith 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 is not subject to discipline, penalty, or liability in any administrative proceeding.

437 (6) The provisions of this part are subject to the laws of
438 this state prescribing powers and duties with respect to
439 autopsies.

440 (7) The person making an anatomical gift and the donor's
441 estate are not liable for any injury or damages that result from
442 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

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447 prospective donor, unless the person knows that the 448 representation is untrue. Section 10. Section 765.521, Florida Statutes, is amended 449 450 to read: 765.521 Donations as part of driver license or 451 452 identification card process.-453 (1) The agency for Health Care Administration and the 454 Department of Highway Safety and Motor Vehicles shall develop 455 and implement a program encouraging and allowing persons to make 456 anatomical gifts as a part of the process of issuing 457 identification cards and issuing and renewing driver licenses. 458 The donor registration card distributed by the Department of 459 Highway Safety and Motor Vehicles shall include the information 460 required by the uniform donor card under s. 765.514 and such 461 additional information as determined necessary by the 462 department. The department shall also develop and implement a 463 program to identify donors τ which includes notations on 464 identification cards, driver licenses, and driver records or 465 such other methods as the department develops to clearly 466 indicate the individual's intent to make an anatomical gift 467 donate the individual's organs, tissues, or eyes. A notation on 468 an individual's driver license or identification card that the 469 individual intends to make an anatomical gift donate organs, 470 tissues, or eyes satisfies all requirements for consent to organ 471 or tissue donation. The agency for Health Care Administration 472 shall provide the necessary supplies and forms from funds 473 appropriated from general revenue or contributions from 474 interested voluntary, nonprofit organizations. The department 475 shall provide the necessary recordkeeping system from funds

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476 appropriated from general revenue. The Department of Highway 477 Safety and Motor Vehicles and the agency for Health Care 478 Administration shall incur no liability in connection with the 479 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.

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

488 Section 11. Section 765.522, Florida Statutes, is amended 489 to read:

490 765.522 Duty of certain hospital administrators; liability
491 of hospital administrators and, organ procurement organizations,
492 eye banks, and tissue banks.-

493 (1) When used in this section, "hospital" means any 494 establishment licensed under chapter 395 except psychiatric and 495 rehabilitation hospitals.

496 (1) (2) If Where, based on accepted medical standards, a 497 hospital patient is a suitable candidate for organ or tissue 498 donation, the hospital administrator or the hospital administrator's designee shall, at or near the time of death, 499 500 notify the appropriate procurement organization organ, eye, or 501 tissue recovery program, which shall access the organ and tissue 502 donor registry created by s. 765.5155 or any other donor 503 registry to ascertain the existence of an entry in the registry 504 which that has not been revoked, a donor card, or a document of

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505 <u>gift</u> executed by the decedent. In the absence of an entry in the 506 donor registry, <u>a document of gift</u> donor card, organ donation 507 sticker or organ donation imprint on a driver's license, or 508 other properly executed document, the <u>procurement organization</u> 509 organ, eye, or tissue recovery program shall request:

510 (a) The patient's health care surrogate, as authorized in 511 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,

516 to consent to the <u>anatomical</u> gift of all or any part of the 517 decedent's body for any purpose specified in this part. Except 518 as provided in s. 765.512, in the absence of actual notice of 519 opposition, consent need only be obtained from the person or 520 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.

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(5) If a document of gift is valid under this section, the

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534 laws of this state govern the interpretation of the document of 535 gift.

536 (6) A document of gift or amendment of an anatomical gift 537 is presumed to be valid unless it was not validly executed or 538 was revoked.

539 (7) (5) There shall be no civil or criminal liability against any organ procurement organization, eye bank, or tissue 540 541 bank certified under s. 765.542 $_{\tau}$ or against any hospital or 542 hospital administrator or designee who complies, when complying 543 with the provisions of this part and agency the rules of the 544 agency for Health Care Administration or if when, in the 545 exercise of reasonable care, a request for organ donation is 546 inappropriate and the gift is not made according to this part 547 and agency the rules of the agency for Health Care 548 Administration.

549 (8) (6) The hospital administrator or a designee shall, at 550 or near the time of death of a potential organ donor, directly 551 notify the affiliated organ procurement organization designated 552 by the United States Department of Health and Human Services of 553 the potential organ donor. The This organ procurement 554 organization must offer any organ from such a donor first to 555 patients on a Florida-based local or state organ sharing 556 transplant list. For the purpose of this subsection, the term 557 "transplant list" includes certain categories of national or 558 regional organ sharing for patients of exceptional need or 559 exceptional match, as approved or mandated by the Organ 560 Procurement and Transplantation Network, or its agent. This notification may not be made to a tissue bank or eye bank in 561 562 lieu of the organ procurement organization unless the tissue

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563 bank or eye bank is also designated as an organ procurement 564 organization by the United States Department of Health and Human 565 Services.

