

By the Committees on Rules; Judiciary; and Health Policy; and
Senator Harrell

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1 A bill to be entitled
2 An act relating to organ donation; amending s.
3 381.0041, F.S.; providing that it is a felony for
4 certain persons who are infected with human
5 immunodeficiency virus to donate blood, plasma,
6 organs, skin, or other human tissue for use in another
7 person, with an exception; amending s. 395.1055, F.S.;
8 requiring the Agency for Health Care Administration to
9 adopt by rule specified minimum standards for certain
10 organ transplants; providing for the expiration of the
11 requirement upon the adoption of specified rules;
12 amending s. 627.6045, F.S.; prohibiting a health
13 insurance policy from limiting or excluding coverage
14 solely on the basis that an insured is a living organ
15 donor; amending s. 765.514, F.S.; revising a written
16 document required for making an anatomical gift to
17 include a specified statement relating to the
18 responsibility of payment for fees associated with
19 certain services; amending s. 765.5155, F.S.; revising
20 the responsibilities of a contractor procured by the
21 agency for the purpose of educating and informing the
22 public about anatomical gifts; amending s. 765.517,
23 F.S.; prohibiting an organ procurement organization
24 from charging a deceased donor or his or her family
25 member any fee for services relating to the
26 procurement or donation of organs; creating s.
27 765.5175, F.S.; prohibiting an organ transplantation
28 facility from charging a living donor or his or her
29 family member any fee for services relating to the

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30 procurement or donation of organs, with an exception;
31 amending s. 765.53, F.S.; requiring the agency to
32 establish the Organ Transplant Technical Advisory
33 Council for a specified purpose; providing for
34 membership, meetings, and duties of the council;
35 requiring the council to submit a report to the
36 Governor, the Legislature, the Secretary of Health
37 Care Administration, and the State Surgeon General by
38 a specified date; providing for sovereign immunity of
39 council members under certain circumstances; requiring
40 the agency to adopt specified rules based on the
41 council's recommendations; providing for future
42 legislative review and repeal of certain provisions;
43 amending s. 765.543, F.S.; revising the duties of the
44 Organ and Tissue Procurement and Transplantation
45 Advisory Board; requiring the board to submit certain
46 recommendations to the agency by a specified date;
47 creating s. 765.548, F.S.; providing additional duties
48 of the agency relating to organ transplantation
49 facilities and organ procurement organizations and
50 organ donation procedures and protocols; requiring the
51 agency to publish certain data and information by a
52 specified date and annually thereafter; amending s.
53 409.815, F.S.; conforming a provision to changes made
54 by the act; providing an effective date.

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

57
58 Section 1. Paragraph (b) of subsection (11) of section

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59 381.0041, Florida Statutes, is amended to read:

60 381.0041 Donation and transfer of human tissue; testing
61 requirements.-

62 (11)

63 (b) Any person who has human immunodeficiency virus
64 infection, who knows he or she is infected with human
65 immunodeficiency virus, and who has been informed that he or she
66 may communicate this disease by donating blood, plasma, organs,
67 skin, or other human tissue who donates blood, plasma, organs,
68 skin, or other human tissue for use in another person commits ~~is~~
69 ~~guilty~~ of a felony of the third degree, punishable as provided
70 in s. 775.082, s. 775.083, or s. 775.084. This paragraph does
71 not apply if the donation is made specifically for a recipient
72 who is infected with human immunodeficiency virus and who knows
73 that the donor is infected with human immunodeficiency virus.

74 Section 2. Paragraph (j) is added to subsection (1) of
75 section 395.1055, Florida Statutes, to read:

76 395.1055 Rules and enforcement.-

77 (1) The agency shall adopt rules pursuant to ss. 120.536(1)
78 and 120.54 to implement the provisions of this part, which shall
79 include reasonable and fair minimum standards for ensuring that:

80 (j) Hospitals providing organ transplants meet the
81 following minimum volume of transplants by organ type:

82 1. For heart transplants, performance of at least 12 such
83 transplants per year.

84 2. For liver transplants, performance of at least 5 such
85 transplants per biennium.

86 3. For adult kidney transplants, performance of at least 15
87 such transplants per biennium.

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88 4. For pediatric kidney transplants, performance of at
89 least 5 such transplants per biennium.

90 5. For adult allogenic and autologous bone marrow
91 transplants, performance of at least 10 transplants per year of
92 each such transplant it offers.

93 6. For pediatric allogenic and autologous bone marrow
94 transplants, performance of at least 10 transplants per year of
95 each such transplant it offers.

96 7. For any other transplant type not specified in
97 subparagraphs 1.-6., performance of at least 10 transplants of
98 such transplant per year.

