

By Senator Oelrich

14-00506-09

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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  
10          relating to a donor's amendment or revocation of an  
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 to the person making a gift and  
15          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  
18          of a valid document of gift, and that a document of  
19          gift is presumed to be valid; amending ss. 765.541,  
20          765.542, 765.543, 765.53, 765.544, and 765.545, F.S.;  
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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

66       (12)~~(4)~~ "Hospital" means a hospital licensed, accredited,  
67 or approved under the laws of any state and includes a hospital  
68 operated by the United States Government or a state, or a  
69 subdivision thereof, although not required to be licensed under  
70 state laws.

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

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

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

82       (16)~~(5)~~ "Physician" or "surgeon" means a physician or  
83 surgeon licensed to practice under chapter 458 or chapter 459 or  
84 similar laws of any state. "Surgeon" includes dental or oral  
85 surgeon.

86       (17) "Procurement organization" means an organ procurement  
87 organization, eye bank, or tissue bank.

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88       (18) "Reasonably available" means able to be contacted by a  
89 procurement organization without undue effort and willing and  
90 able to act in a timely manner consistent with existing medical  
91 protocols necessary for the making of an anatomical gift.

92       (19) "Record" means information that is inscribed on a  
93 tangible medium or that is stored in an electronic or other  
94 medium and is retrievable in perceivable form.

95       (20) "Sign" or "signed" means, with the present intent to  
96 authenticate or adopt a record, to execute or adopt a tangible  
97 symbol, or attach to or logically associate an electronic  
98 symbol, sound, or process with the record.

99       (21) "Tissue bank" means an entity that is accredited by  
100 the American Association of Tissue Banks or otherwise regulated  
101 under federal or state law to engage in the retrieval,  
102 screening, testing, processing, storage, or distribution of  
103 human tissue.

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

106       765.512 Persons who may make an anatomical gift.—

107       (1) Any person who may make a will may make an anatomical  
108 gift ~~give all or part~~ of his or her body for any purpose  
109 specified in s. 765.513. The gift is effective upon the death of  
110 the donor.

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

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

123 (4) A donee may not accept an anatomical gift if the donee  
124 has actual notice of contrary indications by the donor or actual  
125 notice that an anatomical a gift by a member of a class is  
126 opposed by a member of a prior class.

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

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

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

134 (b) The decedent's medical provider, family, or a third  
135 party to furnish medical records requested concerning the  
136 decedent's medical and social history.

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

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

142 765.513 ~~Persons and entities that may become~~ Donees;  
143 purposes for which anatomical gifts may be made.—

144 (1) The following persons or entities may become donees of  
145 anatomical gifts ~~of bodies or parts of them~~ for the purposes

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146 stated:

147 ~~(a)(1)~~ Any procurement organization or accredited hospital,  
 148 ~~surgeon, or physician for~~ medical or dental school, college, or  
 149 university for education, ~~or~~ research, advancement of medical or  
 150 dental science, therapy, or transplantation.

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

154 ~~(3) Any bank or storage facility for medical or dental~~  
 155 ~~education, research, advancement of medical or dental science,~~  
 156 ~~therapy, or transplantation.~~

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

159 (2) If multiple purposes are set forth in the document of  
 160 gift but are not set forth in any priority order, the anatomical  
 161 gift shall be used first for transplantation or therapy, if  
 162 suitable. If the gift cannot be used for transplantation or  
 163 therapy, the gift may be used for research or education.

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

170 Section 4. Section 765.514, Florida Statutes, is amended to  
 171 read:

172 765.514 Manner of making anatomical gifts.—

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

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- 175 (a) Signing an organ and tissue donor card.
- 176 (b) Registering online with the organ and tissue donor  
177 registry.
- 178 (c) Signifying an intent to donate on his or her driver's  
179 license or identification card issued by the Department of  
180 Highway Safety and Motor Vehicles. Revocation, suspension,  
181 expiration, or cancellation of the driver's license or  
182 identification card does not invalidate the gift.
- 183 (d) Expressing a wish to donate in a living will or other  
184 advance directive.
- 185 (e) Executing a will that includes a provision indicating  
186 that the testator wishes to make an anatomical gift. The gift  
187 becomes effective upon the death of the testator without waiting  
188 for probate. If the will is not probated or if it is declared  
189 invalid for testamentary purposes, the gift is nevertheless  
190 valid to the extent that it has been acted upon in good faith.
- 191 (f) Expressing a wish to donate in a document of gift other  
192 than a will. The document must be signed by the donor in the  
193 presence of two witnesses who shall sign the document in the  
194 donor's presence. If the donor cannot sign, the document may be  
195 signed for him or her at the donor's direction and in his or her  
196 presence and the presence of two witnesses who must sign the  
197 document in the donor's presence. Delivery of the document of  
198 gift during the donor's lifetime is not necessary to make the  
199 gift valid. The following form of written document is sufficient  
200 for any person to make an anatomical gift ~~give all or part of~~  
201 ~~his or her body~~ for the purposes of this part:

