

SB 1521

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THE STATE SENATE  
Monday, February 25, 2008

Senate Bill No. 1521

SENATE BILL NO. 1521 - By: RICE, LEFTWICH and CORN of the Senate and STEELE of the House.

An Act relating to insurance; creating Steffanie's Law for Clinical Trial Access; providing short title; defining terms; requiring health benefit plans to provide certain coverage in specified circumstances; prohibiting certain liability; prohibiting certain right or cause of action; permitting certain cost-sharing provisions; prohibiting certain benefits and responsibilities; clarifying applicability of act; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

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

This act shall be known and may be cited as "Steffanie's Law for Clinical Trial Access".

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

As used in Steffanie's Law for Clinical Trial Access:

- 1. "Clinical trial" means a course of treatment provided to a patient for the purpose of prevention of reoccurrence, early detection or treatment of cancer;

1           2. "Cooperative group" means a formal network of facilities  
2 that collaborate on research projects and have an established  
3 National Institutes of Health-approved peer review program operating  
4 within the group;

5           3. "Institutional review board" means a board, committee or  
6 other group that is both:

7           a. formally designated by an institution to approve the  
8 initiation of and to conduct periodic review of  
9 biomedical research involving human subjects and in  
10 which the primary purpose of the review is to assure  
11 the protection of the rights and welfare of the human  
12 subjects and not to review a clinical trial for  
13 scientific merit, and

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

16           4. "Investigational drug or device" means a drug or device that  
17 has not been approved by the Food and Drug Administration;

18           5. "Multiple project assurance contract" means a contract  
19 between an institution and the Department of Health and Human  
20 Services that defines the relationship of the institution to the  
21 Department and sets out the responsibilities of the institution and  
22 the procedures that will be used by the institution to protect human  
23 subjects participating in clinical trials;

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

4           7. "Routine patient care cost":

5           a. means:

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

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

18           b. does not include:

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

21                   (2) the cost of a service that is not related to the  
22                           patient's health care that the patient is

- 1 required to receive as a result of participation  
2 in the cancer clinical trial,
- 3 (3) costs associated with managing the research that  
4 is associated with the cancer clinical trial,
- 5 (4) costs that would not be covered by the patient's  
6 health benefit plan if noninvestigational  
7 treatments were provided,
- 8 (5) costs of those tests that are necessary for the  
9 research of the clinical trial, and
- 10 (6) costs paid or not charged for by the cancer  
11 clinical trial providers.

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

15 Any health benefit plan, including the State and Education  
16 Employees Group Health Insurance Plan, that is offered, issued, or  
17 renewed in this state on or after January 1, 2009, shall provide  
18 coverage for routine patient care costs incurred as a result of the  
19 patient's participation in a phase I, II, III or IV cancer clinical  
20 trial if:

- 21 1. The clinical trial is undertaken for the purposes of the  
22 prevention of reoccurrence, early detection or treatment of cancer

1 for which no equally or more effective standard cancer treatment  
2 exists;

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

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

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

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

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

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

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

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

- 15           a.    are providing the clinical trial or conducting the  
16                    study within their scope of practice, experience and  
17                    training and are capable of providing the clinical  
18                    trial because of their expertise, training and volume  
19                    of patients treated to maintain their expertise,  
20           b.    agree to accept reimbursement as payment in full from  
21                    the health benefit plan at the rates that are  
22                    established by that plan and are not more than the  
23                    level of reimbursement applicable to other similar

1 services provided by health care providers within the  
2 plan's provider network, and  
3 c. agree to provide written notification to the health  
4 benefit plan when the patient enters or leaves a  
5 clinical trial.

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

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

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

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

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

21 B. A health benefit plan shall not provide benefits that  
22 supplant a portion of a cancer clinical trial that is customarily

1 paid for by government, biotechnical, pharmaceutical or medical  
2 devise industry sources.

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

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

9 SECTION 6. This act shall become effective November 1, 2008.

10 COMMITTEE REPORT BY: COMMITTEE ON HEALTH & HUMAN RESOURCES, dated  
11 2-21-08 - DO PASS, As Coauthored.