$\boldsymbol{B}\boldsymbol{y}$  the Committee on Health Regulation and Senator Oelrich

588-02137-09

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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 for the person making a gift and
15	for the donor's estate; amending s. 765.521, F.S.;
16	conforming terms; amending s. 765.522, F.S.; providing
17	that the laws of this state govern the interpretation
18	of a valid document of gift, and that a document of
19	gift is presumed to be valid; amending ss. 765.53,
20	765.541, 765.542, 765.543, 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.
28	

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

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588-02137-09 2009766c1 30 31 Section 1. Section 765.511, Florida Statutes, is amended to 32 read: 33 765.511 Definitions.-As used in this part, the term: (1) "Agency" means the Agency for Health Care 34 Administration. 35 36 (2) "Anatomical gift" or "gift" means a donation of all or 37 part of a human body to take effect after the donor's death and to be used for transplantation, therapy, research, or education. 38 (3) (1) "Bank" or "storage facility" means a facility 39 40 licensed, accredited, or approved under the laws of any state 41 for storage of human bodies or body parts thereof. 42 (4) (4) (2) "Death" means the absence of life as determined, in 43 accordance with currently accepted medical standards, by the 44 irreversible cessation of all respiration and circulatory 45 function, or as determined, in accordance with s. 382.009, by 46 the irreversible cessation of the functions of the entire brain, 47 including the brain stem. (5) "Decedent" means a deceased individual whose body or 48 49 body parts may be, or are, the source of an anatomical gift. 50 (6) "Disinterested witness" means a witness other than a 51 person listed in s. 765.512(3) or other family member. 52 (7) "Document of gift" means any of the documents or 53 mechanisms used in making an anatomical gift under s. 765.514. (8) (3) "Donor" means an individual who makes an anatomical 54 55 a gift of all or part of his or her body. 56 (9) "Donor registry" means a database that contains records 57 of anatomical gifts and amendments to, or revocations of, such

58 gifts.

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88	for transplantation, therapy, research, or education.
89	(18) "Procurement organization" means an organ procurement
90	organization, eye bank, or tissue bank.
91	(19) "Reasonably available" means able to be contacted by a
92	procurement organization in a timely manner without undue
93	effort, and willing and able to act in a manner consistent with
94	existing medical protocols necessary for the making of an
95	anatomical gift.
96	(20) "Record" means information that is inscribed on a
97	tangible medium or that is stored in an electronic or other
98	medium and is retrievable in perceivable form.
99	(21) "Sign" or "signed" means, with the present intent to
100	authenticate or adopt a record, to execute or adopt a tangible
101	symbol, or attach to or logically associate an electronic
102	symbol, sound, or process with the record.
103	(22) "Tissue bank" means an entity that is accredited by
104	the American Association of Tissue Banks or otherwise regulated
105	under federal or state law to engage in the retrieval,
106	screening, testing, processing, storage, or distribution of
107	human tissue.
108	Section 2. Subsections (1), (4), (5), (6), and (7) of
109	section 765.512, Florida Statutes, are amended to read:
110	765.512 Persons who may make an anatomical gift
111	(1) Any person who may make a will may <u>make an anatomical</u>
112	gift give all or part of his or her body <del>for any purpose</del>
113	specified in s. 765.513. The gift is effective upon the death of
114	the donor.
115	(a) If the decedent makes an anatomical gift by one of the
116	methods listed in s. $765.514(1)$ , and in the absence of actual

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588-02137-09 2009766c1 117 notice of contrary indications by the decedent, the document or 118 entry in the donor organ and tissue registry is legally sufficient evidence of the decedent's informed consent to donate 119 120 an anatomical gift. (b) An anatomical gift made by a gualified donor and not 121 122 revoked by the donor, as provided in s. 765.516, is irrevocable 123 after the donor's death. A family member, quardian, 124 representative ad litem, or health care surrogate may not 125 modify, deny, or prevent a donor's wish or intent to make an anatomical gift after the donor's death. 126 127 (4) A donee may not accept an anatomical gift if the donee 128 has actual notice of contrary indications by the donor or actual 129 notice that an anatomical  $\frac{}{a}$  gift by a member of a class is 130 opposed by a member of a prior class. 131 (5) The person authorized by subsection (3) may make the 132 anatomical gift after the decedent's death or immediately before 133 the decedent's death. 134 (6) An anatomical A gift of all or part of a body authorizes: 135 (a) Any examination necessary to assure medical 136 137 acceptability of the gift for the purposes intended. 138 (b) The decedent's medical provider, family, or a third 139 party to furnish medical records requested concerning the 140 decedent's medical and social history. 141 (7) Once the anatomical gift has been made, the rights of 142 the donee are paramount to the rights of others, except as 143 provided by s. 765.517. 144 Section 3. Section 765.513, Florida Statutes, is amended to 145 read:

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588-02137-09 2009766c1 146 765.513 Persons and entities that may become Donees; 147 purposes for which anatomical gifts may be made.-148 (1) The following persons or entities may become donees of 149 anatomical gifts of bodies or parts of them for the purposes 150 stated: 151 (a) (1) Any procurement organization or accredited hospital, 152 surgeon, or physician for medical or dental school, college, or 153 university for education, or research, advancement of medical or dental science, therapy, or transplantation. 154 155 (2) Any accredited medical or dental school, college, or 156 university for education, research, advancement of medical or 157 dental science, or therapy. 158 (3) Any bank or storage facility for medical or dental education, research, advancement of medical or dental science, 159 160 therapy, or transplantation. 161 (b) (4) Any individual specified by name for therapy or 162 transplantation needed by him or her. 163 (2) If multiple purposes are set forth in the document of gift but are not set forth in any priority order, the anatomical 164 165 gift shall be used first for transplantation or therapy, if 166 suitable. If the gift cannot be used for transplantation or 167 therapy, the gift may be used for research or education. 168 (3) However, The Legislature declares that the public 169 policy of this state prohibits restrictions on the possible recipients of an anatomical gift on the basis of race, color, 170 171 religion, gender sex, national origin, age, physical disability 172 handicap, health status, marital status, or economic status, and 173 such restrictions are hereby declared void and unenforceable. 174 Section 4. Section 765.514, Florida Statutes, is amended to

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588-02137-09 2009766c1 175 read: 176 765.514 Manner of making anatomical gifts.-177 (1) A person may make an anatomical a gift of all or part 178 of his or her body under s. 765.512(1) by: 179 (a) Signing an organ and tissue donor card. 180 (b) Registering online with the organ and tissue donor 181 registry. 182 (c) Signifying an intent to donate on his or her driver's 183 license or identification card issued by the Department of Highway Safety and Motor Vehicles. Revocation, suspension, 184 185 expiration, or cancellation of the driver's license or 186 identification card does not invalidate the gift. 187 (d) Expressing a wish to donate in a living will or other 188 advance directive. 189 (e) Executing a will that includes a provision indicating 190 that the testator wishes to make an anatomical gift. The gift 191 becomes effective upon the death of the testator without waiting 192 for probate. If the will is not probated or if it is declared 193 invalid for testamentary purposes, the gift is nevertheless 194 valid to the extent that it has been acted upon in good faith. 195 (f) Expressing a wish to donate in a document other than a 196 will. The document must be signed by the donor in the presence 197 of two witnesses who shall sign the document in the donor's 198 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 presence and the presence of two witnesses who must sign the 201 document in the donor's presence. Delivery of the document of 202 gift during the donor's lifetime is not necessary to make the 203 gift valid. The following form of written document is sufficient