566 Section 12. Subsections (1), (5), and (6) of section 567 765.53, Florida Statutes, are amended to read:

568 765.53 Organ Transplant Advisory Council; membership; 569 responsibilities.-

570 (1) There is hereby created within the agency for Health 571 Care Administration A statewide technical Organ Transplant 572 Advisory Council is created within the agency, consisting of 573 twelve members who are physicians licensed under chapter 458 or 574 chapter 459, to represent the interests of the public and the 575 clients of the Department of Health or the agency. The members 576 shall be physicians licensed according to chapter 458 or chapter 577 459. A person employed by the agency may not be appointed as a 578 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.

584 (6) The responsibilities of the council shall be to 585 recommend to the agency for Health Care Administration 586 indications for adult and pediatric organ transplants. The 587 council shall also formulate guidelines and standards for organ 588 transplants and for the development of End Stage Organ Disease 589 and Tissue/Organ Transplant programs. The recommendations, 590 quidelines, and standards developed by the council are 591 applicable only to those health programs funded through the

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592 agency for Health Care Administration. 593 Section 13. Section 765.541, Florida Statutes, is amended 594 to read: 595 765.541 Certification of procurement organizations engaged 596 in the practice of cadaveric organ and tissue procurement.-The agency for Health Care Administration shall: 597 598 (1) Establish a program for the certification of 599 organizations, corporations agencies, or other entities engaged 600 in the procurement of organs, tissues, and eyes for 601 transplantation.+ 602 (2) Adopt rules that set forth appropriate standards and 603 guidelines for the program in accordance with ss. 765.541-604 765.546 and part II of chapter 408. These standards and 605 quidelines must be substantially based on the existing laws of 606 the Federal Government and this state and the existing standards

607 and guidelines of the United Network for Organ Sharing (UNOS), 608 the American Association of Tissue Banks (AATB), the South-609 Eastern Organ Procurement Foundation (SEOPF), the North American 610 Transplant Coordinators Organization (NATCO), and the Eye Bank Association of America (EBAA). In addition, the agency for 611 612 Health Care Administration shall, before adopting these 613 standards and guidelines, seek input from all organ procurement 614 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;

619 (4) Monitor procurement organizations participating
 620 facilities and agencies for program compliance.; and

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(5) Provide for the administration of the Organ and TissueProcurement and Transplantation Advisory Board.

623 Section 14. Section 765.542, Florida Statutes, is amended 624 to read:

625 765.542 Certification of organ procurement organizations,
 626 tissue banks, and eye banks.

(1) The requirements of part II of chapter 408 apply to the 627 628 provision of services that require licensure pursuant to ss. 629 765.541-765.546 and part II of chapter 408 and to entities 630 licensed or certified by or applying for such licensure or 631 certification from the agency for Health Care Administration 632 pursuant to ss. 765.541-765.546. A person An organization, 633 agency, or other entity may not engage in the practice of organ 634 procurement in this state without being designated as an organ 635 procurement organization by the secretary of the United States 636 Department of Health and Human Services and being appropriately 637 certified by the agency for Health Care Administration. As used in this subsection, the term "procurement" includes the 638 639 retrieval, processing, or distribution of human organs. A 640 physician or organ procurement organization based outside this 641 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 anorgan procurement organization certified by the state.

647 (2) <u>A person</u> An organization, agency, or other entity may
648 not engage in tissue procurement in this state unless it is
649 appropriately certified as a tissue bank by the agency for

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Health Care Administration. As used in this subsection, the term
"procurement" includes any retrieval, processing, storage, or
distribution of human tissue for transplantation.

653 (3) A person An organization, agency, or other entity may 654 not engage in the practice of eye procurement in this state 655 without being appropriately certified as an eye bank by the 656 agency for Health Care Administration. As used in this 657 subsection, the term "procurement" includes the retrieval, 658 processing, or distribution of human eye tissue. Funeral 659 directors or direct disposers who that retrieve eye tissue for 660 an eye bank certified under this subsection are exempt from the 661 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.

669 Section 15. Subsection (3) of section 765.543, Florida670 Statutes, is amended to read:

671 765.543 Organ and Tissue Procurement and Transplantation
672 Advisory Board; creation; duties.-

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(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



679 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 <u>ensure the</u> assure continued improvement in the approval and release of potential organ and tissue donors by the district medical examiners and associate medical examiners;

692 (d) Develop with and recommend to the agency for Health 693 Care Administration the necessary procedures and protocols 694 required to assure that all residents of this state have 695 reasonable access to available organ and tissue transplantation 696 therapy and that residents of this state can be reasonably 697 assured that the statewide procurement transplantation system is 698 will be able to fulfill their organ and tissue requirements 699 within the limits of the available supply and according to the 700 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

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708 of this state that no person or entity profits from the 709 altruistic voluntary donation of organs or tissues.

710 Section 16. Section 765.544, Florida Statutes, is amended 711 to read

712 765.544 Fees; organ and tissue donor education and 713 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.

