

## SENATE BILL No. 558

By Committee on Ways and Means

2-11

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AN ACT relating to insurance; providing coverage for expenses of clinical trials; amending K.S.A. 2001 Supp. 40-2,103 and 40-19c09 and repealing the existing sections.

*Be it enacted by the Legislature of the State of Kansas:*

New Section 1. (a) Any individual or group health insurance policy, medical service plan, contract, hospital service corporation contract, hospital and medical service corporation contract, fraternal benefit society or health maintenance organization which provides coverage for accident and health services and which is delivered, issued for delivery, amended or renewed on or after January 1, 2003, also, shall provide coverage for patient cost to a member in a clinical trial, as a result of:

- (1) Treatment provided for a life-threatening condition; or
- (2) prevention, early detection and treatment studies on cancer.

(b) The coverage under subsection (a) of this section shall be required if:

(1) (A) The treatment is being provided or the studies are being conducted in a phase I, phase II, phase III or phase IV clinical trial for cancer; or

(B) the treatment is being provided in a phase I, phase II, phase III or phase IV clinical trial for any other life-threatening condition; or

(2) the treatment is being provided in a clinical trial approved by:

- (A) One of the national institutes of health;
- (B) an NIH cooperative group or an NIH center;
- (C) the FDA in the form of an investigational new drug application;
- (D) the federal department of veterans affairs;
- (E) the federal department of defense; or
- (F) an institutional review board of an institution in the state which

has a multiple project assurance contract approved by the office of protection from research risks of the national institutes of health; or

(3) the facility and personnel providing the treatment are capable of doing so by virtue of the experience, training and volume of patients treated by such facility and personnel to maintain expertise;

(4) there is no clearly superior, noninvestigational treatment alternative; and

1 (5) the available clinical or preclinical data provide a reasonable ex-  
2 pectation that the treatment will be at least as effective as the noninves-  
3 tigational alternative.

4 (c) In conjunction with the provisions of subsection (a) of this section,  
5 a policy, plan or contract shall provide coverage for patient cost incurred  
6 for drugs and devices that have been approved for sale by the FDA  
7 whether or not the FDA has approved the drug or device for use in  
8 treating the patient's particular condition, to the extent that the drugs or  
9 devices are not paid for by the manufacturer, distributor or provider of  
10 that drug or device.

11 (d) (1) An entity seeking coverage for treatment in a clinical trial  
12 approved by an institutional review board under subsection (b)(2)(E) of  
13 this section shall post electronically and keep up-to-date a list of the clin-  
14 ical trials meeting the requirements of subsections (a) and (b) of this  
15 section.

16 (2) For each clinical trial, the list shall include:

17 (A) The phase for which the trial is approved;

18 (B) the entity approving the trial;

19 (C) whether the trial is for treatment of cancer or another life-threat-  
20 ening disease and, if not cancer, the particular disease; and

21 (D) the estimated number of participants in the trial.

22 (e) This section may not be construed to affect compliance with the  
23 provisions of K.S.A. 40-2,167 through 40-2,170 inclusive, and amend-  
24 ments thereto, regarding coverage for off-label use of drugs.

25 (f) The benefits provided in this act shall be subject to the same  
26 annual deductible or co-insurance established for all other covered ben-  
27 efits within a given policy.

28 (g) As used in this section: (1) "AIDS" shall have the meaning as-  
29 cribed to it in K.S.A. 2001 Supp. 65-6001, and amendments thereto;

30 (2) "cooperative group" means a formal network of facilities that col-  
31 laborate on research projects and have an established NIH-approved peer  
32 review program operating within the group. "Cooperative group"  
33 includes:

34 (A) The national cancer institute clinical cooperative group; and

35 (B) the national cancer institute community clinical oncology  
36 program.

37 (3) "FDA" means the federal food and drug administration.

38 (4) "Member" means a policyholder, subscriber, insured or certifi-  
39 cate holder or a covered dependent of a policyholder, subscriber, insured  
40 or certificate holder.

41 (5) "Multiple project assurance contract" means a contract between  
42 an institution and the federal department of health and human services  
43 that defines the relationship of the institution to the federal department

1 of health and human services and sets out the responsibilities of the in-  
2 stitution and the procedures that will be used by the institution to protect  
3 human subjects.

4 (6) “NIH” means the national institutes of health.

5 (7) “Patient cost” means the cost of a medically necessary health care  
6 service that is incurred as a result of the treatment being provided to the  
7 member for purposes of the clinical trial. “Patient cost” does not include:

8 (A) The cost of an investigational drug or device;

9 (B) the cost of nonhealth care services that a patient may be required  
10 to receive as a result of the treatment being provided for purposes of the  
11 clinical trial;

12 (C) costs associated with managing the research associated with the  
13 clinical trial; or

14 (D) costs that would not be covered under the patient’s policy, plan  
15 or contract for noninvestigational treatments.

