A bill to be entitled

An act relating to experimental treatments for terminal conditions; creating s. 499.0295, F.S.; providing a short title; providing definitions; providing conditions for a manufacturer to provide certain drugs, products, or devices to a patient; specifying insurance coverage requirements and exceptions; providing conditions for provision of certain services by a hospital or health care facility; providing immunity from liability; providing protection from disciplinary or legal action against a health care provider who makes certain treatment recommendations; prohibiting state interference with a patient's access to certain drugs, products, or devices; providing that a cause of action may not be asserted against the manufacturer of certain drugs, products, or devices or a person or entity caring for a patient using such drug, product, or device; providing applicability; providing an effective date.

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

Section 1. Section 499.0295, Florida Statutes, is created to read:

499.0295 Experimental treatments for terminal conditions.—

(1) This section may be cited as the "Right to Try Act."

(2) As used in this section, the term:

(a) "Eligible patient" means a person who:

1. Has a terminal illness, attested to by the patient's treating physician.

2. Has considered all other treatment options currently approved by the United States Food and Drug Administration.

3. Has given written, informed consent for the use of an investigational drug, biological product, or device.

4. Has documentation from his or her physician that the patient meets the requirements of this paragraph.

(b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(c) "Terminal illness" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatments currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will soon result in death.

(d) "Written informed consent" means a document that is signed by the patient, a parent of a minor patient, a court-

appointed guardian for the patient, or a health care surrogate designated by the patient. Written informed consent must include:

1. An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.

2. An attestation that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

3. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

4. A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

5. A statement that the patient's health plan or third-party administrator and health care provider are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless they

are specifically required to do so by law or contract.

6. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

7. A statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

(3) A manufacturer may make available, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device under this section. A manufacturer is not required to make an investigational drug, biological product, or device available to a patient.

(4) A manufacturer may:

(a) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

(5) A health plan, third-party administrator, or governmental agency may provide coverage for the cost of, or the

cost of services related to the use of, an investigational drug, biological product, or device.

(6) A governmental agency is not required to pay the costs associated with providing an investigational drug, biological product, or device or the care or treatment of a patient who uses such drug, product, or device.

(7) A hospital or health care facility licensed under chapter 395 is not required to provide new or additional services unless those services are approved by the hospital or health care facility.

(8) If a patient dies while being treated by an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

(9) A licensing board or disciplinary subcommittee may not revoke, fail to renew, suspend, or 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 recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. An entity responsible for Medicare certification may not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

(10) An official, employee, or agent of the state may not

block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

(11) This section does not create a private cause of action against the manufacturer of an investigational drug, biological product, or device; against a person or entity involved in the care of an eligible patient who is using the investigational drug, biological product, or device; or for any harm to the eligible patient that is a result of the use of the investigational drug, biological product, or device if the manufacturer or other person or entity complies in good faith with the terms of this section and exercises reasonable care.

(12) This section does not expand the coverage an insurer must provide under the Florida Insurance Code.

(13) This section does not affect mandatory health care coverage for participation in clinical trials.

Section 2. This act shall take effect July 1, 2015.