UNIFORM DONOR CARD

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

207 I give:

208 (a) .... any needed organs, tissues, or eyes;

209 (b) .... only the following organs, tissues, or eyes

210 ...[Specify the organs, tissues, or eyes]...

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

213 (c) .... my body for anatomical study if needed.

214 Limitations or special wishes, if any:

215 ...(If applicable, list specific donee; this must be arranged in  
 216 advance with the donee.)...

217  
 218 Signed by the donor and the following witnesses in the presence  
 219 of each other:

221 ...(Signature of donor)...                      ...(Date of birth of donor)...

222 ...(Date signed)...    ...(City and State)...

224 ...(Witness)...    ...(Witness)...

225 ...(Address)...    ...(Address)...

226 (2) The anatomical gift may be made to a donee listed in s.  
 227 765.513, and the donee may be specified by name.

228 (3) An anatomical ~~Any~~ gift by a health care surrogate  
 229 designated by the decedent pursuant to part II of this chapter  
 230 or a member of a class designated in s. 765.512(3) must be made  
 231 by a document signed by that person or made by that person's  
 232 witnessed telephonic discussion, telegraphic message, or other



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233 recorded message.

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

236 765.515 Delivery of donor document.—

237 (1) If an anatomical a gift is made pursuant to s. 765.521,  
238 the completed donor registration card shall be delivered to the  
239 Department of Highway Safety and Motor Vehicles and the  
240 department must communicate the donor's intent to the ~~organ and~~  
241 ~~tissue~~ donor registry, but delivery is not necessary to the  
242 validity of the gift. If the donor withdraws the gift, the  
243 records of the Department of Highway Safety and Motor Vehicles  
244 must be updated to reflect such withdrawal and the department  
245 must communicate the withdrawal to the ~~organ and tissue~~ donor  
246 registry for the purpose of updating the registry.

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

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

258 Section 6. Subsection (2), paragraph (c) of subsection (3),  
259 and subsection (4) of section 765.5155, Florida Statutes, are  
260 amended to read:

261 765.5155 Organ and tissue donor registry; education

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262 program.—

263 (2) The agency ~~for Health Care Administration~~ and the  
264 Department of Highway Safety and Motor Vehicles shall jointly  
265 contract for the operation of an organ and tissue donor registry  
266 and education program. The contractor shall be procured by  
267 competitive solicitation pursuant to chapter 287,  
268 notwithstanding any exemption in s. 287.057(5)(f). When awarding  
269 the contract, priority shall be given to existing nonprofit  
270 groups that are based within the state, have expertise working  
271 with organ and tissue procurement organizations, have expertise  
272 in conducting statewide organ and tissue donor public education  
273 campaigns, and represent the needs of the organ and tissue  
274 donation community in the state.

275 (3) The contractor shall be responsible for:

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

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

281 2. The characteristics of donors as determined from  
282 registry information submitted directly by the donors or by the  
283 Department of Highway Safety and Motor Vehicles;

284 3. The annual dollar amount of voluntary contributions  
285 received by the contractor;

286 4. A description of the educational campaigns and  
287 initiatives implemented during the year and an evaluation of  
288 their effectiveness in increasing enrollment on the registry;  
289 and

290 5. An analysis of Florida's registry compared with other

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291 states' donor registries.

292 (4) Costs for the organ and tissue donor registry and  
293 education program shall be paid by the agency ~~for Health Care~~  
294 ~~Administration~~ from the funds deposited into the Health Care  
295 Trust Fund pursuant to ss. 320.08047 and 322.08, which are  
296 designated for maintaining the organ and tissue donor registry  
297 and education program. In addition, the contractor may receive  
298 and use voluntary contributions to help support the registry and  
299 provide education.

