

LEGISLATIVE ACTION

Senate Comm: RCS 01/29/2020 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 <u>are shall be enforceable by the agency with respect to ss.</u> 408.031-408.045 until such rules are repealed or amended by the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



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.)
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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.
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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 765.5155, Florida Statutes, is amended to read: 71 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 this state relating to anatomical gifts and the need for 78 79 anatomical gifts, including the organ donation and 80 transplantation process. 1. Existing community resources, when available, must be 81 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 her designee, to establish convenient times, dates, and 86 locations for educating that entity's employees. 87 Section 5. Subsection (4) of section 765.517, Florida 88 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



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	<u>s. 20.052.</u>
126	(2) MEMBERS

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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b. Lungs.
<u>c. Heart.</u>
d. Liver.
e. Pancreas.
(d) Appointments made under paragraph (a) are contingent
upon the hospital's compliance with chapter 395 and rules
adopted thereunder. A member of the council appointed under
paragraph (a) whose hospital fails to comply with such law and
rules may serve only as a nonvoting member until the hospital
comes into compliance.
(e) Any vacancy on the council must be filled in the same
manner as the original appointment. Members are eligible for
reappointment.
(f) Members of the council shall serve without compensation
but may be reimbursed as provided in s. 112.061 for per diem and
travel expenses incurred in the performance of their duties
under this section.
(3) MEETINGSThe council shall meet at least twice
annually and upon the call of the chair. The council may use any
method of telecommunications to conduct its meetings.
(4) DUTIES.—The council shall recommend to the agency and
the Legislature the standards for quality care of adult and
pediatric organ transplant patients, including recommendations
on minimum volume of transplants by organ type, personnel,
physical plant, equipment, transportation, and data reporting
for hospitals that perform organ transplants. The council may
further advise the agency and the Legislature regarding research
focused on improving overall organ availability. A voting member
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) REPORTBy 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 IMMUNITYMembers 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.



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.—

(3) The board shall:

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(a) Assist the agency, in collaboration with other relevant <u>public or private entities</u>, in the development of necessary professional qualifications, including, but not limited to, the <u>continuing</u> 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

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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 Anatomical Gift Act and in a manner that assures the residents 2.51 252 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

organ transplant coordinators.

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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.

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

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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

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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 BENEFITSIn 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 servicesCovered 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 <u>Technical</u> 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.
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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

COMMITTEE AMENDMENT

Florida Senate - 2020 Bill No. SB 1516



359 certain provisions; amending s. 765.543, F.S.; 360 revising the duties of the Organ and Tissue Procurement and Transplantation Advisory Board; 361 362 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.