

1 A bill to be entitled
 2 An act relating to anatomical gifts; amending s. 765.511,
 3 F.S.; providing additional definitions; amending s.
 4 765.512, F.S.; conforming terms; amending s. 765.513,
 5 F.S.; revising the list of donees that may accept
 6 anatomical gifts and the purposes for which such gifts may
 7 be used; amending ss. 765.514, 765.515, 765.5155, and
 8 765.51551, F.S.; conforming terms; amending s. 765.516,
 9 F.S.; revising provisions relating to a donor's amendment
 10 or revocation of an anatomical gift; amending s. 765.517,
 11 F.S.; revising provisions relating to a donee's use of an
 12 anatomical gift at the time of the donor's death;
 13 providing liability protection for the person making a
 14 gift and for the donor's estate; amending s. 765.521,
 15 F.S.; conforming terms; amending s. 765.522, F.S.;

16 providing that the laws of this state govern the
 17 interpretation of a valid document of gift and that a
 18 document of gift is presumed to be valid; amending ss.
 19 765.53, 765.541, 765.542, 765.543, 765.544, and 765.545,
 20 F.S.; conforming terms; creating s. 765.547, F.S.;

21 requiring medical examiners and procurement organizations
 22 to cooperate and maximize opportunities for organ
 23 donations; authorizing the Florida Medical Examiners
 24 Commission to adopt rules; amending ss. 408.802 and
 25 408.820, F.S.; conforming terms; providing an effective
 26 date.

27
 28 Be It Enacted by the Legislature of the State of Florida:

29
30 Section 1. Section 765.511, Florida Statutes, is amended
31 to read:

32 765.511 Definitions.--As used in this part, the term:

33 (1) "Agency" means the Agency for Health Care
34 Administration.

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

38 (3)~~(1)~~ "Bank" or "storage facility" means a facility
39 licensed, accredited, or approved under the laws of any state
40 for storage of human bodies or body parts thereof.

41 (4)~~(2)~~ "Death" means the absence of life as determined, in
42 accordance with currently accepted medical standards, by the
43 irreversible cessation of all respiration and circulatory
44 function, or as determined, in accordance with s. 382.009, by
45 the irreversible cessation of the functions of the entire brain,
46 including the brain stem.

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

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

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

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

55 (9)~~(3)~~ "Donor" means an individual who makes an anatomical
56 a gift of all or part of his or her body.

57 (10) "Donor registry" means a database that contains
58 records of anatomical gifts and amendments to, or revocations
59 of, such gifts.

60 (11) "Eye bank" means an entity that is accredited by the
61 Eye Bank Association of America or otherwise regulated under
62 federal or state law to engage in the retrieval, screening,
63 testing, processing, storage, or distribution of human eye
64 tissue.

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

67 (13)~~(4)~~ "Hospital" means a hospital licensed, accredited,
68 or approved under the laws of any state and includes a hospital
69 operated by the United States Government or a state, or a
70 subdivision thereof, although not required to be licensed under
71 state laws.

72 (14) "Identification card" means an official
73 identification card issued by a governmental entity, state
74 agency, or subdivision thereof.

75 (15) "Organ procurement organization" means an entity that
76 is designated as an organ procurement organization by the
77 Secretary of the United States Department of Health and Human
78 Services and that engages in the retrieval, screening, testing,
79 processing, storage, or distribution of human organs.

80 (16) "Part of the body" or "body part" means an organ,
81 eye, or tissue of a human being. The term does not include the
82 whole body.

83 (17)~~(5)~~ "Physician" or "surgeon" means a physician or
84 surgeon licensed to practice under chapter 458 or chapter 459 or

85 similar laws of any state. "Surgeon" includes dental or oral
86 surgeon.

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

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

92 (20) "Reasonably available" means able to be contacted by
93 a procurement organization in a timely manner without undue
94 effort, and willing and able to act in a manner consistent with
95 existing medical protocols necessary for the making of an
96 anatomical gift.

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

100 (22) "Sign" or "signed" means, with the present intent to
101 authenticate or adopt a record, to execute or adopt a tangible
102 symbol, or attach to or logically associate an electronic
103 symbol, sound, or process with the record.