99
100 This paragraph expires upon the agency's adoption of rules
101 pursuant to s. 765.53(7).

102 Section 3. Present subsections (3) and (4) of section
103 627.6045, Florida Statutes, are redesignated as subsections (4)
104 and (5), respectively, and a new subsection (3) is added to that
105 section, to read:

106 627.6045 Preexisting condition.—A health insurance policy
107 must comply with the following:

108 (3) A preexisting condition provision may not limit or
109 exclude coverage solely on the basis that an insured is a living
110 organ donor.

111 Section 4. Paragraph (f) of subsection (1) of section
112 765.514, Florida Statutes, is amended to read:

113 765.514 Manner of making anatomical gifts.—

114 (1) A person may make an anatomical gift of all or part of
115 his or her body under s. 765.512(1) by:

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

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117 will. The document must be signed by the donor in the presence
 118 of two witnesses who shall sign the document in the donor's
 119 presence. If the donor cannot sign, the document may be signed
 120 for him or her at the donor's direction and in his or her
 121 presence and the presence of two witnesses who must sign the
 122 document in the donor's presence. Delivery of the document of
 123 gift during the donor's lifetime is not necessary to make the
 124 gift valid. The following form of written document is sufficient
 125 for any person to make an anatomical gift for the purposes of
 126 this part:

127 UNIFORM DONOR CARD

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

131 I give:

132 (a) any needed organs, tissues, or eyes;

133 (b) only the following organs, tissues, or eyes

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

135 for the purpose of transplantation, therapy, medical research,
 136 or education;

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

138 Limitations or special wishes, if any:

139 ... (If applicable, list specific donee;

140 this must be arranged in advance with the donee.)...

141

142 I understand that neither I nor any member of my family is
 143 responsible for the payment of any fees associated with services
 144 relating to the procurement or donation of my organs, tissues,
 145 or eyes.

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

...(Signature of donor)... ...(Date of birth of donor)...
 ...(Date signed)... ...(City and State)...
 ...(Witness)... ...(Witness)...
 ...(Address)... ...(Address)...

Section 5. Paragraph (b) of subsection (3) of section 765.5155, Florida Statutes, is amended to read:

765.5155 Donor registry; education program.—

(3) The contractor shall be responsible for:

(b) A continuing program to educate and inform medical professionals, law enforcement agencies and officers, other state and local government employees, high school students, minorities, and the public about state and federal ~~the laws of this state~~ relating to anatomical gifts and the need for anatomical gifts, including the organ donation and transplantation process.

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

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

Section 6. Subsection (4) of section 765.517, Florida Statutes, is amended to read:

765.517 Rights and duties at death.—

(4) All reasonable additional expenses incurred in the

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175 procedures to preserve the donor's organs or tissues shall be
176 reimbursed by the procurement organization. An organ procurement
177 organization may not charge a deceased donor or his or her
178 family member any fee for services relating to the procurement
179 or donation of the deceased donor's organs.

180 Section 7. Section 765.5175, Florida Statutes, is created
181 to read:

182 765.5175 Rights and duties of living donors.—An organ
183 transplantation facility may not charge a living donor or his or
184 her family member, other than a family member who is the
185 recipient of the organ, any fee for services relating to the
186 procurement or donation of his or her organs.

187 Section 8. Section 765.53, Florida Statutes, is amended to
188 read:

189 (Substantial rewording of section. See
190 s. 765.53, F.S., for present text.)

191 765.53 Organ Transplant Technical Advisory Council.—

192 (1) CREATION AND PURPOSE.—The Organ Transplant Technical
193 Advisory Council, an advisory council as defined in s. 20.03, is
194 created within the agency to develop standards for measuring
195 quality and outcomes of adult and pediatric organ transplant
196 programs. In order to increase the number of organs available
197 for transplantation in this state, the council shall advise the
198 agency and the Legislature regarding the cost savings, trends,
199 research, and protocols and procedures relating to organ
200 donation and transplantation, including the availability of
201 organs for donation, organ donor benefits, and access to organ
202 transplants for persons with disabilities. Unless expressly
203 provided otherwise in this section, the council shall operate in

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204 a manner consistent with s. 20.052.

205 (2) MEMBERS.—

206 (a) Voting members of the council must have technical
207 expertise in adult or pediatric organ transplantation. The chief
208 executive officers of the following organ transplantation
209 facilities shall each appoint one representative, who must be an
210 organ transplant nurse coordinator licensed under chapter 464 or
211 an organ transplant surgeon licensed under chapter 458 or
212 chapter 459, to serve as a voting member of the council:

213 1. Jackson Memorial Hospital in Miami.

