

SENATE CHAMBER

STATE OF OKLAHOMA

DISPOSITION BY SENATE

FLOOR AMENDMENT

No. _____

(Date)

Mr./Madame President:

I move to amend Senate Bill No. 1039, Page 4, Line 2 ½, as follows:

By inserting new SECTIONS 2-6 to read as per attached and by renumbering subsequent sections.

Submitted by:

Senator Rice

Rice-JM-FA-SB1039
3/5/2009 4:54 PM

1 SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes
2 as Section 6060.9a of Title 36, unless there is created a duplication in numbering, reads as follows:

3 Sections 2 through 6 of this act shall be known and may be cited as “Steffanie’s Law for
4 Clinical Trial Access”.

5 SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes
6 as Section 6060.9b of Title 36, unless there is created a duplication in numbering, reads as follows:

7 As used in Steffanie’s Law for Clinical Trial Access:

8 1. “Clinical trial” means a course of treatment provided to a patient for the purpose of
9 prevention of reoccurrence, early detection or treatment of cancer;

10 2. “Cooperative group” means a formal network of facilities that collaborate on research
11 projects and have an established National Institutes of Health-approved peer review program
12 operating within the group;

13 3. “Institutional review board” means a board, committee or other group that is both:
14 a. formally designated by an institution to approve the initiation of and to conduct
15 periodic review of biomedical research involving human subjects and in which
16 the primary purpose of the review is to assure the protection of the rights and
17 welfare of the human subjects and not to review a clinical trial for scientific
18 merit, and

19 b. approved by the National Institutes of Health for protection of human subjects
20 from research risks;

21 4. “Investigational drug or device” means a drug or device that has not been approved by the
22 Food and Drug Administration;

23 5. “Multiple project assurance contract” means a contract between an institution and the
24 United States Department of Health and Human Services that defines the relationship of the

1 institution to the Department and sets out the responsibilities of the institution and the procedures
2 that will be used by the institution to protect human subjects participating in clinical trials;

3 6. "Patient" means an individual who participates in a cancer clinical trial and who is an
4 insured member or a beneficiary of a health benefit plan; and

5 7. "Routine patient care cost":

6 a. means:

7 (1) a medical service or treatment that is a benefit under a health benefit
8 plan that would be covered if the patient were receiving standard cancer
9 treatment, or

10 (2) a drug provided to a patient during a cancer clinical trial if the drug has
11 been approved by the Food and Drug Administration, whether or not
12 that organization has approved the drug for use in treating the patient's
13 particular condition, but only to the extent that the drug is not paid for
14 by the manufacturer, distributor or provider of the drug, and

15 b. does not include:

16 (1) the cost of an investigational drug, device or procedure,

17 (2) the cost of a service that is not related to the patient's health care that
18 the patient is required to receive as a result of participation in the cancer
19 clinical trial,

20 (3) costs associated with managing the research that is associated with the
21 cancer clinical trial,

22 (4) costs that would not be covered by the patient's health benefit plan if
23 noninvestigational treatments were provided,

24 (5) costs of those tests that are necessary for the research of the clinical
25 trial, and

1 (6) costs paid or not charged for by the cancer clinical trial providers.

2 SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes
3 as Section 6060.9c of Title 36, unless there is created a duplication in numbering, reads as follows:

4 Any health benefit plan, including the State and Education Employees Group Health Insurance
5 Plan, that is offered, issued, or renewed in this state on or after January 1, 2010, shall provide
6 coverage for routine patient care costs incurred as a result of the patient's participation in a phase I,
7 II, III or IV cancer clinical trial if:

8 1. The clinical trial is undertaken for the purposes of the prevention of reoccurrence, early
9 detection or treatment of cancer for which no equally or more effective standard cancer treatment
10 exists;

11 2. The clinical trial is being provided in this state as part of a scientific study of a new therapy
12 or intervention and is for the prevention of reoccurrence, early detection, treatment or palliation of
13 cancer in humans and in which the scientific study includes all of the following:

- 14 a. specific goals,
- 15 b. a rationale and background for the study,
- 16 c. criteria for patient selection,
- 17 d. specific direction for administering the therapy or intervention and for
18 monitoring patients,
- 19 e. a definition of quantitative measures for determining treatment response, and
- 20 f. methods for documenting and treating adverse reactions;

21 3. The clinical trial is being conducted with approval of at least one of the following:

- 22 a. one of the institutes or centers which composes the National Institutes of
23 Health,
- 24 b. a National Institutes of Health cooperative group or center,
- 25 c. the Department of Defense,

- d. the Food and Drug Administration in the form of an investigational new drug application,
- e. the Department of Veteran Affairs, or
- f. a qualified research entity that meets the criteria established by the National Institutes of Health for grant eligibility;

4. The clinical trial is being provided as part of a study being conducted in a phase I, II, III or IV cancer clinical trial;

5. The proposed clinical trial or study has been reviewed and approved by an institutional review board that has a multiple project assurance contract approved by the Office of Protection for Research Risks of the National Institutes of Health; and

6. The personnel providing the clinical trial or conducting the study:

- a. are providing the clinical trial or conducting the study within their scope of practice, experience and training and are capable of providing the clinical trial because of their expertise, training and volume of patients treated to maintain their expertise,
- b. agree to accept reimbursement as payment in full from the health benefit plan at the rates that are established by that plan and are not more than the level of reimbursement applicable to other similar services provided by health care providers within the plan's provider network, and
- c. agree to provide written notification to the health benefit plan when the patient enters or leaves a clinical trial.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 6060.9d of Title 36, unless there is created a duplication in numbering, reads as follows:

A. Pursuant to the patient informed consent document, no third party is liable for damages associated with the treatment provided during a phase of a cancer clinical trial.

1 B. The provisions of this act do not create a private right or cause of action for or on behalf of
2 a patient against the health benefit plan providing coverage.

3 SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes
4 as Section 6060.9e of Title 36, unless there is created a duplication in numbering, reads as follows:

5 A. A health benefit plan may impose deductibles, coinsurance requirements or other standard
6 cost-sharing provision on benefits provided pursuant to this act.

7 B. A health benefit plan shall not provide benefits that supplant a portion of a cancer clinical
8 trial that is customarily paid for by government, biotechnical, pharmaceutical or medical devise
9 industry sources.

10 C. In no event shall the health benefit plan be responsible for out-of-state or out-of-network
11 costs unless the health benefit plan pays for standard treatment out of state or out of network.

12 D. The provisions of this act shall not apply to short-term travel, accident-only or limited or
13 specified disease contracts or policies issued by a health benefit plan.

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