104 (23) "Tissue bank" means an entity that is accredited by
105 the American Association of Tissue Banks or otherwise regulated
106 under federal or state law to engage in the retrieval,
107 screening, testing, processing, storage, or distribution of
108 human tissue.

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

111 765.512 Persons who may make an anatomical gift.--

112 (1) Any person who may make a will may make an anatomical

113 ~~gift give all or part of his or her body for any purpose~~
114 ~~specified in s. 765.513. The gift is effective upon the death of~~
115 ~~the donor.~~

116 (a) If the decedent makes an anatomical gift by one of the
117 methods listed in s. 765.514(1), and in the absence of actual
118 notice of contrary indications by the decedent, the document or
119 entry in the donor ~~organ and tissue~~ registry is legally
120 sufficient evidence of the decedent's informed consent to donate
121 an anatomical gift.

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

128 (4) A donee may not accept an anatomical gift if the donee
129 has actual notice of contrary indications by the donor or actual
130 notice that an anatomical ~~a~~ gift by a member of a class is
131 opposed by a member of a prior class.

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

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

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

139 (b) The decedent's medical provider, family, or a third
140 party to furnish medical records requested concerning the

141 decedent's medical and social history.

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

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

147 765.513 ~~Persons and entities that may become~~ Donees;
148 purposes for which anatomical gifts may be made.--

149 (1) The following persons or entities may become donees of
150 anatomical gifts of bodies or parts of them for the purposes
151 stated:

152 (a) ~~(1)~~ Any procurement organization or accredited
153 ~~hospital, surgeon, or physician for~~ medical or dental school,
154 college, or university for education, ~~or~~ research, advancement
155 ~~of medical or dental science,~~ therapy, or transplantation.

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

159 (3) ~~Any bank or storage facility for~~ medical or dental
160 ~~education, research, advancement of medical or dental science,~~
161 ~~therapy, or transplantation.~~

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

164 (2) If multiple purposes are set forth in the document of
165 gift but are not set forth in any priority order, the anatomical
166 gift shall be used first for transplantation or therapy, if
167 suitable. If the gift cannot be used for transplantation or
168 therapy, the gift may be used for research or education.

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

175 Section 4. Section 765.514, Florida Statutes, is amended
 176 to read:

177 765.514 Manner of making anatomical gifts.--

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

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

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

183 (c) Signifying an intent to donate on his or her driver's
 184 license or identification card issued by the department ~~of~~
 185 ~~Highway Safety and Motor Vehicles~~. Revocation, suspension,
 186 expiration, or cancellation of the driver's license or
 187 identification card does not invalidate the gift.

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

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

196 (f) Expressing a wish to donate in a document other than a

197 will. The document must be signed by the donor in the presence
 198 of two witnesses who shall sign the document in the donor's
 199 presence. If the donor cannot sign, the document may be signed
 200 for him or her at the donor's direction and in his or her
 201 presence and the presence of two witnesses who must sign the
 202 document in the donor's presence. Delivery of the document of
 203 gift during the donor's lifetime is not necessary to make the
 204 gift valid. The following form of written document is sufficient
 205 for any person to make an anatomical gift ~~give all or part of~~
 206 ~~his or her body~~ for the purposes of this part:

207
 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
 212 indicate my desires:

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

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

235 (3) Any anatomical gift by a health care surrogate
 236 designated by the decedent pursuant to part II of this chapter
 237 or a member of a class designated in s. 765.512(3) must be made
 238 by a document signed by that person or made by that person's
 239 witnessed telephonic discussion, telegraphic message, or other
 240 recorded message.

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

243 765.515 Delivery of donor document.--

244 (1) If an anatomical ~~a~~ gift is made pursuant to s.
 245 765.521, the completed donor registration card shall be
 246 delivered to the department ~~of Highway Safety and Motor Vehicles~~
 247 and the department must communicate the donor's intent to the
 248 ~~organ and tissue~~ donor registry, but delivery is not necessary
 249 to the validity of the gift. If the donor withdraws the gift,
 250 the records of the department ~~of Highway Safety and Motor~~
 251 ~~Vehicles~~ must be updated to reflect such withdrawal and the
 252 department must communicate the withdrawal to the ~~organ and~~

253 ~~tissue~~ donor registry for the purpose of updating the registry.