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204
     for any person to make an anatomical gift give all or part of
205
     his or her body for the purposes of this part:
206
                              UNIFORM DONOR CARD
207
208
     The undersigned hereby makes this anatomical gift, if medically
209
     acceptable, to take effect on death. The words and marks below
210
     indicate my desires:
211
     I give:
212
           (a) .... any needed organs, tissues, or eyes;
213
           (b) .... only the following organs, tissues, or eyes
214
                ...[Specify the organs, tissues, or eyes]...
215
     for the purpose of transplantation, therapy, medical research,
216
     or education;
217
           (c) .... my body for anatomical study if needed.
218
     Limitations or special wishes, if any:
219
      ... (If applicable, list specific donee; this must be arranged in
220
                         advance with the donee.)...
221
222
     Signed by the donor and the following witnesses in the presence
223
     of each other:
224
225
     ... (Signature of donor)... ... (Date of birth of donor)...
226
     ... (Date signed) ...
                                                  ... (City and State) ...
227
228
                                                         ... (Witness) ...
     ... (Witness) ...
229
     ... (Address) ...
                                                         ... (Address) ...
230
           (2) The anatomical gift may be made to a donee listed in s.
231
     765.513, and the donee may be specified by name.
232
           (3) Any anatomical gift by a health care surrogate
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588-02137-09 2009766c1 233 designated by the decedent pursuant to part II of this chapter 234 or a member of a class designated in s. 765.512(3) must be made 235 by a document signed by that person or made by that person's 236 witnessed telephonic discussion, telegraphic message, or other 237 recorded message. 238 Section 5. Section 765.515, Florida Statutes, is amended to 239 read: 240 765.515 Delivery of donor document.-241 (1) If an anatomical a gift is made pursuant to s. 765.521, the completed donor registration card shall be delivered to the 242 243 Department of Highway Safety and Motor Vehicles and the 244 department must communicate the donor's intent to the organ and 245 tissue donor registry, but delivery is not necessary to the 246 validity of the gift. If the donor withdraws the gift, the 247 records of the Department of Highway Safety and Motor Vehicles 248 must be updated to reflect such withdrawal and the department 249 must communicate the withdrawal to the organ and tissue donor 250 registry for the purpose of updating the registry. 251 (2) If an anatomical a gift is made by the donor to a 252 specified donee, the document of gift, other than a will, may be

252 specified donee, the document <u>of gift</u>, other than a will, may be 253 delivered to the donee to expedite the appropriate procedures 254 immediately after death, but delivery is not necessary to the 255 validity of the gift. <u>The Such</u> document <u>of gift</u> may be deposited 256 in any hospital, bank, storage facility, or registry office that 257 accepts such documents for safekeeping or to facilitate the 258 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.

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588-02137-09 2009766c1 262 Section 6. Section 765.5155, Florida Statutes, is amended 263 to read: 264 765.5155 Organ and tissue Donor registry; education 265 program.-266 (1) The Legislature finds that: 267 (a) There is a shortage of organ and tissue donors in this 268 state willing to provide the organs and tissue that could save 269 lives or enhance the quality of life for many persons. 270 (b) There is a need to encourage the various minority 271 populations of this state to donate organs and tissue. 272 (c) A statewide organ and tissue donor registry having an 273 online donor registration process coupled with an enhanced 274 program of donor education will lead to an increase in the 275 number of organ and tissue donors registered in this state, thus 276 affording more persons who are awaiting organ or tissue 277 transplants the opportunity for a full and productive life. 278 (2) The agency for Health Care Administration and the 279 Department of Highway Safety and Motor Vehicles shall jointly 280 contract for the operation of a an organ and tissue donor 281 registry and education program. The contractor shall be procured 282 by competitive solicitation pursuant to chapter 287, 283 notwithstanding any exemption in s. 287.057(5)(f). When awarding 284 the contract, priority shall be given to existing nonprofit 285 groups that are based within the state, have expertise working 286 with organ and tissue procurement organizations, have expertise 287 in conducting statewide organ and tissue donor public education 288 campaigns, and represent the needs of the organ and tissue 289 donation community in the state.

290

(3) The contractor shall be responsible for:

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588-02137-09 291 (a) The development, implementation, and maintenance of an 292 interactive web-based organ and tissue donor registry that, 293 through electronic means, allows for online organ donor 294 registration and the recording of organ and tissue donation 295 records submitted through the driver's license identification 296 program or through other sources. 297 1. The registry must be maintained in a manner that allows, 298 through electronic and telephonic methods, immediate access to organ and tissue donation records 24 hours a day, 7 days a week. 299 300 2. Access to the registry must be through coded and secure 301 means to protect the integrity of the data in the registry. 302 (b) A continuing program to educate and inform medical 303 professionals, law enforcement agencies and officers, other

304 state and local government employees, high school students, 305 minorities, and the public about the laws of this state relating 306 to anatomical gifts and the need for anatomical gifts.

307 1. Existing community resources, when available, must be 308 used to support the program and volunteers may assist the 309 program to the maximum extent possible.

310 2. The contractor shall coordinate with the head of a state 311 agency or other political subdivision of the state, or his or 312 her designee, to establish convenient times, dates, and 313 locations for educating that entity's employees.

