



592332

594-03378-15

Proposed Committee Substitute by the Committee on Fiscal Policy
(Appropriations Subcommittee on Health and Human Services)

A bill to be entitled

An act relating to the Florida Right to Try Act;
providing a short title; creating s. 385.213, F.S.;
defining terms; authorizing a manufacturer of an
investigational drug, biological product, or device to
make such drug, product, or device available to
certain eligible patients with a terminal illness
without charge or for a specified cost; authorizing
the manufacturer to require eligible patients to
participate in certain data collection; specifying
that an insurer, a health plan, or a government health
care program is not required to provide coverage for
the cost of such drug, product, or device; authorizing
such entities to provide coverage under specified
circumstances; specifying that such entities are not
required to cover care or treatment needed as the
result of the use of such drug, product, or device
except under certain circumstances; specifying that
the Department of Corrections and the Department of
Juvenile Justice are not required to provide coverage
for such drugs, products, or devices for individuals
in the departments' custody; prohibiting a state
regulatory board or agency from taking action against
the licenses of certain health care providers or
against the licenses or Medicare certifications of
certain health care institutions for specified actions
with respect to an eligible patient's access to,



592332

594-03378-15

28 treatment with, or use of investigational drugs,
29 biological products, or devices; specifying when an
30 investigational drug, biological product, or device
31 may continue to be offered by the manufacturer if the
32 drug, product, or device is found to be ineffective
33 under certain circumstances; requiring certain
34 information relating to clinical trials to be provided
35 to a patient taking an investigational drug,
36 biological product, or device outside of the clinical
37 trial; providing that the section does not create a
38 private cause of action against certain manufacturers,
39 entities, and individuals for any harm to an eligible
40 patient which results from the use of an
41 investigational drug, biological product, or device
42 under certain circumstances; providing a criminal
43 penalty for an official, employee, or agent of the
44 state who blocks or attempts to block the access of an
45 eligible patient to certain investigational drugs,
46 biological products, or devices; creating s. 408.064,
47 F.S.; requiring the Agency for Health Care
48 Administration to establish and maintain a database
49 that allows a state resident to electronically submit
50 a plan that indicates his or her directives for
51 compassionate and palliative care; requiring the
52 database to serve as a clearinghouse of plan
53 information that is accessible by certain health care
54 providers; authorizing the agency to subscribe to or
55 participate in a national or private clearinghouse in
56 lieu of establishing and maintaining an independent



592332

594-03378-15

57 clearinghouse; requiring the agency to publish and
58 disseminate certain information and provide certain
59 training relating to the clearinghouse; providing that
60 implementation is subject to specific appropriation;
61 amending ss. 395.1041, 400.142, and 400.487, F.S.;
62 authorizing hospital personnel, nursing home facility
63 staff, and home health agency personnel, respectively,
64 to withhold or withdraw cardiopulmonary resuscitation
65 if an individual has a Physician Order for Life-
66 Sustaining Treatment (POLST); amending s. 400.605,
67 F.S.; requiring the Department of Elder Affairs in
68 consultation with the Agency for Health Care
69 Administration to adopt by rule procedures for the
70 implementation of POLSTs in hospice care; amending s.
71 400.6095, F.S.; authorizing a hospice care team to
72 withhold or withdraw cardiopulmonary resuscitation if
73 an individual has a POLST; amending s. 401.35, F.S.;
74 requiring the Department of Health to establish
75 circumstances and procedures for honoring a POLST;
76 amending s. 401.45, F.S.; authorizing emergency
77 medical transportation providers to withhold or
78 withdraw cardiopulmonary resuscitation or other
79 medical interventions if an individual has a POLST;
80 providing requirements for a POLST to be valid;
81 amending s. 429.255, F.S.; authorizing assisted living
82 facility staff to withhold or withdraw cardiopulmonary
83 resuscitation if an individual has a POLST; amending
84 s. 429.73, F.S.; requiring the Department of Elder
85 Affairs to adopt rules for the implementation of



592332

594-03378-15

86 POLSTs in adult family-care homes; authorizing a
87 provider of such home to withhold or withdraw
88 cardiopulmonary resuscitation if an individual has a
89 POLST; providing immunity from civil and criminal
90 liability to a provider for such actions; amending s.
91 765.205, F.S.; authorizing a health care surrogate to
92 provide written consent for a POLST; providing an
93 effective date.