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

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

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

267 765.5155 ~~Organ and tissue~~ Donor registry; education
 268 program.--

269 (1) The Legislature finds that:

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

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

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

281 (2) The agency ~~for Health Care Administration~~ and the
282 department ~~of Highway Safety and Motor Vehicles~~ shall jointly
283 contract for the operation of a ~~an organ and tissue~~ donor
284 registry and education program. The contractor shall be procured
285 by competitive solicitation pursuant to chapter 287,
286 notwithstanding any exemption in s. 287.057(5)(f). When awarding
287 the contract, priority shall be given to existing nonprofit
288 groups that are based within the state, have expertise working
289 with ~~organ and tissue~~ procurement organizations, have expertise
290 in conducting statewide organ and tissue donor public education
291 campaigns, and represent the needs of the organ and tissue
292 donation community in the state.

293 (3) The contractor shall be responsible for:

294 (a) The development, implementation, and maintenance of an
295 interactive web-based ~~organ and tissue~~ donor registry that,
296 through electronic means, allows for online organ donor
297 registration and the recording of organ and tissue donation
298 records submitted through the driver's license identification
299 program or through other sources.

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

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

306 (b) A continuing program to educate and inform medical
307 professionals, law enforcement agencies and officers, other
308 state and local government employees, high school students,

309 minorities, and the public about the laws of this state relating
 310 to anatomical gifts and the need for anatomical gifts.

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

314 2. The contractor shall coordinate with the head of a
 315 state agency or other political subdivision of the state, or his
 316 or her designee, to establish convenient times, dates, and
 317 locations for educating that entity's employees.

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

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

323 2. The characteristics of donors as determined from
 324 registry information submitted directly by the donors or by the
 325 department ~~of Highway Safety and Motor Vehicles~~;

326 3. The annual dollar amount of voluntary contributions
 327 received by the contractor;

328 4. A description of the educational campaigns and
 329 initiatives implemented during the year and an evaluation of
 330 their effectiveness in increasing enrollment on the registry;
 331 and

332 5. An analysis of Florida's registry compared with other
 333 states' donor registries.

334 (4) Costs for the ~~organ and tissue~~ donor registry and
 335 education program shall be paid by the agency ~~for Health Care~~
 336 ~~Administration~~ from the funds deposited into the Health Care

337 Trust Fund pursuant to ss. 320.08047 and 322.08, which are
 338 designated for maintaining the ~~organ and tissue~~ donor registry
 339 and education program. In addition, the contractor may receive
 340 and use voluntary contributions to help support the registry and
 341 provide education.

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

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

347 765.51551 ~~Organ and tissue~~ Donor registry; public records
 348 exemption.--

349 (1) Information held in the ~~organ and tissue~~ donor
 350 registry which identifies a donor is confidential and exempt
 351 from s. 119.07(1) and s. 24(a), Art. I of the State
 352 Constitution.

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

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

358 (b) Persons engaged in bona fide research if the person
 359 agrees to:

360 1. Submit a research plan to the agency that specifies the
 361 exact nature of the information requested and the intended use
 362 of the information;

363 2. Maintain the confidentiality of the records or
 364 information if personal identifying information is made

365 available to the researcher;

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

368 4. Not directly or indirectly contact, for any purpose,
369 any donor or donee.

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

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

376 765.516 Donor amendment ~~of the terms of~~ or the revocation
377 of anatomical ~~the~~ gift.--

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

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

383 (b) An oral statement that is made in the presence of two
384 persons, one of whom is ~~must~~ not ~~be~~ a family member, and
385 communicated to the donor's family or attorney or to the donee.
386 An oral statement is effective only if the procurement
387 organization, transplant hospital, or physician or technician
388 has actual notice of the oral amendment or revocation before an
389 incision is made to the decedent's body or an invasive procedure
390 to prepare the recipient has begun.

