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LEGISLATIVE ACTION

Senate

.

House

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Senator Harrell moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Paragraph (b) of subsection (11) of section
381.0041, Florida Statutes, is amended to read:

381.0041 Donation and transfer of human tissue; testing
requirements.—

(11)

(b) Any person who has human immunodeficiency virus
infection, who knows he or she is infected with human



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12 immunodeficiency virus, and who has been informed that he or she
13 may communicate this disease by donating blood, plasma, organs,
14 skin, or other human tissue who donates blood, plasma, organs,
15 skin, or other human tissue for use in another person commits ~~is~~
16 guilty of a felony of the third degree, punishable as provided
17 in s. 775.082, s. 775.083, or s. 775.084. This paragraph does
18 not apply if the donation is made specifically for a recipient
19 who is infected with human immunodeficiency virus and who knows
20 that the donor is infected with human immunodeficiency virus.

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

23 395.1055 Rules and enforcement.—

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

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

29 1. For heart transplants, performance of at least 12 such
30 transplants per year.

31 2. For liver transplants, performance of at least 5 such
32 transplants per year.

33 3. For adult kidney transplants, performance of at least 15
34 such transplants per year.

35 4. For pediatric kidney transplants, performance of at
36 least 5 such transplants per year averaged over a 3-year period.

37 5. For allogeneic and autologous bone marrow transplants,
38 performance of at least 10 transplants per year of each such
39 transplant the hospital offers.

40 6. For lung transplants, performance of at least 10 such



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41 transplants per year.

42

43 This paragraph expires upon the agency's adoption of rules
44 pursuant to s. 765.53(7).

45 Section 3. Present subsections (3) and (4) of section
46 627.6045, Florida Statutes, are redesignated as subsections (4)
47 and (5), respectively, and a new subsection (3) is added to that
48 section, to read:

49 627.6045 Preexisting condition.—A health insurance policy
50 must comply with the following:

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

54 Section 4. Paragraph (f) of subsection (1) of section
55 765.514, Florida Statutes, is amended to read:

56 765.514 Manner of making anatomical gifts.—

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

59 (f) Expressing a wish to donate in a document other than a
60 will. The document must be signed by the donor in the presence
61 of two witnesses who shall sign the document in the donor's
62 presence. If the donor cannot sign, the document may be signed
63 for him or her at the donor's direction and in his or her
64 presence and the presence of two witnesses who must sign the
65 document in the donor's presence. Delivery of the document of
66 gift during the donor's lifetime is not necessary to make the
67 gift valid. The following form of written document is sufficient
68 for any person to make an anatomical gift for the purposes of
69 this part:



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UNIFORM DONOR CARD

70
71 The undersigned hereby makes this anatomical gift, if medically
72 acceptable, to take effect on death. The words and marks below
73 indicate my desires:

74 I give:

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

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

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

78 for the purpose of transplantation, therapy, medical research,
79 or education;

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

81 Limitations or special wishes, if any:

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

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

84

85 I understand that neither I nor any member of my family is
86 responsible for the payment of any fees associated with services
87 relating to the procurement or donation of my organs, tissues,
88 or eyes.

89

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

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

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

94 ... (Witness) ... (Witness) ...

95 ... (Address) ... (Address) ...

96 Section 5. Paragraph (b) of subsection (3) of section
97 765.5155, Florida Statutes, is amended to read:

98 765.5155 Donor registry; education program.-



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99 (3) The contractor shall be responsible for:

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

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

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

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

116 765.517 Rights and duties at death.—

117 (4) All reasonable additional expenses incurred in the
118 procedures to preserve the donor's organs or tissues shall be
119 reimbursed by the procurement organization. An organ procurement
120 organization may not charge a deceased donor or his or her
121 family member any fee for services relating to the procurement
122 or donation of the deceased donor's organs.

