By the Committees on Judiciary; and Health Regulation; and Senator Oelrich

590-02986-09

2009766c2

1 A bill to be entitled 2 An act relating to anatomical gifts; amending s. 3 765.511, F.S.; providing additional definitions; 4 amending s. 765.512, F.S.; conforming terms; amending 5 s. 765.513, F.S.; revising the list of donees that may 6 accept anatomical gifts and the purposes for which 7 such gifts may be used; amending ss. 765.514, 765.515, 8 765.5155, and 765.51551, F.S.; conforming terms; 9 amending s. 765.516, F.S.; revising provisions relating to a donor's amendment or revocation of an 10 11 anatomical gift; amending s. 765.517, F.S.; revising 12 provisions relating to a donee's use of an anatomical 13 gift at the time of the donor's death; providing 14 liability protection for the person making a gift and 15 for the donor's estate; amending s. 765.521, F.S.; 16 conforming terms; amending s. 765.522, F.S.; providing 17 that the laws of this state govern the interpretation of a valid document of gift, and that a document of 18 19 gift is presumed to be valid; amending ss. 765.53, 765.541, 765.542, 765.543, 765.544, and 765.545, F.S.; 20 21 conforming terms; creating s. 765.547, F.S.; requiring 22 medical examiners and procurement organizations to 23 cooperate and maximize opportunities for organ 24 donations; authorizing the Florida Medical Examiners 25 Commission to adopt rules; amending ss. 408.802 and 26 408.820, F.S.; conforming terms; providing an 27 effective date.

28

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

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31	Section 1. Section 765.511, Florida Statutes, is amended to
32	read:
33	765.511 Definitions.—As used in this part, the term:
34	(1) "Agency" means the Agency for Health Care
35	Administration.
36	(2) "Anatomical gift" or "gift" means a donation of all or
37	part of a human body to take effect after the donor's death and
38	to be used for transplantation, therapy, research, or education.
39	(3)(1) "Bank" or "storage facility" means a facility
40	licensed, accredited, or approved under the laws of any state
41	for storage of human bodies or <u>body</u> parts thereof .
42	(4) (2) "Death" means the absence of life as determined, in
43	accordance with currently accepted medical standards, by the
44	irreversible cessation of all respiration and circulatory
45	function, or as determined, in accordance with s. 382.009, by
46	the irreversible cessation of the functions of the entire brain,
47	including the brain stem.
48	(5) "Decedent" means a deceased individual whose body or
49	body parts may be, or are, the source of an anatomical gift.
50	(6) "Department" means the Department of Highway Safety and
51	Motor Vehicles.
52	(7) "Disinterested witness" means a witness other than a
53	person listed in s. 765.512(3) or other family member.
54	(8) "Document of gift" means any of the documents or
55	mechanisms used in making an anatomical gift under s. 765.514.
56	<u>(9)(3) "Donor" means an individual who makes an anatomical</u>
57	a gift of all or part of his or her body.
58	(10) "Donor registry" means a database that contains

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59	records of anatomical gifts and amendments to, or revocations
60	of, such gifts.
61	(11) "Eye bank" means an entity that is accredited by the
62	Eye Bank Association of America or otherwise regulated under
63	federal or state law to engage in the retrieval, screening,
64	testing, processing, storage, or distribution of human eye
65	tissue.
66	(12) "Guardian" means a person appointed pursuant to
67	chapter 744. The term does not include a guardian ad litem.
68	(13) (4) "Hospital" means a hospital licensed, accredited,
69	or approved under the laws of any state and includes a hospital
70	operated by the United States Government or a state, or a
71	subdivision thereof, although not required to be licensed under
72	state laws.
73	(14) "Identification card" means an official identification
74	card issued by a governmental entity, state agency, or
75	subdivision thereof.
76	(15) "Organ procurement organization" means an entity that
77	is designated as an organ procurement organization by the
78	Secretary of the United States Department of Health and Human
79	Services and that engages in the retrieval, screening, testing,
80	processing, storage, or distribution of human organs.
81	(16) "Part of the body" or "body part" means an organ, eye,
82	or tissue of a human being. The term does not include the whole
83	body.
84	<u>(17)(5) "Physician" or "surgeon" means a physician or</u>
85	surgeon licensed to practice under chapter 458 or chapter 459 or
86	
87	surgeon.

