SENATE FILE NO. SF0024

Health insurance-clinical trials.

Sponsored by: Joint Labor, Health and Social Services Interim Committee

A BILL

for

AN ACT relating to insurance; requiring coverage in health insurance policies and certificates for routine care related to the insured's participation in a clinical trial or study as specified; providing exceptions; providing definitions; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 26-20-301 is created to read:

ARTICLE 3

CLINICAL TRIALS COVERAGE

26-20-301. Clinical trials and studies coverage required.

(a) All individual and group health insurance policies providing coverage on an expense incurred basis, individual and group service or indemnity type contracts issued by any insurer including any nonprofit corporation and individual and group service contracts or certificates issued by a health maintenance organization which provide coverage for treatment of cancer shall also provide coverage for routine patient care costs which a policyholder or certificate holder, or his covered dependent, receives as part of a clinical trial or study if:

(i) The medical treatment is provided in a phase II, phase III or phase IV study or clinical trial for the treatment of cancer;

(ii) The clinical trial or study is approved by:

(A) An agency of the national institutes of health as set forth in 42 U.S.C. 281(b) or a research entity that meets the NIH granting criteria;

(B) The United States food and drug administration as an application for a new investigational drug;

(C) The United States department of veterans affairs; or

(D) The United States department of defense.

(iii) The medical treatment is provided by a licensed health care provider practicing within the scope of the provider's license and the facility and personnel providing the treatment have the experience and training to provide the treatment in a competent manner; and

(iv) The participant in the clinical trial or study, before commencing participation, has signed a statement of consent indicating that the participant has been informed of:

(A) The procedure to be undertaken;

(B) Alternative methods of treatment; and

(C) The general nature and extent of risks associated with participation in the clinical trial or study.

(b) Coverage for medical treatment required by this section shall be limited to routine patient care costs.

(c) The coverage required by this section does not include:

(i) Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry;

(ii) Coverage for any drug or device that is paid for by the manufacturer, distributor or provider of the drug or device;

(iii) Health care services that are customarily provided by the sponsors of the clinical trial or study free of charge to the participants in the trial or study;

(iv) Extraneous expenses related to participation in the clinical trial or study including, without limitation, travel, housing and other expenses that a participant or person accompanying a participant may incur;

(v) Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the patient;

(vi) Any costs for the management of research relating to the clinical trial or study.

(d) Nothing in this section shall:

(i) Preclude an insurer from excluding coverage for any claim arising from the practice of medicine or other health care by a person without an applicable physician or health care provider license;

(ii) Preclude an insurer from asserting the right to subrogate for expenses arising from complications

caused by a drug or device that is subsequently approved for usage upon completion of the clinical trial.

(e) For purposes of this section:

(i) "Clinical trial" means an experimental course of treatment provided to a patient in the United States for the purpose of treatment, prevention of reoccurrence or palliation of cancer;

(ii) "Routine patient care cost" means:

(A) A medical service or treatment that is a benefit under a health plan that would be covered if the patient were receiving standard cancer treatment; or

(B) A drug provided to a patient during a cancer clinical trial, other than the drug that is the subject of the clinical trial, if the drug has been approved by the federal food and drug administration for use in treating the patient's particular condition.

Section 2. This act is effective July 1, 2008.

(END)