A bill to be entitled 1 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, F.S.; revising provisions relating to a donee's use of an 11 anatomical gift at the time of the donor's death; 12 providing liability protection for the person making a 13 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 interpretation of a valid document of gift and that a 17 document of gift is presumed to be valid; amending ss. 18 19 765.53, 765.541, 765.542, 765.543, 765.544, and 765.545, F.S.; conforming terms; creating s. 765.547, F.S.; 20 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 408.820, F.S.; conforming terms; providing an effective 25 26 date. 27 28 Be It Enacted by the Legislature of the State of Florida:

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29 Section 1. Section 765.511, Florida Statutes, is amended 30 31 to read: 32 765.511 Definitions.--As used in this part, the term: (1) "Agency" means the Agency for Health Care 33 34 Administration. 35 "Anatomical gift" or "gift" means a donation of all or (2) 36 part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education. 37 (3) (1) "Bank" or "storage facility" means a facility 38 39 licensed, accredited, or approved under the laws of any state for storage of human bodies or body parts thereof. 40 (4) (2) "Death" means the absence of life as determined, in 41 42 accordance with currently accepted medical standards, by the irreversible cessation of all respiration and circulatory 43 44 function, or as determined, in accordance with s. 382.009, by the irreversible cessation of the functions of the entire brain, 45 including the brain stem. 46 47 (5) "Decedent" means a deceased individual whose body or 48 body parts may be, or are, the source of an anatomical gift. 49 "Department" means the Department of Highway Safety (6) 50 and Motor Vehicles. 51 "Disinterested witness" means a witness other than a (7) 52 person listed in s. 765.512(3) or other family member. "Document of gift" means any of the documents or 53 (8) 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.

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57 "Donor registry" means a database that contains (10)58 records of anatomical gifts and amendments to, or revocations 59 of, such gifts. "Eye bank" means an entity that is accredited by the 60 (11)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. (12) "Guardian" means a person appointed pursuant to 65 chapter 744. The term does not include a guardian ad litem. 66 67 (13) (4) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state and includes a hospital 68 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. (14) "Identification card" means an official 72 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, eye, or tissue of a human being. The term does not include the 81 82 whole body. (17) (5) "Physician" or "surgeon" means a physician or 83 84 surgeon licensed to practice under chapter 458 or chapter 459 or Page 3 of 31

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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 <u>a procurement organization in a timely manner without undue</u> 94 <u>effort, and willing and able to act in a manner consistent with</u> 95 <u>existing medical protocols necessary for the making of an</u> 96 anatomical gift.

97 <u>(21) "Record" means information that is inscribed on a</u> 98 <u>tangible medium or that is stored in an electronic or other</u> 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. Section 2. Subsections (1), (4), (5), (6), and (7) of 109 110 section 765.512, Florida Statutes, are amended to read: 111 765.512 Persons who may make an anatomical gift.--(1) Any person who may make a will may make an anatomical 112

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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.

(a) If the decedent makes an anatomical gift by one of the methods listed in s. 765.514(1), and in the absence of actual notice of contrary indications by the decedent, the document or entry in the <u>donor</u> organ and tissue registry is legally sufficient evidence of the decedent's informed consent to donate an anatomical gift.

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

(4) A donee may not accept an anatomical gift if the donee
has actual notice of contrary indications by the donor or actual
notice that <u>an anatomical</u> a gift by a member of a class is
opposed by a member of a prior class.

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

135 (6) <u>An anatomical</u> A gift of all or part of a body 136 authorizes:

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

(b) The decedent's medical provider, family, or a thirdparty to furnish medical records requested concerning the

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141 decedent's medical and social history.

(7) Once the <u>anatomical</u> gift has been made, the rights of
the donee are paramount to the rights of others, except as
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 <u>(1)</u> The following persons or entities may become donees of 150 <u>anatomical</u> gifts of bodies or parts of them for the purposes 151 stated:

152 <u>(a) (1)</u> Any procurement organization or accredited 153 hospital, surgeon, or physician for medical or dental <u>school</u>, 154 <u>college</u>, 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 <u>(b) (4)</u> 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.

