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LEGISLATIVE ACTION

Senate

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House

The Committee on Health Policy (Harrell) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 408.0455, Florida Statutes, is amended
to read:

408.0455 Rules; pending proceedings.—The rules of the
agency in effect on June 30, 2004, ~~shall~~ remain in effect and
are ~~shall be~~ enforceable by the agency with respect to ss.
408.031-408.045 until such rules are repealed or amended by the



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11 agency. Rules 59C-1.039 through 59C-1.044, Florida
12 Administrative Code, including, but not limited to, the minimum
13 volume standards for organ transplantation and neonatal
14 intensive care services, remain in effect for the sole purpose
15 of maintaining licensure requirements for the applicable
16 services until the agency has adopted rules for the
17 corresponding services pursuant to s. 395.1055(1)(i), Florida
18 Statutes 2018.

19 Section 2. Present subsections (3) and (4) of section
20 627.6045, Florida Statutes, are redesignated as subsections (4)
21 and (5), respectively, and a new subsection (3) is added to that
22 section, to read:

23 627.6045 Preexisting condition.—A health insurance policy
24 must comply with the following:

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

28 Section 3. Paragraph (f) of subsection (1) of section
29 765.514, Florida Statutes, is amended to read:

30 765.514 Manner of making anatomical gifts.—

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

33 (f) Expressing a wish to donate in a document other than a
34 will. The document must be signed by the donor in the presence
35 of two witnesses who shall sign the document in the donor's
36 presence. If the donor cannot sign, the document may be signed
37 for him or her at the donor's direction and in his or her
38 presence and the presence of two witnesses who must sign the
39 document in the donor's presence. Delivery of the document of



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40 gift during the donor's lifetime is not necessary to make the
41 gift valid. The following form of written document is sufficient
42 for any person to make an anatomical gift for the purposes of
43 this part:

44 UNIFORM DONOR CARD

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

48 I give:

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

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

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

52 for the purpose of transplantation, therapy, medical research,
53 or education;

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

55 Limitations or special wishes, if any:

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

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

58

59 I understand that neither I nor any member of my family is
60 responsible for the payment of any fees associated with services
61 relating to the procurement or donation of my organs, tissues,
62 or eyes.

63

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

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

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

68 ... (Witness) ... (Witness) ...



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69 ... (Address)... ... (Address)...

70 Section 4. Paragraph (b) of subsection (3) of section
71 765.5155, Florida Statutes, is amended to read:

72 765.5155 Donor registry; education program.—

73 (3) The contractor shall be responsible for:

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

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

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

88 Section 5. Subsection (4) of section 765.517, Florida
89 Statutes, is amended to read:

90 765.517 Rights and duties at death.—

91 (4) All reasonable additional expenses incurred in the
92 procedures to preserve the donor's organs or tissues shall be
93 reimbursed by the procurement organization. An organ
94 transplantation facility may not charge a donor or his or her
95 family member any fee for services relating to the procurement
96 or donation of his or her organs.

97 Section 6. Subsection (3) of section 765.522, Florida



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98 Statutes, is amended to read:

99 765.522 Duty of hospital administrators; liability of
100 hospital administrators and procurement organizations.—

101 (3) The agency shall establish rules and guidelines
102 concerning the education of individuals who may be designated to
103 perform the request and the procedures to be used in making the
104 request, including a requirement that such individuals clearly
105 explain to patients and living organ donors the protocols of the
106 hospital and the federal and state regulations regarding
107 donation. The agency is authorized to adopt rules concerning the
108 documentation of the request, where such request is made.

109 Section 7. Section 765.53, Florida Statutes, is amended to
110 read:

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

113 765.53 Organ Transplant Technical Advisory Council.—

114 (1) CREATION AND PURPOSE.—The Organ Transplant Technical
115 Advisory Council, an advisory council as defined in s. 20.03, is
116 created within the agency to develop standards for measuring
117 quality and outcomes of adult and pediatric organ transplant
118 programs. In order to increase the number of organs available
119 for transplantation in this state, the council shall advise the
120 agency and the Legislature regarding the cost savings, trends,
121 research, and protocols and procedures relating to organ
122 donation and transplantation, including the availability of
123 organs for donation. Unless expressly provided otherwise in this
124 section, the council shall operate in a manner consistent with
125 s. 20.052.

126 (2) MEMBERS.—



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127 (a) Voting members of the council must have technical
128 expertise in adult or pediatric organ transplantation. The chief
129 executive officers of the following organ transplantation
130 facilities shall each appoint one representative, who must be an
131 organ transplant nurse coordinator licensed under chapter 464 or
132 an organ transplant surgeon licensed under chapter 458 or
133 chapter 459, to serve as a voting member of the council:

- 134 1. Jackson Memorial Hospital in Miami.
135 2. Tampa General Hospital in Tampa.
136 3. University of Florida Health Shands Hospital in
137 Gainesville.

