

FLOOR AMENDMENT  
HOUSE OF REPRESENTATIVES  
State of Oklahoma

SPEAKER:

CHAIR:

I move to amend SB1640  
Page 2 Section 2 Lines 4 1/2  
Of the printed Bill  
Of the Engrossed Bill

By inserting new Sections 2 through 10 to read as follows and by renumbering the subsequent section:

(See attached pages)

AMEND TITLE TO CONFORM TO AMENDMENTS

Amendment submitted by: Ryan Kiesel

Adopted: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Reading Clerk

1 "SECTION 2. NEW LAW A new section of law to be codified  
2 in the Oklahoma Statutes as Section 6060.4a of Title 36, unless  
3 there is created a duplication in numbering, reads as follows:

4 Section 3 of this act shall be known and may be cited as "Nick's  
5 Law".

6 SECTION 3. NEW LAW A new section of law to be codified  
7 in the Oklahoma Statutes as Section 6060.4b of Title 36, unless  
8 there is created a duplication in numbering, reads as follows:

9 A. Any individual or group health benefit plan, including the  
10 State and Education Employees Group Health Insurance Plan, that is  
11 offered, issued, or renewed in this state on or after January 1,  
12 2009, shall provide coverage for the screening, diagnosis, testing  
13 and treatment of an autistic spectrum disorder. Coverage provided  
14 under this section is limited to generally recognized services and  
15 treatments that are prescribed by the insured individual's treating  
16 physician in accordance with a treatment plan.

17 B. The coverage required under this section shall not be  
18 subject to dollar limits, visit limitations, deductibles or  
19 coinsurance provisions that are less favorable to an insured  
20 individual than the dollar limits, deductibles, or coinsurance  
21 provisions that apply to physical illness generally under the health  
22 benefit plan. Coverage of services may be subject to other general  
23 exclusions and limitations of the health benefit plan, including,  
24 but not limited to:

- 1 1. The coordination of benefits;
- 2 2. Participating provider requirements;
- 3 3. Services provided by family or household member
- 4 restrictions;
- 5 4. Eligibility; and
- 6 5. Appeals processes.

7 C. The treatment plan required under subsection A shall include  
8 all elements necessary for the insurer to appropriately pay claims.  
9 These elements shall include, but not be limited to:

- 10 1. A diagnosis;
- 11 2. Proposed treatment or treatments by type, frequency and
- 12 duration;
- 13 3. The anticipated outcomes stated as goals;
- 14 4. The frequency by which the treatment plan will be updated;
- 15 and
- 16 5. The treating physician's signature.

17 The insurer shall have the right to request an updated treatment  
18 plan not more than once every six (6) months from the treating  
19 physician to review medical necessity, unless the insurer and the  
20 provider agree that a more frequent review is necessary due to  
21 emerging clinical circumstances.

22 D. A diagnosis of an autistic spectrum disorder by a licensed  
23 physician or board-certified therapist shall be required to be

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1 eligible for benefits and coverage under this section. The  
2 prescribing medical practitioner shall be:

3 1. Licensed, certified or registered by an appropriate agency  
4 of the State of Oklahoma;

5 2. One whose professional credential is recognized and accepted  
6 by an appropriate agency of the United States; or

7 3. One who is certified as a provider under the TRICARE  
8 military health system.

9 The benefits and coverage provided under this section shall be  
10 provided to any eligible person less than twenty-one (21) years of  
11 age.

12 E. The insurer shall provide coverage for all therapies,  
13 treatments, diagnoses and testing, medicines, special diets, and  
14 supplements prescribed by a licensed physician or board-certified  
15 therapist, including but not limited to coverage for behavioral  
16 therapy.

17 F. Coverage for behavioral therapy shall be subject to a  
18 maximum benefit of Seventy-five Thousand Dollars (\$75,000.00) per  
19 year.

20 G. An insurer shall not deny or refuse to issue coverage on,  
21 refuse to contract with, refuse to renew, refuse to reissue, or  
22 otherwise terminate or restrict coverage on an individual under an  
23 insurance policy solely because the individual is diagnosed with an  
24 autistic spectrum disorder.