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FLORIDA HOUSE OF REPRESENTATIVES	F	L	0	R		D	Α	н	0	U	S	Е	0	F	R	Е	Р	R	Е	S	Е	Ν	Т	Α	Т		V	Е	S
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169 However, The Legislature declares that the public (3) 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 to read: 176 177 765.514 Manner of making anatomical gifts.--A person may make an anatomical a gift of all or part 178 (1)179 of his or her body under s. 765.512(1) by: 180 Signing an organ and tissue donor card. (a) 181 (b) Registering online with the organ and tissue donor 182 registry. Signifying an intent to donate on his or her driver's 183 (C) 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 Expressing a wish to donate in a living will or other (d) 189 advance directive. 190 Executing a will that includes a provision indicating (e) 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 invalid for testamentary purposes, the gift is nevertheless 194 valid to the extent that it has been acted upon in good faith. 195 196 Expressing a wish to donate in a document other than a (f)

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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 presence. If the donor cannot sign, the document may be signed 199 for him or her at the donor's direction and in his or her 200 201 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 any needed organs, tissues, or eyes; (a) 215 (b) only the following organs, tissues, or eyes ... [Specify the organs, tissues, or eyes]... 216 217 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: ... (If applicable, list specific donee; this must be arranged in 221 222 advance with the donee.)... 223 224 Signed by the donor and the following witnesses in the presence Page 8 of 31

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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
               Any anatomical gift by a health care surrogate
           (3)
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
     witnessed telephonic discussion, telegraphic message, or other
239
240
     recorded message.
241
          Section 5. Section 765.515, Florida Statutes, is amended
242
     to read:
243
          765.515 Delivery of donor document.--
244
                If an anatomical a gift is made pursuant to s.
           (1)
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
     to the validity of the gift. If the donor withdraws the gift,
249
250
     the records of the department of Highway Safety and Motor
     Vehicles must be updated to reflect such withdrawal and the
251
252
     department must communicate the withdrawal to the organ and
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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.

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

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:

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

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

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

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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:

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

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 secure305 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,

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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:

The number of donors on the registry and an analysis of
 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 contributions327 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 other333 states' donor registries.

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

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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.--

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

353

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

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

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 or364 information if personal identifying information is made

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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 <u>anatomical</u> 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 <u>is</u> 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 <u>made</u> during a terminal illness or injury
392	addressed to an attending physician, who must communicate the
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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 <u>anatomical</u> gift made by a will may also be amended
407	or revoked in the manner provided for <u>the</u> amendment or
408	revocation of wills or as provided in <u>paragraph (1)(a)</u>
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 <u>an anatomical</u>
415	the gift. If the donee accepts a gift of the entire body or a
416	part of the body to be used for <u>research or education</u> 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
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421 mutilation upon the death of the donor and before or after 422 embalming. After removal of the <u>body</u> 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 The time of death shall be determined by a physician (2)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 The organ procurement organizations organization, (3) 442 tissue bank, or eye bank, or hospital medical professionals under the direction thereof, may perform any and all tests to 443 evaluate the deceased as a potential donor and any invasive 444 procedures on the deceased body in order to preserve the 445 potential donor's organs. These procedures do not include the 446 surgical removal of an organ or penetrating any body cavity, 447 448 specifically for the purpose of donation, until:

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449 It has been verified that the deceased's consent to (a) 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 If a properly executed donor card or document of gift (b) 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. A person who acts in good faith and without negligence 461 (5) 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 The provisions of this part are subject to the laws of (6) 471 this state prescribing powers and duties with respect to 472 autopsies. 473 The person making an anatomical gift and the donor's (7) estate are not liable for any injury or damages that result from 474 475 the making or use of the gift. 476 (8) In determining whether an anatomical gift has been

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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 $rac{\partial f}{\partial f}$
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 $_{m{ au}}$ 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 <u>make an anatomical gift</u>
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 <u>make an anatomical gift</u> donate organs,
503	tissues, or eyes satisfies all requirements for consent to organ
504	or tissue donation. The agency for Health Care Administration
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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.