123 Section 7. Section 765.5175, Florida Statutes, is created
124 to read:

125 765.5175 Rights and duties of living donors.—An organ
126 transplantation facility may not charge a living donor or his or
127 her family member, other than a family member who is the



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128 recipient of the organ, any fee for services relating to the
129 procurement or donation of his or her organs.

130 Section 8. Section 765.53, Florida Statutes, is amended to
131 read:

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

134 765.53 Organ Transplant Technical Advisory Council.—

135 (1) CREATION AND PURPOSE.—The Organ Transplant Technical
136 Advisory Council, an advisory council as defined in s. 20.03, is
137 created within the agency to develop standards for measuring
138 quality and outcomes of adult and pediatric organ transplant
139 programs. In order to increase the number of organs available
140 for transplantation in this state, the council shall advise the
141 agency and the Legislature regarding the cost savings, trends,
142 research, and protocols and procedures relating to organ
143 donation and transplantation, including the availability of
144 organs for donation, organ donor benefits, and access to organ
145 transplants for persons with disabilities. Unless otherwise
146 expressly provided in this section, the council shall operate in
147 a manner consistent with s. 20.052.

148 (2) MEMBERS.—

149 (a) Voting members of the council must have technical
150 expertise in adult or pediatric organ transplantation. The chief
151 executive officers of the following organ transplantation
152 facilities shall each appoint one representative, who must be an
153 organ transplant nurse coordinator licensed under chapter 464 or
154 an organ transplant surgeon licensed under chapter 458 or
155 chapter 459, to serve as a voting member of the council:

156 1. Jackson Memorial Hospital in Miami.



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157 2. Tampa General Hospital in Tampa.

158 3. University of Florida Health Shands Hospital in
159 Gainesville.

160 4. AdventHealth Orlando in Orlando.

161 5. Mayo Clinic in Jacksonville.

162 6. Cleveland Clinic Florida in Weston.

163 7. Largo Medical Center in Largo.

164 8. Broward Health Medical Center in Fort Lauderdale.

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

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

170 (d) The Secretary of Health Care Administration shall
171 appoint the following individuals to serve as voting members of
172 the council:

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

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

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

176 4. An adult patient who is on an organ transplant waiting
177 list.

178 5. A licensed organ transplant physician for each of the
179 following organ types:

180 a. Kidneys.

181 b. Lungs.

182 c. Heart.

183 d. Liver.

184 e. Pancreas.

185 6. A representative from an organ procurement organization.



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186 7. An administrator of an organ transplant program.

187 (e) Appointments made under paragraph (a) are contingent
188 upon the hospital's compliance with chapter 395 and rules
189 adopted thereunder. A member of the council appointed under
190 paragraph (a) whose hospital fails to comply with such law and
191 rules may serve only as a nonvoting member until the hospital
192 comes into compliance.

193 (f) Any vacancy on the council must be filled in the same
194 manner as the original appointment. Members are eligible for
195 reappointment.

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

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

203 (4) DUTIES.—The council shall recommend to the agency and
204 the Legislature the standards for quality care of adult and
205 pediatric organ transplant patients, including recommendations
206 on standards related to minimum volume of transplants by organ
207 type; personnel; physical plant; equipment; transportation; and
208 data reporting for hospitals that perform organ transplants. The
209 council may further advise the agency and the Legislature
210 regarding research focused on improving overall organ
211 availability and benefits for organ donors. A voting member may
212 vote on standards related to a specific type of organ only if he
213 or she represents a hospital that has a transplant program for
214 that organ.



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215 (5) REPORT.—By October 1, 2021, and every 5 years
216 thereafter, the council shall submit a report of its
217 recommendations to the Governor, the President of the Senate,
218 the Speaker of the House of Representatives, the Secretary of
219 Health Care Administration, and the State Surgeon General.

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

223 (7) AGENCY RULES.—

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

227 1. Quality of care standards for adult and pediatric organ
228 transplants, including those related to minimum volume
229 thresholds by organ type; personnel; physical plant; equipment;
230 transportation; and data reporting.