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88	(18) "Procurement" means any retrieval, recovery,
89	processing, storage, or distribution of human organs or tissues
90	for transplantation, therapy, research, or education.
91	(19) "Procurement organization" means an organ procurement
92	organization, eye bank, or tissue bank.
93	(20) "Reasonably available" means able to be contacted by a
94	procurement organization in a timely manner without undue
95	effort, and willing and able to act in a manner consistent with
96	existing medical protocols necessary for the making of an
97	anatomical gift.
98	(21) "Record" means information that is inscribed on a
99	tangible medium or that is stored in an electronic or other
100	medium and is retrievable in perceivable form.
101	(22) "Sign" or "signed" means, with the present intent to
102	authenticate or adopt a record, to execute or adopt a tangible
103	symbol, or attach to or logically associate an electronic
104	symbol, sound, or process with the record.
105	(23) "Tissue bank" means an entity that is accredited by
106	the American Association of Tissue Banks or otherwise regulated
107	under federal or state law to engage in the retrieval,
108	screening, testing, processing, storage, or distribution of
109	human tissue.
110	Section 2. Subsections (1), (4), (5), (6), and (7) of
111	section 765.512, Florida Statutes, are amended to read:
112	765.512 Persons who may make an anatomical gift
113	(1) Any person who may make a will may <u>make an anatomical</u>
114	gift give all or part of his or her body for any purpose
115	specified in s. 765.513. The gift is effective upon the death of
116	the donor.

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117	(a) If the decedent makes an anatomical gift by one of the
118	methods listed in s. 765.514(1), and in the absence of actual
119	notice of contrary indications by the decedent, the document or
120	entry in the <u>donor</u> organ and tissue registry is legally
121	sufficient evidence of the decedent's informed consent to donate
122	an anatomical gift.
123	(b) An anatomical gift made by a qualified donor and not
124	revoked by the donor, as provided in s. 765.516, is irrevocable
125	after the donor's death. A family member, guardian,
126	representative ad litem, or health care surrogate may not
127	modify, deny, or prevent a donor's wish or intent to make an
128	anatomical gift after the donor's death.
129	(4) A donee may not accept an anatomical gift if the donee
130	has actual notice of contrary indications by the donor or actual
131	notice that <u>an anatomical</u> a gift by a member of a class is
132	opposed by a member of a prior class.
133	(5) The person authorized by subsection (3) may make the
134	anatomical gift after the decedent's death or immediately before
135	the decedent's death.
136	(6) <u>An anatomical</u> A gift of all or part of a body
137	authorizes:
138	(a) Any examination necessary to assure medical
139	acceptability of the gift for the purposes intended.
140	(b) The decedent's medical provider, family, or a third
141	party to furnish medical records requested concerning the
142	decedent's medical and social history.
143	(7) Once the <u>anatomical</u> gift has been made, the rights of
144	the donee are paramount to the rights of others, except as
145	provided by s. 765.517.

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146	Section 3. Section 765.513, Florida Statutes, is amended to
147	read:
148	765.513 Persons and entities that may become Donees;
149	purposes for which anatomical gifts may be made
150	(1) The following persons or entities may become donees of
151	anatomical gifts of bodies or parts of them for the purposes
152	stated:
153	(a) (1) Any procurement organization or accredited hospital,
154	surgeon, or physician for medical or dental school, college, or
155	university for education, or research, advancement of medical or
156	dental science, therapy, or transplantation.
157	(2) Any accredited medical or dental school, college, or
158	university for education, research, advancement of medical or
159	dental science, or therapy.
160	(3) Any bank or storage facility for medical or dental
161	education, research, advancement of medical or dental science,
162	therapy, or transplantation.
163	<u>(b)</u> (4) Any individual specified by name for therapy or
164	transplantation needed by him or her.
165	(2) If multiple purposes are set forth in the document of
166	gift but are not set forth in any priority order, the anatomical
167	gift shall be used first for transplantation or therapy, if
168	suitable. If the gift cannot be used for transplantation or
169	therapy, the gift may be used for research or education.
170	(3) However, The Legislature declares that the public
171	policy of this state prohibits restrictions on the possible
172	recipients of an anatomical gift on the basis of race, color,
173	religion, <u>gender</u> sex , national origin, age, physical <u>disability</u>
174	handicap, health status, marital status, or economic status, and

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590-02986-09 2009766c2 175 such restrictions are hereby declared void and unenforceable. 176 Section 4. Section 765.514, Florida Statutes, is amended to 177 read: 765.514 Manner of making anatomical gifts.-178 179 (1) A person may make an anatomical a gift of all or part of his or her body under s. 765.512(1) by: 180 181 (a) Signing an organ and tissue donor card. 182 (b) Registering online with the organ and tissue donor 183 registry. 184 (c) Signifying an intent to donate on his or her driver's 185 license or identification card issued by the Department of 186 Highway Safety and Motor Vehicles. Revocation, suspension, 187 expiration, or cancellation of the driver's license or 188 identification card does not invalidate the gift. 189 (d) Expressing a wish to donate in a living will or other 190 advance directive. 191 (e) Executing a will that includes a provision indicating 192 that the testator wishes to make an anatomical gift. The gift becomes effective upon the death of the testator without waiting 193 194 for probate. If the will is not probated or if it is declared 195 invalid for testamentary purposes, the gift is nevertheless 196 valid to the extent that it has been acted upon in good faith. 197 (f) Expressing a wish to donate in a document other than a will. The document must be signed by the donor in the presence 198 199 of two witnesses who shall sign the document in the donor's 200 presence. If the donor cannot sign, the document may be signed 201 for him or her at the donor's direction and in his or her 202 presence and the presence of two witnesses who must sign the 203 document in the donor's presence. Delivery of the document of

