

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

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

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

10 B. "investigational drug, biological product or  
11 device" means a drug, biological product or device that has  
12 successfully completed phase one of a clinical trial but has  
13 not yet been approved for general use by the federal food and  
14 drug administration and remains under investigation in a  
15 clinical trial approved by the federal food and drug  
16 administration;

17 C. "terminal illness" means a progressive disease  
18 or medical or surgical condition that entails significant  
19 functional impairment, that is not considered by a treating  
20 physician to be reversible even with administration of current  
21 federal food and drug administration approved and available  
22 treatments and that, without life-sustaining procedures, will  
23 soon result in death; and

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

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

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

9 (2) an attestation that the patient concurs  
10 with the patient's physician in believing that all currently  
11 approved and conventionally recognized treatments are unlikely  
12 to prolong the patient's life;

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

16 (4) a description of the potentially best and  
17 worst outcomes of using the investigational drug, biological  
18 product or device and a realistic description of the most  
19 likely outcome. The description shall include the possibility  
20 that new, unanticipated, different or worse symptoms might  
21 result and that death could be hastened by the proposed  
22 treatment. The description shall be based on the physician's  
23 knowledge of the proposed treatment in conjunction with an  
24 awareness of the patient's condition;

25 (5) a statement that the patient's health plan

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1 or third party administrator and provider are not obligated to  
2 pay for any care or treatments consequent to the use of the  
3 investigational drug, biological product or device, unless they  
4 are specifically required to do so by law or contract;

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

9 (7) a statement that the patient understands  
10 that the patient is liable for all expenses consequent to the  
11 use of the investigational drug, biological product or device,  
12 and this liability extends to the patient's estate, unless a  
13 contract between the patient and the manufacturer of the drug,  
14 biological product or device provides otherwise.

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

16 A. A manufacturer of an investigational drug,  
17 biological product or device may make available, and an  
18 eligible patient may request, the manufacturer's  
19 investigational drug, biological product or device pursuant to  
20 the Right to Try Act. The Right to Try Act does not require  
21 that a manufacturer make available an investigational drug,  
22 biological product or device to an eligible patient.

23 B. A manufacturer may do either of the following:

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

1 receiving compensation; or

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

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

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

11 B. A health plan, third party administrator or  
12 governmental agency may provide coverage for the cost of an  
13 investigational drug, biological product or device, or the cost  
14 of services related to the use of an investigational drug,  
15 biological product or device pursuant to the Right to Try Act.

16 C. The Right to Try Act does not require any  
17 governmental agency to pay costs associated with the use, care  
18 or treatment of a patient with an investigational drug,  
19 biological product or device.

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

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

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

4 SECTION 6. [NEW MATERIAL] EXEMPTION FROM PROFESSIONAL  
5 DISCIPLINE.--A licensing board or disciplinary subcommittee  
6 shall not revoke, fail to renew, suspend or take any action  
7 against a health care provider's license, based solely on the  
8 health care provider's recommendations to an eligible patient  
9 regarding access to or treatment with an investigational drug,  
10 biological product or device. An entity responsible for  
11 medicare certification shall not take action against a health  
12 care provider's medicare certification based solely on the  
13 health care provider's recommendation that a patient have  
14 access to an investigational drug, biological product or  
15 device.

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

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

1 block an eligible patient's access to an investigational drug,  
2 biological product or device. Counseling, advice or a  
3 recommendation consistent with medical standards of care from a  
4 licensed health care provider is not a violation of this  
5 section.

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

8 A. The Right to Try Act does not create a private  
9 cause of action against a manufacturer of an investigational  
10 drug, biological product or device or against any other person  
11 or entity involved in the care of an eligible patient using the  
12 investigational drug, biological product or device for any harm  
13 done to the eligible patient resulting from the investigational  
14 drug, biological product or device, if the manufacturer or  
15 other person or entity is complying in good faith with the  
16 terms of that act and has exercised reasonable care.

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