214 2. Tampa General Hospital in Tampa.

215 3. University of Florida Health Shands Hospital in
216 Gainesville.

217 4. AdventHealth Orlando in Orlando.

218 5. Mayo Clinic in Jacksonville.

219 6. Cleveland Clinic Florida in Weston.

220 7. Largo Medical Center in Largo.

221 8. Broward Health Medical Center in Fort Lauderdale.

222 (b) Voting members of the council must reflect the ethnic
223 and gender diversity of this state.

224 (c) The Secretary of Health Care Administration, or his or
225 her designee, shall serve as the chair and as a nonvoting member
226 of the council.

227 (d) The Secretary of Health Care Administration shall
228 appoint the following individuals to serve as voting members of
229 the council:

230 1. The State Surgeon General or his or her designee.

231 2. A parent of a child who has had an organ transplant.

232 3. An adult who has had an organ transplant.

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233 4. An adult patient who is on an organ transplant waiting
234 list.

235 5. A licensed organ transplant physician for each of the
236 following areas:

237 a. Kidneys.

238 b. Lungs.

239 c. Heart.

240 d. Liver.

241 e. Pancreas.

242 6. A representative from an organ procurement organization.

243 7. An administrator of an organ transplant program.

244 (e) Appointments made under paragraph (a) are contingent
245 upon the hospital's compliance with chapter 395 and rules
246 adopted thereunder. A member of the council appointed under
247 paragraph (a) whose hospital fails to comply with such law and
248 rules may serve only as a nonvoting member until the hospital
249 comes into compliance.

250 (f) Any vacancy on the council must be filled in the same
251 manner as the original appointment. Members are eligible for
252 reappointment.

253 (g) Members of the council shall serve without compensation
254 but may be reimbursed as provided in s. 112.061 for per diem and
255 travel expenses incurred in the performance of their duties
256 under this section.

257 (3) MEETINGS.—The council shall meet at least twice
258 annually and upon the call of the chair. The council may use any
259 method of telecommunications to conduct its meetings.

260 (4) DUTIES.—The council shall recommend to the agency and
261 the Legislature the standards for quality care of adult and

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262 pediatric organ transplant patients, including recommendations
263 on minimum volume of transplants by organ type, personnel,
264 physical plant, equipment, transportation, and data reporting
265 for hospitals that perform organ transplants. The council may
266 further advise the agency and the Legislature regarding research
267 focused on improving overall organ availability and benefits for
268 organ donors. A voting member may vote on standards related to a
269 specific type of organ only if he or she represents a hospital
270 that has a transplant program for that organ.

271 (5) REPORT.—By October 1, 2021, the council shall submit a
272 report of its recommendations to the Governor, the President of
273 the Senate, the Speaker of the House of Representatives, the
274 Secretary of Health Care Administration, and the State Surgeon
275 General.

276 (6) SOVEREIGN IMMUNITY.—Members of the council acting in
277 good faith in the performance of their duties under this section
278 are considered agents of the state for purposes of s. 768.28.

279 (7) AGENCY RULES.—

280 (a) Based on the recommendations of the council, the agency
281 shall develop and adopt rules for organ transplant programs
282 which, at a minimum, include all of the following:

283 1. Quality of care standards for adult and pediatric organ
284 transplants, including minimum volume thresholds by organ type;
285 personnel; physical plant; equipment; transportation; and data
286 reporting.

287 2. Outcome and survival rate standards that meet or exceed
288 nationally established levels of performance in organ
289 transplantation.

290 3. Specific steps to be taken by the agency and licensed

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291 facilities when the facilities do not meet the volume, outcome,
292 or survival rate standards within a specified timeframe that
293 includes the time required for detailed case reviews and the
294 development and implementation of corrective action plans.

295 (b) This subsection is repealed July 1, 2030, unless
296 reviewed and saved from repeal through reenactment by the
297 Legislature.

