HOUSE HEALTH AND HUMAN SERVICES COMMITTEE SUBSTITUTE FOR
HOUSE BILLS 228 & 263

53RD LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2017

AN ACT

RELATING TO HEALTH CARE; ENACTING THE RIGHT TO TRY ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. [NEW MATERIAL] SHORT TITLE.--This act may be cited as the "Right to Try Act".

SECTION 2. [NEW MATERIAL] DEFINITIONS.--As used in the Right to Try Act:

A. "eligible patient" means an individual who meets all of the following conditions:

(1) has a terminal illness, attested to by the patient's treating physician;

(2) has considered all other treatment options currently approved by the federal food and drug administration;

(3) is ineligible or unable to participate in a clinical trial;

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

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

(6) has documentation from the patient's physician that the patient meets the requirements of this subsection;

B. "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 federal food and drug administration and remains under investigation in a clinical trial approved by the federal food and drug administration;

C. "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 current federal food and drug administration approved and available treatments and that, without life-sustaining procedures, will soon result in death; and

D. "written, informed consent" means a written document that is signed by the patient, by a parent if the

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patient is a minor or by a legal guardian or patient advocate designated by the patient pursuant to the Uniform Health-Care Decisions Act or the Uniform Probate Code, and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

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

(2) 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;

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

(4) 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;

(5) 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;

(6) a statement that the patient's eligibility for hospice care will not be affected if a patient begins curative treatment with the investigational drug, biological product or device; and

(7) 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 this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product or device provides otherwise.

SECTION 3. [NEW MATERIAL] MANUFACTURER OPTIONS.--

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 pursuant to the Right to Try Act. The Right to Try Act does not require that a manufacturer make available an investigational drug, biological product or device to an eligible patient.

B. A manufacturer may do either of the following:

(1) provide an investigational drug, biological product or device to an eligible patient without

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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.

SECTION 4. [NEW MATERIAL] INSURANCE--PAYMENT OF COSTS--ADDITIONAL SERVICES.--

A. The Right to Try Act does not expand coverage required of an insurer pursuant to Section 13-7-11 NMSA 1978, the New Mexico Insurance Code or other applicable state or federal law.

B. A health plan, third party administrator or governmental agency may 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 pursuant to the Right to Try Act.

C. The Right to Try Act 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. The Right to Try Act does not require a health facility licensed pursuant to the Public Health Act to provide new or additional services, unless approved by the health facility.

SECTION 5. [NEW MATERIAL] LIABILITY FOR DEBT.--If a patient dies while being treated by an investigational drug,

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biological product or device, the patient's heirs shall not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

SECTION 6. [NEW MATERIAL] EXEMPTION FROM PROFESSIONAL DISCIPLINE.--A licensing board or disciplinary subcommittee 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 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.

SECTION 7. [NEW MATERIAL] DUTY TO REPORT ADVERSE EVENTS AND SUSPECTED ADVERSE REACTIONS.--An eligible patient's treating and supervising physicians and the manufacturer of the investigational drug, biological product or device used by the eligible patient pursuant to the Right to Try Act shall report in writing every adverse event and suspected adverse reaction within twenty-four hours of its occurrence to the department of health.

SECTION 8. [NEW MATERIAL] PROHIBITED ACTS.--An official, employee or agent of this state shall not block or attempt to

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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 9. [NEW MATERIAL] LIMITATION OF CIVIL LIABILITY--MANDATORY HEALTH CARE COVERAGE.--

A. 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 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 that act and has exercised reasonable care.

B. The Right to Try Act does not affect any mandatory health care coverage for participation in clinical trials pursuant to the New Mexico Insurance Code.

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