



State of Tennessee

PUBLIC CHAPTER NO. 376

HOUSE BILL NO. 143

By Representatives Lundberg, Goins, Butt, Weaver, McManus, Terry, Daniel, Rogers, Holt, Carter, Lynn, Kumar, Jernigan, Shepard, Powell, Hardaway, Byrd, Eldridge, Powers, Coley, Turner, Armstrong, Hazlewood

Substituted for: Senate Bill No. 811

By Senators Hensley, Haile, Stevens

AN ACT to amend Tennessee Code Annotated, Title 56; Title 63 and Title 68, relative to access for certain treatments of patients with advanced illness.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding the following as a new part:

63-6-301. This part shall be known and may be cited as the "Phil Timp-Amanda Wilcox Right to Try Act".

63-6-302. As used in this part, unless the context otherwise requires:

(1) "Advanced illness" means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of current federal drug administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death;

(2) "Eligible patient" means an individual who meets all of the following conditions:

(A) Has an advanced illness, attested to by the patient's treating physician and confirmed by a second physician;

(B) Has considered all other treatment options currently approved by the United States food and drug administration, and is unable to enter, or be accepted within one (1) week after applying to, a clinical trial within fifty (50) miles of the individual's home;

(C) Has received a recommendation from the patient's physician for an investigational drug, biological product, or device;

(D) Has given written, informed consent for the use of the investigational drug, biological product, or device; and

(E) Has documentation from the patient's physician that the patient meets the requirements of this subdivision (2);

(3) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial as documented by the National Institutes of Health but has not yet been approved for general use by the federal food and drug administration (FDA) and remains under investigation in a clinical trial that is approved by the FDA; and

(4) "Written, informed consent" means a written document that is signed by the patient, the patient's parent, if the patient is a minor, the patient's legal guardian, or the patient's attorney-in-fact designated by the patient under title 34, chapter 6, part 2, and

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attested to by the patient's physician and a witness, and that, at a minimum, includes all of the following:

(A) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(B) An attestation that the patient concurs with the patient's physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

(C) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(D) 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;

(E) A release of liability relative to the treating physician, licensed healthcare providers, hospital, and manufacturer of the investigational drug, biological product, procedure, or device;

(F) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract;

(G) 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 care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements; and

(H) A statement that the patient understands that the patient 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 drug, biological product, or device states otherwise.

(5) "Adverse event" means any untoward medical occurrence associated with the use of an investigational drug, biological product, or device in humans, regardless if drug-related;

63-6-303.

(a) A manufacturer of an investigational drug, biological product, or device may make available, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device under this part; provided, that this part does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do all of the following:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; and

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

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(a) This part does not expand the coverage required of an insurer under title 56, chapter 7.

(b) A health plan, third-party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this part.

(c) This part does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device.

(d) This part does not require any hospital or facility licensed under title 68, chapter 11, or any physician or healthcare provider to provide any items or services unless a request by an eligible patient is approved by the hospital, facility, physician, or healthcare provider.

63-6-305. 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.

63-6-306. A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a healthcare provider's license issued under this title 63, based solely on the healthcare 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 shall not take action against a healthcare provider's medicare certification based solely on the healthcare provider's recommendation that a patient have access to an investigational drug, biological product, or device.

63-6-307. An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. The rendering of counseling, advice, or a recommendation consistent with medical standards of care from a licensed healthcare provider is not a violation of this section.

63-6-308.

(1) This part does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this part and has exercised reasonable care.

(2) This part does not affect any mandatory healthcare coverage for participation in clinical trials under § 56-7-2365.

63-6-309. If a patient suffers an adverse event associated with the use of an investigational drug, biological product, or device, the patient's physician shall report the adverse event to the manufacturer of the investigational drug, biological product, or device.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then such invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end the provisions of this act shall be severable.

SECTION 3. This act shall take effect July 1, 2015, the public welfare requiring it.

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PASSED: April 21, 2015



BETH HARWELL, SPEAKER
HOUSE OF REPRESENTATIVES



RON RAMSEY
SPEAKER OF THE SENATE

APPROVED this 8th day of MAY 2015



BILL HASLAM, GOVERNOR