By the Committee on Health Policy; and Senator Brandes

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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, treatment with, or use of investigational drugs, biological products, or devices; specifying when an

investigational drug, biological product, or device may continue to be offered by the manufacturer if the drug, product, or device is found to be ineffective under certain circumstances; requiring certain information relating to clinical trials to be provided to a patient taking an investigational drug, biological product, or device outside of the clinical trial; providing that the section does not create a private cause of action against certain manufacturers, entities, and individuals for any harm to an eligible patient which results from the use of an investigational drug, biological product, or device under certain circumstances; providing a criminal penalty for an official, employee, or agent of the state who blocks or attempts to block the access of an eligible patient to certain investigational drugs, biological products, or devices; creating s. 408.064, F.S.; requiring the Agency for Health Care Administration to establish and maintain a database that allows a state resident to electronically submit a plan that indicates his or her directives for compassionate and palliative care; requiring the database to serve as a clearinghouse of plan information that is accessible by certain health care providers; authorizing the agency to subscribe to or participate in a national or private clearinghouse in lieu of establishing and maintaining an independent clearinghouse; requiring the agency to publish and disseminate certain information and provide certain

training relating to the clearinghouse; amending ss. 395.1041, 400.142, and 400.487, F.S.; authorizing hospital personnel, nursing home facility staff, and home health agency personnel, respectively, to withhold or withdraw cardiopulmonary resuscitation if an individual has a Physician Order for Life-Sustaining Treatment (POLST); amending s. 400.605, F.S.; requiring the Department of Elder Affairs in consultation with the Agency for Health Care Administration to adopt by rule procedures for the implementation of POLSTs in hospice care; amending s. 400.6095, F.S.; authorizing a hospice care team to withhold or withdraw cardiopulmonary resuscitation if an individual has a POLST; amending s. 401.35, F.S.; requiring the Department of Health to establish circumstances and procedures for honoring a POLST; amending s. 401.45, F.S.; authorizing emergency medical transportation providers to withhold or withdraw cardiopulmonary resuscitation or other medical interventions if an individual has a POLST; providing requirements for a POLST to be valid; amending s. 429.255, F.S.; authorizing assisted living facility staff to withhold or withdraw cardiopulmonary resuscitation if an individual has a POLST; amending s. 429.73, F.S.; requiring the Department of Elder Affairs to adopt rules for the implementation of POLSTs in adult family-care homes; authorizing a provider of such home to withhold or withdraw cardiopulmonary resuscitation if an individual has a

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

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

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

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

385.213 Compassionate treatment; access to experimental treatments.—

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

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

1. Has a terminal illness, as determined by the individual's physician and consulting physician;

2. As determined by the individual's physician, does not have any comparable or satisfactory United States Food and Drug Administration-approved option available to be diagnosed, monitored, or treated for the individual's disease or condition, and the probable risk to the individual from the investigational drug, biological product, or device is not greater than the risk from the disease or condition;

3. Has received a prescription or recommendation from the individual's physician for an investigational drug, biological product, or device;

4. Has provided written, informed consent in accordance

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

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

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

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

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

(2) AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.—

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

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

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

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

(b) This section does not require:

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

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

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

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

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

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

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

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

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

(4) CLINICAL TRIALS.—

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

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

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

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

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

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

408.064 Clearinghouse for compassionate and palliative care plans.—

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

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

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

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

395.1041 Access to emergency services and care.—

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

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

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

400.142 Emergency medication kits; orders not to resuscitate.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Statutes, is amended to read:

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

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

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

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

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

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

401.45 Denial of emergency treatment; civil liability.—

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

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

429.255 Use of personnel; emergency care.—

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

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

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

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

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

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

765.205 Responsibility of the surrogate.—

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

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

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

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