SECOND REGULAR SESSION

SENATE BILL NO. 827

91ST GENERAL ASSEMBLY

INTRODUCED BY SENATORS DOUGHERTY, STOLL, GROSS AND DePASCO.

Pre-filed December 13, 2001, and 1,000 copies ordered printed.

TERRY L. SPIELER, Secretary.

2795S.03I

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 376.429, to read as follows:

376.429. 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, 2002, and providing coverage to any resident of this state shall provide coverage for routine patient care costs as defined in subsection 7 of this section incurred as the result of phase I, II, III or IV of a clinical trial that is approved by an entity listed in subsection 4 of this section and is undertaken for the purposes of the prevention, early detection or treatment of cancer or for the treatment of a serious life-threatening illness.

2. In the case of treatment under a clinical trial, the treating facility and personnel must have the expertise and training to provide the treatment and treat a sufficient volume of patients. There must be

equal to or superior, non-investigational treatment alternatives and the available clinical or pre-clinical data must provide a reasonable expectation that the treatment will be superior to the non-investigational alternatives.

3. Coverage required by this section shall include coverage for routine patient care costs incurred for drugs and devices that have been approved for sale by the 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 the drug or device. This shall include coverage for reasonable and medically necessary services needed to administer the drug or use the device under evaluation in the clinical trial.

4. Subsections 1 and 2 of this section requiring coverage for routine patient care costs shall apply to clinical trials that are approved or funded by one of the following entities:

(1) One of the National Institutes of Health (NIH);

(2) An NIH Cooperative Group of Center as defined in subsection 7 of this section;

(3) The FDA in the form of an investigational new drug application;

(4) The federal Departments of Veterans' Affairs or Defense;

(5) An institutional review board of an institution in this state that has a multiple project assurance contract approved by the Office of Protection for the Research Risks of the NIH;

(6) A qualified research entity that meets the criteria for NIH Center support grant eligibility; or

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

5. An entity seeking coverage for treatment, prevention or early detection in a clinical trial approved by an institutional review board under subdivision (5) of subsection 4 of this section shall maintain and post electronically a list of the clinical trials meeting the requirements of subsections 2 and 3 of this section. This list shall include: the phase for which the clinical trial is approved; the entity approving the trial; whether the trial is for the treatment of cancer or other serious or life threatening disease, and if not cancer, the particular disease; and the

number of participants in the trial. If the electronic posting is not practical, the entity seeking coverage shall periodically provide payers and providers in the state with a written list of trials providing the information required in this section.

6. On or before June 1 of each year, each insurer, nonprofit health service plan, health maintenance, health carrier and managed care organization subject to the requirements of this section shall submit to the director of insurance, in a form the director requires, a report on its coverage of clinical trials during the previous year. The director shall compile an annual summary report based on the information provided under this subsection and provide copies to the speaker of the house of representatives and the president pro tem of the senate. The director shall make copies of the report available to the members of the general public upon request and at a reasonable charge for copying and postage.

7. As used in this section, the following terms shall mean:

(1) "Cooperative group", a formal network of facilities that collaborate on research projects and have an established NIH-approved Peer Review Program operating within the group. This includes the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;

(2) "Multiple project assurance contract", a contract between an institution and the federal Department of Health and Human Services (DHHS) that defines the relationship of the institution to the DHHS and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects;

(3) "Routine patient care costs", shall include coverage for reasonable and medically necessary services needed to administer the drug or device under evaluation in the clinical trial;

(4) Exclusion of certain costs: routine patient care costs include all items and services that are otherwise generally available to a qualified individual that are provided in the clinical trial except:

(a) The investigational item or service, itself;

(b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and

(c) Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

8. For the purpose of this section, providers participating in clinical trials shall obtain a patient's informed consent for participation on the clinical trial in a manner that is consistent with current legal and ethical standards. Such documents shall be available to the health insurer upon request.

9. The provisions of this section shall not apply to a policy, plan or contract paid under Title XVIII or Title XIX of the Social Security Act.

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