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204
     gift during the donor's lifetime is not necessary to make the
205
     gift valid. The following form of written document is sufficient
206
     for any person to make an anatomical gift give all or part of
207
     his or her body for the purposes of this part:
208
                              UNIFORM DONOR CARD
209
210
     The undersigned hereby makes this anatomical gift, if medically
211
     acceptable, to take effect on death. The words and marks below
     indicate my desires:
212
213
     I give:
214
           (a) .... any needed organs, tissues, or eyes;
215
           (b) .... only the following organs, tissues, or eyes
216
                ... [Specify the organs, tissues, or eyes]...
217
     for the purpose of transplantation, therapy, medical research,
218
     or education;
219
           (c) .... my body for anatomical study if needed.
220
     Limitations or special wishes, if any:
221
      ... (If applicable, list specific donee; this must be arranged in
222
                         advance with the donee.)...
223
224
     Signed by the donor and the following witnesses in the presence
225
     of each other:
226
227
     ... (Signature of donor)... ... (Date of birth of donor)...
228
     ... (Date signed) ...
                                                  ... (City and State) ...
229
230
     ...(Witness)...
                                                          ... (Witness) ...
231
     ... (Address) ...
                                                          ... (Address) ...
232
           (2) The anatomical gift may be made to a donee listed in s.
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590-02986-09 2009766c2 233 765.513, and the donee may be specified by name. 234 (3) Any anatomical gift by a health care surrogate 235 designated by the decedent pursuant to part II of this chapter 236 or a member of a class designated in s. 765.512(3) must be made 237 by a document signed by that person or made by that person's 238 witnessed telephonic discussion, telegraphic message, or other 239 recorded message. Section 5. Section 765.515, Florida Statutes, is amended to 240 241 read: 2.42 765.515 Delivery of donor document.-(1) If an anatomical a gift is made pursuant to s. 765.521, 243 244 the completed donor registration card shall be delivered to the 245 Department of Highway Safety and Motor Vehicles and the 246 department must communicate the donor's intent to the organ and 247 tissue donor registry, but delivery is not necessary to the 248 validity of the gift. If the donor withdraws the gift, the 249 records of the Department of Highway Safety and Motor Vehicles 250 must be updated to reflect such withdrawal and the department 251 must communicate the withdrawal to the organ and tissue donor 252 registry for the purpose of updating the registry. 253 (2) If an anatomical $\frac{1}{2}$ gift is made by the donor to a 254 specified donee, the document of gift, other than a will, may be 255 delivered to the donee to expedite the appropriate procedures 256 immediately after death, but delivery is not necessary to the 257 validity of the gift. The Such document of gift may be deposited 258 in any hospital, bank, storage facility, or registry office that 259 accepts such documents for safekeeping or to facilitate the 260 donation of organs and tissue after death.

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(3) At the request of any interested party upon or after

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262	the donor's death, the person in possession shall produce the
263	document of gift for examination.
264	Section 6. Section 765.5155, Florida Statutes, is amended
265	to read:
266	765.5155 Organ and tissue Donor registry; education
267	program
268	(1) The Legislature finds that:
269	(a) There is a shortage of organ and tissue donors in this
270	state willing to provide the organs and tissue that could save
271	lives or enhance the quality of life for many persons.
272	(b) There is a need to encourage the various minority
273	populations of this state to donate organs and tissue.
274	(c) A statewide organ and tissue donor registry having an
275	online donor registration process coupled with an enhanced
276	program of donor education will lead to an increase in the
277	number of organ and tissue donors registered in this state, thus
278	affording more persons who are awaiting organ or tissue
279	transplants the opportunity for a full and productive life.
280	(2) The agency for Health Care Administration and the
281	Department of Highway Safety and Motor Vehicles shall jointly
282	contract for the operation of <u>a</u> an organ and tissue donor
283	registry and education program. The contractor shall be procured
284	by competitive solicitation pursuant to chapter 287,
285	notwithstanding any exemption in s. 287.057(5)(f). When awarding
286	the contract, priority shall be given to existing nonprofit
287	groups that are based within the state, have expertise working
288	with organ and tissue procurement organizations, have expertise
289	in conducting statewide organ and tissue donor public education
290	campaigns, and represent the needs of the organ and tissue

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590-02986-09 donation community in the state.

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291

(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.

299 1. The registry must be maintained in a manner that allows, 300 through electronic and telephonic methods, immediate access to 301 organ and tissue donation records 24 hours a day, 7 days a week.