94

95 Be It Enacted by the Legislature of the State of Florida:

96

97 Section 1. This act may be cited as the "Florida Right to
98 Try Act."

99 Section 2. Section 385.213, Florida Statutes, is created to
100 read:

101 385.213 Compassionate treatment; access to experimental
102 treatments.-

103 (1) DEFINITIONS.-As used in this section, the term:

104 (a) "Eligible patient" means an individual who:

105 1. Has a terminal illness, as determined by the

106 individual's physician and consulting physician;

107 2. As determined by the individual's physician, does not

108 have any comparable or satisfactory United States Food and Drug

109 Administration-approved option available to be diagnosed,

110 monitored, or treated for the individual's disease or condition,

111 and the probable risk to the individual from the investigational

112 drug, biological product, or device is not greater than the risk

113 from the disease or condition;

114 3. Has received a prescription or recommendation from the



592332

594-03378-15

115 individual's physician for an investigational drug, biological
116 product, or device;

117 4. Has provided written, informed consent in accordance
118 with s. 766.103 for the use of an investigational drug,
119 biological product, or device or, if the individual is a minor
120 or lacks the mental capacity to provide informed consent, a
121 parent's or legal guardian's written, informed consent on the
122 individual's behalf; and

123 5. Has documentation from the individual's physician
124 indicating that the individual has met all the requirements of
125 this section.

126 (b) "Investigational drug, biological product, or device"
127 means a drug, biological product, or device that has
128 successfully completed phase one of a clinical trial but has not
129 yet been approved for general use by the United States Food and
130 Drug Administration.

131 (c) "Physician" means the physician licensed under chapter
132 458 or chapter 459 who provides medical care or treatment to the
133 eligible patient for the terminal illness.

134 (d) "Terminal illness" means a disease or condition that,
135 without life-sustaining procedures, will result in the patient's
136 death in the near future or a state of permanent unconsciousness
137 from which recovery is unlikely.

138 (2) AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL
139 PRODUCTS, OR DEVICES.-

140 (a) A manufacturer of an investigational drug, biological
141 product, or device may make the investigational drug, biological
142 product, or device, available to an eligible patient. A
143 manufacturer may:



592332

594-03378-15

144 1. Provide the investigational drug, biological product, or
145 device to an eligible patient without charge or require the
146 eligible patient to pay the cost of, or the cost associated
147 with, the manufacture of the investigational drug, biological
148 product, or device.

149 2. Require an eligible patient to participate in data
150 collection relating to the eligible patient's use of the
151 investigational drug, biological product, or device.

152 (b) This section does not require:

153 1. An insurer, a health plan, or a government health care
154 program to provide coverage for:

155 a. The cost of an investigational drug, biological product,
156 or device provided to an eligible patient. An insurer, a health
157 plan, or a government health care program may elect to provide
158 coverage for an investigational drug, biological product, or
159 device that is not part of a clinical trial.

160 b. Care or treatment needed as a result of an eligible
161 patient's use of an investigational drug, biological product, or
162 device unless the use is part of an approved clinical trial.

163 2. The Department of Corrections or the Department of
164 Juvenile Justice to provide coverage for an investigational
165 drug, biological product, or device for individuals in the
166 custody of the Department of Corrections or the Department of
167 Juvenile Justice.

168 (3) ACTION AGAINST PROVIDER LICENSURE PROHIBITED.—

169 Notwithstanding any other law, a state regulatory board or
170 agency:

171 (a) May not take any action against a health care
172 provider's license issued under chapter 458 or chapter 459 based



592332

594-03378-15

173 solely on the health care provider's recommendation to an
174 eligible patient regarding access to or treatment with an
175 investigational drug, biological product, or device.

176 (b) May not, with respect to a health care institution
177 licensed in this state, take any action against the
178 institution's:

179 1. License based solely on the institution's participation
180 in the treatment with, or in any other use of, an
181 investigational drug, biological product, or device.

182 2. Medicare certification based solely on a health care
183 provider's recommendation to an eligible patient regarding
184 access to an investigational drug, biological product, or
185 device.

186 (4) CLINICAL TRIALS.—

187 (a) If a clinical trial of an investigational drug,
188 biological product, or device is not effective for a certain
189 patient or condition and the trial is closed due to lack of
190 efficacy, the manufacturer or health care provider may continue
191 to offer the investigational drug, biological product, or device
192 for a different condition to the patient or to new patients.

