[As Amended by Senate Committee of the Whole]

As Amended by Senate Committee

Session of 2008

SENATE BILL No. 629

By Committee on Financial Institutions and Insurance

2-15

AN ACT concerning insurance; relating to coverage for patient care services in a cancer clinical trial; amending K.S.A. 2007 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) As used in this section: (1) "Clinical trial" means the controlled clinical testing in human subjects of investigational new drugs, items, devices, services, treatments, diagnostics or comparisons of approved drugs, items, devices, services, treatments or diagnostics, to assess the safety, efficacy, benefits, costs, adverse reactions or outcomes, or both, of such drugs, items, devices, services, treatments or diagnostics;

(2) "cooperative group" means a formal network of facilities that collaborate on research projects and have an established peer review program, including, but not limited to, the national cancer institute clinical cooperative group and the national cancer institute community clinical oncology program;

(3) "individual" means a member, subscriber, insured or certificate holder or a covered dependent policy holder, subscriber, insured or certificate holder; and

(4) (A) "patient care service" means medically necessary drugs, devices, items, services, treatments or diagnostics that are provided to an individual enrolled in a clinical trial, if such drugs, items, devices, services, treatments or diagnostics would otherwise be covered under the individual's health plan or insurance contract, if the individual was not enrolled in a clinical trial. Such drugs, items, devices, services, treatments or diagnostics shall include the following:

(i) Health care services typically provided absent a clinical trial;

(ii) health care services required for the clinically appropriate monitoring of the investigational drug, item, device, service, treatment or diagnostic;

(iii) health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, serv-

ice, treatment or diagnostic; and

(iv) health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, service, treatment or diagnostic, including the diagnosis or treatment of the complications.

(B) "Patient care service" does not include the following:

(i) The cost of an investigational drug or device;

(ii) non-health care services, including, but not limited to, travel, housing, companion expenses and other nonclinical expenses that a patient may be subjected to as a result of the treatment being provided for purposes of the clinical trial;

(iii) services associated with managing the research associated with the clinical trial; and

(iv) services that would not be covered under the patient's policy, plan, agreement or contract for noninvestigational treatments.

(b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the state shall provide coverage for patient care services provided to an individual in a cancer clinical trial that is a prevention, screening, early detection, treatment and survivorship study for cancer for a pilot or feasibility trial or a phase I, phase II, phase III or phase IV clinical trial; and has been peer reviewed and is approved by the national institutes of health, a qualified nongovernmental research entity identified in guidelines issued by the national institutes of health cooperative group, the federal food and drug administration in the form of an investigational new drug application, the United States department of defense or veterans affairs or a qualified institutional review board ***[registered with the federal office for human research protections]***.

~~(c) Coverage under this section shall be required if the cancer program conducting the clinical trial is capable of doing so by virtue of the experience and training of such facility and personnel and treats a sufficient volume of patients to maintain such expertise and maintains accreditation by the American college of surgeons commission on cancer.~~

~~(d)~~ ***[(c)]*** Coverage under this section shall be subject to all other terms and conditions of the policy, contract, agreement, plan or certificate of insurance, including, but not limited to, provisions requiring the use of participating providers and provisions related to utilization review. Payment to health care providers under this section shall be subject to the terms and conditions of the applicable agreement between the provider and the member, including, but not limited to, provisions relating to utilization review, audits and the financial liability of covered persons.

~~(e)~~ ***[(d)]*** Each such policy, contract, agreement, plan or certificate of insurance shall provide written notice, as currently required, to all enrollees, insureds and subscribers regarding the coverage required by the

provisions of this section.

~~(f)~~ ***[(e)]*** No such policy, contract, agreement, plan or certificate of insurance shall deny to a patient eligibility, or continued eligibility, to enroll or to renew coverage under terms of the policy, contract, agreement, plan or certificate, solely for the purpose of avoiding the requirements of this section.

~~(g)~~ ***[(f)]*** The provisions of this section shall not apply to any policy or certificate which provides coverage for any specified disease, specified accident or accident only coverage, credit, dental, disability income, hospital indemnity, long-term care insurance as defined by K.S.A. 40-2227, and amendments thereto, vision care or any other limited supplemental benefit nor to any medicare supplement policy of insurance as defined by the commissioner of insurance by rule and regulation, any coverage issued as a supplement to liability insurance, workers' compensation or similar insurance, automobile medical-payment insurance or any insurance under which benefits are payable with or without regard to fault, whether written on a group, blanket or individual basis.

~~(h)~~ ***[(g)]*** Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if they were not delivered in a clinical trial.

~~(i)~~ ***[(h)]*** The provision of services when required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

~~(j)~~ ***[(i)]*** Nothing in this section shall be construed to prohibit a plan, policy, agreement or contract from restricting ~~coverage for clinical trials~~ ***[the coverage required under subsection (b)]*** to participating hospitals and physicians in Kansas ~~unless the protocol for the clinical trial is not provided for at a Kansas hospital or by a Kansas physician~~.

