By the Committees on Fiscal Policy; and Health Policy; and Senator Brandes

594-04436-15 20151052c2

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 an eligible patient; specifying insurance coverage requirements and exceptions; providing conditions for the provision of certain services by a hospital or health care facility; providing immunity from liability; providing protection from disciplinary or legal action against a physician who makes certain treatment recommendations; 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 drugs, products, or devices under certain circumstances; 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 condition that is attested to by the patient’s physician and confirmed by a second independent

evaluation by a board-certified physician in an appropriate specialty for that condition;

2. Has considered all other treatment options for the terminal condition 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; and

4. Has documentation from his or her treating 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 condition" 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 treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

(d) "Written informed consent" means a document that is signed by a patient, a parent of a minor patient, a court-appointed guardian for a patient, or a health care surrogate designated by a patient and includes:

1. An explanation of the currently approved products and

treatments for the patient's terminal condition.

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

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

4. A realistic description of the most likely outcomes of using the investigational drug, biological product, or device. 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 efficacy of proposed treatment for the patient's terminal condition.

5. A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless 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 treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the 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 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) Upon the request of an eligible patient, a manufacturer may:

(a) Make its investigational drug, biological product, or device available under this section.

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

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

(4) 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.

(5) 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.

(6) If an eligible patient dies while using an investigational drug, biological product, or device pursuant to this section, the patient’s heirs are not liable for any outstanding debt related to the patient’s use of the investigational drug, biological product, or device.

(7) A licensing board may not revoke, fail to renew, suspend, or take any action against a physician’s license issued under chapter 458 or chapter 459 based solely on the physician’s recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or

device. A state entity responsible for Medicare certification may not take action against a physician's Medicare certification based solely on the physician's recommendation that an eligible patient have access to an investigational drug, biological product, or device.

(8) 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.

(9) This section does not expand the coverage an insurer must provide under the Florida Insurance Code and does not affect mandatory health coverage for participation in clinical trials.

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