# LEGISLATIVE ACTION Senate House Comm: RCS 01/29/2020

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

## Senate Amendment (with title amendment)

3 4 and insert:

1

2

5

7

8 9

10

Delete everything after the enacting clause

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remain in effect and are shall be enforceable by the agency with respect to ss. 408.031-408.045 until such rules are repealed or amended by the

21

22

23

24

2.5

26

27

28

29

30

31

32

33

34 35

36

37

38

39



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 of maintaining licensure requirements for the applicable 15 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

627.6045, Florida Statutes, are redesignated as subsections (4) and (5), respectively, and a new subsection (3) is added to that section, to read:

- 627.6045 Preexisting condition.—A health insurance policy must comply with the following:
- (3) A preexisting condition provision may not limit or exclude coverage solely on the basis that an insured is a living organ donor.

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

765.514 Manner of making anatomical gifts.-

- (1) A person may make an anatomical gift of all or part of his or her body under s. 765.512(1) by:
- (f) Expressing a wish to donate in a document other than a will. The document must be signed by the donor in the presence of two witnesses who shall sign the document in the donor's presence. If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must sign the document in the donor's presence. Delivery of the document of



40 gift during the donor's lifetime is not necessary to make the gift valid. The following form of written document is sufficient 41 42 for any person to make an anatomical gift for the purposes of 43 this part: UNIFORM DONOR CARD 44 45 The undersigned hereby makes this anatomical gift, if medically acceptable, to take effect on death. The words and marks below 46 indicate my desires: 47 48 I give: 49 (a) .... any needed organs, tissues, or eyes; 50 (b) .... only the following organs, tissues, or eyes ...[Specify the organs, tissues, or eyes]... 51 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. 6.3 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)... ...(Date signed)... (City and State)... 67 68 ...(Witness)... (Witness)...

73

74

75

76

77

78 79

80

81 82

8.3

84

85

86

87

88 89

90

91

92

93

94

95

96

97



69 ...(Address)... ... (Address) ... 70 Section 4. 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 5. 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 procedures to preserve the donor's organs or tissues shall be reimbursed by the procurement organization. An organ transplantation facility may not charge a donor or his or her family member any fee for services relating to the procurement or donation of his or her organs.

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



Statutes, is amended to read:

98

99

100

101

102

103

104

105

106

107

108

109

110

111

112

113

114 115

116

117

118

119

120

121

122

123

124

125

126

765.522 Duty of hospital administrators; liability of hospital administrators and procurement organizations.-

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

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

(Substantial rewording of section. See

s. 765.53, F.S., for present text.)

765.53 Organ Transplant Technical Advisory Council.-

(1) CREATION AND PURPOSE.—The Organ Transplant Technical Advisory Council, an advisory council as defined in s. 20.03, is created within the agency to develop standards for measuring quality and outcomes of adult and pediatric organ transplant programs. In order to increase the number of organs available for transplantation in this state, the council shall advise the agency and the Legislature regarding the cost savings, trends, research, and protocols and procedures relating to organ donation and transplantation, including the availability of organs for donation. Unless expressly provided otherwise in this

(2) MEMBERS.—

s. 20.052.

section, the council shall operate in a manner consistent with



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	<pre>list.</pre>
153	5. A licensed physician who practices in each of the
154	following organ transplantation areas:
155	a. Kidneys.

b. Lungs.

156



157 c. Heart. d. Liver. 158 159 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. (3) MEETINGS.—The council shall meet at least twice 173 174 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

186

187

188 189

190

191

192

193 194

195

196

197

198

199

200

201

202

203

204

205

206

207

208

209

210

211

212

213



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

- (5) REPORT.—By October 1, 2021, the council shall submit a report of its recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General.
- (6) SOVEREIGN IMMUNITY.—Members of the council acting in good faith in the performance of their duties under this section are considered agents of the state for purposes of s. 768.28.
  - (7) AGENCY RULES.—
- (a) Based on the recommendations of the council, the agency shall develop and adopt rules for organ transplant programs which, at a minimum, include all of the following:
- 1. Quality of care standards for adult and pediatric organ transplants, including minimum volume thresholds by organ type, personnel, physical plant, equipment, transportation, and data reporting.
- 2. Outcome and survival rate standards that meet or exceed nationally established levels of performance in organ transplantation.
- 3. Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the volume, outcome, or survival rate standards within a specified timeframe that includes the time required for detailed case reviews and the development and implementation of corrective action plans.
- (b) This subsection is repealed July 1, 2030, unless reviewed and saved from repeal through reenactment by the Legislature.

215

216

217

218

219

220

221

222 223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242



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

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

- (3) The board shall:
- (a) Assist the agency, in collaboration with other relevant public or private entities, in the development of necessary professional qualifications, including, but not limited to, the continuing education, training, and performance of persons engaged in the various facets of organ and tissue procurement, processing, preservation, and distribution for transplantation;
- (b) Assist the agency in monitoring the appropriate and legitimate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;
- (c) Provide assistance to the Florida Medical Examiners Commission in the development of appropriate procedures and protocols to ensure the continued improvement in the approval and release of potential donors by the district medical examiners and associate medical examiners;
- (d) Develop with and recommend to the agency the necessary procedures and protocols required to assure that all residents of this state have reasonable access to available organ and tissue transplantation therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is able to fulfill their organ and tissue

244

2.45

246

247

248

249

250

2.51 252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

270

271



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

- (e) Develop with and recommend to the agency any changes to the laws of this state or administrative rules or procedures to ensure that the statewide organ and tissue procurement and transplantation system is able to function smoothly, effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents of this state that no person or entity profits from the altruistic voluntary donation of organs or tissues. In addition to the general duties described in this subsection, by September 1, 2021, the board shall submit to the agency recommendations that address the following:
- 1. The frequency of communication between patients and organ transplant coordinators.
- 2. The monitoring of each organ transplantation facility and the annual reporting and publication of relevant information regarding the statewide number of patients placed on waiting lists and the number of patients who receive transplants, aggregated by the facility.
- 3. The establishment of a coordinated communication system between organ transplantation facilities and living organ donors for the purpose of minimizing the cost and time required for duplicative lab tests, including the sharing of lab results between facilities.
- 4. The potential incentives for organ transplantation facilities that may be necessary to increase organ donation in this state.



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

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

300



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 eligible child under ss. 409.810-409.821, the health benefits 309 310 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 quidelines set by the Organ Transplant Technical Advisory 317 Council under s. 765.53 or the Bone Marrow Transplant Advisory Panel under s. 627.4236. 318 319 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

Health Care Administration; amending s. 627.6045,

329

331

332

333

334

335

336

337

338

339

340

341

342

343

344

345

346

347

348

349

350

351

352

353

354

355

356

357

358



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

360

361 362

363

364

365

366

367

368

369

370

371



certain provisions; amending s. 765.543, F.S.; revising the duties of the Organ and Tissue Procurement and Transplantation Advisory Board; requiring the board to submit certain recommendations to the agency by a specified date; creating s. 765.548, F.S.; providing additional duties of the agency relating to organ transplantation facilities and organ procurement organizations and organ donation procedures and protocols; requiring the agency to publish certain data and information by a specified date and annually thereafter; amending s. 409.815, F.S.; conforming a provision to changes made by the act; providing an effective date.