302 2. Access to the registry must be through coded and secure303 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.

309 1. Existing community resources, when available, must be 310 used to support the program and volunteers may assist the 311 program to the maximum extent possible.

312 2. The contractor shall coordinate with the head of a state 313 agency or other political subdivision of the state, or his or 314 her designee, to establish convenient times, dates, and 315 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:

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1. The number of donors on the registry and an analysis of

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590-02986-09 2009766c2 320 the registration rates by location and method of donation; 321 2. The characteristics of donors as determined from 322 registry information submitted directly by the donors or by the 323 Department of Highway Safety and Motor Vehicles; 324 3. The annual dollar amount of voluntary contributions 325 received by the contractor; 326 4. A description of the educational campaigns and 327 initiatives implemented during the year and an evaluation of 328 their effectiveness in increasing enrollment on the registry; 329 and 330 5. An analysis of Florida's registry compared with other 331 states' donor registries. 332 (4) Costs for the organ and tissue donor registry and 333 education program shall be paid by the agency for Health Care 334 Administration from the funds deposited into the Health Care 335 Trust Fund pursuant to ss. 320.08047 and 322.08, which are 336 designated for maintaining the organ and tissue donor registry 337 and education program. In addition, the contractor may receive 338 and use voluntary contributions to help support the registry and 339 provide education. 340 (5) The organ and tissue donor registry established by this 341 section is designated as the "Joshua Abbott Organ and Tissue 342 Registry." 343 Section 7. Section 765.51551, Florida Statutes, is amended 344 to read 345 765.51551 Organ and tissue Donor registry; public records 346 exemption.-

347 (1) Information held in the organ and tissue donor registry
 348 which identifies a donor is confidential and exempt from s.

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590-02986-09 2009766c2 349 119.07(1) and s. 24(a), Art. I of the State Constitution. 350 (2) Such information may be disclosed to the following: 351 (a) Organ, tissue, and eye Procurement organizations that 352 have been certified by the agency for Health Care Administration 353 for the purpose of ascertaining or effectuating the existence of 354 a gift under s. 765.522. (b) Persons engaged in bona fide research if the person 355 356 agrees to: 357 1. Submit a research plan to the agency that specifies the 358 exact nature of the information requested and the intended use 359 of the information; 360 2. Maintain the confidentiality of the records or 361 information if personal identifying information is made 362 available to the researcher; 363 3. Destroy any confidential records or information obtained 364 after the research is concluded; and 365 4. Not directly or indirectly contact, for any purpose, any 366 donor or donee. 367 (3) This section is subject to the Open Government Sunset 368 Review Act in accordance with s. 119.15 and shall stand repealed 369 on October 2, 2013, unless reviewed and saved from repeal through reenactment by the Legislature. 370 371 Section 8. Section 765.516, Florida Statutes, is amended to 372 read: 373 765.516 Donor amendment of the terms of or the revocation 374 of anatomical the gift.-375 (1) A donor may amend the terms of or revoke an anatomical 376 qift by: (a) The execution and delivery to the donee of a signed 377

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378	statement witnessed by at least two adults, at least one of whom
379	is a disinterested witness.
380	(b) An oral statement that is made in the presence of two
381	persons, one of whom <u>is</u> must not be a family member, and
382	communicated to the donor's family or attorney or to the donee.
383	An oral statement is effective only if the procurement
384	organization, transplant hospital, or physician or technician
385	has actual notice of the oral amendment or revocation before an
386	incision is made to the decedent's body or an invasive procedure
387	to prepare the recipient has begun.
388	(c) A statement <u>made</u> during a terminal illness or injury
389	addressed to an attending physician, who must communicate the
390	revocation of the gift to the procurement organization that is
391	certified by the state.
392	(d) A signed document found on or about the donor's person.
393	(e) Removing his or her name from the organ and tissue
394	donor registry.
395	(f) A later-executed document of gift which amends or
396	revokes a previous anatomical gift or portion of an anatomical
397	gift, either expressly or by inconsistency.
398	(g) By the destruction or cancellation of the document of
399	gift or the destruction or cancellation of that portion of the
400	document of gift used to make the gift with the intent to revoke
401	the gift.
402	(2) Any <u>anatomical</u> gift made by a will may also be amended
403	or revoked in the manner provided for <u>the</u> amendment or
404	revocation of wills or as provided in <u>paragraph (1)(a)</u>
405	subsection (1).
406	Section 9. Section 765.517, Florida Statutes, is amended to

