GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 2001

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SENATE BILL 781

Short Title:	Health Insurance: Clinical Trials Coverage.	(Public)
Sponsors:	Senators Odom; and Carpenter.	
Referred to:	Insurance and Consumer Protection.	

April 3, 2001

A BILL TO BE ENTITLED

AN ACT TO REQUIRE HEALTH INSURANCE PLANS AND THE TEACHERS' AND STATE EMPLOYEES' COMPREHENSIVE MAJOR MEDICAL PLAN TO PROVIDE COVERAGE FOR PATIENT COSTS INCURRED AS A RESULT OF TREATMENT PROVIDED IN A CLINICAL TRIAL FOR ALL CANCERS AND FOR LIFE-THREATENING, DEGENERATIVE, OR PERMANENTLY DISABLING CONDITIONS.

The General Assembly of North Carolina enacts:

SECTION 1. Article 3 of Chapter 58 of the General Statutes is amended by adding the following new section to read:

"**§ 58-3-216. Coverage for costs incurred as a result of treatment provided in certain clinical trials.**

(a) Every insurer providing a health benefit plan that provides hospital, medical, surgical, or pharmaceutical benefits shall provide coverage for patient cost incurred as a result of treatment provided in a clinical trial for life-threatening, degenerative, or permanently disabling medical conditions and all cancers. Coverage is required only if:

(1) The treatment is being provided in a phase II, phase III, or phase IV clinical trial for a life-threatening, degenerative, or permanently disabling medical condition or for any type of cancer.

(2) The treatment is provided in a clinical trial approved by any of the following:

a. One of the National Institutes of Health (NIH).

b. An NIH cooperative group or center.

c. The Department of Defense.

d. The United States Department of Veterans Affairs.

e. An Institutional Review Board of an institution in the State that has a multiple project assurance contract approved by the Office

of Protection from Research Risks of the National Institutes of Health.

(3) The trial is conducted in and by facilities and personnel that maintain a high level of expertise because of their training, experience, and volume of patients.

(4) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.

(b) Notwithstanding any other provision of law to the contrary, coverage required under this section shall include coverage for patient cost incurred for drugs and devices that have been approved for sale by the United States Food and Drug Administration (FDA) whether or not the FDA has approved the drug or device for use in treating the patient's particular condition, to the extent that the drugs or devices are not paid for by the manufacturer, distributor, or provider of that drug or device.

(c) An insurer subject to this section shall provide a process for expedited review of a request for coverage under this section that is denied by the insurer. The expedited review process shall provide for review and final determination within five business days of receipt of the request for review made by the insured or the insured's health care provider acting on the insured's behalf.

(d) As used in this section:

(1) 'Cooperative group' means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group.

(2) 'Health benefit plan' has the meaning provided in G.S. 58-3-167.

(3) 'Insurer' has the meaning provided in G.S. 58-3-167.

(4) 'Multiple project assurance contract' means a contract between an institution and the United States Department of Health and Human Services that defines the relationship of the institution to the United States Department of Health and Human Services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(5) 'Patient cost' means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the insured for purposes of the clinical trial. 'Patient cost' does not include any of the following:

a. The cost of an investigational drug or device that is paid for by the manufacturer, distributor, or provider of the drug or device.

b. The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided for purposes of the clinical trial.

c. Costs associated with managing the research associated with the clinical trial.

d. Costs that would not be covered under the health benefit plan for noninvestigational treatments."

SECTION 2.(a) G.S. 135-40.1(1b) reads as rewritten:

"(1b) Clinical Trials. – Patient research studies designed to evaluate new treatments, including prescription drugs. Regardless of the type of trial phases covered by the Plan, all covered trials must involve the treatment of ~~life-threatening medical conditions, must be clearly superior to available noninvestigational treatment alternatives, and must have clinical and preclinical data that shows the trials will be at least as effective as noninvestigational alternatives.~~life-threatening, degenerative, or permanently disabling medical conditions, including all cancers, and must have clinical and preclinical data that provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternatives. Trials must also involve determinations by treating physicians, relevant scientific data, and opinions of experts in relevant fields of medicine. Covered trials must be approved by the National Institutes of Health, a National Institutes of Health cooperative group or center, ~~the U. S. Food and Drug Administration, ~~the U.S. Department of Defense, ~~or ~~the U.S. Department of Veterans ~~Affairs.~~Affairs, or an Institutional Review Board of an institution in the State that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the National Institutes of Health. The Plan may also cover clinical trials sponsored by other entities. Trials must also be approved by applicable qualified institutional review boards. All covered trials must be conducted in and by facilities and personnel that maintain a high level of expertise because of their training, experience, and volume of patients. To be covered by the Plan, patients participating in clinical trials must meet substantially all protocol requirements of the trials and exercise informed consent in the trials. Only medically necessary costs of health care services involved in treatments provided to patients for the purpose of the trials are covered by the Plan to the extent that such costs are not customarily funded by national agencies, commercial manufacturers, distributors, or other such providers. Clinical trial costs not covered by the Plan include, but are not limited to, the costs of services that are not health care services and costs associated with managing research in the trials. The Plan shall not exclude benefits for covered clinical trials if the proposed treatment is the only appropriate protocol for the condition being treated."

SECTION 2.(b) G.S. 135-40.1(7a)d. reads as rewritten:

"d. Is provided as part of a research or phase I clinical ~~or phase II clinical ~~trial not approved by the Plan;".

SECTION 2.(c) G.S. 135-40.7(19) reads as rewritten:

"(19) Any service, treatment, facility, equipment, drug, supply, or procedure that is experimental or investigational as defined in G.S. 135-40.1(7a).

Clinical trial phases II, III and IV are covered by the ~~Plan as is clinical trial phase II when approved by the Plan.~~Plan."

SECTION 2.(d) G.S. 135-40.6A(9) is repealed.

SECTION 3. Section 2 of this act becomes effective January 1, 2002. The remainder of this act is effective when it becomes law and applies to health benefit plans that are delivered, issued for delivery, or renewed on and after January 1, 2002. For purposes of this act, renewal of a health benefit plan is presumed to occur on each anniversary of the date on which coverage was first effective on the person or persons covered by the health benefit plan.