

Regular Session, 1999

SENATE BILL NO. 761

BY SENATORS BEAN, HINES, BAJOIE, CAMPBELL, CASANOVA, CRAVINS, DARDENNE, DYESS, ELLINGTON, EWING, C. FIELDS, HOLLIS, IRONS, JOHNSON, JORDAN, LAMBERT, LANDRY, MALONE, ROBICHAUX, ROMERO, SCHEDLER, SIRACUSA, SMITH, THEUNISSEN AND THOMAS AND REPRESENTATIVES BOWLER, BRUNEAU, DONELON, DOWNER, JOHNS, MARTINY, MURRAY AND PINAC

AN ACT

To enact R.S. 22:230.3, relative to health insurance; to provide for coverage of certain patients participating in selected clinical trials; to provide for approval of entities conducting such trials; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:230.3 is hereby enacted to read as follows:

§230.3. Health coverage; participants in clinical trials

**R.S. 22:230.3 is all new law.**

A. As used in this Section, the following terms and phrases shall have the following meanings unless the context clearly indicates otherwise:

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

(2) "Cooperative group" includes the following:

(a) National Cancer Institute funded clinical cooperative groups such as the Southwestern Oncology Group, Radiation Therapy

Oncology Group, etc.

(b) The National Cancer Institute Community Clinical Oncology Program and its minority-based affiliates.

(3) "FDA" means the Federal Food and Drug Administration.

(4) "Member" means a policyholder, subscriber, insured, or certificate holder or a covered dependent of a policyholder, subscriber, insured, or certificate holder.

(5) "Multiple project assurance contract" means a contract between an institution and the United States Department of Health and Human Services office for protection from research risks which contract defines the relationship of the institution to the office for protection from research risks and which sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(6) "NIH" means the National Institutes of Health.

(7) "NCI" means the National Cancer Institute.

(8) "Patient" means a policyholder, subscriber, or certificate holder or a covered dependent of a policyholder, subscriber, or certificate holder.

(9) "Patient cost" means any of the cost of health care services, treatments or testing, that are incurred as part of the protocol treatment being provided to the patient for purposes of the clinical trial. "Patient cost" shall not include the following items:

(a) The cost of non-health care services that a patient may be required to receive as a result of the treatment being provided pursuant to the clinical trial.

(b) Costs associated with managing the research data associated

with the clinical trial.

(c) The cost of such investigational devices or drugs not required to be covered under R.S. 22:215.20.

(d) Costs not otherwise covered under the insured, subscriber, or enrollee's policy, plan or contract of coverage for noninvestigational treatments.

(10) "Health insurance coverage" means benefits consisting of medical care provided or arranged for directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer.

(11) "Health insurance issuer" means an insurance company, including a health maintenance organization as defined and licensed pursuant to Part XII of Chapter 2 of this Title, unless preempted as an employee benefit plan under the Employee Retirement Income Security Act of 1974. For purposes of this Section and Part VI-D of Chapter 1 of this Title, a "health insurance issuer" shall include the State Employees Group Benefits Program.

B. The provisions of this Section shall apply to all health insurance coverage issued by a health insurance insurer for delivery in this state, except limited benefit and short duration health insurance policies that provide cash benefits directly to the insured when hospitalized, injured or ill. The provisions of this Section as applied to the State Employees Group Benefits Program shall become effective on July 1, 2000.

C. This Section shall not apply to any policy or plan or contract paid for under Title XVII or Title X of the federal Social Security Act.

D. Each policy or plan subject to the provisions of this Section shall provide coverage for patient costs incurred as a result of a treatment being provided in accordance with a clinical trial for cancer except any applicable copayment, deductible, or coinsurance amounts. Such costs shall include coverage for costs incurred for health related services not otherwise required under R.S. 22:215.20.

E. Costs of investigational treatments and costs of associated protocol related patient care shall be covered if all of the following criteria are met:

(1) The treatment is being provided with a therapeutic or palliative intent for patients with cancer, or for the prevention or early detection of cancer.

(2) The treatment is being provided or the studies are being conducted in a Phase II, Phase III, or Phase IV clinical trial for cancer.

(3) The treatment is being provided in accordance with a clinical trial approved by one of the following entities:

(a) One of the United States National Institutes of Health.

(b) A cooperative group funded by one of the National Institutes of Health.

(c) The FDA in the form of an investigational new drug application.

(d) The United States Department of Veterans Affairs.

(e) The United States Department of Defense.

(f) A federally funded general clinical research center.

(g) The Coalition of National Cancer Cooperative Groups.

(4) The proposed protocol must have been reviewed and approved by a qualified institutional review board which operates in this state and which has a multiple project assurance contract approved by the office of protection from research risks.

(5) The facility and personnel providing the protocol must provide the treatment within their scope of practice, experience, and training and are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(6) There must be no clearly superior, non-investigational approach.

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

(8) The patient has signed an institutional review board approved consent form.

F. Any entity seeking coverage for treatment in a clinical trial approved by an institutional review board shall post electronically, and keep up-to-date, a list of the cancer clinical trials meeting these requirements and the list shall include the following for each clinical trial:

(1) The phase for which the trial is approved.

(2) The entity approving the trial which renders it eligible for reimbursement.

(3) The cancer or cancers for which the trial is approved.

(4) The estimated number of participants in the trial.

G. The provisions of this Section shall not be construed to affect compliance or coverage for off-label use of drugs not directly affected

by this Section.

H. The commissioner may promulgate necessary rules and regulations, pursuant to R.S. 22:3, to provide for submission of annual reports by health insurers describing clinical trials for which coverage was provided to insureds, subscribers, or enrollees.

Section 2. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_