~~(k)~~ ***[(j)]*** The provisions of this section shall be applicable to the Kansas state employees health care benefits program and municipal funded pools.

~~(l)~~ ***[(k)]*** The provisions of K.S.A. 40-2249a, and amendments thereto, shall not apply to the provisions of this section.

~~(m)~~ ***[(l)]*** The provisions of this section shall not apply to a policy, plan or contract paid for under title XVIII or title XIX of the federal social security act.

~~(n)~~ ***[(m)]*** The provisions of this act shall apply to all policies, contracts, agreements, plans or certificates of insurance issued or delivered within the state on or after January 1, ~~2008~~ ***2009***, and to all policies, contracts, agreements, plans or certificates of insurance in effect before January 1, ~~2008~~ ***2009***, upon renewal or amendment, on or after January 1, ~~2008~~ ***2009***.

Sec. 2. K.S.A. 2007 Supp. 40-2,103 is hereby amended to read as

follows: 40-2,103. The requirements of K.S.A. 40-2,100, 40-2,101, 40-2,102, 40-2,104, 40-2,105, 40-2,114, 40-2,160, 40-2,165 through 40-2,170, inclusive, 40-2250, K.S.A. 2007 Supp. 40-2,105a ~~and~~, 40-2,105b *and section 1*, and amendments thereto, shall apply to all insurance policies, subscriber contracts or certificates of insurance delivered, renewed or issued for delivery within or outside of this state or used within this state by or for an individual who resides or is employed in this state.

Sec. 3. K.S.A. 2007 Supp. 40-19c09 is hereby amended to read as follows: 40-19c09. (a) Corporations organized under the nonprofit medical and hospital service corporation act shall be subject to the provisions of the Kansas general corporation code, articles 60 to 74, inclusive, of chapter 17 of the Kansas Statutes Annotated, applicable to nonprofit corporations, to the provisions of K.S.A. 40-214, 40-215, 40-216, 40-218, 40-219, 40-222, 40-223, 40-224, 40-225, 40-226, 40-229, 40-230, 40-231, 40-235, 40-236, 40-237, 40-247, 40-248, 40-249, 40-250, 40-251, 40-252, 40-254, 40-2,100, 40-2,101, 40-2,102, 40-2,103, 40-2,104, 40-2,105, 40-2,116, 40-2,117, 40-2,153, 40-2,154, 40-2,160, 40-2,161, 40-2,163 through 40-2,170, inclusive, 40-2a01 et seq., 40-2111 to 40-2116, inclusive, 40-2215 to 40-2220, inclusive, 40-2221a, 40-2221b, 40-2229, 40-2230, 40-2250, 40-2251, 40-2253, 40-2254, 40-2401 to 40-2421, inclusive, and 40-3301 to 40-3313, inclusive, K.S.A. 2007 Supp. 40-2,105a ~~and~~, 40-2,105b *and section 1*, and amendments thereto, except as the context otherwise requires, and shall not be subject to any other provisions of the insurance code except as expressly provided in this act.

(b) No policy, agreement, contract or certificate issued by a corporation to which this section applies shall contain a provision which excludes, limits or otherwise restricts coverage because medicaid benefits as permitted by title XIX of the social security act of 1965 are or may be available for the same accident or illness.

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

New Sec. 4. (a) (1) There is hereby created a clinical trials coverage advisory committee which shall assess the economic impact of the health insurance coverage required by this act for patient care costs in clinical trials. In order to assess the costs and benefits of insurance coverage for patient care costs incurred in clinical trials, the advisory committee may request and collect from insurers aggregate clinical and financial data related to coverage for services provided pursuant to this act.

(2) The clinical trials coverage advisory committee shall be attached to the insurance department. The insurance department shall provide staff and administrative support required by the advisory committee.

(b) The advisory committee shall consist of nine members appointed by the commissioner of insurance as follows:

(1) Four persons, two of whom shall be medical directors of health insurers, selected from nominations made by the Kansas association of health plans;

(2) one person representing the university of Kansas school of medicine nominated by the dean of such school;

(3) one licensed physician who has experience in cancer treatment and clinical trials nominated by the Kansas medical society;

(4) one person representing hospitals nominated by the Kansas hospital association;

(5) one person representing the general public appointed by the commissioner of insurance; and

(6) the commissioner of insurance or the commissioner's designee.

(c) Each appointment to the clinical trials coverage advisory committee shall be for a term of three years.

(d) The insurance commissioner or the commissioner's designee shall serve as chairperson of the clinical trials coverage advisory committee.

(e) The clinical trials coverage advisory committee shall prepare a report of its findings and any recommendations for changes to this act to the chairs of the house committee on insurance and financial institutions and the senate financial institutions and insurance committee on or before January 1, 2011.

Sec. ~~4.~~ ***5.*** K.S.A. 2007 Supp. 40-2,103 and 40-19c09 are hereby repealed.

Sec. ~~5.~~ ***6.*** This act shall take effect and be in force from and after its publication in the statute book.