391 (c) A statement made during a terminal illness or injury
392 addressed to an attending physician, who must communicate the

393 | revocation of the gift to the procurement organization ~~that is~~
 394 | ~~certified by the state.~~

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

397 | (e) Removing his or her name from the ~~organ and tissue~~
 398 | donor registry.

399 | (f) A later-executed document of gift which amends or
 400 | revokes a previous anatomical gift or portion of an anatomical
 401 | gift, either expressly or by inconsistency.

402 | (g) The destruction or cancellation of the document of
 403 | gift or the destruction or cancellation of that portion of the
 404 | document of gift used to make the gift with the intent to revoke
 405 | the gift.

406 | (2) Any anatomical gift made by a will may also be amended
 407 | or revoked in the manner provided for the amendment or
 408 | revocation of wills or as provided in paragraph (1)(a)
 409 | ~~subsection (1).~~

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

412 | 765.517 Rights and duties at death.--

413 | (1) The donee, pursuant to ~~as specified under the~~
 414 | ~~provisions of s. 765.515(2),~~ may accept or reject an anatomical
 415 | ~~the gift.~~ If the donee accepts a gift ~~of the entire body or a~~
 416 | ~~part of the body~~ to be used for research or education ~~scientific~~
 417 | ~~purposes other than a transplant,~~ the donee may authorize
 418 | embalming and the use of the body in funeral services, subject
 419 | to the terms of the gift. If the gift is of a part of the body,
 420 | the donee shall cause the part to be removed without unnecessary

421 mutilation upon the death of the donor and before or after
422 embalming. After removal of the body part, custody of the
423 remainder of the body vests in the surviving spouse, next of
424 kin, or other persons under obligation to dispose of the body.

425 (2) The time of death shall be determined by a physician
426 who attends the donor at the donor's death or, if there is no
427 such physician, the physician who certifies the death. After
428 death, those physicians or the donor's primary care ~~and in the~~
429 ~~absence of other qualified personnel, this~~ physician may
430 participate in, but may ~~shall~~ not obstruct, the procedures to
431 preserve the donor's organs or tissues and may ~~shall~~ not be paid
432 or reimbursed for such participation ~~by~~, nor be associated with
433 or employed by, a ~~an organ~~ procurement organization, ~~tissue~~
434 ~~bank, or eye bank.~~ These physicians may ~~This physician shall~~ not
435 participate in the procedures for removing or transplanting a
436 part. However, this subsection does not prevent a physician from
437 serving in a voluntary capacity on the board of directors of a
438 procurement organization or participating on any board, council,
439 commission, or similar body related to the organ and tissue
440 procurement system.

441 (3) The ~~organ~~ procurement organizations ~~organization,~~
442 ~~tissue bank, or eye bank,~~ or hospital medical professionals
443 under the direction thereof, may perform any and all tests to
444 evaluate the deceased as a potential donor and any invasive
445 procedures on the deceased body in order to preserve the
446 potential donor's organs. These procedures do not include the
447 surgical removal of an organ or penetrating any body cavity,
448 specifically for the purpose of donation, until:

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

452 (b) If a properly executed ~~donor card or~~ document of gift
 453 cannot be located or the deceased's consent is not listed in the
 454 ~~organ and tissue~~ donor registry, a person specified in s.
 455 765.512(2) or (3) has been located, has been notified of the
 456 death, and has granted legal permission for the donation.

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

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

470 (6) The provisions of this part are subject to the laws of
 471 this state prescribing powers and duties with respect to
 472 autopsies.

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

476 (8) In determining whether an anatomical gift has been

477 made, amended, or revoked under this part, a person may rely
 478 upon the representation of an individual listed in s. 765.512,
 479 relating to the individual's relationship to the donor or
 480 prospective donor, unless the person knows that the
 481 representation is untrue.

