GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

H **D**

HOUSE BILL 652
PROPOSED COMMITTEE SUBSTITUTE H652-PCS20314-TK-12

Short Title: Right to Try Act for Terminally Ill Patients. (Public)

Sponsors:

Referred to:

April 14, 2015

A BILL TO BE ENTITLED

AN ACT ESTABLISHING A RIGHT TO TRY ACT TO PROVIDE EXPANDED ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS DIAGNOSED WITH TERMINAL ILLNESS.

The General Assembly of North Carolina enacts:

SECTION 1. Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article 23A.

"Right to Try Act.

"**§ 90-325. Short title; purpose.**

(a) This Article shall be known and may be cited as the Right to Try Act.

(b) The purpose of this Article is to authorize access to and use of experimental treatments for patients with a terminal illness; to establish conditions for use of experimental treatment; to prohibit sanctions of health care providers solely for recommending or providing experimental treatment; to clarify duties of a health insurer with regard to experimental treatment authorized under this Article; to prohibit certain actions by State officials, employees, and agents; and to restrict certain causes of action arising from experimental treatment.

"**§ 90-325.1. Definitions.**

The following definitions apply in this Article, unless the context requires otherwise:

(1) Eligible patient. – An individual who meets all of the following criteria:

a. Has a terminal illness, attested to by a treating physician.

b. Has, in consultation with a treating physician, considered all other treatment options currently approved by the United States Food and Drug Administration.

c. Has received a recommendation from the treating physician for use of an investigational drug, biological product, or device for treatment of the terminal illness.

d. Has given informed consent in writing to use of the investigational drug, biological product, or device for treatment of the terminal illness or, if the individual is a minor or is otherwise incapable of providing informed consent, the parent or legal guardian has given informed consent in writing to use of the investigational drug, biological product, or device.

e. Has documentation from the treating physician that the individual meets all of the criteria for this definition. This documentation shall include an attestation from the treating physician that the treating

physician was consulted in the creation of the written, informed consent required under this Article.

(2) Investigational drug, biological product, or device. – A drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet 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.

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

(4) Written, informed consent. – A written document that is signed by an eligible patient; or if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes all of the following:

a. An explanation of the currently approved products and treatments for the eligible patient's terminal illness.

b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life.

c. Clear identification of the specific investigational drug, biological product, or device proposed for treatment of the eligible patient's terminal illness.

d. A description of the potentially best and worst outcomes resulting from use of the investigational drug, biological product, or device to treat the eligible patient's terminal illness, along with a realistic description of the most likely outcome. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's terminal illness and shall include a statement acknowledging that new, unanticipated, different, or worse symptoms might result from, and that death could be hastened by, the proposed treatment.

e. A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the terminal illness with an investigational drug, biological product, or device and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements.

f. A statement that the eligible patient's health benefit 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 specifically required to do so by law or contract.

g. A statement that the eligible 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 eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

h. A statement that the eligible patient or, for an eligible patient who is a minor or lacks capacity to provide informed consent, that the parent or legal guardian consents to the use of the investigational drug, biological product, or device for treatment of the terminal condition.

"**§ 90-325.2. Authorized access to and use of investigational drugs, biological products, and devices.**

(a) A manufacturer of an investigational drug, biological product, or device may make available to an eligible patient, and an eligible patient may request, the manufacturer's investigational drug, biological product, or device. However, nothing in this Article shall be construed to require a manufacturer of an investigational drug, biological product, or device to make such investigational drug, biological product, or device available to an eligible patient.

(b) A manufacturer of an investigational drug, biological product, or device may provide the investigational drug, biological product, or device to an eligible patient without receiving compensation or may require the eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

"**§ 90-352.3. No liability to heirs for outstanding debt related to use of investigational drugs, biological products, or devices.**

If an eligible patient dies while being treated with an investigational drug, biological product, or device, the eligible patient's heirs are not liable for any outstanding debt related to the treatment, including any costs attributed to lack of insurance coverage for the treatment.

"**§ 90-325.4. Sanctions against health care providers prohibited.**

(a) A licensing board shall not revoke, fail to renew, suspend, or take any other disciplinary action against a health care provider licensed under this Chapter, 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.

(b) An entity responsible for Medicare certification shall 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.

"**§ 90-325.5. Prohibited conduct by State officials.**

No official, employee, or agent of this State shall 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 does not constitute a violation of this section.

"**§ 90-325.6. No private right of action against manufacturers of investigational drugs, biological products, or devices.**

No private right of action may be brought 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 an investigational drug, biological product, or device, for any harm caused to the eligible patient resulting from use of the investigational drug, biological product, or device as long as the manufacturer or other person or entity has made a good-faith effort to comply with the provisions of this Article and has exercised reasonable care in actions undertaken pursuant to this Article.

"**§ 90-325.7. Insurance coverage of clinical trials.**

Nothing in this Article shall be construed to affect a health benefit plan's obligation to provide coverage for an insured's participation in a clinical trial pursuant to G.S. 58-3-255."

SECTION 2. This act becomes effective October 1, 2015.