193 (b) If the United States Food and Drug Administration or
194 the safety committee for a clinical trial provides notice of
195 information for an investigational drug, biological product, or
196 device that is being taken by a patient outside of the clinical
197 trial, the manufacturer of such drug, product, or device or the
198 patient's physician shall notify the patient of the information.

199 (5) NO CAUSE OF ACTION.—This section does not create a
200 private cause of action against a manufacturer of an
201 investigational drug, biological product, or device or against



592332

594-03378-15

202 an entity or individual involved in the care of an eligible
203 patient for any harm to the eligible patient which results from
204 the use of the investigational drug, biological product, or
205 device if the manufacturer, entity, or individual is complying
206 in good faith with this section, unless the manufacturer,
207 entity, or individual failed to exercise reasonable care.

208 (6) PENALTY.—An official, employee, or agent of the state
209 who blocks or attempts to block the access of an eligible
210 patient to an investigational drug, biological product, or
211 device that has been recommended to the eligible patient by his
212 or her physician and that has not been banned or removed from a
213 clinical trial as unsafe by the United States Food and Drug
214 Administration commits a misdemeanor of the second degree,
215 punishable as provided in s. 775.082 or s. 775.083.

216 Section 3. Section 408.064, Florida Statutes, is created to
217 read:

218 408.064 Clearinghouse for compassionate and palliative care
219 plans.—

220 (1) The agency shall establish and maintain a reliable and
221 secure database that allows a resident of this state to
222 electronically submit a plan that indicates his or her
223 directives for compassionate and palliative care. The database
224 shall serve as a clearinghouse of plan information that may be
225 accessed by a health care provider who is treating the resident.
226 The agency shall seek advice from residents, compassionate and
227 palliative care providers, and health care facilities for the
228 development and implementation of the clearinghouse.

229 (2) The agency may subscribe to or otherwise participate in
230 a national or private clearinghouse that will accomplish the



592332

594-03378-15

231 requirements under subsection (1) in lieu of establishing and
232 maintaining an independent clearinghouse for this state's
233 residents.

234 (3) The agency shall publish and disseminate information to
235 the residents of this state regarding the availability of the
236 clearinghouse. The agency must also provide training to health
237 care providers and health care facilities in this state on how
238 to access plans through the clearinghouse.

239 (4) Implementation of this section is subject to a specific
240 appropriation provided to the agency under the General
241 Appropriations Act.

242 Section 4. Paragraph (1) of subsection (3) of section
243 395.1041, Florida Statutes, is amended to read:

244 395.1041 Access to emergency services and care.—

245 (3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF
246 FACILITY OR HEALTH CARE PERSONNEL.—

247 (1) Hospital personnel may withhold or withdraw
248 cardiopulmonary resuscitation if presented with an order not to
249 resuscitate executed pursuant to s. 401.45 or a Physician Order
250 for Life-Sustaining Treatment (POLST). Facility staff and
251 facilities shall not be subject to criminal prosecution or civil
252 liability, nor be considered to have engaged in negligent or
253 unprofessional conduct, for withholding or withdrawing
254 cardiopulmonary resuscitation pursuant to either ~~such an~~ order.
255 The absence of an order not to resuscitate executed pursuant to
256 s. 401.45 or a POLST does not preclude a physician from
257 withholding or withdrawing cardiopulmonary resuscitation as
258 otherwise permitted by law.

259 Section 5. Subsection (3) of section 400.142, Florida



592332

594-03378-15

260 Statutes, is amended to read

261 400.142 Emergency medication kits; orders not to
262 resuscitate.—

263 (3) Facility staff may withhold or withdraw cardiopulmonary
264 resuscitation if presented with an order not to resuscitate
265 executed pursuant to s. 401.45 or a Physician Order for Life-
266 Sustaining Treatment (POLST). Facility staff and facilities are
267 not subject to criminal prosecution or civil liability, or
268 considered to have engaged in negligent or unprofessional
269 conduct, for withholding or withdrawing cardiopulmonary
270 resuscitation pursuant to either ~~such~~ order. The absence of an
271 order not to resuscitate executed pursuant to s. 401.45 or a
272 POLST does not preclude a physician from withholding or
273 withdrawing cardiopulmonary resuscitation as otherwise permitted
274 by law.