231 2. Outcome and survival rate standards that meet or exceed
232 nationally established levels of performance in organ
233 transplantation.

234 3. Specific steps to be taken by the agency and licensed
235 facilities when the facilities do not meet the volume, outcome,
236 or survival rate standards within a specified timeframe that
237 includes the time required for detailed case reviews and the
238 development and implementation of corrective action plans.

239 (b) This subsection is repealed July 1, 2030, unless
240 reviewed and saved from repeal through reenactment by the
241 Legislature.

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



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244 765.543 Organ and Tissue Procurement and Transplantation
245 Advisory Board; creation; duties.—

246 (3) The board shall:

247 (a) Assist the agency, in collaboration with other relevant
248 public or private entities, in the development of necessary
249 professional qualifications, including, but not limited to, the
250 continuing education, training, and performance of persons
251 engaged in the various facets of organ and tissue procurement,
252 processing, preservation, and distribution for transplantation;

253 (b) Assist the agency in monitoring the appropriate and
254 legitimate expenses associated with organ and tissue
255 procurement, processing, and distribution for transplantation
256 and developing methodologies to assure the uniform statewide
257 reporting of data to facilitate the accurate and timely
258 evaluation of the organ and tissue procurement and
259 transplantation system;

260 (c) Provide assistance to the Florida Medical Examiners
261 Commission in the development of appropriate procedures and
262 protocols to ensure the continued improvement in the approval
263 and release of potential donors by the district medical
264 examiners and associate medical examiners;

265 (d) Develop with and recommend to the agency the necessary
266 procedures and protocols required to assure that all residents
267 of this state have reasonable access to available organ and
268 tissue transplantation therapy and that residents of this state
269 can be reasonably assured that the statewide procurement
270 transplantation system is able to fulfill their organ and tissue
271 requirements within the limits of the available supply and
272 according to the severity of their medical condition and need;



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273 and

274 (e) Develop with and recommend to the agency any changes to
275 the laws of this state or administrative rules or procedures to
276 ensure that the statewide organ and tissue procurement and
277 transplantation system is able to function smoothly,
278 effectively, and efficiently, in accordance with the Federal
279 Anatomical Gift Act and in a manner that assures the residents
280 of this state that no person or entity profits from the
281 altruistic voluntary donation of organs or tissues.

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

285 1. The frequency of communication between patients and
286 organ transplant coordinators.

287 2. The monitoring of each organ transplantation facility
288 and the annual reporting and publication of relevant information
289 regarding the statewide number of patients placed on waiting
290 lists and the number of patients who receive transplants,
291 aggregated by the facility.

292 3. The establishment of a coordinated communication system
293 between organ transplantation facilities and living organ donors
294 for the purpose of minimizing the cost and time required for
295 duplicative lab tests, including the sharing of lab results
296 between facilities.

297 4. The potential incentives for organ transplantation
298 facilities which may be necessary to increase organ donation in
299 this state.

300 5. The evaluation and encouragement of an efficient living
301 organ donor process.



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302 6. The potential opportunities and incentives for organ
303 transplantation research.

304 7. The best practices for organ transplantation facilities
305 and organ procurement organizations which promote the most
306 efficient and effective outcomes for patients.

307 8. The monitoring of organ procurement organizations.

308 Section 10. Section 765.548, Florida Statutes, is created
309 to read:

310 765.548 Duties of the agency; organ donation.—

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

312 (a) Monitor the operation of each organ transplantation
313 facility and organ procurement organization located in this
314 state.

315 (b) Develop uniform statewide rules regarding organ
316 donation. The rules must require that each hospital that
317 performs organ transplants designate at least one employee or
318 representative of the hospital who is educated on the protocols
319 of the hospital and federal and state regulations regarding
320 organ donation to provide a clear explanation of such subjects
321 to any patient, or a patient's representative, who is
322 considering posthumous or living organ donation. The rules may
323 also include, but need not be limited to, procedures for
324 maintaining a coordinated system of communication between organ
325 transplantation facilities.