1 H. This section shall not apply to limited benefits policies,  
2 including, but not limited to:

- 3 1. Accident-only policies;
- 4 2. Specified disease policies;
- 5 3. Hospital indemnity policies;
- 6 4. Medicare supplement policies; or
- 7 5. Long-term care policies.

8 I. For purposes of this section:

9 1. "Autistic spectrum disorder" means a neurological disorder  
10 that is marked by severe impairment in social interaction,  
11 communication, and imaginative play, with onset generally during the  
12 first three (3) years of life and is included in a group of  
13 disorders known as autism spectrum disorders;

14 2. "Autism spectrum disorder" means any of the pervasive  
15 developmental disorders as defined by the most recent edition of the  
16 Diagnostic and Statistical Manual of the Mental Disorders (DSM)  
17 including Autistic Disorder, Asperger's Disorder, and Pervasive  
18 Developmental Disorder not otherwise specified (NOS), Rett Disorder,  
19 and Childhood Degenerative Disorder; and

20 3. "Neurobiological disorder" means an illness of the nervous  
21 system caused by genetic, metabolic, or other biological factors.

22 SECTION 4. AMENDATORY 36 O.S. 2001, Section 6060.8a, is  
23 amended to read as follows:

1 Section 6060.8a Any health benefit plan, including the State  
2 and Education Employees Group Health Insurance Plan, that is  
3 offered, issued or renewed in this state on or after January 1, ~~2002~~  
4 2009, which provides medical and surgical benefits, shall ~~offer~~  
5 provide coverage for colorectal cancer examinations and laboratory  
6 tests for cancer for any nonsymptomatic covered individual, in  
7 accordance with standard, accepted published medical practice  
8 guidelines for colorectal cancer screening, who is:

- 9 1. At least fifty (50) years of age; or
- 10 2. Less than fifty (50) years of age and at high risk for  
11 colorectal cancer according to the standard, accepted published  
12 medical practice guidelines.

13 B. The coverage provided for by this section shall be subject  
14 to the same annual deductibles, co-payments or coinsurance limits as  
15 established for other covered benefits under the health plan.

16 C. To minimize costs for nonsymptomatic screening, third-party  
17 reimbursement may be at the existing Medicaid rate which shall be  
18 payment in full.

19 D. As used in this section, "health benefit plan" means any  
20 plan or arrangement as defined in subsection D of Section 6060.8 of  
21 ~~Title 36 of the Oklahoma Statutes~~ this title; provided, however, the  
22 provisions of this section shall not apply to policies or  
23 certificates issued to individuals or to groups with fifty (50) or  
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1 fewer employees, ~~or to plans offered under the state Medicaid~~  
2 ~~program.~~

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

6 This section and Sections 6 through 9 of this act shall be known  
7 and may be cited as "Steffanie's Law for Clinical Trial Access".

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

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

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

15 2. "Cooperative group" means a formal network of facilities  
16 that collaborate on research projects and have an established peer  
17 review program approved by the National Institutes of Health  
18 operating within the group;

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

21 a. formally designated by an institution to approve the  
22 initiation of and to conduct periodic review of  
23 biomedical research involving human subjects and in  
24 which the primary purpose of the review is to assure

1 the protection of the rights and welfare of the human  
2 subjects and not to review a clinical trial for  
3 scientific merit, and

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

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

8 5. "Multiple project assurance contract" means a contract  
9 between an institution and the Department of Health and Human  
10 Services that defines the relationship of the institution to the  
11 Department and sets out the responsibilities of the institution and  
12 the procedures that will be used by the institution to protect human  
13 subjects participating in clinical trials;

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

17 7. "Routine patient care cost":

18 a. means:

19 (1) a medical service or treatment that is a benefit  
20 under a health benefit plan that would be covered  
21 if the patient were receiving standard cancer  
22 treatment, or

23 (2) a drug provided to a patient during a cancer  
24 clinical trial if the drug has been approved by

1 the Food and Drug Administration, whether or not  
2 that organization has approved the drug for use  
3 in treating the patient's particular condition,  
4 but only to the extent that the drug is not paid  
5 for by the manufacturer, distributor or provider  
6 of the drug, and

7 b. does not include:

- 8 (1) the cost of an investigational drug, device or  
9 procedure,  
10 (2) the cost of a service that is not related to the  
11 patient's health care that the patient is  
12 required to receive as a result of participation  
13 in the cancer clinical trial,  
14 (3) costs associated with managing the research that  
15 is associated with the cancer clinical trial,  
16 (4) costs that would not be covered by the patient's  
17 health benefit plan if noninvestigational  
18 treatments were provided,  
19 (5) costs of those tests that are necessary for the  
20 research of the clinical trial, and  
21 (6) costs paid or not charged for by the cancer  
22 clinical trial providers.  
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1           SECTION 7.           NEW LAW           A new section of law to be codified  
2 in the Oklahoma Statutes as Section 6060.9c of Title 36, unless  
3 there is created a duplication in numbering, reads as follows:

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

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

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

- 19           a. specific goals,
- 20           b. a rationale and background for the study,
- 21           c. criteria for patient selection,
- 22           d. specific direction for administering the therapy or  
23           intervention and for monitoring patients,

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- e. a definition of quantitative measures for determining treatment response, and
- f. methods for documenting and treating adverse reactions;

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

- a. one of the institutes or centers which composes the National Institutes of Health,
- b. a National Institutes of Health cooperative group or center,
- c. the Department of Defense,
- d. the Food and Drug Administration in the form of an investigational new drug application,
- e. the Department of Veterans 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

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

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

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

20           A. Pursuant to the patient informed consent document, no third  
21 party is liable for damages associated with the treatment provided  
22 during a phase of a cancer clinical trial.  
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1 B. The provisions of this act do not create a private right or  
2 cause of action for or on behalf of a patient against the health  
3 benefit plan providing coverage.

4 SECTION 9. NEW LAW A new section of law to be codified  
5 in the Oklahoma Statutes as Section 6060.9e of Title 36, unless  
6 there is created a duplication in numbering, reads as follows:

7 A. A health benefit plan may impose deductibles, coinsurance  
8 requirements or other standard cost-sharing provision on benefits  
9 provided pursuant to this section and Sections 5 through 8 of this  
10 act.

11 B. A health benefit plan shall not provide benefits that  
12 supplant a portion of a cancer clinical trial that is customarily  
13 paid for by government, biotechnical, pharmaceutical or medical  
14 device industry sources.

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

18 D. The provisions of this section and Sections 5 through 8 of  
19 this act shall not apply to short-term travel, accident-only or  
20 limited or specified disease contracts or policies issued by a  
21 health benefit plan.

22 SECTION 10. NEW LAW A new section of law to be codified  
23 in the Oklahoma Statutes as Section 6060.13a of Title 36, unless  
24 there is created a duplication in numbering, reads as follows:

1 A. As used in this section:

2 1. "Inherited metabolic disease" means a disease caused by an  
3 inherited abnormality of body chemistry, and includes, but is not  
4 limited to, a disease for which this state screens newborn babies;

5 2. "Low-protein modified food product" means a food product  
6 that is:

7 a. specially formulated to have less than one (1) gram of  
8 protein per serving, and

9 b. intended to be used under the direction of a physician  
10 for the dietary treatment of an inherited metabolic  
11 disease.

12 Low-protein modified food product shall not include a natural food  
13 that is naturally low in protein; and

14 3. "Medical food" means a food that is:

15 a. intended for the dietary treatment of a disease or  
16 condition for which nutritional requirements are  
17 established by medical evaluation, and

18 b. formulated to be consumed or administered internally  
19 under the direction of a physician.

20 B. The provisions of this section shall apply to a nonprofit  
21 health service plan, a hospital or major medical insurance policy, a  
22 group or blanket health insurance policy, and a health maintenance  
23 organization benefit package of health care services that:

24 1. Is written on an expense-incurred basis;

1 2. Provides coverage for a family member of the insured; and

2 3. Is delivered or issued for delivery in this state.

3 C. The health plan, insurance policies, and health maintenance  
4 organization benefit package of health care services provided in  
5 subsection B of this section shall include under the coverage of the  
6 family member, coverage for medical foods and low-protein modified  
7 food products for the treatment of inherited metabolic diseases if  
8 the medical foods or low-protein modified food products are:

9 1. Prescribed as medically necessary for the therapeutic  
10 treatment of inherited metabolic diseases; and

11 2. Administered pursuant to the direction of a physician."

12  
13 51-2-11139 MMP 04/15/08