

SECOND REGULAR SESSION  
SENATE COMMITTEE SUBSTITUTE FOR  
**SENATE BILLS NOS. 567 & 792**  
93RD GENERAL ASSEMBLY

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Reported from the Committee on Aging, Families, Mental and Public Health, April 3, 2006, with recommendation that the Senate Committee Substitute do pass.

3385S.03C

TERRY L. SPIELER, Secretary.

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**AN ACT**

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

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*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Section A. Section 376.429, RSMo, is repealed and one new section  
2 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  
2 are delivered, issued for delivery, continued or renewed on or after August 28,  
3 [2002] **2006**, and providing coverage to any resident of this state shall provide  
4 coverage for routine patient care costs as defined in subsection 6 of this section  
5 incurred as the result of phase II, III, or IV of a clinical trial that is approved by  
6 an entity listed in subsection 4 of this section and is undertaken for the purposes  
7 of the prevention, early detection, or treatment of cancer.

8 2. In the case of treatment under a clinical trial, the treating facility and  
9 personnel must have the expertise and training to provide the treatment and  
10 treat a sufficient volume of patients. There must be equal to or superior,  
11 noninvestigational treatment alternatives and the available clinical or preclinical  
12 data must provide a reasonable expectation that the treatment will be superior  
13 to the noninvestigational alternatives.

14 3. Coverage required by this section shall include coverage for routine  
15 patient care costs incurred for drugs and devices that have been approved for sale  
16 by the Food and Drug Administration (FDA), regardless of whether approved by  
17 the FDA for use in treating the patient's particular condition, including coverage  
18 for reasonable and medically necessary services needed to administer the drug or

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

19 use the device under evaluation in the clinical trial.

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

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

24 (2) An NIH cooperative group or center as defined in subsection 6 of this  
25 section;

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

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

28 (5) An institutional review board in this state that has an appropriate  
29 assurance approved by the Department of Health and Human Services assuring  
30 compliance with and implementation of regulations for the protection of human  
31 subjects (45 CFR 46); or

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

34 5. An entity seeking coverage for treatment, prevention, or early detection  
35 in a clinical trial approved by an institutional review board under subdivision (5)  
36 of subsection 4 of this section shall maintain and post electronically a list of the  
37 clinical trials meeting the requirements of subsections 2 and 3 of this  
38 section. This list shall include: the phase for which the clinical trial is approved;  
39 the entity approving the trial; the particular disease; and the number of  
40 participants in the trial. If the electronic posting is not practical, the entity  
41 seeking coverage shall periodically provide payers and providers in the state with  
42 a written list of trials providing the information required in this section.

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

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

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

53 (3) "Routine patient care costs" shall include coverage for reasonable and  
54 medically necessary services needed to administer the drug or device under

55 evaluation in the clinical trial. Routine patient care costs include all items and  
56 services that are otherwise generally available to a qualified individual that are  
57 provided in the clinical trial except:

- 58 (a) The investigational item or service itself;
- 59 (b) Items and services provided solely to satisfy data collection and  
60 analysis needs and that are not used in the direct clinical management of the  
61 patient; and
- 62 (c) Items and services customarily provided by the research sponsors free  
63 of charge for any enrollee in the trial.

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

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

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

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