326 (c) Evaluate the current protocols and procedures used by
327 organ transplantation facilities and make recommendations for
328 improving such protocols and procedures.

329 (d) Establish annual reporting requirements for organ
330 transplantation facilities and organ procurement organizations.



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

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

339 Section 11. Paragraph (e) of subsection (2) of section
340 409.815, Florida Statutes, is amended to read:

341 409.815 Health benefits coverage; limitations.—

342 (2) BENCHMARK BENEFITS.—In order for health benefits
343 coverage to qualify for premium assistance payments for an
344 eligible child under ss. 409.810-409.821, the health benefits
345 coverage, except for coverage under Medicaid and Medikids, must
346 include the following minimum benefits, as medically necessary.

347 (e) *Organ transplantation services.*—Covered services
348 include pretransplant, transplant, and postdischarge services
349 and treatment of complications after transplantation for
350 transplants deemed necessary and appropriate within the
351 guidelines set by the Organ Transplant Technical Advisory
352 Council under s. 765.53 or the Bone Marrow Transplant Advisory
353 Panel under s. 627.4236.

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

355
356 ===== T I T L E A M E N D M E N T =====

357 And the title is amended as follows:

358 Delete everything before the enacting clause
359 and insert:



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360 A bill to be entitled
361 An act relating to organ donation; amending s.
362 381.0041, F.S.; providing that it is a felony for
363 certain persons who are infected with human
364 immunodeficiency virus to donate blood, plasma,
365 organs, skin, or other human tissue for use in another
366 person, with an exception; amending s. 395.1055, F.S.;
367 requiring the Agency for Health Care Administration to
368 adopt by rule specified minimum standards for certain
369 organ transplants; providing for the expiration of the
370 requirement upon the adoption of specified rules;
371 amending s. 627.6045, F.S.; prohibiting a health
372 insurance policy from limiting or excluding coverage
373 solely on the basis that an insured is a living organ
374 donor; amending s. 765.514, F.S.; revising a written
375 document required for making an anatomical gift to
376 include a specified statement relating to the
377 responsibility of payment for fees associated with
378 certain services; amending s. 765.5155, F.S.; revising
379 the responsibilities of a contractor procured by the
380 agency for the purpose of educating and informing the
381 public about anatomical gifts; amending s. 765.517,
382 F.S.; prohibiting an organ procurement organization
383 from charging a deceased donor or his or her family
384 member any fee for services relating to the
385 procurement or donation of organs; creating s.
386 765.5175, F.S.; prohibiting an organ transplantation
387 facility from charging a living donor or his or her
388 family member any fee for services relating to the



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389 procurement or donation of organs, with an exception;
390 amending s. 765.53, F.S.; establishing the Organ
391 Transplant Technical Advisory Council within the
392 agency for a specified purpose; providing for
393 membership, meetings, and duties of the council;
394 requiring the council to submit a report to the
395 Governor, the Legislature, the Secretary of Health
396 Care Administration, and the State Surgeon General by
397 a specified date and periodically thereafter;
398 providing for sovereign immunity of council members
399 under certain circumstances; requiring the agency to
400 adopt specified rules based on the council's
401 recommendations; providing for future legislative
402 review and repeal of certain provisions; amending s.
403 765.543, F.S.; revising the duties of the Organ and
404 Tissue Procurement and Transplantation Advisory Board;
405 requiring the board to submit certain recommendations
406 to the agency by a specified date; creating s.
407 765.548, F.S.; providing additional duties of the
408 agency relating to organ transplantation facilities
409 and organ procurement organizations and organ donation
410 procedures and protocols; requiring the agency to
411 publish certain data and information by a specified
412 date and annually thereafter; amending s. 409.815,
413 F.S.; conforming a provision to changes made by the
414 act; providing an effective date.