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407 read: 408 765.517 Rights and duties at death.-409 (1) The donee, pursuant to as specified under the 410 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 411 part of the body to be used for research or education scientific 412 413 purposes other than a transplant, the donee may authorize 414 embalming and the use of the body in funeral services, subject 415 to the terms of the gift. If the gift is of a part of the body, 416 the donee shall cause the part to be removed without unnecessary 417 mutilation upon the death of the donor and before or after 418 embalming. After removal of the body part, custody of the 419 remainder of the body vests in the surviving spouse, next of 420 kin, or other persons under obligation to dispose of the body. 421 (2) The time of death shall be determined by a physician 422 who attends the donor at the donor's death or, if there is no 423 such physician, the physician who certifies the death. After 424 death, those physicians or the donor's primary care and in the 425 absence of other qualified personnel, this physician may 426 participate in, but may shall not obstruct, the procedures to 427 preserve the donor's organs or tissues and may shall not be paid 428 or reimbursed for such participation by, nor be associated with 429 or employed by, a, an organ procurement organization, tissue 430 bank, or eye bank. These physicians may This physician shall not participate in the procedures for removing or transplanting a 431 432 part. However, this subsection does not prevent a physician from

433 <u>serving in a voluntary capacity on the board of directors of a</u> 434 procurement organization or participating on any board, council,

435 commission, or similar body related to the organ and tissue

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436 procurement system.

437 (3) The organ procurement organizations organization, 438 tissue bank, or eye bank, or hospital medical professionals 439 under the direction thereof, may perform any and all tests to 440 evaluate the deceased as a potential donor and any invasive 441 procedures on the deceased body in order to preserve the 442 potential donor's organs. These procedures do not include the 443 surgical removal of an organ or penetrating any body cavity, 444 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.

457 (5) A person who acts in good faith and without negligence 458 in accord with the terms of this part or under the anatomical 459 gift laws of another state or a foreign country, or attempts to 460 do so, may not be subject to any civil action for damages, may 461 not be subject to any criminal proceeding, and may not be 462 subject to discipline, penalty, or liability in any 463 administrative proceeding is not liable for damages in any civil 464 action or subject to prosecution for his or her acts in any

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465	criminal proceeding.
466	(6) The provisions of this part are subject to the laws of
467	this state prescribing powers and duties with respect to
468	autopsies.
469	(7) The person making an anatomical gift and the donor's
470	estate are not liable for any injury or damages that result from
471	the making or use of the gift.
472	(8) In determining whether an anatomical gift has been
473	made, amended, or revoked under this part, a person may rely
474	upon the representation of an individual listed in s. 765.512,
475	relating to the individual's relationship to the donor or
476	prospective donor, unless the person knows that the
477	representation is untrue.
478	Section 10. Section 765.521, Florida Statutes, is amended
479	to read:
480	765.521 Donations as part of driver license or
481	identification card process
482	(1) The agency for Health Care Administration and the
483	Department of Highway Safety and Motor Vehicles shall develop
484	and implement a program encouraging and allowing persons to make
485	anatomical gifts as a part of the process of issuing
486	identification cards and issuing and renewing driver licenses.
487	The donor registration card distributed by the Department of
488	Highway Safety and Motor Vehicles shall include the information
489	required by the uniform donor card under s. 765.514 and such
490	additional information as determined necessary by the
491	department. The department shall also develop and implement a
492	program to identify donors $_{m{ au}}$ which includes notations on
493	identification cards, driver licenses, and driver records or

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590-02986-09 2009766c2 494 such other methods as the department develops to clearly 495 indicate the individual's intent to make an anatomical gift 496 donate the individual's organs, tissues, or eyes. A notation on an individual's driver license or identification card that the 497 498 individual intends to make an anatomical gift donate organs, 499 tissues, or eyes satisfies all requirements for consent to organ 500 or tissue donation. The agency for Health Care Administration 501 shall provide the necessary supplies and forms from funds 502 appropriated from general revenue or contributions from 503 interested voluntary, nonprofit organizations. The department 504 shall provide the necessary recordkeeping system from funds 505 appropriated from general revenue. The Department of Highway 506 Safety and Motor Vehicles and the agency for Health Care 507 Administration shall incur no liability in connection with the 508 performance of any acts authorized herein. 509 (2) The Department of Highway Safety and Motor Vehicles,

510 after consultation with and concurrence by the agency for Health 511 Care Administration, shall adopt rules to implement the 512 provisions of this section according to the provisions of 513 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.

