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. 765.5155, F.S.; revising the responsibilities of a 13 14 contractor procured by the agency for the purpose of educating and informing the public about anatomical 15 gifts; amending s. 765.517, F.S.; prohibiting an organ 16 17 transplantation facility from charging a donor or his or her family member any fee for services relating to 18 19 the procurement or donation of organs; amending s. 765.522, F.S.; revising a requirement that the agency 20 21 establish rules and guidelines relating to the 22 education of certain individuals designated to perform 23 certain organ donation procedures; amending s. 765.53, F.S.; requiring the agency to establish the Organ 24 25 Transplant Technical Advisory Council for a specified

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26 purpose; providing for membership, meetings, and 27 duties of the council; requiring the council to submit 28 a report to the Governor, the Legislature, the 29 Secretary of Health Care Administration, and the State 30 Surgeon General by a specified date; providing for 31 sovereign immunity of council members under certain 32 circumstances; requiring the agency to adopt specified 33 rules based on the council's recommendations; providing for future legislative review and repeal of 34 certain provisions; amending s. 765.543, F.S.; 35 36 revising the duties of the Organ and Tissue 37 Procurement and Transplantation Advisory Board; requiring the board to submit certain recommendations 38 39 to the agency by a specified date; creating s. 765.548, F.S.; providing duties of the agency relating 40 41 to organ transplantation facilities and organ 42 procurement organizations and organ donation 43 procedures and protocols; requiring the agency to publish certain data and information by a specified 44 date; providing an effective date. 45 46 47 Be It Enacted by the Legislature of the State of Florida: 48 49 Section 1. Section 408.0455, Florida Statutes, is amended 50 to read:

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408.0455 Rules; pending proceedings.-The rules of the 51 52 agency in effect on June 30, 2004, shall remain in effect and 53 are shall be enforceable by the agency with respect to ss. 54 408.031-408.045 until such rules are repealed or amended by the 55 agency. Rules 59C-1.039 through 59C-1.044, Florida 56 Administrative Code, including, but not limited to, the minimum 57 volume standards for organ transplantation and neonatal intensive care services, remain in effect for the sole purpose 58 of maintaining licensure requirements for the applicable 59 services until the agency has adopted rules for the 60 corresponding services pursuant to s. 395.1055(1)(i), Florida 61 62 Statutes 2018. Section 2. Subsections (3) and (4) of section 627.6045, 63 64 Florida Statutes, are renumbered as subsections (4) and (5), 65 respectively, and a new subsection (3) is added to that section, 66 to read: 627.6045 Preexisting condition.-A health insurance policy 67 68 must comply with the following: 69 (3) A preexisting condition provision may not limit or 70 exclude coverage solely on the basis that an insured is a living 71 organ donor. 72 Section 3. Paragraph (f) of subsection (1) of section 765.514, Florida Statutes, is amended to read: 73 74 765.514 Manner of making anatomical gifts.-75 (1) A person may make an anatomical gift of all or part of

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76 his or her body under s. 765.512(1) by:

77 Expressing a wish to donate in a document other than a (f) 78 will. The document must be signed by the donor in the presence 79 of two witnesses who shall sign the document in the donor's 80 presence. If the donor cannot sign, the document may be signed 81 for him or her at the donor's direction and in his or her 82 presence and the presence of two witnesses who must sign the 83 document in the donor's presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the 84 gift valid. The following form of written document is sufficient 85 for any person to make an anatomical gift for the purposes of 86 87 this part: 88 UNIFORM DONOR CARD 89 The undersigned hereby makes this anatomical gift, if medically acceptable, to take effect on death. The words and marks below 90 indicate my desires: 91 92 I give: 93 any needed organs, tissues, or eyes; (a) 94 only the following organs, tissues, or eyes (b)

95 ...[Specify the organs, tissues, or eyes]... 96 for the purpose of transplantation, therapy, medical research, 97 or education;

98 (c) ... my body for anatomical study if needed.
99 Limitations or special wishes, if any:
100 ... (If applicable, list specific donee;

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101	this must be arranged in advance with the donee.)
102	I understand that neither I nor any member of my family is
103	responsible for the payment of any fees associated with services
104	relating to the procurement or donation of my organs, tissues,
105	or eyes.
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
117	professionals, law enforcement agencies and officers, other
118	state and local government employees, high school students,
119	minorities, and the public about \underline{state} and $\underline{federal}$ \underline{the} laws \overline{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.

