

SECOND REGULAR SESSION

HOUSE BILL NO. 1952

91ST GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES MONACO, CRUMP, ABEL, O'TOOLE,
BOWMAN (Co-sponsors), O'CONNOR, FOLEY, NAEGER, SHIELDS AND McKENNA.

Read 1st time February 14, 2002, and 1000 copies ordered printed.

TED WEDEL, Chief Clerk

4623L.011

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
2 known as section 376.429, to read as follows:

376.429. 1. All health benefit plans, as defined in section 376.1350, that are
2 delivered, issued for delivery, continued or renewed on or after August 28, 2002, and
3 providing coverage to any resident of this state shall provide coverage for routine patient
4 care costs as defined in subsection 7 of this section incurred as the result of phase I, II, III,
5 or IV of a clinical trial that is approved by an entity listed in subsection 4 of this section
6 and is undertaken for the purposes of the prevention, early detection, or treatment of
7 cancer or for the treatment of a serious life-threatening illness.

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

13 3. Coverage required by this section shall include coverage for routine patient care
14 costs incurred for drugs and devices that have been approved for sale by the Food and
15 Drug Administration (FDA), regardless of whether approved by the FDA for use in
16 treating the patient's particular condition, to the extent that the drugs or devices are not
17 paid for by the manufacturer, distributor, or provider of the drug or device, including
18 coverage for reasonable and medically necessary services needed to administer the drug

19 or use the device under evaluation in the clinical trial.

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

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

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

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

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

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

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

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

34 **5. An entity seeking coverage for treatment, prevention, or early detection in a**
35 **clinical trial approved by an institutional review board under subdivision (5) of subsection**
36 **4 of this section shall maintain and post electronically a list of the clinical trials meeting the**
37 **requirements of subsections 2 and 3 of this section. This list shall include: the phase for**
38 **which the clinical trial is approved; the entity approving the trial; whether the trial is for**
39 **the treatment of cancer or other serious or life threatening disease, and if not cancer, the**
40 **particular disease; and the number of participants in the trial. If the electronic posting is**
41 **not practical, the entity seeking coverage shall periodically provide payers and providers**
42 **in the state with 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 research**
45 **projects and have an established NIH-approved Peer Review Program operating within**
46 **the group, including the NCI Clinical Cooperative Group and the NCI Community Clinical**
47 **Oncology Program;**

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

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

58 (a) The investigational item or service itself;

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

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

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

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