314 (c) Preparing and submitting an annual written report to 315 the agency for Health Care Administration by December 31 of each 316 year. The report must include:

317 1. The number of donors on the registry and an analysis of 318 the registration rates by location and method of donation;

- 319
- 2. The characteristics of donors as determined from

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588-02137-09 2009766c1 320 registry information submitted directly by the donors or by the 321 Department of Highway Safety and Motor Vehicles; 322 3. The annual dollar amount of voluntary contributions 323 received by the contractor; 324 4. A description of the educational campaigns and 325 initiatives implemented during the year and an evaluation of 326 their effectiveness in increasing enrollment on the registry; 327 and 328 5. An analysis of Florida's registry compared with other 329 states' donor registries. 330 (4) Costs for the organ and tissue donor registry and 331 education program shall be paid by the agency for Health Care 332 Administration from the funds deposited into the Health Care 333 Trust Fund pursuant to ss. 320.08047 and 322.08, which are 334 designated for maintaining the organ and tissue donor registry 335 and education program. In addition, the contractor may receive 336 and use voluntary contributions to help support the registry and 337 provide education. 338 (5) The organ and tissue donor registry established by this 339 section is designated as the "Joshua Abbott Organ and Tissue 340 Registry."

341 Section 7. Section 765.51551, Florida Statutes, is amended 342 to read

343 765.51551 Organ and tissue Donor registry; public records 344 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.
(2) Such information may be disclosed to the following:

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588-02137-09 2009766c1 349 (a) Organ, tissue, and eye Procurement organizations that 350 have been certified by the agency for Health Care Administration 351 for the purpose of ascertaining or effectuating the existence of 352 a gift under s. 765.522. 353 (b) Persons engaged in bona fide research if the person 354 agrees to: 355 1. Submit a research plan to the agency that specifies the 356 exact nature of the information requested and the intended use 357 of the information; 358 2. Maintain the confidentiality of the records or 359 information if personal identifying information is made 360 available to the researcher; 361 3. Destroy any confidential records or information obtained 362 after the research is concluded; and 363 4. Not directly or indirectly contact, for any purpose, any 364 donor or donee. 365 (3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed 366 367 on October 2, 2013, unless reviewed and saved from repeal through reenactment by the Legislature. 368 369 Section 8. Section 765.516, Florida Statutes, is amended to 370 read: 371 765.516 Donor amendment of the terms of or the revocation 372 of anatomical the gift.-(1) A donor may amend the terms of or revoke an anatomical 373 374 gift by: 375 (a) The execution and delivery to the donee of a signed 376 statement witnessed by at least two adults, at least one of whom 377 is a disinterested witness.

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

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407 (1) The donee, pursuant to as specified under the 408 provisions of s. 765.515(2), may accept or reject an anatomical 409 the gift. If the donee accepts a gift of the entire body or a 410 part of the body to be used for research or education scientific 411 purposes other than a transplant, the donee may authorize 412 embalming and the use of the body in funeral services, subject 413 to the terms of the gift. If the gift is of a part of the body, 414 the donee shall cause the part to be removed without unnecessary mutilation upon the death of the donor and before or after 415 416 embalming. After removal of the body part, custody of the 417 remainder of the body vests in the surviving spouse, next of 418 kin, or other persons under obligation to dispose of the body.

419 (2) The time of death shall be determined by a physician 420 who attends the donor at the donor's death or, if there is no 421 such physician, the physician who certifies the death. After 422 death, those physicians or the donor's primary care and in the 423 absence of other qualified personnel, this physician may 424 participate in, but may shall not obstruct, the procedures to 425 preserve the donor's organs or tissues and may shall not be paid 426 or reimbursed for such participation by, nor be associated with 427 or employed by, a, an organ procurement organization, tissue 428 bank, or eye bank. These physicians may This physician shall not 429 participate in the procedures for removing or transplanting a 430 part. However, this subsection does not prevent a physician from 431 serving in a voluntary capacity on the board of directors of a 432 procurement organization or participating on any board, council, 433 commission, or similar body related to the organ and tissue 434 procurement system.