731 2. Each bone and tissue procurement <u>organization</u> agency or 732 bone and tissue bank shall pay the greater of \$1,000 or 0.25 733 percent of its total revenues from procurement and processing 734 activity in this state by the certificateholder during its most 735 recently completed fiscal <u>year</u> or operational year.

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3. Each eye bank shall pay the greater of \$500 or 0.25

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737 percent of its total revenues produced from procurement activity 738 in this state by the certificateholder during its most recently 739 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.

758 Section 17. Section 765.545, Florida Statutes, is amended 759 to read:

760 765.545 Physician supervision of cadaveric organ and tissue 761 procurement coordinators. Organ Procurement organizations, 762 tissue banks, and eye banks may employ coordinators, who are 763 registered nurses, physician's assistants, or other medically 764 trained personnel who meet the relevant standards for organ 765 procurement organizations, tissue banks, or eye banks as adopted



766 by the agency for Health Care Administration under s. 765.541, 767 to assist in the medical management of organ donors or in the 768 surgical procurement of cadaveric organs, tissues, or eyes for 769 transplantation or research. A coordinator who assists in the 770 medical management of organ donors or in the surgical 771 procurement of cadaveric organs, tissues, or eyes for 772 transplantation or research must do so under the direction and 773 supervision of a licensed physician medical director pursuant to 774 rules and guidelines to be adopted by the agency for Health Care 775 Administration. With the exception of organ procurement surgery, this supervision may be indirect supervision. For purposes of 776 777 this section, the term "indirect supervision" means that the 778 medical director is responsible for the medical actions of the 779 coordinator, that the coordinator is operating under protocols 780 expressly approved by the medical director, and that the medical 781 director or his or her physician designee is always available, 782 in person or by telephone, to provide medical direction, 783 consultation, and advice in cases of organ, tissue, and eye 784 donation and procurement. Although indirect supervision is 785 authorized under this section, direct physician supervision is 786 to be encouraged when appropriate.

787 Section 18. Section 765.547, Florida Statutes, is created 788 to read:

789 <u>765.547 Cooperation between medical examiner and</u> 790 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.

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795	(2) The Florida Medical Examiners Commission shall adopt
796	rules establishing cooperative responsibilities between medical
797	examiners and procurement organizations to facilitate and
798	expedite completion of the medical examiner's responsibilities
799	under chapter 406 in a manner that will maximize opportunities
800	to recover anatomical gifts.
801	(3) This part does not supersede any part of chapter 406
802	relating to medical examiners and the disposition of dead
803	bodies.
804	Section 19. Subsection (30) of section 408.802, Florida
805	Statutes, is amended to read:
806	408.802 Applicability.—The provisions of this part apply to
807	the provision of services that require licensure as defined in
808	this part and to the following entities licensed, registered, or
809	certified by the agency, as described in chapters 112, 383, 390,
810	394, 395, 400, 429, 440, 483, and 765:
811	(30) Organ <u>,</u> and tissue, and eye procurement organizations
812	agencies, as provided under <u>part V of</u> chapter 765.
813	Section 20. Subsection (29) of section 408.820, Florida
814	Statutes, is amended to read:
815	408.820 ExemptionsExcept as prescribed in authorizing
816	statutes, the following exemptions shall apply to specified
817	requirements of this part:
818	(29) Organ <u>,</u> and tissue, and eye procurement organizations
819	agencies , as provided under <u>part V of</u> chapter 765, are exempt
820	from s. 408.810(5)-(10).
821	Section 21. This act shall take effect July 1, 2009.
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824	And the title is amended as follows:
825	Delete everything before the enacting clause
826	and insert:
827	A bill to be entitled
828	An act relating to anatomical gifts; amending s. 765.511, F.S.;
829	providing additional definitions; amending s. 765.512, F.S.;
830	conforming terms; amending s. 765.513, F.S.; revising the list
831	of donees that may accept anatomical gifts and the purposes for
832	which such gifts may be used; amending ss. 765.514, 765.515,
833	765.5155, and 765.51551, F.S.; conforming terms; amending s.
834	765.516, F.S.; revising provisions relating to a donor's
835	amendment or revocation of an anatomical gift; amending s.
836	765.517, F.S.; revising provisions relating to a donee's use of
837	an anatomical gift at the time of the donor's death; providing
838	liability protection for the person making a gift and for the
839	donor's estate; amending s. 765.521, F.S.; conforming terms;
840	amending s. 765.522, F.S.; providing that the laws of this state
841	govern the interpretation of a valid document of gift, and that
842	a document of gift is presumed to be valid; amending ss. 765.53,
843	765.541, 765.542, 765.543, 765.544, and 765.545, F.S.;
844	conforming terms; creating s. 765.547, F.S.; requiring medical
845	examiners and procurement organizations to cooperate and
846	maximize opportunities for organ donations; authorizing the
847	Florida Medical Examiners Commission to adopt rules; amending
848	ss. 408.802 and 408.820, F.S.; conforming terms; providing an
849	effective date.