FIRST REGULAR SESSION

SENATE BILL NO. 375

95TH GENERAL ASSEMBLY

INTRODUCED BY SENATORS MAYER, WRIGHT-JONES, ENGLER, SCOTT, DEMPSEY, GOODMAN, JUSTUS AND GREEN.

Read 1st time February 12, 2009, and ordered printed.

TERRY L. SPIELER, Secretary.

1815S.01I

AN ACT

To repeal section 376.429, RSMo, and to enact in lieu thereof one new section relating to health insurance coverage for clinical trials.

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

Section A. Section 376.429, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 376.429, to read as follows:

376.429. 1. All health benefit plans, as defined in section 376.1350, that are delivered, issued for delivery, continued or renewed on or after August 28, **[**2006**]** **2009**, 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. **[**Health benefit plans may limit coverage for the routine patient care costs of patients in phase II of a clinical trial to those treating facilities within the health benefit plans' provider network; except that, this provision shall not be construed as relieving a health benefit plan of the sufficiency of network requirements under state statute.**]**

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, noninvestigational treatment alternatives and the available clinical or preclinical data must provide a reasonable expectation that the treatment will be superior to the noninvestigational alternatives.

3. Coverage required by this section shall include coverage for routine

EXPLANATION–Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

patient care costs incurred for drugs and devices that have been approved for sale by the Food and Drug Administration (FDA), regardless of whether approved by the FDA for use in treating the patient's particular condition, including 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 **[**phase III or IV of**]** 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 or 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 in this state that has an appropriate assurance approved by the Department of Health and Human Services assuring compliance with and implementation of regulations for the protection of human subjects (45 CFR 46); or

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

5. **[**Subsections 1 and 2 of this section requiring coverage for routine patient care costs shall apply to phase II of clinical trials if:

(1) Phase II of a clinical trial is sanctioned by the National Institutes of Health (NIH) or National Cancer Institute (NCI) and conducted at academic or National Cancer Institute Center; and

(2) The person covered under this section is enrolled in the clinical trial. This section shall not apply to persons who are only following the protocol of phase II of a clinical trial, but not actually enrolled.

6.**]** 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; 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.

[7.**]** **6.** 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, including 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. 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.**]** **7.** 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 made available to the health insurer upon request.

[9.**]** **8.** 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.

[10.**]** **9.** Nothing in this section shall apply to any accident-only policy, specified disease policy, hospital indemnity policy, Medicare supplement policy, long-term care policy, short-term major medical policy of six months or less duration, or other limited benefit health insurance policies.

[11. The provisions of this section regarding phase II of a clinical trial shall not apply automatically to an individually underwritten health benefit plan, but shall be an option to any such plan.**]**

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