STATE OF OKLAHOMA

1st Session of the 55th Legislature (2015)

SENATE BILL 616 By: Schulz

AS INTRODUCED

An Act relating to experimental treatments for persons with terminal illnesses; providing short title; providing definitions; permitting manufacturers to make available certain treatments to certain persons under certain circumstances; providing certain construction; permitting certain coverage; providing waiver of certain liability to certain persons; prohibiting certain licensing entities from taking certain administrative actions; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3081 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. This act shall be known and may be cited as the "Right to Try Act".

B. As used in this act:

1. "Terminal 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 treatments approved by the United States Food and Drug Administration (FDA) and that, without life-sustaining procedures, will soon result in death;

2. "Eligible patient" means an individual who:

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

b. has considered all treatment options currently approved by the Food and Drug Administration,

c. has received a recommendation from his or her 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 his or her physician that he or she meets the requirements of this act;

3. "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 yet been approved for general use by the United States Food and Drug Administration and remains under investigation in an FDA-approved clinical trial;

4. "Written, informed consent" means a written document that is signed by the patient; parent, if the patient is a minor; legal guardian; or patient advocate designated by the patient and attested

to by the patient's physician and a witness 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 his or her 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 may 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 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,

f. 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

g. 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.

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3082 of Title 63, unless there is created a duplication in numbering, reads as follows:

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. Nothing in this act shall be construed as to require

that a manufacturer make available an investigational drug, biological product or device to an eligible patient.

B. Manufacturers of investigational drugs, biological products or devices may:

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.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3083 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Nothing in this act shall be construed as to expand the coverage required of an insurer under the insurance code of this state.

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 act.

C. Nothing in this act shall be construed as to 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. Nothing in this act shall be construed as to require a hospital, nursing home, long-term care facility or other facility providing health care services and licensed in this state to provide new or additional services unless approved by the hospital, nursing home, long-term care facility or other facility providing health care services.

E. In the event 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.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3084 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Medical Licensure and Supervision, the Oklahoma Board of Nursing, and the State Board of Osteopathic Examiners shall not revoke, fail to renew, suspend, or take any action against a health care provider's license 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 in this state 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.

B. An official, employee or other agent of this state shall not block 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 shall not be construed as a violation of this act.

C. Nothing in this act shall be construed as to create a private cause of action against a manufacturer of an investigational drug, biological product or device 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 act and has exercised reasonable and prudent care.

D. Nothing in this act shall be construed as to affect any mandatory health care coverage for participation in clinical trials under the insurance code of this state.

SECTION 5. This act shall become effective November 1, 2015.

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