

By the Committees on 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.
3 408.0455, F.S.; revising a provision relating to the
4 operation of certain rules adopted by the Agency for
5 Health Care Administration; amending s. 627.6045,
6 F.S.; prohibiting a health insurance policy from
7 limiting or excluding coverage solely on the basis
8 that an insured is a living organ donor; amending s.
9 765.514, F.S.; revising a written document required
10 for making an anatomical gift to include a specified
11 statement relating to the responsibility of payment
12 for fees associated with certain services; amending s.
13 765.5155, F.S.; revising the responsibilities of a
14 contractor procured by the agency for the purpose of
15 educating and informing the public about anatomical
16 gifts; amending s. 765.517, F.S.; prohibiting an organ
17 transplantation facility from charging a donor or his
18 or her family member any fee for services relating to
19 the procurement or donation of organs; amending s.
20 765.53, F.S.; requiring the agency to establish the
21 Organ Transplant Technical Advisory Council for a
22 specified purpose; providing for membership, meetings,
23 and duties of the council; requiring the council to
24 submit a report to the Governor, the Legislature, the
25 Secretary of Health Care Administration, and the State
26 Surgeon General by a specified date; providing for
27 sovereign immunity of council members under certain
28 circumstances; requiring the agency to adopt specified
29 rules based on the council's recommendations;

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30 providing for future legislative review and repeal of
31 certain provisions; amending s. 765.543, F.S.;
32 revising the duties of the Organ and Tissue
33 Procurement and Transplantation Advisory Board;
34 requiring the board to submit certain recommendations
35 to the agency by a specified date; creating s.
36 765.548, F.S.; providing additional duties of the
37 agency relating to organ transplantation facilities
38 and organ procurement organizations and organ donation
39 procedures and protocols; requiring the agency to
40 publish certain data and information by a specified
41 date and annually thereafter; amending s. 409.815,
42 F.S.; conforming a provision to changes made by the
43 act; providing an effective date.

44
45 Be It Enacted by the Legislature of the State of Florida:

46
47 Section 1. Section 408.0455, Florida Statutes, is amended
48 to read:

49 408.0455 Rules; pending proceedings.—The rules of the
50 agency in effect on June 30, 2004, ~~shall~~ remain in effect and
51 are shall be enforceable by the agency with respect to ss.
52 408.031-408.045 until such rules are repealed or amended by the
53 agency. Rules 59C-1.039 through 59C-1.044, Florida
54 Administrative Code, including, but not limited to, the minimum
55 volume standards for organ transplantation and neonatal
56 intensive care services, remain in effect for the sole purpose
57 of maintaining licensure requirements for the applicable
58 services until the agency has adopted rules for the

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59 corresponding services pursuant to s. 395.1055(1)(i), Florida
60 Statutes 2018.

61 Section 2. Present subsections (3) and (4) of section
62 627.6045, Florida Statutes, are redesignated as subsections (4)
63 and (5), respectively, and a new subsection (3) is added to that
64 section, to read:

65 627.6045 Preexisting condition.—A health insurance policy
66 must comply with the following:

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

70 Section 3. Paragraph (f) of subsection (1) of section
71 765.514, Florida Statutes, is amended to read:

72 765.514 Manner of making anatomical gifts.—

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

75 (f) Expressing a wish to donate in a document other than a
76 will. The document must be signed by the donor in the presence
77 of two witnesses who shall sign the document in the donor's
78 presence. If the donor cannot sign, the document may be signed
79 for him or her at the donor's direction and in his or her
80 presence and the presence of two witnesses who must sign the
81 document in the donor's presence. Delivery of the document of
82 gift during the donor's lifetime is not necessary to make the
83 gift valid. The following form of written document is sufficient
84 for any person to make an anatomical gift for the purposes of
85 this part:

86 UNIFORM DONOR CARD

87 The undersigned hereby makes this anatomical gift, if medically

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88 acceptable, to take effect on death. The words and marks below
 89 indicate my desires:

90 I give:

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

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

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

94 for the purpose of transplantation, therapy, medical research,
 95 or education;

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

97 Limitations or special wishes, if any:

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

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

100

101 I understand that neither I nor any member of my family is
 102 responsible for the payment of any fees associated with services
 103 relating to the procurement or donation of my organs, tissues,
 104 or eyes.

105

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

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

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

110 ... (Witness)... ... (Witness)...

111 ... (Address)... ... (Address)...

112 Section 4. Paragraph (b) of subsection (3) of section
 113 765.5155, Florida Statutes, is amended to read:

114 765.5155 Donor registry; education program.—

115 (3) The contractor shall be responsible for:

116 (b) A continuing program to educate and inform medical

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117 professionals, law enforcement agencies and officers, other
118 state and local government employees, high school students,
119 minorities, and the public about state and federal ~~the~~ laws ~~of~~
120 ~~this state~~ relating to anatomical gifts and the need for
121 anatomical gifts, including the organ donation and
122 transplantation process.