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

484 765.521 Donations as part of driver license or
 485 identification card process.--

486 (1) The agency ~~for Health Care Administration~~ and the
 487 department ~~of Highway Safety and Motor Vehicles~~ shall develop
 488 and implement a program encouraging and allowing persons to make
 489 anatomical gifts as a part of the process of issuing
 490 identification cards and issuing and renewing driver licenses.
 491 The donor registration card distributed by the department ~~of~~
 492 ~~Highway Safety and Motor Vehicles~~ shall include the information
 493 required by the uniform donor card under s. 765.514 and such
 494 additional information as determined necessary by the
 495 department. The department shall also develop and implement a
 496 program to identify donors, which includes notations on
 497 identification cards, driver licenses, and driver records or
 498 such other methods as the department develops to clearly
 499 indicate the individual's intent to make an anatomical gift
 500 ~~donate the individual's organs, tissues, or eyes~~. A notation on
 501 an individual's driver license or identification card that the
 502 individual intends to make an anatomical gift ~~donate organs,~~
 503 ~~tissues, or eyes~~ satisfies all requirements for consent to organ
 504 or tissue donation. The agency ~~for Health Care Administration~~

505 shall provide the necessary supplies and forms from funds
 506 appropriated from general revenue or contributions from
 507 interested voluntary, nonprofit organizations. The department
 508 shall provide the necessary recordkeeping system from funds
 509 appropriated from general revenue. The department ~~of Highway~~
 510 ~~Safety and Motor Vehicles~~ and the agency ~~for Health Care~~
 511 ~~Administration~~ shall incur no liability in connection with the
 512 performance of any acts authorized herein.

513 (2) The department ~~of Highway Safety and Motor Vehicles,~~
 514 after consultation with and concurrence by the agency ~~for Health~~
 515 ~~Care Administration,~~ shall adopt rules to implement the
 516 provisions of this section according to the provisions of
 517 chapter 120.

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

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

523 765.522 Duty of ~~certain~~ hospital administrators; liability
 524 of hospital administrators and, ~~organ~~ procurement organizations,
 525 ~~eye banks, and tissue banks.--~~

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

529 (1) ~~(2)~~ If ~~Where,~~ based on accepted medical standards, a
 530 hospital patient is a suitable candidate for organ or tissue
 531 donation, the hospital administrator or the hospital
 532 administrator's designee shall, at or near the time of death,

CS/CS/HB 209

2009

533 notify the appropriate procurement organization ~~organ, eye, or~~
534 ~~tissue recovery program~~, which shall access the ~~organ and tissue~~
535 donor registry created by s. 765.5155 or any other donor
536 registry to ascertain the existence of an entry in the registry
537 which ~~that~~ has not been revoked, ~~a donor card~~, or a document of
538 gift executed by the decedent. In the absence of an entry in the
539 donor registry, a document of gift ~~donor card, organ donation~~
540 ~~sticker or organ donation imprint on a driver's license~~, or
541 other properly executed document, the procurement organization
542 ~~organ, eye, or tissue recovery program~~ shall request:

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

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

548
549 to consent to the anatomical gift ~~of all or any part~~ of the
550 decedent's body for any purpose specified in this part. Except
551 as provided in s. 765.512, in the absence of actual notice of
552 opposition, consent need only be obtained from the person or
553 persons in the highest priority class reasonably available.

554 (3) A document of gift is valid if ~~made pursuant to a~~
555 ~~request required by this section shall be~~ executed in accordance
556 with this part or the laws of the state or country where it was
557 executed and where the person making the anatomical gift was
558 domiciled, has a place of residence, or was a citizen at the
559 time the document of gift was executed ~~pursuant to s. 765.514.~~

560 (4) The agency ~~for Health Care Administration~~ shall

561 establish rules and guidelines concerning the education of
562 individuals who may be designated to perform the request and the
563 procedures to be used in making the request. The agency is
564 authorized to adopt rules concerning the documentation of the
565 request, where such request is made.

566 (5) If a document of gift is valid under this section, the
567 laws of this state govern the interpretation of the document of
568 gift.

