HOUSE BILL 263

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

INTRODUCED BY

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AN ACT

RELATING TO ACCESS TO TREATMENTS FOR TERMINALLY ILL PATIENTS; ENACTING THE RIGHT TO TRY ACT; DECLARING AN EMERGENCY.

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. "adverse event" means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related;

B. "eligible patient" means a person who:

(1) is at least eighteen years of age;

(2) is a resident of New Mexico;

(3) has been diagnosed with a terminal illness

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by the patient's treating physician;

(4) has received a recommendation from the patient's treating physician or supervising physician to use an investigational drug, biologic product or device;

(5) is competent to make health care decisions;

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

(7) is not an inpatient in a hospital or other licensed health care facility;

C. "financial relationship" means an arrangement, agreement or business interest involving:

(1) any payment or transfer of value, including cash, cash equivalent, in-kind items or services and stock;

(2) payment of consulting fees;

(3) compensation for services other than consulting;

(4) compensation for speaking at an event or honoraria;

(5) receipt of gifts, entertainment, food or travel;

(6) royalties or licenses;

(7) current or prospective ownership or

investment interests;

(8) grants; or

(9) ownership or investment interests held by a physician's immediate family member;

D. "investigational drug, biologic product or device" means a drug, biologic product or device for which a phase one clinical trial approved by the United States food and drug administration has been completed, that remains under investigation and that has not yet been approved for general use;

E. "physician" means a licensed physician or osteopathic physician;

F. "supervising physician" means a physician who supervises an eligible patient's use of an investigational drug, biologic product or device pursuant to the Right to Try Act;

G. "suspected adverse reaction" means any adverse event for which there is a reasonable possibility that the drug caused the adverse event; and

H. "terminal illness" means a disease or illness that will lead to death within six months, as diagnosed and confirmed in writing by the patient's treating physician.

SECTION 3. [NEW MATERIAL] WRITTEN INFORMED CONSENT REQUIREMENTS--WAIVER OF LIABILITY.--

A. A written informed consent to the use of an

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investigational drug, biologic product or device shall:

(1) include a dated written statement from the patient's treating physician that specifies the patient's terminal illness and diagnosis;

(2) explain the purpose, benefits and potential risks of:

(a) currently approved products, treatments and interventions for the patient's terminal illness; and

(b) the investigational drug, biologic product or device the patient wishes to use;

(3) disclose ongoing clinical trials being conducted within one hundred miles of the patient's home for patients diagnosed with the same terminal illness;

(4) designate a supervising physician and specify the treatment plan that will be followed by the supervising physician with respect to such investigational drug, biologic product or device;

(5) disclose any financial relationship between the patient's treating or supervising physician and the manufacturer of such investigational drug, biologic product or device;

(6) contain a warning that:

(a) the use of the investigational drug, biologic product or device and treatment for subsequent

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symptoms or health conditions caused by or related to the use of the investigational drug, biologic product or device may not be covered by the patient's health insurance or health plan;

(b) the patient will not be eligible for hospice care while using the investigational drug, biologic product or device; and

(c) in-home health care during treatment and afterward may not be covered by the patient's health insurance or health plan;

(7) require the patient to attest that the patient understands that the patient, or the patient's estate, is liable for all the patient's expenses incidental to the use of the investigational drug, biologic product or device;

(8) advise the patient of the patient's right to enter into a contract with the manufacturer of the investigational drug, biologic product or device indemnifying the patient, or the patient's estate, for all or part of the patient's expenses incidental to the use of the investigational drug, biologic product or device;

(9) include a waiver of liability in favor of the treating physician and supervising physician for all damages arising solely from:

(a) the treating physician's or supervising physician's recommendation that a patient use an investigational drug, biologic product or device; or

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(b) the supervising physician's supervision of the patient's use of the investigational drug, biologic product or device in accordance with the recommendations of the manufacturer of such investigational drug, biologic product or device; and

(10) be executed by the patient, the patient's treating and supervising physicians and a witness.

B. A copy of the written informed consent required pursuant to this section shall be provided to the patient and to the patient's treating and supervising physicians.

SECTION 4. [NEW MATERIAL] EXEMPTION FROM CRIMINAL AND CIVIL PENALTIES AND PROFESSIONAL DISCIPLINE.--

A. A physician shall not be subject to arrest or prosecution, any criminal or civil fines or penalties or professional discipline for recommending the use of an investigational drug, biologic product or device pursuant to the Right to Try Act.

B. A supervising physician shall not be subject to arrest or prosecution, any criminal or civil fines or penalties or professional discipline for supervising the use of an investigational drug, biologic product or device pursuant to the Right to Try Act and in accordance with the recommendations of the manufacturer of such investigational drug, biologic product or device.

SECTION 5. [NEW MATERIAL] DUTY TO REPORT ADVERSE EVENTS

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AND SUSPECTED ADVERSE REACTIONS.--

A. An eligible patient's treating and supervising physicians and the manufacturer of the investigational drug, biologic 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.

B. Nothing in the Right to Try Act shall be construed to relieve the eligible patient's treating and supervising physicians and the manufacturer of the investigational drug, biologic product or device used by the eligible patient of their respective obligation to report an adverse event or suspected adverse reaction under other state and federal laws.

SECTION 6. [NEW MATERIAL] ACCESS TO INVESTIGATIONAL DRUG, BIOLOGIC PRODUCT OR DEVICE.--A manufacturer of an investigational drug, biologic product or device may provide such investigational drug, biologic product or device to an eligible patient at no cost to the patient. Nothing in the Right to Try Act shall be construed to require a manufacturer of an investigational drug, biologic product or device to provide such investigational drug, biologic product or device to an eligible patient free of charge.

SECTION 7. [NEW MATERIAL] INSURANCE COVERAGE FOR INVESTIGATIONAL DRUG, BIOLOGIC PRODUCT OR DEVICE.--Nothing in

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the Right to Try Act shall be construed to require a health insurer or health plan to cover an eligible patient's use of an investigational drug, biologic product or device or treatment for subsequent symptoms or health conditions caused by or related solely to the use of the investigational drug, biologic product or device, except as required by Sections 13-7-11 and 59A-22-43 NMSA 1978, Paragraph (13) of Subsection C of Section 59A-23-4 NMSA 1978, Paragraph (14) of Subsection A of Section 59A-46-30 NMSA 1978 and Subsection U of Section 59A-47-33 NMSA 1978 or other applicable state or federal law.

SECTION 8. EMERGENCY.--It is necessary for the public peace, health and safety that this act take effect immediately.

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