517 Section 11. Section 765.522, Florida Statutes, is amended 518 to read:

519 765.522 Duty of certain hospital administrators; liability 520 of hospital administrators and, organ procurement organizations, 521 eye banks, and tissue banks.-

522

(1) When used in this section, "hospital" means any

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590-02986-09 2009766c2 523 establishment licensed under chapter 395 except psychiatric and 524 rehabilitation hospitals. 525 (1) (2) If Where, based on accepted medical standards, a 526 hospital patient is a suitable candidate for organ or tissue 527 donation, the hospital administrator or the hospital 528 administrator's designee shall, at or near the time of death, 529 notify the appropriate procurement organization organ, eye, or 530 tissue recovery program, which shall access the organ and tissue 531 donor registry created by s. 765.5155 or any other donor 532 registry to ascertain the existence of an entry in the registry 533 which that has not been revoked, a donor card, or a document of 534 gift executed by the decedent. In the absence of an entry in the 535 donor registry, a document of gift donor card, organ donation 536 sticker or organ donation imprint on a driver's license, or 537 other properly executed document, the procurement organization 538 organ, eye, or tissue recovery program shall request: 539 (a) The patient's health care surrogate, as authorized in 540 s. 765.512(2); or (b) If the patient does not have a surrogate, or the 541 542 surrogate is not reasonably available, any of the persons 543 specified in s. 765.512(3), in the order and manner listed, 544 545 to consent to the anatomical gift of all or any part of the decedent's body for any purpose specified in this part. Except 546 547 as provided in s. 765.512, in the absence of actual notice of 548 opposition, consent need only be obtained from the person or persons in the highest priority class reasonably available. 549 550 (3) A document of gift is valid if made pursuant to a

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request required by this section shall be executed in accordance

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552	with this part or the laws of the state or country where it was
553	executed and where the person making the anatomical gift was
554	domiciled, has a place of residence, or was a citizen at the
555	time the document of gift was executed pursuant to s. 765.514.
556	(4) The agency for Health Care Administration shall
557	establish rules and guidelines concerning the education of
558	individuals who may be designated to perform the request and the
559	procedures to be used in making the request. The agency is
560	authorized to adopt rules concerning the documentation of the
561	request, where such request is made.
562	(5) If a document of gift is valid under this section, the
563	laws of this state govern the interpretation of the document of
564	gift.
565	(6) A document of gift or amendment of an anatomical gift
566	is presumed to be valid unless it was not validly executed or
567	was revoked.
568	(7) (5) There shall be no civil or criminal liability
569	against any organ procurement organization , eye bank, or tissue
570	$rac{bank}{bank}$ certified under s. 765.542 $_{ au}$ or against any hospital or
571	hospital administrator or designee who complies, when complying
572	with the provisions of this part and <u>agency</u> the rules of the
573	agency for Health Care Administration or <u>if</u> when, in the
574	exercise of reasonable care, a request for organ donation is
575	inappropriate and the gift is not made according to this part
576	and <u>agency</u> the rules of the agency for Health Care
577	Administration.
578	<u>(8)(6) The hospital administrator or a designee shall, at</u>

578 (8)(6) The hospital administrator of a designee shall, at 579 or near the time of death of a potential organ donor, directly 580 notify the affiliated organ procurement organization designated

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590-02986-09 2009766c2 581 by the United States Department of Health and Human Services of 582 the potential organ donor. The This organ procurement 583 organization must offer any organ from such a donor first to 584 patients on a Florida-based local or state organ sharing 585 transplant list. For the purpose of this subsection, the term "transplant list" includes certain categories of national or 586 regional organ sharing for patients of exceptional need or 587 588 exceptional match, as approved or mandated by the Organ 589 Procurement and Transplantation Network, or its agent. This 590 notification may not be made to a tissue bank or eye bank in 591 lieu of the organ procurement organization unless the tissue 592 bank or eye bank is also designated as an organ procurement 593 organization by the United States Department of Health and Human 594 Services. 595 Section 12. Subsections (1), (5), and (6) of section 596 765.53, Florida Statutes, are amended to read: 597 765.53 Organ Transplant Advisory Council; membership; 598 responsibilities.-599 (1) There is hereby created within the agency for Health 600 Care Administration A statewide technical Organ Transplant 601 Advisory Council is created within the agency, consisting of 602 twelve members who are physicians licensed under chapter 458 or 603 chapter 459, to represent the interests of the public and the 604 clients of the Department of Health or the agency. The members

605 shall be physicians licensed according to chapter 458 or chapter 606 459. A person employed by the agency may not be appointed as a 607 member of the council.

608 (5) Members of the council shall receive no compensation,609 but shall be reimbursed for per diem and travel expenses by the

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590-02986-09 2009766c2 610 agency for Health Care Administration in accordance with the 611 provisions of s. 112.061 while engaged in the performance of 612 their duties. 613 (6) The responsibilities of the council shall be to 614 recommend to the agency for Health Care Administration indications for adult and pediatric organ transplants. The 615 616 council shall also formulate guidelines and standards for organ 617 transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The recommendations, 618 619 guidelines, and standards developed by the council are 620 applicable only to those health programs funded through the 621 agency for Health Care Administration. 622 Section 13. Section 765.541, Florida Statutes, is amended 623 to read: 624 765.541 Certification of procurement organizations; agency 625 responsibilities engaged in the practice of cadaveric organ and 626 tissue procurement.-The agency for Health Care Administration 627 shall: 628 (1) Establish a program for the certification of 629 organizations, corporations agencies, or other entities engaged 630 in the procurement of organs, tissues, and eyes for 631 transplantation.+ 632 (2) Adopt rules that set forth appropriate standards and 633 guidelines for the program in accordance with ss. 765.541-634 765.546 and part II of chapter 408. These standards and 635