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

572 (7)~~(5)~~ There shall be no civil or criminal liability
573 against any ~~organ~~ procurement organization, ~~eye bank, or tissue~~
574 ~~bank~~ certified under s. 765.542~~7~~, or against any hospital or
575 hospital administrator or designee who complies, ~~when complying~~
576 with the provisions of this part and agency ~~the rules of the~~
577 ~~agency for Health Care Administration~~ or if ~~when~~, in the
578 exercise of reasonable care, a request for organ donation is
579 inappropriate and the gift is not made according to this part
580 and agency ~~the rules of the agency for Health Care~~
581 ~~Administration.~~

582 (8)~~(6)~~ The hospital administrator or a designee shall, at
583 or near the time of death of a potential ~~organ~~ donor, directly
584 notify the affiliated organ procurement organization ~~designated~~
585 ~~by the United States Department of Health and Human Services of~~
586 the potential ~~organ~~ donor. This ~~This organ~~ procurement
587 organization must offer any organ from such a donor first to
588 patients on a Florida-based local or state organ sharing

CS/CS/HB 209

2009

589 transplant list. For the purpose of this subsection, the term
590 "transplant list" includes certain categories of national or
591 regional organ sharing for patients of exceptional need or
592 exceptional match, as approved or mandated by the Organ
593 Procurement and Transplantation Network, or its agent. This
594 notification may not be made to a tissue bank or eye bank in
595 lieu of the organ procurement organization unless the tissue
596 bank or eye bank is also designated as an organ procurement
597 organization ~~by the United States Department of Health and Human~~
598 ~~Services.~~

599 Section 12. Subsections (1), (5), and (6) of section
600 765.53, Florida Statutes, are amended to read:

601 765.53 Organ Transplant Advisory Council; membership;
602 responsibilities.--

603 (1) ~~There is hereby created within the agency for Health~~
604 ~~Care Administration~~ A statewide technical Organ Transplant
605 Advisory Council is created within the agency, consisting of 12
606 ~~twelve~~ members who are physicians licensed under chapter 458 or
607 chapter 459, to represent the interests of the public and the
608 clients of the Department of Health or the agency. ~~The members~~
609 ~~shall be physicians licensed according to chapter 458 or chapter~~
610 ~~459.~~ A person employed by the agency may not be appointed as a
611 member of the council.

612 (5) Members of the council shall receive no compensation,
613 but shall be reimbursed for per diem and travel expenses by the
614 agency ~~for Health Care Administration~~ in accordance with ~~the~~
615 ~~provisions of~~ s. 112.061 while engaged in the performance of
616 their duties.

617 (6) The responsibilities of the council shall be to
618 recommend to the agency ~~for Health Care Administration~~
619 indications for adult and pediatric organ transplants. The
620 council shall also formulate guidelines and standards for organ
621 transplants and for the development of End Stage Organ Disease
622 and Tissue/Organ Transplant programs. The recommendations,
623 guidelines, and standards developed by the council are
624 applicable only to those health programs funded through the
625 agency ~~for Health Care Administration~~.

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

628 765.541 Certification of procurement organizations; agency
629 responsibilities ~~engaged in the practice of cadaveric organ and~~
630 ~~tissue procurement.~~--The agency ~~for Health Care Administration~~
631 shall:

632 (1) Establish a program for the certification of
633 organizations, corporations ~~agencies~~, or other entities engaged
634 in the procurement of organs, tissues, and eyes for
635 transplantation. ~~†~~

636 (2) Adopt rules that set forth appropriate standards and
637 guidelines for the program in accordance with ss. 765.541-
638 765.546 and part II of chapter 408. These standards and
639 guidelines must be substantially based on the existing laws of
640 the Federal Government and this state and the existing standards
641 and guidelines of the United Network for Organ Sharing (UNOS),
642 the American Association of Tissue Banks (AATB), the South-
643 Eastern Organ Procurement Foundation (SEOPF), the North American
644 Transplant Coordinators Organization (NATCO), and the Eye Bank

645 Association of America (EBAA). In addition, the agency ~~for~~
646 ~~Health Care Administration~~ shall, before adopting these
647 standards and guidelines, seek input from all ~~organ~~ procurement
648 organizations, ~~tissue banks, and eye banks~~ based in this state. ~~;~~

649 (3) Collect, keep, and make available to the Governor and
650 the Legislature information regarding the numbers and
651 disposition of organs, and tissues, and eyes procured by each
652 certified procurement organization. ~~entity;~~

653 (4) Monitor procurement organizations ~~participating~~
654 ~~facilities and agencies~~ for program compliance. ~~;~~ ~~and~~

