

By the Committee on Health Policy; and Senator Brandes

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1 A bill to be entitled
2 An act relating to the Florida Right to Try Act;
3 providing a short title; creating s. 385.213, F.S.;
4 defining terms; authorizing a manufacturer of an
5 investigational drug, biological product, or device to
6 make such drug, product, or device available to
7 certain eligible patients with a terminal illness
8 without charge or for a specified cost; authorizing
9 the manufacturer to require eligible patients to
10 participate in certain data collection; specifying
11 that an insurer, a health plan, or a government health
12 care program is not required to provide coverage for
13 the cost of such drug, product, or device; authorizing
14 such entities to provide coverage under specified
15 circumstances; specifying that such entities are not
16 required to cover care or treatment needed as the
17 result of the use of such drug, product, or device
18 except under certain circumstances; specifying that
19 the Department of Corrections and the Department of
20 Juvenile Justice are not required to provide coverage
21 for such drugs, products, or devices for individuals
22 in the departments' custody; prohibiting a state
23 regulatory board or agency from taking action against
24 the licenses of certain health care providers or
25 against the licenses or Medicare certifications of
26 certain health care institutions for specified actions
27 with respect to an eligible patient's access to,
28 treatment with, or use of investigational drugs,
29 biological products, or devices; specifying when an

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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
57 clearinghouse; requiring the agency to publish and
58 disseminate certain information and provide certain

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

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88 POLST; providing immunity from civil and criminal
89 liability to a provider for such actions; amending s.
90 765.205, F.S.; authorizing a health care surrogate to
91 provide written consent for a POLST; providing an
92 effective date.

93

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

95

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

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

100 385.213 Compassionate treatment; access to experimental
101 treatments.-

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

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

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

105 individual's physician and consulting physician;

106 2. As determined by the individual's physician, does not
107 have any comparable or satisfactory United States Food and Drug

108 Administration-approved option available to be diagnosed,

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

110 and the probable risk to the individual from the investigational

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

112 from the disease or condition;

113 3. Has received a prescription or recommendation from the

114 individual's physician for an investigational drug, biological

115 product, or device;

116 4. Has provided written, informed consent in accordance

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

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

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

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

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

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

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

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

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146 with, the manufacture of the investigational drug, biological
147 product, or device.

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

151 (b) This section does not require:

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

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

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

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

167 (3) ACTION AGAINST PROVIDER LICENSURE PROHIBITED.—
168 Notwithstanding any other law, a state regulatory board or
169 agency:

170 (a) May not take any action against a health care
171 provider's license issued under chapter 458 or chapter 459 based
172 solely on the health care provider's recommendation to an
173 eligible patient regarding access to or treatment with an
174 investigational drug, biological product, or device.

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

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

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

185 (4) CLINICAL TRIALS.—

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

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

198 (5) NO CAUSE OF ACTION.—This section does not create a
199 private cause of action against a manufacturer of an
200 investigational drug, biological product, or device or against
201 an entity or individual involved in the care of an eligible
202 patient for any harm to the eligible patient which results from
203 the use of the investigational drug, biological product, or

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204 device if the manufacturer, entity, or individual is complying
205 in good faith with this section, unless the manufacturer,
206 entity, or individual failed to exercise reasonable care.

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

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

217 408.064 Clearinghouse for compassionate and palliative care
218 plans.—

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

228 (2) The agency may subscribe to or otherwise participate in
229 a national or private clearinghouse that will accomplish the
230 requirements under subsection (1) in lieu of establishing and
231 maintaining an independent clearinghouse for this state's
232 residents.

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

238 Section 4. Paragraph (1) of subsection (3) of section
239 395.1041, Florida Statutes, is amended to read:

240 395.1041 Access to emergency services and care.—

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

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

255 Section 5. Subsection (3) of section 400.142, Florida
256 Statutes, is amended to read

257 400.142 Emergency medication kits; orders not to
258 resuscitate.—

259 (3) Facility staff may withhold or withdraw cardiopulmonary
260 resuscitation if presented with an order not to resuscitate
261 executed pursuant to s. 401.45 or a Physician Order for Life-

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262 Sustaining Treatment (POLST). Facility staff and facilities are
263 not subject to criminal prosecution or civil liability, or
264 considered to have engaged in negligent or unprofessional
265 conduct, for withholding or withdrawing cardiopulmonary
266 resuscitation pursuant to either ~~such~~ order. The absence of an
267 order not to resuscitate executed pursuant to s. 401.45 or a
268 POLST does not preclude a physician from withholding or
269 withdrawing cardiopulmonary resuscitation as otherwise permitted
270 by law.

