

SESSION OF 2008

SUPPLEMENTAL NOTE ON SENATE BILL NO. 629

As Amended by Senate Committee of the Whole

Brief*

SB 629 would require any insurance policy, coverage, or other certificate issued, delivered, or renewed on and after January 1, 2009, including the State Employee Health Benefit Program and the municipal group funded pool, within Kansas to shall provide coverage for patient care services provided to an individual in a cancer clinical trial.

Cancer Clinical Trial Coverage – Patient Care Services

The bill would create definitions for the terms “clinical trial,” “cooperative group,” “individual,” and “patient care service.” A “patient care service” would be defined to mean “medically necessary drugs, devices, items, services, treatments or diagnostics that are provided 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.”

Specifically, the coverage is to be provided for 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; the trial must have been peer reviewed and 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

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

investigational new drug application, the U.S. Department of Defense or Veterans Affairs, or a qualified institutional review board registered with the federal Office for Human Research Protections.

The bill also would specify that the coverage is to be subject to all other terms and conditions of the policy, certificate, or similar agreement including the use of participating providers (networks) and utilization review. Each entity providing coverage would be required to notify its insureds (policyholders) of the coverage required under this Act, and coverage could not be denied solely for the purpose of avoiding the requirements of the Act. Copayments and deductibles to the services delivered in the clinical trial would be identical to those applied to the same services if they were not delivered in a clinical trial.

Cancer Clinical Trial Coverage – Exceptions

The coverage requirement would not apply to any policy or certificate that provides coverage for a specified disease or accident, credit, dental, disability income, hospital indemnity, long-term care insurance, vision care, or any other limited supplemental benefit policy. Additionally the coverage requirement would not apply to any policy or plan under Title XVIII or XIX of the federal Social Security Act.

The bill also would specify that the test track outlined in KSA 40-2249a for the study of proposed mandated coverage does not apply to the cancer clinical trial requirements in the bill.

This act is to apply to all insurance policies, contracts, agreements, or certificates issued or delivered, effective, and renewed, within Kansas on and after January 1, 2009.

Current Kansas law applying to all insurance policies and nonprofit medical and hospital service corporations would be amended to include the cancer clinical trial coverage provisions.

Advisory Committee

The bill would create a Clinical Trials Coverage Advisory Committee, which would assess the economic impact of the costs for patient care coverage that would be required by the bill. The nine members of the committee would be appointed by the Insurance Commissioner, to three-year terms; the Commissioner or the Commissioner's designee would be chairperson, and the Insurance Department would provide staff and administrative support. This committee would report on its findings and any recommendations for changes to the requirements in this bill to the chairpersons of the House Committee on Insurance and Financial Institutions and the Senate Financial Institutions and Insurance Committee on or before January 1, 2011.

The bill would specify the members to be appointed by the Insurance Commissioner:

- Four selected from nominations made by the Kansas Association of Health Plans; two are to be medical directors of health insurers;
- One representing the University of Kansas School of Medicine, nominated by the dean of that school;
- One licensed physician who has experience in cancer treatment and clinical trials, nominated by the Kansas Medical Society;
- One representing hospitals, nominated by the Kansas Hospital Association; and
- One representing the general public, appointed by the Insurance Commissioner.

The Insurance Commissioner or the Commissioner's designee also would serve on the committee.

Background

The bill was introduced at the request of Senator Barbara Allen, who testified that the bill would assure Kansans their

health plan will pay for the costs of routine patient care services when they are accepted into a *bona fide* cancer clinical trial, if those same routine patient care services are covered off-trial. The services, Senator Allen noted, are the usual costs of medical care, such as doctor visits, hospital stays, clinical laboratory tests, x-rays and other routine services one would receive whether or not he/she was participating in a clinical trial. Senator Allen also testified that the enactment of the bill was necessary as the University of Kansas Cancer Center would be submitting its application to become a National Cancer Institute (NCI)-Designated Cancer Center in 2010 and the number of patients enrolled in cancer clinical trials is an important factor. Other conferees appearing in support of the bill at the Committee hearing included representatives of the University of Kansas Cancer Center; Kansas Medical Society; American Cancer Society; and the Kansas Hospital Association. Neutral conferees included representatives of the Kansas Health Policy Authority and the Kansas Insurance Department.

Opponents to the bill included the Kansas Association of Health Plans and America's Health Insurance Plans. They testified that the mandate proposed in the bill is unnecessary, because the vast majority of health plans currently do offer this coverage and those that do not are considering adding this coverage. They also said that the mandate would increase costs because it would require insurance companies to pay for more than routine costs under "patient care services," for example, additional MRI scans and monitoring of the experimental treatment. The opponents also suggested that this mandate should follow the "test track" procedures of KSA 40-2249a.

The Senate Committee on Financial Institutions and Insurance adopted an amendment that would create the Clinical Trials Coverage Advisory Committee, as described above. The amendment was requested by Senator Allen. The Senate Committee also recommended a technical amendment to change the applicability dates originally in the bill.

The Senate Committee of the Whole amended the bill to require that a qualified institutional review board that could approve a trial be registered with the federal Office for Human Research Protections. The amendment also deleted two provisions. The first provision would have required coverage if the cancer program conducting the clinical trial is capable of doing so by virtue of the experience and training of the facility and personnel, treats a sufficient volume of patients to maintain such expertise, and maintains accreditation by the American College of Surgeons Commission on Cancer. The other provision would have allowed a plan, policy, agreement or contract to restrict coverage to participating hospitals and physicians in Kansas except when the protocol for the clinical trial is not provided for at a Kansas hospital or by a Kansas physician.

The fiscal note prepared by the Division of the Budget on the bill as introduced states that the Kansas Insurance Department indicates the bill could be implemented within existing resources. A request for fiscal information was made to the Kansas Health Policy Authority; the estimation of the fiscal effect of the bill on the State Employee Health Benefits Plan requires an actuarial review that is not yet complete. A revised fiscal note will be provided once this information has been received. Any fiscal effect associated with the passage of the bill is not included in *The FY 2009 Governor's Budget Report*.