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-

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639	Eastern Organ Procurement Foundation (SEOPF), the North American
640	Transplant Coordinators Organization (NATCO), and the Eye Bank
641	Association of America (EBAA). In addition, the agency for
642	Health Care Administration shall, before adopting these
643	standards and guidelines, seek input from all organ procurement
644	organizations, tissue banks, and eye banks based in this state.;
645	(3) Collect, keep, and make available to the Governor and
646	the Legislature information regarding the numbers and
647	disposition of organs, and tissues, and eyes procured by each
648	certified procurement organization. entity;
649	(4) Monitor procurement organizations participating
650	facilities and agencies for program compliance.; and
651	(5) Provide for the administration of the Organ and Tissue
652	Procurement and Transplantation Advisory Board.
653	Section 14. Section 765.542, Florida Statutes, is amended
654	to read:
655	765.542 <u>Requirements to engage in organ, tissue, or eye</u>
656	Certification of organ procurement organizations, tissue banks,
657	and eye banks
658	(1) The requirements of part II of chapter 408 apply to the
659	provision of services that require licensure pursuant to ss.
660	765.541-765.546 and part II of chapter 408 and to entities
661	licensed or certified by or applying for such licensure or
662	certification from the agency for Health Care Administration
663	pursuant to ss. 765.541-765.546. <u>A person</u> An organization,
664	agency, or other entity may not engage in the practice of organ
665	procurement in this state without being designated as an organ
666	procurement organization by the secretary of the United States
667	Department of Health and Human Services and being appropriately

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590-02986-09 2009766c2 668 certified by the agency for Health Care Administration. As used 669 in this subsection, the term "procurement" includes the 670 retrieval, processing, or distribution of human organs. A physician or organ procurement organization based outside this 671 672 state is exempt from these certification requirements if: (a) The organs are procured for an out-of-state patient who 673 674 is listed on, or referred through, the United Network for Organ 675 Sharing System; and 676 (b) The organs are procured through an agreement of an 677 organ procurement organization certified by the state. 678 (2) A person An organization, agency, or other entity may 679 not engage in tissue procurement in this state unless it is 680 appropriately certified as a tissue bank by the agency for Health Care Administration. As used in this subsection, the term 681 682 "procurement" includes any retrieval, processing, storage, or distribution of human tissue for transplantation. 683 684 (3) A person An organization, agency, or other entity may 685 not engage in the practice of eye procurement in this state 686 without being appropriately certified as an eye bank by the 687 agency for Health Care Administration. As used in this 688 subsection, the term "procurement" includes the retrieval, 689 processing, or distribution of human eye tissue. Funeral 690 directors or direct disposers who that retrieve eye tissue for 691 an eye bank certified under this subsection are exempt from the 692 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

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697
     that the tissue bank or eye bank is adequately staffed and
698
     equipped to operate in conformity with the rules adopted under
699
     this section.
700
          Section 15. Subsection (3) of section 765.543, Florida
701
     Statutes, is amended to read:
702
          765.543 Organ and Tissue Procurement and Transplantation
703
     Advisory Board; creation; duties.-
704
          (3) The board shall:
705
           (a) Assist the agency for Health Care Administration in the
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     development of necessary professional qualifications, including,
707
     but not limited to, the education, training, and performance of
     persons engaged in the various facets of organ and tissue
708
     procurement, processing, preservation, and distribution for
709
710
     transplantation;
711
           (b) Assist the agency for Health Care Administration in
712
     monitoring the appropriate and legitimate expenses associated
713
     with organ and tissue procurement, processing, and distribution
714
     for transplantation and developing methodologies to assure the
715
     uniform statewide reporting of data to facilitate the accurate
716
     and timely evaluation of the organ and tissue procurement and
717
     transplantation system;
718
           (c) Provide assistance to the Florida Medical Examiners
719
     Commission in the development of appropriate procedures and
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720 protocols to <u>ensure the</u> assure continued improvement in the 721 approval and release of potential organ and tissue donors by the 722 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