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

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

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

132 765.517 Rights and duties at death.—

133 (4) All reasonable additional expenses incurred in the
134 procedures to preserve the donor's organs or tissues shall be
135 reimbursed by the procurement organization. An organ
136 transplantation facility may not charge a deceased donor or his
137 or her family member any fee for services relating to the
138 procurement or donation of the deceased donor's organs. An organ
139 transplantation facility may not charge a living donor for
140 services relating to the procurement or donation of his or her
141 organs.

142 Section 6. Section 765.53, Florida Statutes, is amended to
143 read:

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

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146 765.53 Organ Transplant Technical Advisory Council.—

147 (1) CREATION AND PURPOSE.—The Organ Transplant Technical
148 Advisory Council, an advisory council as defined in s. 20.03, is
149 created within the agency to develop standards for measuring
150 quality and outcomes of adult and pediatric organ transplant
151 programs. In order to increase the number of organs available
152 for transplantation in this state, the council shall advise the
153 agency and the Legislature regarding the cost savings, trends,
154 research, and protocols and procedures relating to organ
155 donation and transplantation, including the availability of
156 organs for donation, organ donor benefits, and access to organ
157 transplants for persons with disabilities. Unless expressly
158 provided otherwise in this section, the council shall operate in
159 a manner consistent with s. 20.052.

160 (2) MEMBERS.—

161 (a) Voting members of the council must have technical
162 expertise in adult or pediatric organ transplantation. The chief
163 executive officers of the following organ transplantation
164 facilities shall each appoint one representative, who must be an
165 organ transplant nurse coordinator licensed under chapter 464 or
166 an organ transplant surgeon licensed under chapter 458 or
167 chapter 459, to serve as a voting member of the council:

168 1. Jackson Memorial Hospital in Miami.

169 2. Tampa General Hospital in Tampa.

170 3. University of Florida Health Shands Hospital in
171 Gainesville.

172 4. AdventHealth Orlando in Orlando.

173 5. Mayo Clinic in Jacksonville.

174 6. Cleveland Clinic Florida in Weston.

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175 7. Largo Medical Center in Largo.

176 8. Broward Health Medical Center in Fort Lauderdale.

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

179 (c) The Secretary of Health Care Administration shall serve
180 as the chair and a nonvoting member of the council.

181 (d) The Secretary of Health Care Administration shall
182 appoint the following individuals to serve as voting members of
183 the council:

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

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

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

187 4. An adult patient who is on an organ transplant waiting
188 list.

189 5. A licensed pediatric and adult organ transplant
190 physician for each of the following areas:

191 a. Kidneys.

192 b. Lungs.

193 c. Heart.

194 d. Liver.

195 e. Pancreas.

196 6. A representative from an organ procurement organization.

197 7. An administrator of an organ transplant program.

198 (e) Appointments made under paragraph (a) are contingent
199 upon the hospital's compliance with chapter 395 and rules
200 adopted thereunder. A member of the council appointed under
201 paragraph (a) whose hospital fails to comply with such law and
202 rules may serve only as a nonvoting member until the hospital
203 comes into compliance.

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204 (f) Any vacancy on the council must be filled in the same
205 manner as the original appointment. Members are eligible for
206 reappointment.

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

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

214 (4) DUTIES.—The council shall recommend to the agency and
215 the Legislature the standards for quality care of adult and
216 pediatric organ transplant patients, including recommendations
217 on minimum volume of transplants by organ type, personnel,
218 physical plant, equipment, transportation, and data reporting
219 for hospitals that perform organ transplants. The council may
220 further advise the agency and the Legislature regarding research
221 focused on improving overall organ availability and benefits for
222 organ donors. A voting member may vote on standards related to a
223 specific type of organ only if he or she represents a hospital
224 that has a transplant program for that organ.

225 (5) REPORT.—By October 1, 2021, the council shall submit a
226 report of its recommendations to the Governor, the President of
227 the Senate, the Speaker of the House of Representatives, the
228 Secretary of Health Care Administration, and the State Surgeon
229 General.

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

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233 (7) AGENCY RULES.-

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

237 1. Quality of care standards for adult and pediatric organ
238 transplants, including minimum volume thresholds by organ type,
239 personnel, physical plant, equipment, transportation, and data
240 reporting.

241 2. Outcome and survival rate standards that meet or exceed
242 nationally established levels of performance in organ
243 transplantation.

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

249 (b) This subsection is repealed July 1, 2030, unless
250 reviewed and saved from repeal through reenactment by the
251 Legislature.

