FIRST REGULAR SESSION

SENATE BILL NO. 627

91ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR DOUGHERTY.

Read 1st time March 1, 2001, and 1,000 copies ordered printed.

TERRY L. SPIELER, Secretary.

2177S.01I

AN ACT

To amend chapter 376, RSMo, by adding thereto one new section relating to coverage for clinical trials.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 376, RSMo, is amended by adding thereto one new section, to be known as section 376.1252, to read as follows:

376.1252. 1. All individual and group health insurance policies providing coverage on an expense-incurred basis, individual and group service or indemnity type contracts issued by a nonprofit corporation, individual and group service contracts issued by a health maintenance organization or a health carrier, all self-insured group arrangements to the extent not preempted by federal law and all managed health care delivery entities of any type or description, that are delivered, issued for delivery, continued or renewed on or after August 28, 2001, and providing coverage to any resident of this state shall provide benefits or coverage for patient costs, that are directly associated with a cancer or a special condition clinical trial that is offered in this state and in which the patient participates voluntarily.

2. A cancer or special condition clinical trial is a course of treatment in which all of the following apply:

(1) The treatment is part of a scientific study of a new therapy or intervention that is being conducted at an institution in this state, that is for the treatment, palliation or prevention of cancer or a special condition 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 directions for administering the therapy and monitoring patients;

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

(f) Methods for documenting and treating adverse reactions;

(2) The treatment is being provided as part of a study being conducted in a phase I, phase II, phase III or phase IV cancer or a special condition clinical trial;

(3) The treatment 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 national institutes of health;

(b) A national institute's of health cooperative group or center;

(c) The United States Food and Drug Administration in the form of an investigational new drug application;

(d) The United States Department of Defense;

(e) The United States Department of Veterans' Affairs;

(f) A qualified research entity that meets the criteria established by the national institute's of health for grant eligibility;

(g) A panel of qualified recognized experts in clinical research within academic health institutions in this state;

(4) The proposed treatment or study has been reviewed and approved by an institutional review board of an institution in this state;

(5) The personnel providing the treatment or conducting the study:

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

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

(6) There is no clearly superior, noninvestigational treatment alternative;

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

3. Pursuant to the patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of a cancer or a special condition clinical trial.

4. Each contract or policy delivered or issued for delivery in this state shall provide benefits under the contract or policy, and those benefits shall not supplant any portion of the clinical trial that is customarily paid for by government, biotechnical,

pharmaceutical or medical device industry sources.

5. Nothing in this subsection prohibits the health carrier from imposing deductibles, coinsurance or other cost-sharing measures in relation to benefits provided pursuant to this subsection.

6. Coverage and benefits related to the examinations and tests as required by this section shall be at least as favorable and subject to the same dollar limits, deductible, and co-payments as other covered benefits or services.

7. A trade association that represents hospital service corporations, medical service corporations and health carriers as defined in section 376.1350 may select a representative to voluntarily serve on the institutional review board of an institution in this state that reviews and approves the proposed treatment or study conducted during the cancer or a special condition clinical trial.

8. Nothing in this section shall apply to accident-only, hospital indemnity, Medicare supplement, long-term care, or other limited benefit health insurance policies.

9. The provisions of this section shall not apply to short-term major medical policies of six months or less duration.

10. For the purposes of this section, the following terms mean:

(1) "Cooperative group", a formal network of facilities that collaborates on research projects and that has an established national institute's of health approved peer review program operating within the group. This term includes but is not limited to the National Cancer Institute Clinical Cooperative Group and the National Cancer Institute Community Clinical Oncology Program;

(2) "Institutional review board", any 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 such 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;

(b) Approved by the National Institute's of Health Office for Protection from Research Risks;

(3) "Multiple project assurance contract", 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 that sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects;

(4) "Patient", the enrollee as defined in section 376.1350;

(5) "Patient cost", any fee or expense that is covered under the contract or policy

and that is for a service or treatment that would be required if the patient were receiving usual and customary care. Patient cost does not include the cost:

(a) Of any drug or device provided in a phase I cancer clinical trial;

(b) Of any investigational drug or device;

(c) Of nonhealth services that might be required for a person to receive treatment or intervention;

(d) Of managing the research of the clinical trial;

(e) That would not be covered under the patient's contract;

(f) Of treatment or services provided outside this state.

(6) "Special condition", a condition or disease that is life-threatening, degenerative or disabling and requires specialized medical care over a prolonged period of time.

T