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590-02986-09 2009766c2 726 reasonable access to available organ and tissue transplantation 727 therapy and that residents of this state can be reasonably 728 assured that the statewide procurement transplantation system is 729 will be able to fulfill their organ and tissue requirements 730 within the limits of the available supply and according to the 731 severity of their medical condition and need; and 732 (e) Develop with and recommend to the agency for Health 733 Care Administration any changes to the laws of this state or 734 administrative rules or procedures required to ensure assure 735 that the statewide organ and tissue procurement and 736 transplantation system is will be able to function smoothly, 737 effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents 738 739 of this state that no person or entity profits from the 740 altruistic voluntary donation of organs or tissues. 741 Section 16. Section 765.544, Florida Statutes, is amended 742 to read 743 765.544 Fees; organ and tissue donor education and 744 procurement.-745 (1) In accordance with s. 408.805, an applicant or a 746 certificateholder shall pay a fee for each application submitted 747 under this part, part II of chapter 408, and applicable rules. 748 The amount of the fee shall be as follows: 749 (a) An initial application fee of \$1,000 from organ 750 procurement organizations and tissue banks and \$500 from eye 751 banks. 752 (b) Annual fees to be used, in the following order of

752 (b) Annual lees to be used, in the following order of 753 priority, for the certification program, the advisory board, 754 maintenance of the organ and tissue donor registry, and the

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755 organ and tissue donor education program in the following 756 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.

762 2. Each bone and tissue procurement <u>organization</u> agency or 763 bone and tissue bank shall pay the greater of \$1,000 or 0.25 764 percent of its total revenues from procurement and processing 765 activity in this state by the certificateholder during its most 766 recently completed fiscal year or operational year.

767 3. Each eye bank shall pay the greater of \$500 or 0.25 768 percent of its total revenues produced from procurement activity 769 in this state by the certificateholder during its most recently 770 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.

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784
          (4) As used in this section, the term "procurement activity
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     in this state" includes the bringing into this state for
786
     processing, storage, distribution, or transplantation of organs
787
     or tissues that are initially procured in another state or
788
     country.
789
          Section 17. Section 765.545, Florida Statutes, is amended
790
     to read:
791
          765.545 Physician supervision of cadaveric organ and tissue
792
     procurement coordinators.-Organ Procurement organizations,
793
     tissue banks, and eye banks may employ coordinators, who are
794
     registered nurses, physician's assistants, or other medically
795
     trained personnel who meet the relevant standards for organ
796
     procurement organizations, tissue banks, or eye banks as adopted
797
     by the agency for Health Care Administration under s. 765.541,
798
     to assist in the medical management of organ donors or in the
799
     surgical procurement of cadaveric organs, tissues, or eyes for
800
     transplantation or research. A coordinator who assists in the
801
     medical management of organ donors or in the surgical
802
     procurement of cadaveric organs, tissues, or eyes for
803
     transplantation or research must do so under the direction and
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     supervision of a licensed physician medical director pursuant to
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     rules and guidelines to be adopted by the agency for Health Care
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     Administration. With the exception of organ procurement surgery,
807
     this supervision may be indirect supervision. For purposes of
808
     this section, the term "indirect supervision" means that the
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     medical director is responsible for the medical actions of the
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     coordinator, that the coordinator is operating under protocols
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     expressly approved by the medical director, and that the medical
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     director or his or her physician designee is always available,
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813	in person or by telephone, to provide medical direction,
814	consultation, and advice in cases of organ, tissue, and eye
815	donation and procurement. Although indirect supervision is
816	authorized under this section, direct physician supervision is
817	to be encouraged when appropriate.
818	Section 18. Section 765.547, Florida Statutes, is created
819	to read:
820	765.547 Cooperation between medical examiner and
821	procurement organization
822	(1) A medical examiner and procurement organization shall
823	cooperate with each other in order to maximize opportunities to
824	recover anatomical gifts for the purpose of transplantation,
825	therapy, research, or education.
826	(2) The Florida Medical Examiners Commission shall adopt
827	rules establishing cooperative responsibilities between medical
828	examiners and procurement organizations to facilitate and
829	expedite completion of the medical examiner's responsibilities
830	under chapter 406 in a manner that will maximize opportunities
831	to recover anatomical gifts.
832	(3) This part does not supersede any part of chapter 406
833	relating to medical examiners and the disposition of dead
834	bodies.
835	Section 19. Subsection (30) of section 408.802, Florida
836	Statutes, is amended to read:
837	408.802 Applicability.—The provisions of this part apply to
838	the provision of services that require licensure as defined in
839	this part and to the following entities licensed, registered, or
840	certified by the agency, as described in chapters 112, 383, 390,
841	394, 395, 400, 429, 440, 483, and 765:

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842	(30) Organ <u>,</u> and tissue, and eye procurement organizations
843	agencies, as provided under <u>part V of</u> chapter 765.
844	Section 20. Subsection (29) of section 408.820, Florida
845	Statutes, is amended to read:
846	408.820 ExemptionsExcept as prescribed in authorizing
847	statutes, the following exemptions shall apply to specified
848	requirements of this part:
849	(29) Organ <u>,</u> and tissue, and eye procurement organizations
850	agencies , as provided under <u>part V of</u> chapter 765, are exempt
851	from s. 408.810(5)-(10).
852	Section 21. This act shall take effect July 1, 2009.
853	

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