By Senator Brandes

22-00658A-15 20151052__

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; 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. This act shall take effect July 1, 2015.