300 Section 7. Paragraph (a) of subsection (2) of section  
301 765.51551, Florida Statutes, is amended to read:

302 765.51551 Organ and tissue donor registry; public records  
303 exemption.—

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

305 (a) Organ, tissue, and eye procurement organizations that  
306 have been certified by the agency ~~for Health Care Administration~~  
307 for the purpose of ascertaining or effectuating the existence of  
308 a gift under s. 765.522.

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

311 765.516 Donor amendment ~~of the terms of~~ or ~~the~~ revocation  
312 of anatomical ~~the~~ gift.—

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

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

318 (b) An oral statement that is made in the presence of two  
319 persons, one of whom is ~~must~~ not ~~be~~ a family member, and

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320 communicated to the donor's family or attorney or to the donee.  
321 An oral statement is effective only if the procurement  
322 organization, transplant hospital, or physician or technician  
323 knows of the amendment or revocation before an incision is made  
324 to the decedent's body or an invasive procedure to prepare the  
325 recipient has begun.

326 (c) A statement made during a terminal illness or injury  
327 addressed to an attending physician, who must communicate the  
328 revocation of the gift to the procurement organization ~~that is~~  
329 ~~certified by the state.~~

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

331 (e) Removing his or her name from the ~~organ and tissue~~  
332 donor registry.

333 (f) A later-executed document of gift which amends or  
334 revokes a previous anatomical gift or portion of an anatomical  
335 gift, either expressly or by inconsistency.

336 (g) By the destruction or cancellation of the document of  
337 gift or the destruction or cancellation of that portion of the  
338 document of gift used to make the gift with the intent to revoke  
339 the gift.

340 (2) Any anatomical gift made by a will may also be amended  
341 or revoked in the manner provided for the amendment or  
342 revocation of wills or as provided in subsection (1).

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

345 765.517 Rights and duties at death.—

346 (1) The donee, pursuant to ~~as specified under the~~  
347 ~~provisions of~~ s. 765.515(2), may accept or reject an anatomical  
348 ~~the gift. If the donee accepts a gift of the entire body or a~~

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349 ~~part of the body~~ to be used for research or education ~~scientific~~  
 350 purposes ~~other than a transplant~~, the donee may authorize  
 351 embalming and the use of the body in funeral services, subject  
 352 to the terms of the gift. If the gift is of a part of the body,  
 353 the donee shall cause the part to be removed without unnecessary  
 354 mutilation upon the death of the donor and before or after  
 355 embalming. After removal of the body part, custody of the  
 356 remainder of the body vests in the surviving spouse, next of  
 357 kin, or other persons under obligation to dispose of the body.

358 (2) The time of death shall be determined by a physician  
 359 who attends the donor at the donor's death or, if there is no  
 360 such physician, the physician who certifies the death. After  
 361 death, those physicians or the patient's primary care physician  
 362 ~~and in the absence of other qualified personnel, this physician~~  
 363 may participate in, but may shall not obstruct, the procedures  
 364 to preserve the donor's organs or tissues and may shall not be  
 365 paid, ~~or reimbursed by, nor be associated with~~ or employed by a  
 366 ~~an organ procurement organization, tissue bank, or eye bank.~~  
 367 This physician may shall not participate in the procedures for  
 368 removing or transplanting a part.

369 (3) The ~~organ procurement organization, tissue bank, or eye~~  
 370 ~~bank,~~ or hospital medical professionals under the direction  
 371 thereof, may perform any and all tests to evaluate the deceased  
 372 as a potential donor and any invasive procedures on the deceased  
 373 body in order to preserve the potential donor's organs. These  
 374 procedures do not include the surgical removal of an organ or  
 375 penetrating any body cavity, specifically for the purpose of  
 376 donation, until:

377 (a) It has been verified that the deceased's consent to

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378 donate appears in the ~~organ and tissue~~ donor registry or a  
379 properly executed ~~donor card or~~ document of gift is located; or

380 (b) If a properly executed ~~donor card or~~ document of gift  
381 cannot be located or the deceased's consent is not listed in the  
382 ~~organ and tissue~~ donor registry, a person specified in s.  
383 765.512(2) or (3) has been located, has been notified of the  
384 death, and has granted legal permission for the donation.

