SENATE BILL 240

45TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2001

INTRODUCED BY

Dede Feldman

AN ACT

RELATING TO HEALTH; REQUIRING HEALTH PLAN COVERAGE OF CERTAIN PATIENT COSTS INCURRED AS A RESULT OF TREATMENT PROVIDED TO A PATIENT PARTICIPATING IN CANCER CLINICAL TRIALS.

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

Section 1. A new section of the New Mexico Insurance Code is enacted to read:

"[NEW MATERIAL] REQUIRED COVERAGE OF PATIENT COSTS INCURRED IN CANCER CLINICAL TRIALS.--

A. A health care plan shall provide coverage for routine patient care costs incurred as a result of the patient's participation in a phase I, II, III or IV cancer clinical trial if:

(1) the clinical trial is undertaken for the

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purposes of the prevention, early detection or treatment of cancer for which standard cancer treatment has not been effective;

(2) the clinical trial is not designed exclusively to test toxicity or disease pathophysiology and it has a therapeutic intent;

(3) the clinical trial is being provided in this state as part of a scientific study of a new therapy or intervention that is being conducted at an institution in this state and is for the treatment, palliation or prevention of cancer in humans and in which the scientific study includes all of the following:

(a) specific goals;

(b) a rationale and background for the study;

(c) criteria for patient selection;

(d) specific direction for administering the therapy or intervention and for monitoring patients;

(e) a definition of quantitative measures for determining treatment response;

(f) methods for documenting and treating adverse reactions; and

(g) a reasonable expectation that the treatment will be at least as efficacious as standard cancer treatment;

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(4) the clinical trial is being provided as part of a study being conducted in accordance with a clinical trial approved by at least one of the following:

(a) one of the federal national institutes of health;

(b) a federal national institutes of health cooperative group or center;

(c) the federal department of defense;

(d) the federal food and drug administration in the form of an investigational new drug application;

(e) the federal department of veterans affairs; or

(f) a qualified research entity that meets the criteria established by the federal national institutes of health for grant eligibility;

(5) the clinical trial is being provided as part of a study being conducted in a phase I, phase II, phase III or phase IV cancer clinical trial;

(6) the proposed clinical trial or study has been reviewed and approved by an institutional review board that has a multiple project assurance contract approved by the office of protection from research risks of the federal national institutes of health;

(7) the personnel providing the clinical trial

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or conducting the study:

(a) are providing the clinical trial or conducting the study within their scope of practice, experience and training and are capable of providing the clinical trial because of their experience, training and volume of patients treated to maintain their expertise; and

(b) agree to accept reimbursement as payment in full from the health care plan at the rates that are established by that plan and are not more than the level of reimbursement applicable to other similar services provided by health care providers within the plan's provider network;

(8) there is no non-investigational treatment equivalent to the clinical trial; and

(9) the available clinical or preclinical data provide a reasonable expectation that the clinical trial will be at least as efficacious as any non-investigational alternative.

B. Pursuant to the patient informed consent document, no third party is liable for damages associated with the treatment provided during a phase of a cancer clinical trial.

C. A health plan shall not provide benefits that supplant a portion of a cancer clinical trial that is customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources.

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D. The provisions of this section do not create a private right or cause of action for or on behalf of a patient against the health plan providing coverage. This section provides only an administrative remedy to the superintendent of insurance in the public regulation commission for violation of this section or a related rule promulgated by the superintendent.

E. A health plan may impose deductibles, coinsurance requirements or other standard cost-sharing provisions on benefits provided pursuant to this section.

F. As used in this section:

(1) "clinical trial" means a course of treatment provided to a patient;

(2) "cooperative group" means a formal network of facilities that collaborate on research projects and have an established federal national institutes of health- approved peer review program operating within the group;

(3) "health plan" means one of the following entities that directly or through agents provide hospital, medical, surgical or pharmaceutical benefits to individuals or groups on an expense-incurred basis:

(a) a health insurer;

(b) a nonprofit health service provider;

(c) a health maintenance organization;

(d) a managed care organization;

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(e) a provider service organization; or

(f) the state's medical assistance program, whether providing services on a managed care or fee-for-service basis;

(4) "institutional review board" means a board, committee or other group that is both:

(a) formally designated by an institution to approve the initiation of and to conduct periodic review of biomedical research involving human subjects and in which the primary purpose of the review is to assure the protection of the rights and welfare of the human subjects and not to review a clinical trial for scientific merit; and

(b) approved by the federal national institutes of health for protection of the research risks;

(5) "investigational drug or device" means a drug or device that has not been approved by the federal food and drug administration;

(6) "multiple project assurance contract" means a contract between an institution and the federal department of health and human services that defines the relationship of the institution to that department and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects participating in clinical trials;

(7) "patient" means an individual who

participates in a cancer clinical trial and who is an insured, a member or a beneficiary of a health plan; and

(8) "routine patient care cost":

(a) means: 1) a medical service or treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or 2) a drug provided to a patient during a cancer clinical trial if the drug has been approved by the federal food and drug administration, whether or not that organization has approved the drug for use in treating the patient's particular condition, but only to the extent that the drug is not paid for by the manufacturer, distributor or provider of the drug; and

(b) does not include: 1) the cost of an investigational drug, device or procedure; 2) the cost of a non-health care service that the patient is required to receive as a result of participation in the cancer clinical trial; 3) costs associated with managing the research that is associated with the cancer clinical trial; 4) costs that would not be covered by the patient's health plan if non-investigational treatments were provided; and 5) costs paid or not charged for by the cancer clinical trial providers."

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