LEGISLATURE OF NEBRASKA

ONE HUNDRED FIRST LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 378

Introduced by Gloor, 35.

Read first time January 16, 2009

Committee: Banking, Commerce and Insurance

A BILL

FOR AN ACT relating to medical clinical trials; to require coverage of routine patient care costs by certain insurance policies and benefit plans.

Be it enacted by the people of the State of Nebraska,

Section 1. (1) Notwithstanding section 44-3,131, (a) any individual or group sickness and accident insurance policy or subscriber contract delivered, issued for delivery, or renewed in this state and any hospital, medical, or surgical expense-incurred policy, except for policies that provide coverage for a specified disease or other limited-benefit coverage, and (b) any self-funded employee benefit plan to the extent not preempted by federal law shall include coverage for routine patient care costs that a policyholder or certificate holder, or his or her dependent, receives during enrollment in a clinical trial if:

(i) The clinical trial is approved by an institutional review board pursuant to 45 C.F.R. 46 as such regulation existed on January 1, 2009;

(ii) The patient care is provided by a certified, registered, or licensed health care provider practicing within the scope of his or her practice and the facility and personnel providing the treatment have the experience and training to provide the treatment in a competent manner; and

(iii) Prior to participation in the clinical trial, the covered person has signed a statement of consent indicating that the person has been informed of the procedure to be undertaken, alternative methods of treatment, and the general nature and extent of risks associated with participation in the clinical trial.

(2) The coverage required pursuant to subsection (1) of this section does not include:

(a) Any portion of the clinical trial that is paid for by a government or an entity that is part of the biotechnical, pharmaceutical, or medical industry;

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

(c) Extraneous expenses related to participation in the clinical trial, including, but not limited to, travel, housing, and other expenses that a participant or person accompanying a participant may incur;

(d) An item or service that is provided solely to satisfy a need for data collection or analysis that is not directly related to the clinical management of the participant; or

(e) Costs for the management of research relating to the clinical trial.

(3) For purposes of this section:

(a) Clinical trial means an experiment in which a drug or device is administered to, dispensed to, or used by one or more persons. An experiment may include the use of a combination of drugs or the use of a drug in combination with an alternative therapy or dietary supplement; and

(b) Routine patient care cost means the cost of a medical service or treatment that is a benefit under a health coverage plan that would be covered if the covered person were not involved in a clinical trial. For a clinical trial involving therapy combined with two or more drugs or treatments that would not normally

be covered in that combination, the cost of the more expensive therapy shall be the covered routine patient care cost if it would normally be covered in the absence of a clinical trial involving a combination of other drugs and treatments.

(4) This section applies to policies, contracts, and certificates of insurance issued or renewed on or after the effective date of this act.