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

389 (5) A person who acts in good faith and ~~without negligence~~  
390 in accord with the terms of this part or under the anatomical  
391 gift laws of another state or a foreign country, or attempts in  
392 good faith to do so, is not liable for damages in any civil  
393 action, ~~or~~ subject to prosecution for his or her acts in any  
394 criminal proceeding, or liable in any administrative proceeding.

395 (6) The provisions of this part are subject to the laws of  
396 this state prescribing powers and duties with respect to  
397 autopsies.

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

401 (8) In determining whether an anatomical gift has been  
402 made, amended, or revoked under this part, a person may rely  
403 upon representation of an individual listed in s. 765.512,  
404 relating to the individual's relationship to the donor or  
405 prospective donor, unless the person knows that the  
406 representation is untrue.

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

409 765.521 Donations as part of driver license or  
410 identification card process.—

411 (1) The agency ~~for Health Care Administration~~ and the  
412 Department of Highway Safety and Motor Vehicles shall develop  
413 and implement a program encouraging and allowing persons to make  
414 anatomical gifts as a part of the process of issuing  
415 identification cards and issuing and renewing driver licenses.  
416 The donor registration card distributed by the Department of  
417 Highway Safety and Motor Vehicles shall include the information  
418 required by the uniform donor card under s. 765.514 and such  
419 additional information as determined necessary by the  
420 department. The department shall also develop and implement a  
421 program to identify donors, which includes notations on  
422 identification cards, driver licenses, and driver records or  
423 such other methods as the department develops to clearly  
424 indicate the individual's intent to make an anatomical gift  
425 ~~donate the individual's organs, tissues, or eyes~~. A notation on  
426 an individual's driver license or identification card that the  
427 individual intends to make a gift ~~donate organs, tissues, or~~  
428 ~~eyes~~ satisfies all requirements for consent to organ or tissue  
429 donation. The agency ~~for Health Care Administration~~ shall  
430 provide the necessary supplies and forms from funds appropriated  
431 from general revenue or contributions from interested voluntary,  
432 nonprofit organizations. The department shall provide the  
433 necessary recordkeeping system from funds appropriated from  
434 general revenue. The Department of Highway Safety and Motor  
435 Vehicles and the agency ~~for Health Care Administration~~ shall

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436 incur no liability in connection with the performance of any  
437 acts authorized herein.

438 (2) The Department of Highway Safety and Motor Vehicles,  
439 after consultation with and concurrence by the agency ~~for Health~~  
440 ~~Care Administration~~, shall adopt rules to implement the  
441 provisions of this section according to the provisions of  
442 chapter 120.

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

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

448 765.522 Duty of ~~certain~~ hospital administrators; liability  
449 of hospital administrators and, ~~organ~~ procurement organizations,  
450 ~~eye banks, and tissue banks.~~

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

454 (1) ~~(2)~~ If ~~Where~~, based on accepted medical standards, a  
455 hospital patient is a suitable candidate for organ or tissue  
456 donation, the hospital administrator or the hospital  
457 administrator's designee shall, at or near the time of death,  
458 notify the appropriate procurement organization ~~organ, eye, or~~  
459 ~~tissue recovery program~~, which shall access the ~~organ and tissue~~  
460 donor registry created by s. 765.5155 or any other donor  
461 registry to ascertain the existence of an entry in the registry  
462 which ~~that~~ has not been revoked, ~~a donor card~~, or a document of  
463 gift executed by the decedent. In the absence of an entry in the  
464 donor registry or a document of gift, ~~donor card, organ donation~~



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465 ~~sticker or organ donation imprint on a driver's license,~~ or  
466 other properly executed document, the organ, eye, or tissue  
467 recovery program shall request:

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

470 (b) If the patient does not have a surrogate, or the  
471 surrogate is not reasonably available, any of the persons  
472 specified in s. 765.512(3), in the order and manner listed,  
473  
474 to consent to the gift of all or any part of the decedent's body  
475 for any purpose specified in this part. Except as provided in s.  
476 765.512, in the absence of actual notice of opposition, consent  
477 need only be obtained from the person or persons in the highest  
478 priority class reasonably available.

479 (3) A document of gift is valid if made pursuant to a  
480 request required by this section shall be executed in accordance  
481 with this part or the laws of the state or country where it was  
482 executed and where the person making the anatomical gift was  
483 domiciled, has a place of residence, or was a citizen at the  
484 time the document of gift was executed pursuant to s. 765.514.