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The contractor shall coordinate with the head of a 126 2. 127 state agency or other political subdivision of the state, or his 128 or 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. Section 6. Subsection (3) of section 765.522, Florida 139 140 Statutes, is amended to read: 765.522 Duty of hospital administrators; liability of 141 142 hospital administrators and procurement organizations.-143 The agency shall establish rules and guidelines (3) 144 concerning the education of individuals who may be designated to perform the request and the procedures to be used in making the 145 146 request, including a requirement that such individuals clearly 147 explain to patients and living organ donors the protocols of the hospital and the federal and state regulations regarding 148 149 donation. The agency is authorized to adopt rules concerning the 150 documentation of the request, where such request is made.

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151	Section 7. Section 765.53, Florida Statutes, is amended to
152	read:
153	(Substantial rewording of section. See
154	s. 765.53, F.S., for present text.)
155	765.53 Organ Transplant Technical Advisory Council
156	(1) CREATION AND PURPOSE The Organ Transplant Technical
157	Advisory Council, an advisory council as defined in s. 20.03, is
158	created within the agency to develop standards for measuring
159	quality and outcomes of adult and pediatric organ transplant
160	programs. In order to increase the number of organs available
161	for transplant in this state, the council shall advise the
162	agency and Legislature regarding the cost savings, trends,
163	research, and protocols and procedures relating to organ
164	donation and transplantation, including the availability of
165	organs for donation. Unless expressly provided otherwise in this
166	section, the council shall operate in a manner consistent with
167	<u>s. 20.052.</u>
168	(2) MEMBERS.—
169	(a) Voting members of the council must have technical
170	expertise in adult or pediatric organ transplantation. The chief
171	executive officer of each of the following organ transplantation
172	facilities shall each appoint one representative, who must be an
173	organ transplant nurse coordinator licensed under chapter 464 or
174	an organ transplant surgeon licensed under chapter 458 or
175	chapter 459, to serve as a voting member of the council:

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FLORIDA HOUSE OF	R E P R E S E N T A T I V E S
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1. Jackson Memorial Hospital in Miami.

Tampa General Hospital in Tampa.

HB 1187

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3. University of Florida Health Shands Hospital in Gainesville. 4. AdventHealth Orlando in Orlando. 5. Mayo Clinic in Jacksonville. 6. Cleveland Clinic Florida in Weston. 7. Largo Medical Center in Largo. 8. Broward Health Medical Center in Fort Lauderdale. (b) The Secretary of Health Care Administration shall serve as the chair and a nonvoting member of the council. (C) The Secretary of Health Care Administration shall appoint the following individuals to serve as voting members of the council: The State Surgeon General or his or her designee. 1. 2. A parent of a child who has an organ transplant. 3. An adult who has an organ transplant. 4. An adult patient who is on an organ transplant waiting list. 5. A licensed physician who practices in each of the following organ transplantation areas: a. Kidneys. b. Lungs. c. Heart.

200 d. Liver.

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201	e. Pancreas.
202	(d) Appointments made under paragraph (a) are contingent
203	upon the hospital's compliance with chapter 395 and rules
204	adopted thereunder. A member of the council appointed under
205	paragraph (a) whose hospital fails to comply with such law and
206	rules may serve only as a nonvoting member until the hospital
207	comes into compliance.
208	(e) Any vacancy on the council must be filled in the same
209	manner as the original appointment. Members are eligible for
210	reappointment.
211	(f) Members of the council shall serve without
212	compensation but may be reimbursed as provided in s. 112.061 for
213	per diem and travel expenses incurred in the performance of
214	their duties under this section.
215	(3) MEETINGSThe council shall meet at least twice
216	annually and upon the call of the chair. The council may use any
217	method of telecommunications to conduct its meetings.
218	(4) DUTIESThe council shall recommend to the agency and
219	the Legislature the standards for quality care of adult and
220	pediatric organ transplant patients, including recommendations
221	on minimum volume of transplants by organ type, personnel,
222	physical plant, equipment, transportation, and data reporting
223	for hospitals that perform organ transplants. The council may
224	further advise the agency and the Legislature regarding research
225	focused on improving overall organ availability. A voting member
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226	may vote on standards related to a specific type of organ only
227	if he or she represents a hospital that has a transplant program
228	for that organ.
229	(5) REPORTBy October 1, 2021, the council shall submit a
230	report of its recommendations to the Governor, the President of
231	the Senate, the Speaker of the House of Representatives, the
232	Secretary of Health Care Administration, and the State Surgeon
233	General.
234	(6) SOVEREIGN IMMUNITYMembers of the council acting in
235	good faith in the performance of their duties under this section
236	are considered agents of the state for purposes of s. 768.28.
237	(7) AGENCY RULES.—
238	(a) Based on the recommendations of the council, the
239	agency shall develop and adopt rules for organ transplant
240	programs which, at a minimum, include all of the following:
241	1. Quality of care standards for adult and pediatric organ
242	transplants, including minimum volume thresholds by organ type,
243	personnel, physical plant, equipment, transportation, and data
244	reporting.
245	2. Outcome and survival rate standards that meet or exceed
246	nationally established levels of performance in organ
247	transplantation.
248	3. Specific steps to be taken by the agency and licensed
249	facilities when the facilities do not meet the volume, outcome,
250	or survival rate standards within a specified timeframe that