- 138 4. AdventHealth Orlando in Orlando.
139 5. Mayo Clinic in Jacksonville.
140 6. Cleveland Clinic Florida in Weston.
141 7. Largo Medical Center in Largo.
142 8. Broward Health Medical Center in Fort Lauderdale.

143 (b) The Secretary of Health Care Administration shall serve
144 as the chair and a nonvoting member of the council.

145 (c) The Secretary of Health Care Administration shall
146 appoint the following individuals to serve as voting members of
147 the council:

- 148 1. The State Surgeon General or his or her designee.
149 2. A parent of a child who has had an organ transplant.
150 3. An adult who has had an organ transplant.
151 4. An adult patient who is on an organ transplant waiting
152 list.

153 5. A licensed physician who practices in each of the
154 following organ transplantation areas:

- 155 a. Kidneys.



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156 b. Lungs.

157 c. Heart.

158 d. Liver.

159 e. Pancreas.

160 (d) Appointments made under paragraph (a) are contingent
161 upon the hospital's compliance with chapter 395 and rules
162 adopted thereunder. A member of the council appointed under
163 paragraph (a) whose hospital fails to comply with such law and
164 rules may serve only as a nonvoting member until the hospital
165 comes into compliance.

166 (e) Any vacancy on the council must be filled in the same
167 manner as the original appointment. Members are eligible for
168 reappointment.

169 (f) Members of the council shall serve without compensation
170 but may be reimbursed as provided in s. 112.061 for per diem and
171 travel expenses incurred in the performance of their duties
172 under this section.

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

176 (4) DUTIES.—The council shall recommend to the agency and
177 the Legislature the standards for quality care of adult and
178 pediatric organ transplant patients, including recommendations
179 on minimum volume of transplants by organ type, personnel,
180 physical plant, equipment, transportation, and data reporting
181 for hospitals that perform organ transplants. The council may
182 further advise the agency and the Legislature regarding research
183 focused on improving overall organ availability. A voting member
184 may vote on standards related to a specific type of organ only



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185 if he or she represents a hospital that has a transplant program
186 for that organ.

187 (5) REPORT.—By October 1, 2021, the council shall submit a
188 report of its recommendations to the Governor, the President of
189 the Senate, the Speaker of the House of Representatives, the
190 Secretary of Health Care Administration, and the State Surgeon
191 General.

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

195 (7) AGENCY RULES.—

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

199 1. Quality of care standards for adult and pediatric organ
200 transplants, including minimum volume thresholds by organ type,
201 personnel, physical plant, equipment, transportation, and data
202 reporting.

203 2. Outcome and survival rate standards that meet or exceed
204 nationally established levels of performance in organ
205 transplantation.

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

211 (b) This subsection is repealed July 1, 2030, unless
212 reviewed and saved from repeal through reenactment by the
213 Legislature.



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214 Section 8. Subsection (3) of section 765.543, Florida
215 Statutes, is amended to read:

216 765.543 Organ and Tissue Procurement and Transplantation
217 Advisory Board; creation; duties.-

218 (3) The board shall:

219 (a) Assist the agency, in collaboration with other relevant
220 public or private entities, in the development of necessary
221 professional qualifications, including, but not limited to, the
222 continuing education, training, and performance of persons
223 engaged in the various facets of organ and tissue procurement,
224 processing, preservation, and distribution for transplantation;

225 (b) Assist the agency in monitoring the appropriate and
226 legitimate expenses associated with organ and tissue
227 procurement, processing, and distribution for transplantation
228 and developing methodologies to assure the uniform statewide
229 reporting of data to facilitate the accurate and timely
230 evaluation of the organ and tissue procurement and
231 transplantation system;

232 (c) Provide assistance to the Florida Medical Examiners
233 Commission in the development of appropriate procedures and
234 protocols to ensure the continued improvement in the approval
235 and release of potential donors by the district medical
236 examiners and associate medical examiners;

237 (d) Develop with and recommend to the agency the necessary
238 procedures and protocols required to assure that all residents
239 of this state have reasonable access to available organ and
240 tissue transplantation therapy and that residents of this state
241 can be reasonably assured that the statewide procurement
242 transplantation system is able to fulfill their organ and tissue



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243 requirements within the limits of the available supply and
244 according to the severity of their medical condition and need;
245 and

246 (e) Develop with and recommend to the agency any changes to
247 the laws of this state or administrative rules or procedures to
248 ensure that the statewide organ and tissue procurement and
249 transplantation system is able to function smoothly,
250 effectively, and efficiently, in accordance with the Federal
251 Anatomical Gift Act and in a manner that assures the residents
252 of this state that no person or entity profits from the
253 altruistic voluntary donation of organs or tissues. In addition
254 to the general duties described in this subsection, by September
255 1, 2021, the board shall submit to the agency recommendations
256 that address the following:

257 1. The frequency of communication between patients and
258 organ transplant coordinators.