16 (h) The provisions of this section shall be applicable to health main-  
17 tenance organizations organized under article 32 of chapter 40 of the  
18 Kansas Statutes Annotated.

19 (i) The provisions of this section shall not apply to any medicare sup-  
20 plement policy of insurance, as defined by the commissioner of insurance  
21 by rule and regulation.

22 (j) The provisions of this section shall be applicable to the Kansas  
23 state employees health care benefits program and municipal funded  
24 pools.

25 (k) The provisions of this section shall not apply to any policy or cer-  
26 tificate which provides coverage for any specified disease, specified ac-  
27 cident or accident only coverage, credit, dental, disability income, hospital  
28 indemnity, long-term care insurance as defined by K.S.A. 40-2227 and  
29 amendments thereto, vision care or any other limited supplemental ben-  
30 efit nor to any medicare supplement policy of insurance as defined by  
31 the commissioner of insurance by rule and regulation, any coverage issued  
32 as a supplement to liability insurance, workers compensation or similar  
33 insurance, automobile medical-payment insurance or any insurance un-  
34 der which benefits are payable with or without regard to fault, whether  
35 written on a group, blanket or individual basis.

36 (l) This section does not apply to a policy, plan or contract paid for  
37 under Title XVIII or Title XIX of the social security act.

38 Sec. 2. On and after January 1, 2003, K.S.A. 2001 Supp. 40-2,103 is  
39 hereby amended to read as follows: 40-2,103. The requirements of K.S.A.  
40 40-2,100, 40-2,101, 40-2,102, 40-2,104, 40-2,105, 40-2,114, 40-2,160, 40-  
41 2,165 through 40-2,170, inclusive, 40-2250, K.S.A. 2001 Supp. 40-2,105a  
42 ~~and 40-2,105b~~, 40-2,105b and section 1, and amendments thereto, shall  
43 apply to all insurance policies, subscriber contracts or certificates of in-

1 surance delivered, renewed or issued for delivery within or outside of this  
2 state or used within this state by or for an individual who resides or is  
3 employed in this state.

4 Sec. 3. On and after January 1, 2003, K.S.A. 2001 Supp. 40-19c09 is  
5 hereby amended to read as follows: 40-19c09. (a) Corporations organized  
6 under the nonprofit medical and hospital service corporation act shall be  
7 subject to the provisions of the Kansas general corporation code, articles  
8 60 to 74, inclusive, of chapter 17 of the Kansas Statutes Annotated, ap-  
9 plicable to nonprofit corporations, to the provisions of K.S.A. 40-214, 40-  
10 215, 40-216, 40-218, 40-219, 40-222, 40-223, 40-224, 40-225, 40-226, 40-  
11 229, 40-230, 40-231, 40-235, 40-236, 40-237, 40-247, 40-248, 40-249,  
12 40-250, 40-251, 40-252, 40-254, 40-2,100, 40-2,101, 40-2,102, 40-2,103,  
13 40-2,104, 40-2,105, 40-2,116, 40-2,117, 40-2,153, 40-2,154, 40-2,160, 40-  
14 2,161, 40-2,163 through 40-2,170, inclusive, 40-2a01 *et seq.*, 40-2111 to  
15 40-2116, inclusive, 40-2215 to 40-2220, inclusive, 40-2221a, 40-2221b,  
16 40-2229, 40-2230, 40-2250, 40-2251, 40-2253, 40-2254, 40-2401 to 40-  
17 2421, inclusive, and 40-3301 to 40-3313, inclusive, K.S.A. 2001 Supp. 40-  
18 2,105a and ~~40-2,105b~~, *40-2,105b and section 1*, and amendments thereto,  
19 except as the context otherwise requires, and shall not be subject to any  
20 other provisions of the insurance code except as expressly provided in  
21 this act.

22 (b) No policy, agreement, contract or certificate issued by a corpo-  
23 ration to which this section applies shall contain a provision which ex-  
24 cludes, limits or otherwise restricts coverage because medicaid benefits  
25 as permitted by title XIX of the social security act of 1965 are or may be  
26 available for the same accident or illness.

27 (c) Violation of subsection (b) shall be subject to the penalties pre-  
28 scribed by K.S.A. 40-2407 and 40-2411, and amendments thereto.

29 Sec. 4. On January 1, 2003, K.S.A. 2001 Supp. 40-2,103 and 40-  
30 19c09 are hereby repealed.

31 Sec. 5. This act shall take effect and be in force from and after its  
32 publication in the statute book.

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