435

(3) The organ procurement organizations organization,

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436 tissue bank, or eye bank, or hospital medical professionals 437 under the direction thereof, may perform any and all tests to 438 evaluate the deceased as a potential donor and any invasive 439 procedures on the deceased body in order to preserve the 440 potential donor's organs. These procedures do not include the 441 surgical removal of an organ or penetrating any body cavity, 442 specifically for the purpose of donation, until:

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

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

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

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

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

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588-02137-09 2009766c1 465 (7) The person making an anatomical gift and the donor's 466 estate are not liable for any injury or damages that result from 467 the making or use of the gift. 468 (8) In determining whether an anatomical gift has been made, amended, or revoked under this part, a person may rely 469 470 upon the representation of an individual listed in s. 765.512, 471 relating to the individual's relationship to the donor or 472 prospective donor, unless the person knows that the 473 representation is untrue. 474 Section 10. Section 765.521, Florida Statutes, is amended 475 to read: 476 765.521 Donations as part of driver license or 477 identification card process.-478 (1) The agency for Health Care Administration and the 479 Department of Highway Safety and Motor Vehicles shall develop 480 and implement a program encouraging and allowing persons to make 481 anatomical gifts as a part of the process of issuing 482 identification cards and issuing and renewing driver licenses. 483 The donor registration card distributed by the Department of 484 Highway Safety and Motor Vehicles shall include the information 485 required by the uniform donor card under s. 765.514 and such 486 additional information as determined necessary by the 487 department. The department shall also develop and implement a 488 program to identify donors  $\tau$  which includes notations on 489 identification cards, driver licenses, and driver records or 490 such other methods as the department develops to clearly 491 indicate the individual's intent to make an anatomical gift 492 donate the individual's organs, tissues, or eyes. A notation on 493 an individual's driver license or identification card that the

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494 individual intends to make an anatomical gift donate organs, 495 tissues, or eyes satisfies all requirements for consent to organ 496 or tissue donation. The agency for Health Care Administration 497 shall provide the necessary supplies and forms from funds 498 appropriated from general revenue or contributions from 499 interested voluntary, nonprofit organizations. The department 500 shall provide the necessary recordkeeping system from funds 501 appropriated from general revenue. The Department of Highway 502 Safety and Motor Vehicles and the agency for Health Care 503 Administration shall incur no liability in connection with the 504 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.

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

513 Section 11. Section 765.522, Florida Statutes, is amended 514 to read:

515 765.522 Duty of certain hospital administrators; liability 516 of hospital administrators and, organ procurement organizations, 517 eye banks, and tissue banks.-

518 (1) When used in this section, "hospital" means any 519 establishment licensed under chapter 395 except psychiatric and 520 rehabilitation hospitals.

521 (1) (2) If Where, based on accepted medical standards, a 522 hospital patient is a suitable candidate for organ or tissue

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588-02137-09 2009766c1 523 donation, the hospital administrator or the hospital 524 administrator's designee shall, at or near the time of death, 525 notify the appropriate procurement organization organ, eye, or 526 tissue recovery program, which shall access the organ and tissue 527 donor registry created by s. 765.5155 or any other donor 528 registry to ascertain the existence of an entry in the registry 529 which that has not been revoked, a donor card, or a document of 530 gift executed by the decedent. In the absence of an entry in the 531 donor registry, a document of gift donor card, organ donation 532 sticker or organ donation imprint on a driver's license, or 533 other properly executed document, the procurement organization 534 organ, eye, or tissue recovery program shall request: 535 (a) The patient's health care surrogate, as authorized in 536 s. 765.512(2); or 537 (b) If the patient does not have a surrogate, or the 538 surrogate is not reasonably available, any of the persons 539 specified in s. 765.512(3), in the order and manner listed, 540 541 to consent to the anatomical gift of all or any part of the 542 decedent's body for any purpose specified in this part. Except as provided in s. 765.512, in the absence of actual notice of 543 544 opposition, consent need only be obtained from the person or 545 persons in the highest priority class reasonably available. 546 (3) A document of gift is valid if made pursuant to a 547 request required by this section shall be executed in accordance 548 with this part or the laws of the state or country where it was 549 executed and where the person making the anatomical gift was 550 domiciled, has a place of residence, or was a citizen at the 551 time the document of gift was executed <del>pursuant to s. 765.514</del>.

