

**Kansas Administrative Regulations
Agency 40. Insurance Department
Article 4. Accident and Health Insurance**

K.A.R. 40-4-43. Hospital, medical, and surgical expense insurance policies and certificates; prohibiting certain types of discrimination. (a) A hospital, medical, or surgical expense policy or certificate issued by an insurance company, nonprofit health service corporation, nonprofit medical and hospital service corporation, or health maintenance organization shall not be delivered or issued for delivery in this state on an individual, group, blanket, franchise, or association basis if the amount of benefits payable or a term, condition, or type of coverage is or could be restricted, modified, excluded, or reduced on the basis of whether both of the following conditions are met:

(1) The insured or prospective insured has been diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer.

(2) The treating physician who is providing covered health care services to the insured recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the insured.

(b) Each policy or certificate covered by this regulation shall provide coverage for all routine patient care costs associated with the provision of health care services, including drugs, items, devices, treatments, diagnostics, and services that would otherwise be covered under the insurance policy or certificate if those drugs, items, devices, treatments, diagnostics, and services were not provided in connection with an approved clinical trial program, including health care services typically provided to patients not participating in a clinical trial.

(c) For purposes of this regulation, "routine patient care costs" shall not include the costs associated with the provision of any of the following:

(1) Drugs or devices that have not been approved by the federal food and drug administration and that are associated with the clinical trial;

(2) services other than health care services, including travel, housing, companion expenses, and other nonclinical expenses, that an insured could require as a result of the treatment being provided for purposes of the clinical trial;

(3) any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient;

(4) health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the insured's hospital, medical, or surgical expense policy or certificate; or

(5) health care services customarily provided by the research sponsors of a trial free of charge for any insured in the trial.

(d) This regulation shall not apply if the amount of benefits, the terms, the conditions, or the type of coverage varies as a result of the application of permissible rate differentials or as a result of negotiations between the insurer and insured.

(Authorized by K.S.A. 40-103 and K.S.A. 40-2404a; implementing K.S.A. 2009 Supp. 40-2404(7); effective June 4, 2010.)