

By the Committee on Health Policy; and Senator Harrell

588-02737-20

20201516c1

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 for making
10 an anatomical gift to include a specified statement
11 relating to the responsibility of payment for fees
12 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;

588-02737-20

20201516c1

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

588-02737-20

20201516c1

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

588-02737-20

20201516c1

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

588-02737-20

20201516c1

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 donor or his or her
137 family member any fee for services relating to the procurement
138 or donation of his or her organs.

139 Section 6. Section 765.53, Florida Statutes, is amended to
140 read:

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

143 765.53 Organ Transplant Technical Advisory Council.—

144 (1) CREATION AND PURPOSE.—The Organ Transplant Technical
145 Advisory Council, an advisory council as defined in s. 20.03, is

588-02737-20

20201516c1

146 created within the agency to develop standards for measuring
147 quality and outcomes of adult and pediatric organ transplant
148 programs. In order to increase the number of organs available
149 for transplantation in this state, the council shall advise the
150 agency and the Legislature regarding the cost savings, trends,
151 research, and protocols and procedures relating to organ
152 donation and transplantation, including the availability of
153 organs for donation. Unless expressly provided otherwise in this
154 section, the council shall operate in a manner consistent with
155 s. 20.052.

156 (2) MEMBERS.—

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

164 1. Jackson Memorial Hospital in Miami.

165 2. Tampa General Hospital in Tampa.

166 3. University of Florida Health Shands Hospital in
167 Gainesville.

168 4. AdventHealth Orlando in Orlando.

169 5. Mayo Clinic in Jacksonville.

170 6. Cleveland Clinic Florida in Weston.

171 7. Largo Medical Center in Largo.

172 8. Broward Health Medical Center in Fort Lauderdale.

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

588-02737-20

20201516c1

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

177 (d) The Secretary of Health Care Administration shall
178 appoint the following individuals to serve as voting members of
179 the council:

180 1. The State Surgeon General or his or her designee.
181 2. A parent of a child who has had an organ transplant.
182 3. An adult who has had an organ transplant.
183 4. An adult patient who is on an organ transplant waiting
184 list.

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

187 a. Kidneys.
188 b. Lungs.
189 c. Heart.
190 d. Liver.
191 e. Pancreas.

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

198 (f) Any vacancy on the council must be filled in the same
199 manner as the original appointment. Members are eligible for
200 reappointment.

201 (g) Members of the council shall serve without compensation
202 but may be reimbursed as provided in s. 112.061 for per diem and
203 travel expenses incurred in the performance of their duties

588-02737-20

20201516c1

204 under this section.

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

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

219 (5) REPORT.—By October 1, 2021, the council shall submit a
220 report of its recommendations to the Governor, the President of
221 the Senate, the Speaker of the House of Representatives, the
222 Secretary of Health Care Administration, and the State Surgeon
223 General.

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

227 (7) AGENCY RULES.—

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

231 1. Quality of care standards for adult and pediatric organ
232 transplants, including minimum volume thresholds by organ type,

588-02737-20

20201516c1

233 personnel, physical plant, equipment, transportation, and data
234 reporting.

235 2. Outcome and survival rate standards that meet or exceed
236 nationally established levels of performance in organ
237 transplantation.

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

243 (b) This subsection is repealed July 1, 2030, unless
244 reviewed and saved from repeal through reenactment by the
245 Legislature.

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

248 765.543 Organ and Tissue Procurement and Transplantation
249 Advisory Board; creation; duties.—

250 (3) The board shall:

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

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

588-02737-20

20201516c1

262 evaluation of the organ and tissue procurement and
263 transplantation system;

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

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

278 (e) Develop with and recommend to the agency any changes to
279 the laws of this state or administrative rules or procedures to
280 ensure that the statewide organ and tissue procurement and
281 transplantation system is able to function smoothly,
282 effectively, and efficiently, in accordance with the Federal
283 Anatomical Gift Act and in a manner that assures the residents
284 of this state that no person or entity profits from the
285 altruistic voluntary donation of organs or tissues. In addition
286 to the general duties described in this subsection, by September
287 1, 2021, the board shall submit to the agency recommendations
288 that address the following:

289 1. The frequency of communication between patients and
290 organ transplant coordinators.

588-02737-20

20201516c1

291 2. The monitoring of each organ transplantation facility
292 and the annual reporting and publication of relevant information
293 regarding the statewide number of patients placed on waiting
294 lists and the number of patients who receive transplants,
295 aggregated by the facility.

296 3. The establishment of a coordinated communication system
297 between organ transplantation facilities and living organ donors
298 for the purpose of minimizing the cost and time required for
299 duplicative lab tests, including the sharing of lab results
300 between facilities.

301 4. The potential incentives for organ transplantation
302 facilities that may be necessary to increase organ donation in
303 this state.

304 5. The creation of a more efficient regional or statewide
305 living organ donor process.

306 6. The potential opportunities and incentives for organ
307 transplantation research.

308 7. The best practices for organ transplantation facilities
309 and organ procurement organizations which promote the most
310 efficient and effective outcomes for patients.

311 8. The monitoring of organ procurement organizations.

312 Section 8. Section 765.548, Florida Statutes, is created to
313 read:

314 765.548 Duties of the agency; organ donation.—

315 (1) The agency shall:

316 (a) Monitor the operation of each organ transplantation
317 facility and organ procurement organization located in this
318 state.

319 (b) Develop uniform statewide rules regarding organ

588-02737-20

20201516c1

320 donations. The rules must include the requirement that each
321 hospital designate at least one employee or representative of
322 the hospital who is educated on the protocols of the hospital
323 and federal and state regulations regarding organ donation, to
324 provide a clear explanation of such subjects to any patient, or
325 a patient's representative, who is considering posthumous or
326 living organ donation. The rules may also include, but need not
327 be limited to, procedures for maintaining a coordinated system
328 of communication between organ transplantation facilities.

329 (c) Evaluate the current protocols and procedures used by
330 organ transplantation facilities and make recommendations for
331 improving such protocols and procedures.

332 (d) Establish annual reporting requirements for organ
333 transplantation facilities and organ procurement organizations.

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

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

342 Section 9. Paragraph (e) of subsection (2) of section
343 409.815, Florida Statutes, is amended to read:

344 409.815 Health benefits coverage; limitations.—

345 (2) BENCHMARK BENEFITS.—In order for health benefits
346 coverage to qualify for premium assistance payments for an
347 eligible child under ss. 409.810-409.821, the health benefits
348 coverage, except for coverage under Medicaid and Medikids, must

588-02737-20

20201516c1

349 include the following minimum benefits, as medically necessary.

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

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