252 Section 7. Subsection (3) of section 765.543, Florida
253 Statutes, is amended to read:

254 765.543 Organ and Tissue Procurement and Transplantation
255 Advisory Board; creation; duties.-

256 (3) The board shall:

257 (a) Assist the agency, in collaboration with other relevant
258 public or private entities, in the development of necessary
259 professional qualifications, including, but not limited to, the
260 continuing education, training, and performance of persons
261 engaged in the various facets of organ and tissue procurement,

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262 processing, preservation, and distribution for transplantation;

263 (b) Assist the agency in monitoring the appropriate and
264 legitimate expenses associated with organ and tissue
265 procurement, processing, and distribution for transplantation
266 and developing methodologies to assure the uniform statewide
267 reporting of data to facilitate the accurate and timely
268 evaluation of the organ and tissue procurement and
269 transplantation system;

270 (c) Provide assistance to the Florida Medical Examiners
271 Commission in the development of appropriate procedures and
272 protocols to ensure the continued improvement in the approval
273 and release of potential donors by the district medical
274 examiners and associate medical examiners;

275 (d) Develop with and recommend to the agency the necessary
276 procedures and protocols required to assure that all residents
277 of this state have reasonable access to available organ and
278 tissue transplantation therapy and that residents of this state
279 can be reasonably assured that the statewide procurement
280 transplantation system is able to fulfill their organ and tissue
281 requirements within the limits of the available supply and
282 according to the severity of their medical condition and need;
283 and

284 (e) Develop with and recommend to the agency any changes to
285 the laws of this state or administrative rules or procedures to
286 ensure that the statewide organ and tissue procurement and
287 transplantation system is able to function smoothly,
288 effectively, and efficiently, in accordance with the Federal
289 Anatomical Gift Act and in a manner that assures the residents
290 of this state that no person or entity profits from the

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291 altruistic voluntary donation of organs or tissues. In addition
292 to the general duties described in this subsection, by September
293 1, 2021, the board shall submit to the agency recommendations
294 that address all of the following:

295 1. The frequency of communication between patients and
296 organ transplant coordinators.

297 2. The monitoring of each organ transplantation facility
298 and the annual reporting and publication of relevant information
299 regarding the statewide number of patients placed on waiting
300 lists and the number of patients who receive transplants,
301 aggregated by the facility.

302 3. The establishment of a coordinated communication system
303 between organ transplantation facilities and living organ donors
304 for the purpose of minimizing the cost and time required for
305 duplicative lab tests, including the sharing of lab results
306 between facilities.

307 4. The potential incentives for organ transplantation
308 facilities which may be necessary to increase organ donation in
309 this state.

310 5. The creation of a more efficient regional or statewide
311 living organ donor process.

312 6. The potential opportunities and incentives for organ
313 transplantation research.

314 7. The best practices for organ transplantation facilities
315 and organ procurement organizations which promote the most
316 efficient and effective outcomes for patients.

317 8. The monitoring of organ procurement organizations.

318 Section 8. Section 765.548, Florida Statutes, is created to
319 read:

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320 765.548 Duties of the agency; organ donation.—

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

322 (a) Monitor the operation of each organ transplantation
323 facility and organ procurement organization located in this
324 state.

325 (b) Develop uniform statewide rules regarding organ
326 donations. The rules must include the requirement that each
327 hospital designate at least one employee or representative of
328 the hospital who is educated on the protocols of the hospital
329 and federal and state regulations regarding organ donation, to
330 provide a clear explanation of such subjects to any patient, or
331 a patient's representative, who is considering posthumous or
332 living organ donation. The rules may also include, but need not
333 be limited to, procedures for maintaining a coordinated system
334 of communication between organ transplantation facilities.

335 (c) Evaluate the current protocols and procedures used by
336 organ transplantation facilities and make recommendations for
337 improving such protocols and procedures.

338 (d) Establish annual reporting requirements for organ
339 transplantation facilities and organ procurement organizations.

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

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

348 Section 9. Paragraph (e) of subsection (2) of section

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349 409.815, Florida Statutes, is amended to read:

350 409.815 Health benefits coverage; limitations.—

351 (2) BENCHMARK BENEFITS.—In order for health benefits
352 coverage to qualify for premium assistance payments for an
353 eligible child under ss. 409.810-409.821, the health benefits
354 coverage, except for coverage under Medicaid and Medikids, must
355 include the following minimum benefits, as medically necessary.

356 (e) *Organ transplantation services*.—Covered services
357 include pretransplant, transplant, and postdischarge services
358 and treatment of complications after transplantation for
359 transplants deemed necessary and appropriate within the
360 guidelines set by the Organ Transplant Technical Advisory
361 Council under s. 765.53 or the Bone Marrow Transplant Advisory
362 Panel under s. 627.4236.

363 Section 10. This act shall take effect July 1, 2020.