485 (4) ~~The agency for Health Care Administration~~ shall  
486 establish rules and guidelines concerning the education of  
487 individuals who may be designated to perform the request and the  
488 procedures to be used in making the request. The agency is  
489 authorized to adopt rules concerning the documentation of the  
490 request, where such request is made.

491 (5) If a document of gift is valid under this section, the  
492 laws of this state govern the interpretation of the document of  
493 gift.

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

497       (7)~~(5)~~ There shall be no civil or criminal liability  
498 against any ~~organ~~ procurement organization, ~~eye bank, or tissue~~  
499 ~~bank~~ certified under s. 765.542, or against any hospital or  
500 hospital administrator or designee who complies, ~~when complying~~  
501 with the provisions of this part and agency ~~the rules of the~~  
502 ~~agency for Health Care Administration~~ or if ~~when~~, in the  
503 exercise of reasonable care, a request for organ donation is  
504 inappropriate and the gift is not made according to this part  
505 and agency ~~the rules of the agency for Health Care~~  
506 ~~Administration.~~

507       (8)~~(6)~~ The hospital administrator or a designee shall, at  
508 or near the time of death of a potential ~~organ~~ donor, directly  
509 notify the affiliated organ procurement organization ~~designated~~  
510 ~~by the United States Department of Health and Human Services of~~  
511 ~~the potential organ donor.~~ The ~~This~~ organ procurement  
512 organization must offer any organ from such a donor first to  
513 patients on a Florida-based local or state organ sharing  
514 transplant list. For the purpose of this subsection, the term  
515 "transplant list" includes certain categories of national or  
516 regional organ sharing for patients of exceptional need or  
517 exceptional match, as approved or mandated by the Organ  
518 Procurement and Transplantation Network, or its agent. This  
519 notification may not be made to a tissue bank or eye bank in  
520 lieu of the organ procurement organization unless the tissue  
521 bank or eye bank is also designated as an organ procurement  
522 organization ~~by the United States Department of Health and Human~~

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523 ~~Services.~~

524 Section 12. Section 765.541, Florida Statutes, is amended  
525 to read:

526 765.541 Certification of procurement organizations ~~engaged~~  
527 ~~in the practice of cadaveric organ and tissue procurement.~~The  
528 agency ~~for Health Care Administration~~ shall:

529 (1) Establish a program for the certification of  
530 organizations, corporations ~~agencies~~, or other entities engaged  
531 in the procurement of organs, tissues, and eyes for  
532 transplantation. ~~†~~

533 (2) Adopt rules that set forth appropriate standards and  
534 guidelines for the program in accordance with ss. 765.541-  
535 765.546 and part II of chapter 408. These standards and  
536 guidelines must be substantially based on the existing laws of  
537 the Federal Government and this state and the existing standards  
538 and guidelines of the United Network for Organ Sharing (UNOS),  
539 the American Association of Tissue Banks (AATB), the South-  
540 Eastern Organ Procurement Foundation (SEOPF), the North American  
541 Transplant Coordinators Organization (NATCO), and the Eye Bank  
542 Association of America (EBAA). In addition, the agency ~~for~~  
543 ~~Health Care Administration~~ shall, before adopting these  
544 standards and guidelines, seek input from all ~~organ~~ procurement  
545 organizations, ~~tissue banks, and eye banks~~ based in this state. ~~†~~

546 (3) Collect, keep, and make available to the Governor and  
547 the Legislature information regarding the numbers and  
548 disposition of organs, ~~and~~ tissues, and eyes procured by each  
549 certified procurement organization. ~~entity;†~~

550 (4) Monitor certified procurement organizations  
551 ~~participating facilities and agencies~~ for program compliance. ~~†~~

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552 and

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

555 Section 13. Section 765.542, Florida Statutes, is amended  
556 to read:

557 765.542 Certification of organ procurement organizations,  
558 tissue banks, and eye banks.—