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

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 <u>and</u>, organ procurement organizations, 525 cyc 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 <u>(1)(2)</u> <u>If</u> 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,

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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 gift executed by the decedent. In the absence of an entry in the 538 donor registry, a document of gift donor card, organ donation 539 540 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 in544 s. 765.512(2); or

(b) If the patient does not have a surrogate, or the surrogate is not reasonably available, any of the persons specified in s. 765.512(3), in the order and manner listed, 548

549 to consent to the <u>anatomical</u> 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 A document of gift is valid if made pursuant to a (3) 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 domiciled, has a place of residence, or was a citizen at the 558 559 time the document of gift was executed pursuant to s. 765.514. 560 The agency for Health Care Administration shall (4)

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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 $_{\tau}$ or against any hospital or hospital administrator or designee who complies, when complying 575 576 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 <u>(8)(6)</u> 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. <u>The This organ</u> procurement 587 organization must offer any organ from such a donor first to 588 patients on a Florida-based local or state organ sharing

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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 There is hereby created within the agency for Health (1)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 chapter 459, to represent the interests of the public and the 607 608 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.

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

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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 council shall also formulate guidelines and standards for organ 620 621 transplants and for the development of End Stage Organ Disease 622 and Tissue/Organ Transplant programs. The recommendations, 623 quidelines, 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 <u>procurement</u> organizations engaged
 629 in the practice of cadaveric organ and tissue procurement.--The
 630 agency for Health Care Administration shall:

(1) Establish a program for the certification of
organizations, <u>corporations</u> agencies, or other entities engaged
in the procurement of organs, tissues, and eyes for
transplantation.;

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

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645 Health Care Administration shall, before adopting these 646 standards and guidelines, seek input from all organ procurement 647 organizations, tissue banks, and eye banks based in this state.; 648 Collect, keep, and make available to the Governor and (3) 649 the Legislature information regarding the numbers and 650 disposition of organs, and tissues, and eyes procured by each 651 certified procurement organization. entity; 652 Monitor procurement organizations participating (4) 653 facilities and agencies for program compliance.; and 654 (5) Provide for the administration of the Organ and Tissue 655 Procurement and Transplantation Advisory Board. 656 Section 14. Section 765.542, Florida Statutes, is amended 657 to read: 658 765.542 Certification of organ procurement organizations 659 tissue banks, and eye banks. --660 (1)The requirements of part II of chapter 408 apply to 661 the provision of services that require licensure pursuant to ss. 662 765.541-765.546 and part II of chapter 408 and to entities 663 licensed or certified by or applying for such licensure or 664 certification from the agency for Health Care Administration 665 pursuant to ss. 765.541-765.546. A person An organization, 666 agency, or other entity may not engage in the practice of organ 667 procurement in this state without being designated as an organ 668 procurement organization by the secretary of the United States Department of Health and Human Services and being appropriately 669 certified by the agency for Health Care Administration. As used 670 in this subsection, the term "procurement" includes the 671 672 retrieval, processing, or distribution of human organs. A Page 24 of 31

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673 physician or organ procurement organization based outside this674 state is exempt from these certification requirements if:

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

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

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

686 A person An organization, agency, or other entity may (3) 687 not engage in the practice of eye procurement in this state 688 without being appropriately certified as an eye bank by the 689 agency for Health Care Administration. As used in this 690 subsection, the term "procurement" includes the retrieval, 691 processing, or distribution of human eye tissue. Funeral 692 directors or direct disposers who that retrieve eye tissue for 693 an eye bank certified under this subsection are exempt from the 694 certification requirements under this subsection.

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

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701 this section.

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

704 765.543 Organ and Tissue Procurement and Transplantation
 705 Advisory Board; creation; duties.--

706

(3) The board shall:

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

(b) Assist the agency for Health Care Administration in monitoring the appropriate and legitimate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to <u>ensure</u> assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;

(c) Provide assistance to the Florida Medical Examiners Commission in the development of appropriate procedures and protocols to <u>ensure</u> assure continued improvement in the approval and release of potential organ and tissue donors by the district medical examiners and associate medical examiners;

(d) Develop with and recommend to the agency for Health
Care Administration the necessary procedures and protocols
required to assure that all residents of this state have
reasonable access to available organ and tissue transplantation

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therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is will be able to fulfill their organ and tissue requirements within the limits of the available supply and according to the severity of their medical condition and need; and

734 Develop with and recommend to the agency for Health (e) 735 Care Administration any changes to the laws of this state or 736 administrative rules or procedures required to ensure assure 737 that the statewide organ and tissue procurement and transplantation system is will be able to function smoothly, 738 739 effectively, and efficiently, in accordance with the Federal 740 Anatomical Gift Act and in a manner that assures the residents 741 of this state that no person or entity profits from the 742 altruistic voluntary donation of organs or tissues.