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

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

659 765.542 Requirements to engage in organ, tissue, or eye
660 ~~Certification of organ procurement organizations, tissue banks,~~
661 ~~and eye banks.--~~

662 (1) The requirements of part II of chapter 408 apply to
663 the provision of services that require licensure pursuant to ss.
664 765.541-765.546 and part II of chapter 408 and to entities
665 licensed or certified by or applying for such licensure or
666 certification from the agency ~~for Health Care Administration~~
667 pursuant to ss. 765.541-765.546. A person ~~An organization,~~
668 ~~agency, or other entity~~ may not engage in the practice of organ
669 procurement in this state without being designated as an organ
670 procurement organization ~~by the secretary of the United States~~
671 ~~Department of Health and Human Services~~ and being appropriately
672 certified by the agency ~~for Health Care Administration.~~ ~~As used~~

673 ~~in this subsection, the term "procurement" includes the~~
674 ~~retrieval, processing, or distribution of human organs. A~~
675 ~~physician or organ procurement organization based outside this~~
676 ~~state is exempt from these certification requirements if:~~

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

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

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

688 (3) A person ~~An organization, agency, or other entity~~ may
689 not engage in the practice of eye procurement in this state
690 without being appropriately certified as an eye bank by the
691 agency ~~for Health Care Administration. As used in this~~
692 ~~subsection, the term "procurement" includes the retrieval,~~
693 ~~processing, or distribution of human eye tissue. Funeral~~
694 ~~directors or direct disposers~~ who ~~that~~ retrieve eye tissue for
695 an eye bank certified under this subsection are exempt from the
696 certification requirements under this subsection.

697 (4) A limited certificate may be issued to a tissue bank
698 or eye bank, certifying only those components of procurement
699 which the bank has chosen to perform. The agency ~~for Health Care~~
700 ~~Administration~~ may issue a limited certificate if it determines

701 that the tissue bank or eye bank is adequately staffed and
 702 equipped to operate in conformity with the rules adopted under
 703 this section.

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

706 765.543 Organ and Tissue Procurement and Transplantation
 707 Advisory Board; creation; duties.--

708 (3) The board shall:

709 (a) Assist the agency ~~for Health Care Administration~~ in
 710 the development of necessary professional qualifications,
 711 including, but not limited to, the education, training, and
 712 performance of persons engaged in the various facets of organ
 713 and tissue procurement, processing, preservation, and
 714 distribution for transplantation;

715 (b) Assist the agency ~~for Health Care Administration~~ in
 716 monitoring the appropriate and legitimate expenses associated
 717 with organ and tissue procurement, processing, and distribution
 718 for transplantation and developing methodologies to ensure
 719 ~~assure~~ the uniform statewide reporting of data to facilitate the
 720 accurate and timely evaluation of the organ and tissue
 721 procurement and transplantation system;

722 (c) Provide assistance to the Florida Medical Examiners
 723 Commission in the development of appropriate procedures and
 724 protocols to ensure ~~assure~~ continued improvement in the approval
 725 and release of potential ~~organ and tissue~~ donors by the district
 726 medical examiners and associate medical examiners;

727 (d) Develop with and recommend to the agency ~~for Health~~
 728 ~~Care Administration~~ the necessary procedures and protocols

729 required to assure that all residents of this state have
 730 reasonable access to available organ and tissue transplantation
 731 therapy and that residents of this state can be reasonably
 732 assured that the statewide procurement transplantation system is
 733 ~~will be~~ able to fulfill their organ and tissue requirements
 734 within the limits of the available supply and according to the
 735 severity of their medical condition and need; and

736 (e) Develop with and recommend to the agency ~~for Health~~
 737 ~~Care Administration~~ any changes to the laws of this state or
 738 administrative rules or procedures ~~required~~ to ensure ~~assure~~
 739 that the statewide organ and tissue procurement and
 740 transplantation system is ~~will be~~ able to function smoothly,
 741 effectively, and efficiently, in accordance with the Federal
 742 Anatomical Gift Act and in a manner that assures the residents
 743 of this state that no person or entity profits from the
 744 altruistic voluntary donation of organs or tissues.

