SENATE FILE NO. SF0134

Health insurance-clinical trials coverage.

Sponsored by: Senator(s) Hastert, Johnson, Massie, Ross and Sessions and Representative(s) Cohee, Iekel, Martin, Millin, Slater and Throne

A BILL

for

AN ACT relating to insurance; requiring coverage in health insurance policies for claims arising from the insured's receipt of treatment as part of a clinical trial or study as specified; providing exceptions; 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 issued by a health maintenance organization which provide coverage for treatment of cancer shall also provide coverage for medical treatment which a policyholder or certificate holder receives as part of a clinical trial or study if:

(i) The medical treatment is provided in a phase I, 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);

(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 health care provider and the facility and personnel have the experience and training to provide the treatment in a competent manner;

(iv) There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment; and

(v) 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:

(i) Coverage for any drug or device that is approved for sale by the United States food and drug administration without regard to whether the approved drug or device has been approved for use in the study participant's medical treatment;

(ii) The cost of any reasonably necessary health care services that are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services would otherwise be covered under the policy or certificate of insurance;

(iii) The initial consultation to determine whether the policyholder or certificate holder is eligible to participate in the clinical trial or study;

(iv) Health care services required for the clinically appropriate monitoring of the policyholder or subscriber during the clinical trial or study.

(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 policyholder or subscriber;

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

(d) Nothing in this section precludes 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.

Section 2. This act is effective July 1, 2007.

(END)