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251 includes the time required for detailed case reviews and the 252 development and implementation of corrective action plans. 253 This subsection is repealed July 1, 2030, unless (b) 254 reviewed and saved from repeal through reenactment by the 255 Legislature. 256 Section 8. Subsection (3) of section 765.543, Florida 257 Statutes, is amended to read: 258 765.543 Organ and Tissue Procurement and Transplantation 259 Advisory Board; creation; duties.-260 (3) The board shall: 261 Assist the agency, in collaboration with other (a) 262 relevant public or private entities, in the development of 263 necessary professional qualifications, including, but not 264 limited to, the continuing education, training, and performance 265 of persons engaged in the various facets of organ and tissue 266 procurement, processing, preservation, and distribution for 267 transplantation; 268 (b) Assist the agency in monitoring the appropriate and 269 legitimate expenses associated with organ and tissue 270 procurement, processing, and distribution for transplantation 271 and developing methodologies to assure the uniform statewide 272 reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and 273 274 transplantation system; (c) Provide assistance to the Florida Medical Examiners 275

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276 Commission in the development of appropriate procedures and 277 protocols to ensure the continued improvement in the approval 278 and release of potential donors by the district medical 279 examiners and associate medical examiners;

280 Develop with and recommend to the agency the necessary (d) 281 procedures and protocols required to assure that all residents 282 of this state have reasonable access to available organ and 283 tissue transplantation therapy and that residents of this state 284 can be reasonably assured that the statewide procurement 285 transplantation system is able to fulfill their organ and tissue requirements within the limits of the available supply and 286 287 according to the severity of their medical condition and need; 288 and

289 (e) Develop with and recommend to the agency any changes 290 to the laws of this state or administrative rules or procedures 291 to ensure that the statewide organ and tissue procurement and 292 transplantation system is able to function smoothly, 293 effectively, and efficiently, in accordance with the Federal 294 Anatomical Gift Act and in a manner that assures the residents 295 of this state that no person or entity profits from the 296 altruistic voluntary donation of organs or tissues. In addition 297 to the general duties described in this subsection, the board must submit to the agency, by September 1, 2021, recommendations 298 299 that address the following:

300

1. The frequency of communication between patients and

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301	organ transplant coordinators.
302	2. The monitoring of each organ transplantation facility
303	and the annual reporting and publication of relevant information
304	regarding the statewide number of patients placed on waiting
305	lists and the number of patients who receive transplants,
306	aggregated by the facility.
307	3. The establishment of a coordinated communication system
308	between organ transplantation facilities and living organ donors
309	for the purpose of minimizing the cost and time required for
310	duplicative lab tests, including the sharing of lab results
311	between facilities.
312	4. The potential incentives for organ transplantation
313	facilities that may be necessary to increase organ donation in
314	the state.
315	5. The creation of a more efficient regional or statewide
316	living organ donor process.
317	6. The potential opportunities and incentives for organ
318	transplantation research.
319	7. The best practices for organ transplantation facilities
320	and organ procurement organizations that promote the most
321	efficient and effective outcomes for patients.
322	8. The monitoring of organ procurement organizations.
323	Section 9. Section 765.548, Florida Statutes, is created
324	to read:
325	765.548 Duties of the agency; organ donation
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326 (1) The agency shall: 327 Monitor the operation of each organ transplantation (a) 328 facility and organ procurement organization located in the 329 state. 330 (b) Develop uniform statewide rules regarding organ 331 donations which may include, but need not be limited to, 332 procedures for maintaining a coordinated system of communication 333 between organ transplantation facilities. (C) 334 Evaluate the current protocols and procedures used by 335 organ transplantation facilities and make recommendations for improving such protocols and procedures. 336 337 (d) Establish annual reporting requirements for organ 338 transplantation facilities and organ procurement organizations. 339 Develop, in consultation with the State Board of (e) 340 Education and the contractor procured by the agency pursuant to 341 s. 765.5155, a curriculum for educating high school students 342 regarding the laws of this state relating to organ donation. 343 (2) By December 1, 2021, and each year thereafter, the 344 agency shall publish any data and other information relevant to 345 adequately inform patients and potential donors. 346 Section 10. This act shall take effect July 1, 2020.

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