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552	(4) The agency for Health Care Administration shall
553	establish rules and guidelines concerning the education of
554	individuals who may be designated to perform the request and the
555	procedures to be used in making the request. The agency is
556	authorized to adopt rules concerning the documentation of the
557	request, where such request is made.
558	(5) If a document of gift is valid under this section, the
559	laws of this state govern the interpretation of the document of
560	gift.
561	(6) A document of gift or amendment of an anatomical gift
562	is presumed to be valid unless it was not validly executed or
563	was revoked.
564	(7) <del>(5)</del> There shall be no civil or criminal liability
565	against any <del>organ</del> procurement organization <del>, eye bank, or tissue</del>
566	$rac{bank}{bank}$ certified under s. 765.542 $_{ au}$ or against any hospital or
567	hospital administrator or designee <u>who complies</u> , when complying
568	with the provisions of this part and <u>agency</u> <del>the</del> rules <del>of the</del>
569	agency for Health Care Administration or <u>if</u> when, in the
570	exercise of reasonable care, a request for organ donation is
571	inappropriate and the gift is not made according to this part
572	and <u>agency the</u> rules <del>of the agency for Health Care</del>
573	Administration.
574	<u>(8)<del>(</del>6)</u> The hospital administrator or a designee shall, at
575	or near the time of death of a potential <del>organ</del> donor, directly
576	notify the affiliated organ procurement organization designated
577	by the United States Department of Health and Human Services of
578	the potential organ donor. The <del>This</del> organ procurement
579	organization must offer any organ from such a donor first to
580	patients on a Florida-based local or state organ sharing

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588-02137-09 2009766c1 581 transplant list. For the purpose of this subsection, the term 582 "transplant list" includes certain categories of national or 583 regional organ sharing for patients of exceptional need or 584 exceptional match, as approved or mandated by the Organ 585 Procurement and Transplantation Network, or its agent. This 586 notification may not be made to a tissue bank or eye bank in 587 lieu of the organ procurement organization unless the tissue 588 bank or eye bank is also designated as an organ procurement 589 organization by the United States Department of Health and Human 590 Services. 591 Section 12. Subsections (1), (5), and (6) of section 592 765.53, Florida Statutes, are amended to read: 593 765.53 Organ Transplant Advisory Council; membership; 594 responsibilities.-595 (1) There is hereby created within the agency for Health

596 Care Administration A statewide technical Organ Transplant 597 Advisory Council is created within the agency, consisting of 598 twelve members who are physicians licensed under chapter 458 or 599 chapter 459, to represent the interests of the public and the 600 clients of the Department of Health or the agency. The members 601 shall be physicians licensed according to chapter 458 or chapter 602 459. A person employed by the agency may not be appointed as a 603 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.

609

(6) The responsibilities of the council shall be to

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610	recommend to the agency for Health Care Administration
611	indications for adult and pediatric organ transplants. The
612	council shall also formulate guidelines and standards for organ
613	transplants and for the development of End Stage Organ Disease
614	and Tissue/Organ Transplant programs. The recommendations,
615	guidelines, and standards developed by the council are
616	applicable only to those health programs funded through the
617	agency for Health Care Administration.
618	Section 13. Section 765.541, Florida Statutes, is amended
619	to read:
620	765.541 Certification of <u>procurement</u> organizations <del>engaged</del>
621	in the practice of cadaveric organ and tissue procurementThe
622	agency for Health Care Administration shall:
623	(1) Establish a program for the certification of
624	organizations, corporations agencies, or other entities engaged
625	in the procurement of organs, tissues, and eyes for
626	transplantation <u>.</u> +
627	(2) Adopt rules that set forth appropriate standards and
628	guidelines for the program in accordance with ss. 765.541-
629	765.546 and part II of chapter 408. These standards and
630	guidelines must be substantially based on the existing laws of
631	the Federal Government and this state and the existing standards
632	and guidelines of the United Network for Organ Sharing (UNOS),
633	the American Association of Tissue Banks (AATB), the South-
634	Eastern Organ Procurement Foundation (SEOPF), the North American
635	Transplant Coordinators Organization (NATCO), and the Eye Bank
636	Association of America (EBAA). In addition, the agency <del>for</del>
637	Health Care Administration shall, before adopting these
638	standards and guidelines, seek input from all <del>organ</del> procurement