275 Section 6. Section 400.487, Florida Statutes, is amended to
276 read:

277 400.487 Home health service agreements; physician's,
278 physician assistant's, and advanced registered nurse
279 practitioner's treatment orders; patient assessment;
280 establishment and review of plan of care; provision of services;
281 orders not to resuscitate; physician orders for life-sustaining
282 treatment.—

283 (1) Services provided by a home health agency must be
284 covered by an agreement between the home health agency and the
285 patient or the patient's legal representative specifying the
286 home health services to be provided, the rates or charges for
287 services paid with private funds, and the sources of payment,
288 which may include Medicare, Medicaid, private insurance,



592332

594-03378-15

289 personal funds, or a combination thereof. A home health agency
290 providing skilled care must make an assessment of the patient's
291 needs within 48 hours after the start of services.

292 (2) If ~~When~~ required by the ~~provisions of~~ chapter 464, ~~+~~
293 part I, part III, or part V of chapter 468, ~~+~~ or chapter 486, the
294 attending physician, physician assistant, or advanced registered
295 nurse practitioner, acting within his or her respective scope of
296 practice, shall establish treatment orders for a patient who is
297 to receive skilled care. The treatment orders must be signed by
298 the physician, physician assistant, or advanced registered nurse
299 practitioner before a claim for payment for the skilled services
300 is submitted by the home health agency. If the claim is
301 submitted to a managed care organization, the treatment orders
302 must be signed within the time allowed under the provider
303 agreement. The treatment orders shall be reviewed, as frequently
304 as the patient's illness requires, by the physician, physician
305 assistant, or advanced registered nurse practitioner in
306 consultation with the home health agency.

307 (3) A home health agency shall arrange for supervisory
308 visits by a registered nurse to the home of a patient receiving
309 home health aide services in accordance with the patient's
310 direction, approval, and agreement to pay the charge for the
311 visits.

312 (4) Each patient has the right to be informed of and to
313 participate in the planning of his or her care. Each patient
314 must be provided, upon request, a copy of the plan of care
315 established and maintained for that patient by the home health
316 agency.

317 (5) If ~~When~~ nursing services are ordered, the home health



592332

594-03378-15

318 agency to which a patient has been admitted for care must
319 provide the initial admission visit, all service evaluation
320 visits, and the discharge visit by a direct employee. Services
321 provided by others under contractual arrangements to a home
322 health agency must be monitored and managed by the admitting
323 home health agency. The admitting home health agency is fully
324 responsible for ensuring that all care provided through its
325 employees or contract staff is delivered in accordance with this
326 part and applicable rules.

327 (6) The skilled care services provided by a home health
328 agency, directly or under contract, must be supervised and
329 coordinated in accordance with the plan of care.

330 (7) Home health agency personnel may withhold or withdraw
331 cardiopulmonary resuscitation if presented with an order not to
332 resuscitate executed pursuant to s. 401.45 or a Physician Order
333 for Life-Sustaining Treatment (POLST). The agency shall adopt
334 rules providing for the implementation of such orders. Home
335 health personnel and agencies shall not be subject to criminal
336 prosecution or civil liability, nor be considered to have
337 engaged in negligent or unprofessional conduct, for withholding
338 or withdrawing cardiopulmonary resuscitation pursuant to such
339 orders ~~an order~~ and rules adopted by the agency.

340 Section 7. Paragraph (e) of subsection (1) of section
341 400.605, Florida Statutes, is amended to read:

342 400.605 Administration; forms; fees; rules; inspections;
343 fines.—

344 (1) The agency, in consultation with the department, may
345 adopt rules to administer the requirements of part II of chapter
346 408. The department, in consultation with the agency, shall by



592332

594-03378-15

347 rule establish minimum standards and procedures for a hospice
348 pursuant to this part. The rules must include:

349 (e) Procedures relating to the implementation of advanced
350 directives; physician orders for life-sustaining treatment; and
351 do-not-resuscitate orders.

352 Section 8. Subsection (8) of section 400.6095, Florida
353 Statutes, is amended to read:

354 400.6095 Patient admission; assessment; plan of care;
355 discharge; death.—

356 (8) The hospice care team may withhold or withdraw
357 cardiopulmonary resuscitation if presented with an order not to
358 resuscitate executed pursuant to s. 401.45 or a Physician Order
359 for Life-Sustaining Treatment (POLST). The department shall
360 adopt rules providing for the implementation of such orders.
361 Hospice staff shall not be subject to criminal prosecution or
362 civil liability, nor be considered to have engaged in negligent
363 or unprofessional conduct, for withholding or withdrawing
364 cardiopulmonary resuscitation pursuant to such an order and
365 applicable rules. The absence of an order to resuscitate
366 executed pursuant to s. 401.45 or a POLST does not preclude a
367 physician from withholding or withdrawing cardiopulmonary
368 resuscitation as otherwise permitted by law.