271 Section 6. Section 400.487, Florida Statutes, is amended to
272 read:

273 400.487 Home health service agreements; physician's,
274 physician assistant's, and advanced registered nurse
275 practitioner's treatment orders; patient assessment;
276 establishment and review of plan of care; provision of services;
277 orders not to resuscitate; physician orders for life-sustaining
278 treatment.-

279 (1) Services provided by a home health agency must be
280 covered by an agreement between the home health agency and the
281 patient or the patient's legal representative specifying the
282 home health services to be provided, the rates or charges for
283 services paid with private funds, and the sources of payment,
284 which may include Medicare, Medicaid, private insurance,
285 personal funds, or a combination thereof. A home health agency
286 providing skilled care must make an assessment of the patient's
287 needs within 48 hours after the start of services.

288 (2) If ~~When~~ required by ~~the provisions of~~ chapter 464, ~~†~~
289 part I, part III, or part V of chapter 468, ~~†~~ or chapter 486, the
290 attending physician, physician assistant, or advanced registered

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291 nurse practitioner, acting within his or her respective scope of
292 practice, shall establish treatment orders for a patient who is
293 to receive skilled care. The treatment orders must be signed by
294 the physician, physician assistant, or advanced registered nurse
295 practitioner before a claim for payment for the skilled services
296 is submitted by the home health agency. If the claim is
297 submitted to a managed care organization, the treatment orders
298 must be signed within the time allowed under the provider
299 agreement. The treatment orders shall be reviewed, as frequently
300 as the patient's illness requires, by the physician, physician
301 assistant, or advanced registered nurse practitioner in
302 consultation with the home health agency.

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

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

313 (5) If ~~When~~ nursing services are ordered, the home health
314 agency to which a patient has been admitted for care must
315 provide the initial admission visit, all service evaluation
316 visits, and the discharge visit by a direct employee. Services
317 provided by others under contractual arrangements to a home
318 health agency must be monitored and managed by the admitting
319 home health agency. The admitting home health agency is fully

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320 responsible for ensuring that all care provided through its
321 employees or contract staff is delivered in accordance with this
322 part and applicable rules.

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

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

336 Section 7. Paragraph (e) of subsection (1) of section
337 400.605, Florida Statutes, is amended to read:

338 400.605 Administration; forms; fees; rules; inspections;
339 fines.—

340 (1) The agency, in consultation with the department, may
341 adopt rules to administer the requirements of part II of chapter
342 408. The department, in consultation with the agency, shall by
343 rule establish minimum standards and procedures for a hospice
344 pursuant to this part. The rules must include:

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

348 Section 8. Subsection (8) of section 400.6095, Florida

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349 Statutes, is amended to read:

350 400.6095 Patient admission; assessment; plan of care;
351 discharge; death.—

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

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

367 401.35 Rules.—The department shall adopt rules, including
368 definitions of terms, necessary to carry out the purposes of
369 this part.

370 (4) The rules must establish circumstances and procedures
371 under which emergency medical technicians and paramedics may
372 honor orders by the patient's physician not to resuscitate and a
373 Physician Order for Life-Sustaining Treatment (POLST) and the
374 documentation and reporting requirements for handling such
375 requests.

376 Section 10. Paragraph (a) of subsection (3) of section
377 401.45, Florida Statutes, are amended to read:

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378 401.45 Denial of emergency treatment; civil liability.—

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

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

401 429.255 Use of personnel; emergency care.—

402 (4) Facility staff may withhold or withdraw cardiopulmonary
403 resuscitation or the use of an automated external defibrillator
404 if presented with an order not to resuscitate executed pursuant
405 to s. 401.45 or a Physician Order for Life-Sustaining Treatment
406 (POLST). The department shall adopt rules providing for the

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407 implementation of such orders. Facility staff and facilities
408 shall not be subject to criminal prosecution or civil liability,
409 nor be considered to have engaged in negligent or unprofessional
410 conduct, for withholding or withdrawing cardiopulmonary
411 resuscitation or use of an automated external defibrillator
412 pursuant to such orders ~~an order~~ and rules adopted by the
413 department. The absence of an order to resuscitate executed
414 pursuant to s. 401.45 or a POLST does not preclude a physician
415 from withholding or withdrawing cardiopulmonary resuscitation or
416 use of an automated external defibrillator as otherwise
417 permitted by law.

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

420 429.73 Rules and standards relating to adult family-care
421 homes.—

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

432 Section 13. Paragraph (c) of subsection (1) of section
433 765.205, Florida Statutes, is amended to read:

434 765.205 Responsibility of the surrogate.—

435 (1) The surrogate, in accordance with the principal's

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436 instructions, unless such authority has been expressly limited
437 by the principal, shall:

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

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