559 (1) The requirements of part II of chapter 408 apply to the  
560 provision of services that require licensure pursuant to ss.  
561 765.541-765.546 and part II of chapter 408 and to entities  
562 licensed or certified by or applying for such licensure or  
563 certification from the agency ~~for Health Care Administration~~  
564 pursuant to ss. 765.541-765.546. An organization, agency, or  
565 other entity may not engage in the practice of organ procurement  
566 in this state without being designated as an organ procurement  
567 organization by the secretary of the United States Department of  
568 Health and Human Services and being appropriately certified by  
569 the agency ~~for Health Care Administration. As used in this~~  
570 ~~subsection, the term "procurement" includes the retrieval,~~  
571 ~~processing, or distribution of human organs.~~ A physician or  
572 organ procurement organization based outside this state is  
573 exempt from these certification requirements if:

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

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

579 (2) An organization, corporation ~~agency~~, or other entity  
580 may not engage in tissue procurement in this state unless it is

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581 appropriately certified as a tissue bank by the agency ~~for~~  
582 ~~Health Care Administration. As used in this subsection, the term~~  
583 ~~"procurement" includes any retrieval, processing, storage, or~~  
584 ~~distribution of human tissue for transplantation.~~

585 (3) An organization, corporation ~~agency~~, or other entity  
586 may not engage in the practice of eye procurement in this state  
587 without being appropriately certified as an eye bank by the  
588 ~~agency for Health Care Administration. As used in this~~  
589 ~~subsection, the term "procurement" includes the retrieval,~~  
590 ~~processing, or distribution of human eye tissue.~~ Funeral  
591 directors or direct disposers who ~~that~~ retrieve eye tissue for  
592 an eye bank certified under this subsection are exempt from the  
593 certification requirements under this subsection.

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

601 Section 14. Subsection (3) of section 765.543, Florida  
602 Statutes, is amended to read:

603 765.543 Organ and Tissue Procurement and Transplantation  
604 Advisory Board; creation; duties.-

605 (3) The board shall:

606 (a) Assist the agency ~~for Health Care Administration~~ in the  
607 development of necessary professional qualifications, including,  
608 but not limited to, the education, training, and performance of  
609 persons engaged in the various facets of organ and tissue

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610 procurement, processing, preservation, and distribution for  
611 transplantation;

612 (b) Assist the agency ~~for Health Care Administration~~ in  
613 monitoring the appropriate and legitimate expenses associated  
614 with organ and tissue procurement, processing, and distribution  
615 for transplantation and developing methodologies to assure the  
616 uniform statewide reporting of data to facilitate the accurate  
617 and timely evaluation of the organ and tissue procurement and  
618 transplantation system;

619 (c) Provide assistance to the Florida Medical Examiners  
620 Commission in the development of appropriate procedures and  
621 protocols to ensure the ~~assure~~ continued improvement in the  
622 approval and release of potential ~~organ and tissue~~ donors by the  
623 district medical examiners and associate medical examiners;

624 (d) Develop with and recommend to the agency ~~for Health~~  
625 ~~Care Administration~~ the necessary procedures and protocols  
626 required to assure that all residents of this state have  
627 reasonable access to available organ and tissue transplantation  
628 therapy and that residents of this state can be reasonably  
629 assured that the statewide procurement transplantation system is  
630 ~~will be~~ able to fulfill their organ and tissue requirements  
631 within the limits of the available supply and according to the  
632 severity of their medical condition and need; and

633 (e) Develop with and recommend to the agency ~~for Health~~  
634 ~~Care Administration~~ any changes to the laws of this state or  
635 administrative rules or procedures ~~required~~ to ensure ~~assure~~  
636 that the statewide organ and tissue procurement and  
637 transplantation system is ~~will be~~ able to function smoothly,  
638 effectively, and efficiently, in accordance with the Federal

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639 Anatomical Gift Act and in a manner that assures the residents  
640 of this state that no person or entity profits from the  
641 altruistic voluntary donation of organs or tissues.

642 Section 15. Subsections (1), (5), and (6) of section  
643 765.53, Florida Statutes, are amended to read:

644 765.53 Organ Transplant Advisory Council; membership;  
645 responsibilities.-

646 (1) ~~There is hereby created within the agency for Health~~  
647 ~~Care Administration~~ A statewide technical Organ Transplant  
648 Advisory Council is created within the agency, consisting of  
649 twelve members, who are physicians, to represent the interests  
650 of the public and the clients of the Department of Health or the  
651 agency. ~~The members shall be physicians licensed according to~~  
652 ~~chapter 458 or chapter 459.~~ A person employed by the agency may  
653 not be appointed as a member of the council.