743 Section 16. Section 765.544, Florida Statutes, is amended744 to read

745 765.544 Fees; organ and tissue donor education and 746 procurement.--

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

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

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

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757 organ and tissue donor education program in the following 758 amounts, which may not exceed \$35,000 per organization:

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

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

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

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

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

(b) Moneys deposited in the trust fund pursuant to this
section must be used exclusively for the implementation,
administration, and operation of the certification program and
the advisory board, for maintaining the organ and tissue donor

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785 registry, and for organ and tissue donor education.

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

791 Section 17. Section 765.545, Florida Statutes, is amended 792 to read:

793 765.545 Physician supervision of cadaveric organ and 794 tissue procurement coordinators.--Organ Procurement 795 organizations, tissue banks, and eye banks may employ 796 coordinators, who are registered nurses, physician's assistants, 797 or other medically trained personnel who meet the relevant 798 standards for organ procurement organizations, tissue banks, or 799 eye banks as adopted by the agency for Health Care 800 Administration under s. 765.541, to assist in the medical 801 management of organ donors or in the surgical procurement of 802 cadaveric organs, tissues, or eyes for transplantation or 803 research. A coordinator who assists in the medical management of 804 organ donors or in the surgical procurement of cadaveric organs, 805 tissues, or eyes for transplantation or research must do so 806 under the direction and supervision of a licensed physician 807 medical director pursuant to rules and guidelines to be adopted 808 by the agency for Health Care Administration. With the exception 809 of organ procurement surgery, this supervision may be indirect supervision. For purposes of this section, the term "indirect 810 811 supervision" means that the medical director is responsible for 812 the medical actions of the coordinator, that the coordinator is

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813 operating under protocols expressly approved by the medical 814 director, and that the medical director or his or her physician 815 designee is always available, in person or by telephone, to 816 provide medical direction, consultation, and advice in cases of 817 organ, tissue, and eye donation and procurement. Although 818 indirect supervision is authorized under this section, direct 819 physician supervision is to be encouraged when appropriate. 820 Section 18. Section 765.547, Florida Statutes, is created to read: 821 765.547 Cooperation between medical examiner and 822 823 procurement organization. --824 (1) A medical examiner and procurement organization shall 825 cooperate with each other in order to maximize opportunities to 826 recover anatomical gifts for the purpose of transplantation, therapy, research, or education. 827 The Florida Medical Examiners Commission shall adopt 828 (2) 829 rules establishing cooperative responsibilities between medical 830 examiners and procurement organizations to facilitate and 831 expedite completion of the medical examiner's responsibilities 832 under chapter 406 in a manner that will maximize opportunities 833 to recover anatomical gifts. 834 This part does not supersede any part of chapter 406 (3) 835 relating to medical examiners and the disposition of dead 836 bodies. 837 Section 19. Subsection (30) of section 408.802, Florida 838 Statutes, is amended to read: 839 408.802 Applicability.--The provisions of this part apply 840 to the provision of services that require licensure as defined Page 30 of 31

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841 in this part and to the following entities licensed, registered, 842 or certified by the agency, as described in chapters 112, 383, 843 390, 394, 395, 400, 429, 440, 483, and 765: 844 (30) Organ, and tissue, and eye procurement organizations 845 agencies, as provided under part V of chapter 765. 846 Section 20. Subsection (29) of section 408.820, Florida 847 Statutes, is amended to read: 848 408.820 Exemptions.--Except as prescribed in authorizing 849 statutes, the following exemptions shall apply to specified requirements of this part: 850 851 (29) Organ, and tissue, and eye procurement organizations 852 agencies, as provided under part V of chapter 765, are exempt 853 from s. 408.810(5)-(10). 854 Section 21. This act shall take effect July 1, 2009.

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