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639	organizations, tissue banks, and eye banks based in this state.;
640	(3) Collect, keep, and make available to the Governor and
641	the Legislature information regarding the numbers and
642	disposition of organs <u>,</u> and tissues, and eyes procured by each
643	certified procurement organization. entity;
644	(4) Monitor procurement organizations participating
645	facilities and agencies for program compliance.; and
646	(5) Provide for the administration of the Organ and Tissue
647	Procurement and Transplantation Advisory Board.
648	Section 14. Section 765.542, Florida Statutes, is amended
649	to read:
650	765.542 Certification of <del>organ</del> procurement organizations $_{m{ au}}$
651	tissue banks, and eye banks
652	(1) The requirements of part II of chapter 408 apply to the
653	provision of services that require licensure pursuant to ss.
654	765.541-765.546 and part II of chapter 408 and to entities
655	licensed or certified by or applying for such licensure or
656	certification from the agency <del>for Health Care Administration</del>
657	pursuant to ss. 765.541-765.546. <u>A person</u> <del>An organization,</del>
658	agency, or other entity may not engage in the practice of organ
659	procurement in this state without being designated as an organ
660	procurement organization by the secretary of the United States
661	Department of Health and Human Services and being appropriately
662	certified by the agency <del>for Health Care Administration</del> . <del>As used</del>
663	in this subsection, the term "procurement" includes the
664	retrieval, processing, or distribution of human organs. A
665	physician or organ procurement organization based outside this
666	state is exempt from these certification requirements if:
667	(a) The organs are procured for an out-of-state patient who

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588-02137-09 2009766c1 668 is listed on, or referred through, the United Network for Organ 669 Sharing System; and 670 (b) The organs are procured through an agreement of an 671 organ procurement organization certified by the state. 672 (2) A person An organization, agency, or other entity may 673 not engage in tissue procurement in this state unless it is appropriately certified as a tissue bank by the agency for 674 675 Health Care Administration. As used in this subsection, the term "procurement" includes any retrieval, processing, storage, or 676 677 distribution of human tissue for transplantation. 678 (3) A person An organization, agency, or other entity may 679 not engage in the practice of eye procurement in this state 680 without being appropriately certified as an eye bank by the 681 agency for Health Care Administration. As used in this 682 subsection, the term "procurement" includes the retrieval,

683 processing, or distribution of human eye tissue. Funeral 684 directors or direct disposers who that retrieve eye tissue for 685 an eye bank certified under this subsection are exempt from the 686 certification requirements under this subsection.

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

694 Section 15. Subsection (3) of section 765.543, Florida 695 Statutes, is amended to read:

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765.543 Organ and Tissue Procurement and Transplantation

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697 Advisory Board; creation; duties.-

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(3) The board shall:

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

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

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

717 (d) Develop with and recommend to the agency for Health 718 Care Administration the necessary procedures and protocols 719 required to assure that all residents of this state have 720 reasonable access to available organ and tissue transplantation 721 therapy and that residents of this state can be reasonably 722 assured that the statewide procurement transplantation system is 723 will be able to fulfill their organ and tissue requirements 724 within the limits of the available supply and according to the 725 severity of their medical condition and need; and

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588-02137-09 2009766c1 726 (e) Develop with and recommend to the agency for Health 727 Care Administration any changes to the laws of this state or 728 administrative rules or procedures required to ensure assure 729 that the statewide organ and tissue procurement and 730 transplantation system is will be able to function smoothly, 731 effectively, and efficiently, in accordance with the Federal 732 Anatomical Gift Act and in a manner that assures the residents 733 of this state that no person or entity profits from the 734 altruistic voluntary donation of organs or tissues. 735 Section 16. Section 765.544, Florida Statutes, is amended to read 736 737 765.544 Fees; organ and tissue donor education and 738 procurement.-739 (1) In accordance with s. 408.805, an applicant or a certificateholder shall pay a fee for each application submitted 740 741 under this part, part II of chapter 408, and applicable rules. 742 The amount of the fee shall be as follows: 743 (a) An initial application fee of \$1,000 from organ 744 procurement organizations and tissue banks and \$500 from eye 745 banks. (b) Annual fees to be used, in the following order of 746 747 priority, for the certification program, the advisory board, 748 maintenance of the organ and tissue donor registry, and the organ and tissue donor education program in the following 749 750 amounts, which may not exceed \$35,000 per organization: 751 1. Each general organ procurement organization shall pay 752 the greater of \$1,000 or 0.25 percent of its total revenues