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

747 765.544 Fees; organ and tissue donor education and
 748 procurement.--

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

753 (a) An initial application fee of \$1,000 from organ
 754 procurement organizations and tissue banks and \$500 from eye
 755 banks.

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

757 priority, for the certification program, the advisory board,
758 maintenance of the ~~organ and tissue~~ donor registry, and the
759 organ and tissue donor education program ~~in the following~~
760 ~~amounts~~, which may not exceed \$35,000 per organization:

761 1. Each ~~general~~ organ procurement organization shall pay
762 the greater of \$1,000 or 0.25 percent of its total revenues
763 produced from procurement activity in this state by the
764 certificateholder during its most recently completed fiscal ~~year~~
765 or operational year.

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

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

775 (2) The agency ~~for Health Care Administration~~ shall
776 specify by rule the administrative penalties for the purpose of
777 ensuring adherence to the standards of quality and practice
778 required by this chapter, part II of chapter 408, and applicable
779 rules of the agency for continued certification.

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

783 (b) Moneys deposited in the trust fund pursuant to this
784 section must be used exclusively for the implementation,

785 administration, and operation of the certification program and
 786 the advisory board, for maintaining the ~~organ and tissue~~ donor
 787 registry, and for organ and tissue donor education.

788 (4) As used in this section, the term "procurement
 789 activity in this state" includes the bringing into this state
 790 for processing, storage, distribution, or transplantation of
 791 organs or tissues that are initially procured in another state
 792 or country.

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

795 765.545 Physician supervision of cadaveric organ and
 796 tissue procurement coordinators.--~~Organ~~ Procurement
 797 organizations, ~~tissue banks, and eye banks~~ may employ
 798 coordinators, who are registered nurses, physician's assistants,
 799 or other medically trained personnel who meet the relevant
 800 standards for ~~organ~~ procurement organizations, ~~tissue banks, or~~
 801 ~~eye banks~~ as adopted by the agency for Health Care
 802 Administration under s. 765.541, to assist in the medical
 803 management of organ donors or in the surgical procurement of
 804 cadaveric organs, tissues, or eyes for transplantation or
 805 research. A coordinator who assists in the medical management of
 806 organ donors or in the surgical procurement of cadaveric organs,
 807 tissues, or eyes for transplantation or research must do so
 808 under the direction and supervision of a ~~licensed~~ physician
 809 medical director pursuant to rules and guidelines ~~to be~~ adopted
 810 by the agency for Health Care Administration. With the exception
 811 of organ procurement surgery, this supervision may be indirect
 812 supervision. For purposes of this section, the term "indirect

813 supervision" means that the medical director is responsible for
814 the medical actions of the coordinator, that the coordinator is
815 operating under protocols expressly approved by the medical
816 director, and that the medical director or his or her physician
817 designee is always available, in person or by telephone, to
818 provide medical direction, consultation, and advice in cases of
819 organ, tissue, and eye donation and procurement. Although
820 indirect supervision is authorized under this section, direct
821 physician supervision is to be encouraged when appropriate.

822 Section 18. Section 765.547, Florida Statutes, is created
823 to read:

824 765.547 Cooperation between medical examiner and
825 procurement organization.--

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

830 (2) The Florida Medical Examiners Commission shall adopt
831 rules establishing cooperative responsibilities between medical
832 examiners and procurement organizations to facilitate and
833 expedite completion of the medical examiner's responsibilities
834 under chapter 406 in a manner that will maximize opportunities
835 to recover anatomical gifts.

836 (3) This part does not supersede any part of chapter 406
837 relating to medical examiners and the disposition of dead
838 bodies.

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

841 408.802 Applicability.--The provisions of this part apply
 842 to the provision of services that require licensure as defined
 843 in this part and to the following entities licensed, registered,
 844 or certified by the agency, as described in chapters 112, 383,
 845 390, 394, 395, 400, 429, 440, 483, and 765:

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

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

850 408.820 Exemptions.--Except as prescribed in authorizing
 851 statutes, the following exemptions shall apply to specified
 852 requirements of this part:

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

856 Section 21. This act shall take effect July 1, 2009.