259 2. The monitoring of each organ transplantation facility
260 and the annual reporting and publication of relevant information
261 regarding the statewide number of patients placed on waiting
262 lists and the number of patients who receive transplants,
263 aggregated by the facility.

264 3. The establishment of a coordinated communication system
265 between organ transplantation facilities and living organ donors
266 for the purpose of minimizing the cost and time required for
267 duplicative lab tests, including the sharing of lab results
268 between facilities.

269 4. The potential incentives for organ transplantation
270 facilities that may be necessary to increase organ donation in
271 this state.



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272 5. The creation of a more efficient regional or statewide
273 living organ donor process.

274 6. The potential opportunities and incentives for organ
275 transplantation research.

276 7. The best practices for organ transplantation facilities
277 and organ procurement organizations which promote the most
278 efficient and effective outcomes for patients.

279 8. The monitoring of organ procurement organizations.

280 Section 9. Section 765.548, Florida Statutes, is created to
281 read:

282 765.548 Duties of the agency; organ donation.-

283 (1) The agency shall:

284 (a) Monitor the operation of each organ transplantation
285 facility and organ procurement organization located in this
286 state.

287 (b) Develop uniform statewide rules regarding organ
288 donations, which may include, but need not be limited to,
289 procedures for maintaining a coordinated system of communication
290 between organ transplantation facilities.

291 (c) Evaluate the current protocols and procedures used by
292 organ transplantation facilities and make recommendations for
293 improving such protocols and procedures.

294 (d) Establish annual reporting requirements for organ
295 transplantation facilities and organ procurement organizations.

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

300 (2) By December 1, 2021, and each year thereafter, the



301 agency shall publish any data and other relevant information to
302 adequately inform patients and potential donors about organ
303 donation and organ transplantation.

304 Section 10. Paragraph (e) of subsection (2) of section
305 409.815, Florida Statutes, is amended to read:

306 409.815 Health benefits coverage; limitations.—

307 (2) BENCHMARK BENEFITS.—In order for health benefits
308 coverage to qualify for premium assistance payments for an
309 eligible child under ss. 409.810-409.821, the health benefits
310 coverage, except for coverage under Medicaid and Medikids, must
311 include the following minimum benefits, as medically necessary.

312 (e) *Organ transplantation services.*—Covered services
313 include pretransplant, transplant, and postdischarge services
314 and treatment of complications after transplantation for
315 transplants deemed necessary and appropriate within the
316 guidelines set by the Organ Transplant Technical Advisory
317 Council under s. 765.53 or the Bone Marrow Transplant Advisory
318 Panel under s. 627.4236.

319 Section 11. This act shall take effect July 1, 2020.

320
321 ===== T I T L E A M E N D M E N T =====

322 And the title is amended as follows:

323 Delete everything before the enacting clause
324 and insert:

325 A bill to be entitled
326 An act relating to organ donation; amending s.
327 408.0455, F.S.; revising a provision relating to the
328 operation of certain rules adopted by the Agency for
329 Health Care Administration; amending s. 627.6045,



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330 F.S.; prohibiting a health insurance policy from
331 limiting or excluding coverage solely on the basis
332 that an insured is a living organ donor; amending s.
333 765.514, F.S.; revising a written document for making
334 an anatomical gift to include a specified statement
335 relating to the responsibility of payment for fees
336 associated with certain services; amending s.
337 765.5155, F.S.; revising the responsibilities of a
338 contractor procured by the agency for the purpose of
339 educating and informing the public about anatomical
340 gifts; amending s. 765.517, F.S.; prohibiting an organ
341 transplantation facility from charging a donor or his
342 or her family member any fee for services relating to
343 the procurement or donation of organs; amending s.
344 765.522, F.S.; revising a requirement that the agency
345 establish rules and guidelines relating to the
346 education of certain individuals designated to perform
347 certain organ donation procedures; amending s. 765.53,
348 F.S.; requiring the agency to establish the Organ
349 Transplant Technical Advisory Council for a specified
350 purpose; providing for membership, meetings, and
351 duties of the council; requiring the council to submit
352 a report to the Governor, the Legislature, the
353 Secretary of Health Care Administration, and the State
354 Surgeon General by a specified date; providing for
355 sovereign immunity of council members under certain
356 circumstances; requiring the agency to adopt specified
357 rules based on the council's recommendations;
358 providing for future legislative review and repeal of



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359 certain provisions; amending s. 765.543, F.S.;

360 revising the duties of the Organ and Tissue

361 Procurement and Transplantation Advisory Board;

362 requiring the board to submit certain recommendations

363 to the agency by a specified date; creating s.

364 765.548, F.S.; providing additional duties of the

365 agency relating to organ transplantation facilities

366 and organ procurement organizations and organ donation

367 procedures and protocols; requiring the agency to

368 publish certain data and information by a specified

369 date and annually thereafter; amending s. 409.815,

370 F.S.; conforming a provision to changes made by the

371 act; providing an effective date.