**CHAPTER 30**

**CHAPTER 30, LAWS 2002**

AN ACT

RELATING TO HEALTH; UPDATING THE ASSURANCE CONTRACT REFERENCE AND DEFINITION; AMENDING A SECTION OF THE NMSA 1978.

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

Section 1. Section 59A-22-43 NMSA 1978 (being Laws 2001, Chapter 27, Section 1) is amended to read:

"59A-22-43. REQUIRED COVERAGE OF PATIENT COSTS INCURRED IN CANCER CLINICAL TRIALS.--

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

(1) the clinical trial is undertaken for the purposes of the prevention of reoccurrence of cancer, early detection or treatment of cancer for which no equally or more effective standard cancer treatment exists;

(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 and is for the prevention of reoccurrence, early detection, treatment or palliation 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;

(4) the clinical trial is being conducted with approval of 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 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 an active federal-wide assurance of protection for human subjects;

(7) the personnel providing the clinical trial 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;

(b) agree to accept reimbursement as payment in full from the health 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;

and

(c) agree to provide written notification to the health plan when a patient enters or leaves a clinical trial;

(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. If a patient is denied coverage of a cost and contends that the denial is in violation of this section, the patient may appeal the decision to deny the coverage of a cost to the superintendent, and that appeal shall be expedited to ensure resolution of the appeal within no more than thirty days after the date of appeal to the superintendent. Programs pursuant to Title 19 or Title 21 of the federal Social Security Act, which have their respective expedited appeal processes, shall be exempt from this subsection.

D. 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.

E. 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 for violation of this section or a related rule promulgated by the superintendent.

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

G. In no event shall the health plan be responsible for out-of-state or out-of-network costs unless the health plan pays for standard treatment out of state or out of network.

H. The provisions of this section do not apply to short-term travel, accident-only or limited or specified disease contracts or policies issued by a health plan.

I. As used in this section:

(1) "clinical trial" means a course of treatment provided to a patient for the purpose of prevention of reoccurrence, early detection or treatment of cancer;

(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":

(a) means: 1) a health insurer; 2) a nonprofit health service provider; 3) a health maintenance organization; 4) a managed care organization; 5) a provider service organization; or 6) the state's medical assistance program, whether providing services on a managed care or fee-for-service basis; and

(b) does not include individual policies intended to supplement major medical group-type coverages such as medicare supplement, long-term care, disability income, specified disease, accident only, hospital indemnity or other limited-benefit health insurance policies;

(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) "federal-wide assurance of protection for human subjects" means a contract between an institution and the office for human research protections of 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; 5) costs of those extra tests that would not be performed except for participation in the cancer clinical trial; and 6) costs paid or not charged for by the cancer clinical trial providers."