HOUSE OF REPRESENTATIVES - FLOOR VERSION

STATE OF OKLAHOMA

1st Session of the 55th Legislature (2015)

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 1074

By: Morrissette and Echols of the House

and

Standridge of the Senate

COMMITTEE SUBSTITUTE

An Act relating to public health and safety; creating the Right to Try Act; defining terms; permitting certain manufacturer to make certain drugs available to eligible patient; permitting health insurance carrier to provide certain coverage; permitting insurer to deny certain coverage under certain conditions; prohibiting certain acts of licensing board of health care providers; prohibiting state officials from blocking eligible patients' access to certain drugs; providing certain act does not create private cause of action; providing for construction; 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 3091.1 of Title 63, unless there is created a duplication in numbering, reads as follows:

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

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.2 of Title 63, unless there is created a duplication in numbering, reads as follows:

For purposes of the Right to Try Act:

1. "Eligible patient" means a person who has:

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

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

c. been unable to participate in a clinical trial for the terminal illness within one hundred (100) miles of the patient's home address, or not been accepted to the clinical trial within one (1) week of completion of the clinical trial application process,

d. received a recommendation from his or her physician for the use of an investigational drug, biological product or device,

e. given written, informed consent for the use of the investigational drug, biological product or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal

guardian has given written, informed consent on the patient's behalf, and

f. documentation from his or her physician that he or she meets the requirements of this paragraph.

"Eligible patient" does not include a person being treated as an inpatient in a hospital licensed pursuant to the provisions of Section 1-701 et seq. of Title 63 of the Oklahoma Statutes;

2. "Investigational drug, biological product or device" means a drug, biological product or device that has successfully completed phase one 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" means a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely; and

4. "Written, informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum:

a. explains the currently approved products and treatments for the disease or condition from which the patient suffers,

b. attests to the fact 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. clearly identifies the specific proposed investigational drug, biological product or device that the patient is seeking to use,

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

e. makes clear that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product or device,

f. makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements,

g. makes clear that in-home health care may be denied if treatment begins, and

h. states 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 drug, biological product or device states otherwise.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.3 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 the manufacturer's investigational drug, biological product or device to eligible patients pursuant to the Right to Try Act. An investigational drug, biological product or device may be made available through a pharmacy. This act does not require that a manufacturer make available an investigational drug, biological product or device to an eligible patient.

B. A manufacturer may:

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

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.

C. A health insurance carrier may, but is not required to, provide coverage for the cost of an investigational drug, biological product or device.

D. An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug, biological product or device through a period not to exceed six (6) months from the time the investigational drug, biological product or device is no longer used by the eligible patient; provided, that coverage may not be denied for a preexisting condition and for coverage for benefits which commenced prior to the time the eligible patient begins use of such drug, biological product or device.

E. 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.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.4 of Title 63, unless there is created a duplication in numbering, reads as follows:

Notwithstanding any other law, a licensing board may 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, as long as the recommendations are consistent with medical standards of care. 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 is prohibited.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.5 of Title 63, unless there is created a duplication in numbering, reads as follows:

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. Counseling, advice or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.6 of Title 63, unless there is created a duplication in numbering, reads as follows:

The Right to Try Act does not create a private cause of action against a manufacturer of an investigational drug, biological product or device or against another 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, so long as the manufacturer or other person or entity is complying in good faith with the terms of the Right to Try Act, unless there was a failure to exercise reasonable care.

SECTION 7. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3091.7 of Title 63, unless there is created a duplication in numbering, reads as follows:

Nothing in the Right to Try Act affects the mandatory health care coverage for participation in clinical trials.

SECTION 8. This act shall become effective November 1, 2015.

COMMITTEE REPORT BY: COMMITTEE ON PUBLIC HEALTH, dated 02/25/2015 - DO PASS, As Amended and Coauthored.