369 Section 9. Subsection (4) of section 401.35, Florida
370 Statutes, is amended to read:

371 401.35 Rules.—The department shall adopt rules, including
372 definitions of terms, necessary to carry out the purposes of
373 this part.

374 (4) The rules must establish circumstances and procedures
375 under which emergency medical technicians and paramedics may



592332

594-03378-15

376 honor orders by the patient's physician not to resuscitate and a
377 Physician Order for Life-Sustaining Treatment (POLST) and the
378 documentation and reporting requirements for handling such
379 requests.

380 Section 10. Paragraph (a) of subsection (3) of section
381 401.45, Florida Statutes, are amended to read:

382 401.45 Denial of emergency treatment; civil liability.—

383 (3) (a) Resuscitation or other forms of medical intervention
384 may be withheld or withdrawn from a patient by an emergency
385 medical technician, ~~or paramedic,~~ or other health care
386 professional if evidence of a Physician Order for Life-
387 Sustaining Treatment (POLST) or an order not to resuscitate is
388 presented to that professional. To be valid, a POLST must be on
389 the form adopted by rule of the department and signed by the
390 patient's physician after consultation with the patient,
391 patient's guardian, or legally authorized proxy or surrogate by
392 ~~the patient's physician is presented to the emergency medical~~
393 ~~technician or paramedic. To be valid,~~ an order not to
394 resuscitate, ~~to be valid,~~ must be on the form adopted by rule of
395 the department. The form must be signed by the patient's
396 physician and by the patient or, if the patient is
397 incapacitated, the patient's health care surrogate or proxy as
398 provided in chapter 765, court-appointed guardian as provided in
399 chapter 744, or attorney in fact under a durable power of
400 attorney as provided in chapter 709. The court-appointed
401 guardian or attorney in fact must have been delegated authority
402 to make health care decisions on behalf of the patient.

403 Section 11. Subsection (4) of section 429.255, Florida
404 Statutes, is amended to read:



592332

594-03378-15

405 429.255 Use of personnel; emergency care.-

406 (4) Facility staff may withhold or withdraw cardiopulmonary
407 resuscitation or the use of an automated external defibrillator
408 if presented with an order not to resuscitate executed pursuant
409 to s. 401.45 or a Physician Order for Life-Sustaining Treatment
410 (POLST). The department shall adopt rules providing for the
411 implementation of such orders. Facility staff and facilities
412 shall not be subject to criminal prosecution or civil liability,
413 nor be considered to have engaged in negligent or unprofessional
414 conduct, for withholding or withdrawing cardiopulmonary
415 resuscitation or use of an automated external defibrillator
416 pursuant to such orders ~~an order~~ and rules adopted by the
417 department. The absence of an order to resuscitate executed
418 pursuant to s. 401.45 or a POLST does not preclude a physician
419 from withholding or withdrawing cardiopulmonary resuscitation or
420 use of an automated external defibrillator as otherwise
421 permitted by law.

422 Section 12. Subsection (3) of section 429.73, Florida
423 Statutes, is amended to read:

424 429.73 Rules and standards relating to adult family-care
425 homes.-

426 (3) The department shall adopt rules providing for the
427 implementation of orders not to resuscitate and Physician Orders
428 for Life-Sustaining Treatment (POLST). The provider may withhold
429 or withdraw cardiopulmonary resuscitation if presented with an
430 order not to resuscitate executed pursuant to s. 401.45 or a
431 POLST. The provider shall not be subject to criminal prosecution
432 or civil liability, nor be considered to have engaged in
433 negligent or unprofessional conduct, for withholding or



592332

594-03378-15

434 withdrawing cardiopulmonary resuscitation pursuant to such
435 orders ~~an order~~ and applicable rules.

436 Section 13. Paragraph (c) of subsection (1) of section
437 765.205, Florida Statutes, is amended to read:

438 765.205 Responsibility of the surrogate.—

439 (1) The surrogate, in accordance with the principal's
440 instructions, unless such authority has been expressly limited
441 by the principal, shall:

442 (c) Provide written consent using an appropriate form
443 whenever consent is required, including a physician's order not
444 to resuscitate or a Physician Order for Life-Sustaining
445 Treatment (POLST).

446 Section 14. This act shall take effect July 1, 2015.