298 Section 9. Subsection (3) of section 765.543, Florida
299 Statutes, is amended to read:

300 765.543 Organ and Tissue Procurement and Transplantation
301 Advisory Board; creation; duties.—

302 (3) The board shall:

303 (a) Assist the agency, in collaboration with other relevant
304 public or private entities, in the development of necessary
305 professional qualifications, including, but not limited to, the
306 continuing education, training, and performance of persons
307 engaged in the various facets of organ and tissue procurement,
308 processing, preservation, and distribution for transplantation;

309 (b) Assist the agency in monitoring the appropriate and
310 legitimate expenses associated with organ and tissue
311 procurement, processing, and distribution for transplantation
312 and developing methodologies to assure the uniform statewide
313 reporting of data to facilitate the accurate and timely
314 evaluation of the organ and tissue procurement and
315 transplantation system;

316 (c) Provide assistance to the Florida Medical Examiners
317 Commission in the development of appropriate procedures and
318 protocols to ensure the continued improvement in the approval
319 and release of potential donors by the district medical

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320 examiners and associate medical examiners;

321 (d) Develop with and recommend to the agency the necessary
322 procedures and protocols required to assure that all residents
323 of this state have reasonable access to available organ and
324 tissue transplantation therapy and that residents of this state
325 can be reasonably assured that the statewide procurement
326 transplantation system is able to fulfill their organ and tissue
327 requirements within the limits of the available supply and
328 according to the severity of their medical condition and need;
329 and

330 (e) Develop with and recommend to the agency any changes to
331 the laws of this state or administrative rules or procedures to
332 ensure that the statewide organ and tissue procurement and
333 transplantation system is able to function smoothly,
334 effectively, and efficiently, in accordance with the Federal
335 Anatomical Gift Act and in a manner that assures the residents
336 of this state that no person or entity profits from the
337 altruistic voluntary donation of organs or tissues.

338 (f) In addition to the general duties described in this
339 subsection, by September 1, 2021, submit to the agency
340 recommendations that address all of the following:

341 1. The frequency of communication between patients and
342 organ transplant coordinators.

343 2. The monitoring of each organ transplantation facility
344 and the annual reporting and publication of relevant information
345 regarding the statewide number of patients placed on waiting
346 lists and the number of patients who receive transplants,
347 aggregated by the facility.

348 3. The establishment of a coordinated communication system

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349 between organ transplantation facilities and living organ donors
350 for the purpose of minimizing the cost and time required for
351 duplicative lab tests, including the sharing of lab results
352 between facilities.

353 4. The potential incentives for organ transplantation
354 facilities which may be necessary to increase organ donation in
355 this state.

356 5. The evaluation and encouragement of an efficient living
357 organ donor process.

358 6. The potential opportunities and incentives for organ
359 transplantation research.

360 7. The best practices for organ transplantation facilities
361 and organ procurement organizations which promote the most
362 efficient and effective outcomes for patients.

363 8. The monitoring of organ procurement organizations.

364 Section 10. Section 765.548, Florida Statutes, is created
365 to read:

366 765.548 Duties of the agency; organ donation.—

367 (1) The agency shall do all of the following:

368 (a) Monitor the operation of each organ transplantation
369 facility and organ procurement organization located in this
370 state.

371 (b) Develop uniform statewide rules regarding organ
372 donation. The rules must require that each hospital that
373 performs organ transplants designate at least one employee or
374 representative of the hospital who is educated on the protocols
375 of the hospital and federal and state regulations regarding
376 organ donation, to provide a clear explanation of such subjects
377 to any patient, or a patient's representative, who is

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378 considering posthumous or living organ donation. The rules may
379 also include, but need not be limited to, procedures for
380 maintaining a coordinated system of communication between organ
381 transplantation facilities.

382 (c) Evaluate the current protocols and procedures used by
383 organ transplantation facilities and make recommendations for
384 improving such protocols and procedures.

385 (d) Establish annual reporting requirements for organ
386 transplantation facilities and organ procurement organizations.

387 (e) In consultation with the State Board of Education and
388 the contractor procured by the agency pursuant to s. 765.5155,
389 develop a curriculum for educating high school students
390 regarding the laws of this state relating to organ donation.

391 (2) By December 1, 2021, and each year thereafter, the
392 agency shall publish any data and other relevant information to
393 adequately inform patients and potential donors about organ
394 donation and organ transplantation.

395 Section 11. Paragraph (e) of subsection (2) of section
396 409.815, Florida Statutes, is amended to read:

397 409.815 Health benefits coverage; limitations.—

398 (2) BENCHMARK BENEFITS.—In order for health benefits
399 coverage to qualify for premium assistance payments for an
400 eligible child under ss. 409.810-409.821, the health benefits
401 coverage, except for coverage under Medicaid and Medikids, must
402 include the following minimum benefits, as medically necessary.

403 (e) *Organ transplantation services.*—Covered services
404 include pretransplant, transplant, and postdischarge services
405 and treatment of complications after transplantation for
406 transplants deemed necessary and appropriate within the

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407 guidelines set by the Organ Transplant Technical Advisory
408 Council under s. 765.53 or the Bone Marrow Transplant Advisory
409 Panel under s. 627.4236.

410 Section 12. This act shall take effect July 1, 2020.