654 (5) Members of the council shall receive no compensation,  
655 but shall be reimbursed for per diem and travel expenses by the  
656 agency ~~for Health Care Administration~~ in accordance with ~~the~~  
657 ~~provisions of~~ s. 112.061 while engaged in the performance of  
658 their duties.

659 (6) The responsibilities of the council shall be to  
660 recommend to the agency ~~for Health Care Administration~~  
661 indications for adult and pediatric organ transplants. The  
662 council shall also formulate guidelines and standards for organ  
663 transplants and for the development of End Stage Organ Disease  
664 and Tissue/Organ Transplant programs. The recommendations,  
665 guidelines, and standards developed by the council are  
666 applicable only to those health programs funded through the  
667 agency ~~for Health Care Administration~~.

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668 Section 16. Paragraph (b) of subsection (1) and subsection  
669 (2) of section 765.544, Florida Statutes, is amended to read:

670 765.544 Fees; organ and tissue donor education and  
671 procurement.—

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

676 (b) Annual fees to be used, in the following order of  
677 priority, for the certification program, the advisory board,  
678 maintenance of the organ and tissue donor registry, and the  
679 organ and tissue donor education program ~~in the following~~  
680 ~~amounts~~, which may not exceed \$35,000 per organization:

681 1. Each general organ procurement organization shall pay  
682 the greater of \$1,000 or 0.25 percent of its total revenues  
683 produced from procurement activity in this state by the  
684 certificateholder during its most recently completed fiscal ~~year~~  
685 or operational year.

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

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

695 (2) The agency ~~for Health Care Administration~~ shall specify  
696 by rule ~~the~~ administrative penalties for ~~the purpose of~~ ensuring



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697 adherence to the standards of quality and practice required by  
698 this chapter, part II of chapter 408, and applicable rules of  
699 the agency for continued certification.

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

702 765.545 Physician supervision of cadaveric organ and tissue  
703 procurement coordinators. ~~Organ~~ Procurement organizations,  
704 ~~tissue banks, and eye banks~~ may employ coordinators, who are  
705 registered nurses, physician's assistants, or other medically  
706 trained personnel who meet the relevant standards for organ  
707 procurement organizations, tissue banks, or eye banks ~~as~~ adopted  
708 by the agency ~~for Health Care Administration~~ under s. 765.541,  
709 to assist in the medical management of organ donors or in the  
710 surgical procurement of cadaveric organs, tissues, or eyes for  
711 transplantation or research. A coordinator who assists in the  
712 medical management of organ donors or in the surgical  
713 procurement of cadaveric organs, tissues, or eyes for  
714 transplantation or research must do so under the direction and  
715 supervision of a ~~licensed~~ physician medical director pursuant to  
716 rules and guidelines ~~to be~~ adopted by the agency ~~for Health Care~~  
717 ~~Administration~~. With the exception of organ procurement surgery,  
718 this supervision may be indirect supervision. For purposes of  
719 this section, the term "indirect supervision" means that the  
720 medical director is responsible for the medical actions of the  
721 coordinator, that the coordinator is operating under protocols  
722 expressly approved by the medical director, and that the medical  
723 director or his or her physician designee is always available,  
724 in person or by telephone, to provide medical direction,  
725 consultation, and advice in cases of organ, tissue, and eye

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726 donation and procurement. Although indirect supervision is  
727 authorized under this section, direct physician supervision is  
728 to be encouraged when appropriate.

729 Section 18. Section 765.547, Florida Statutes, is created  
730 to read:

731 765.547 Cooperation between medical examiner and  
732 procurement organization.-

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

737 (2) The Florida Medical Examiners Commission shall adopt  
738 rules to govern the working relationships of medical examiners  
739 and procurement organizations in order to facilitate organ  
740 donation.

741 (3) This part does not supersede any part of chapter 406  
742 relating to medical examiners and the disposition of dead  
743 bodies.

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

746 408.802 Applicability.—The provisions of this part apply to  
747 the provision of services that require licensure as defined in  
748 this part and to the following entities licensed, registered, or  
749 certified by the agency, as described in chapters 112, 383, 390,  
750 394, 395, 400, 429, 440, 483, and 765:

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

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

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755           408.820 Exemptions.—Except as prescribed in authorizing  
756 statutes, the following exemptions shall apply to specified  
757 requirements of this part:

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

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