certificateholder during its most recently completed fiscal year

produced from procurement activity in this state by the

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     or operational year.
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          2. Each bone and tissue procurement organization agency or
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     bone and tissue bank shall pay the greater of $1,000 or 0.25
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     percent of its total revenues from procurement and processing
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     activity in this state by the certificateholder during its most
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     recently completed fiscal year or operational year.
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          3. Each eye bank shall pay the greater of $500 or 0.25
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     percent of its total revenues produced from procurement activity
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     in this state by the certificateholder during its most recently
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     completed fiscal year or operational year.
765
           (2) The agency for Health Care Administration shall specify
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     by rule the administrative penalties for the purpose of ensuring
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     adherence to the standards of quality and practice required by
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     this chapter, part II of chapter 408, and applicable rules of
769
     the agency for continued certification.
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           (3) (a) Proceeds from fees, administrative penalties, and
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     surcharges collected pursuant to this section must be deposited
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     into the Health Care Trust Fund.
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           (b) Moneys deposited in the trust fund pursuant to this
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     section must be used exclusively for the implementation,
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     administration, and operation of the certification program and
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     the advisory board, for maintaining the organ and tissue donor
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     registry, and for organ and tissue donor education.
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           (4) As used in this section, the term "procurement activity
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     in this state" includes the bringing into this state for
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     processing, storage, distribution, or transplantation of organs
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781 or tissues that are initially procured in another state or 782 country.

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Section 17. Section 765.545, Florida Statutes, is amended

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to read:

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785 765.545 Physician supervision of cadaveric organ and tissue 786 procurement coordinators. - Organ Procurement organizations, 787 tissue banks, and eye banks may employ coordinators, who are 788 registered nurses, physician's assistants, or other medically 789 trained personnel who meet the relevant standards for organ 790 procurement organizations, tissue banks, or eye banks as adopted 791 by the agency for Health Care Administration under s. 765.541, 792 to assist in the medical management of organ donors or in the 793 surgical procurement of cadaveric organs, tissues, or eyes for 794 transplantation or research. A coordinator who assists in the 795 medical management of organ donors or in the surgical 796 procurement of cadaveric organs, tissues, or eyes for 797 transplantation or research must do so under the direction and 798 supervision of a licensed physician medical director pursuant to 799 rules and quidelines to be adopted by the agency for Health Care 800 Administration. With the exception of organ procurement surgery, 801 this supervision may be indirect supervision. For purposes of 802 this section, the term "indirect supervision" means that the 803 medical director is responsible for the medical actions of the 804 coordinator, that the coordinator is operating under protocols 805 expressly approved by the medical director, and that the medical 806 director or his or her physician designee is always available, in person or by telephone, to provide medical direction, 807 808 consultation, and advice in cases of organ, tissue, and eye 809 donation and procurement. Although indirect supervision is 810 authorized under this section, direct physician supervision is 811 to be encouraged when appropriate.

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Section 18. Section 765.547, Florida Statutes, is created

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588-02137-09 2009766c1 813 to read: 814 765.547 Cooperation between medical examiner and 815 procurement organization.-816 (1) A medical examiner and procurement organization shall 817 cooperate with each other in order to maximize opportunities to 818 recover anatomical gifts for the purpose of transplantation, 819 therapy, research, or education. 820 (2) The Florida Medical Examiners Commission shall adopt 821 rules establishing cooperative responsibilities between medical 822 examiners and procurement organizations to facilitate and 823 expedite completion of the medical examiner's responsibilities 824 under chapter 406 in a manner that will maximize opportunities 825 to recover anatomical gifts. 826 (3) This part does not supersede any part of chapter 406 827 relating to medical examiners and the disposition of dead 828 bodies. 829 Section 19. Subsection (30) of section 408.802, Florida Statutes, is amended to read: 830 831 408.802 Applicability.-The provisions of this part apply to 832 the provision of services that require licensure as defined in 833 this part and to the following entities licensed, registered, or 834 certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765: 835 (30) Organ, and tissue, and eye procurement organizations 836 837 agencies, as provided under part V of chapter 765. 838 Section 20. Subsection (29) of section 408.820, Florida 839 Statutes, is amended to read: 840 408.820 Exemptions.-Except as prescribed in authorizing 841 statutes, the following exemptions shall apply to specified

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requirements of this part:
 (29) Organ, and tissue, and eye procurement organizations
agencies, as provided under part V of chapter 765, are exempt
from s. 408.810(5)-(10).
 Section 21. This act shall take effect July 1, 2009.