First Regular Session
Sixty-seventh General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 09-0394.01 Kristen Forrestal **HOUSE BILL 09-1059**

HOUSE SPONSORSHIP

Primavera,

SENATE SPONSORSHIP

(None),

House Committees
Health and Human Services

Senate Committees

A BILL FOR AN ACT

CONCERNING THE CONTINUATION OF HEALTH CARE COVERAGE WHILE PARTICIPATING IN A CLINICAL TRIAL.

Bill Summary

(Note: This summary applies to this bill as introduced and does not necessarily reflect any amendments that may be subsequently adopted.)

Requires all individual and group health benefit plans to provide coverage for routine patient care costs while the covered person participates in a clinical trial or study as long as the coverage is a benefit that the covered person would receive if he or she were receiving standard chronic disease treatment outside of the clinical trial or study. Requires the clinical trial or study to meet specific standards of approval.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. 10-16-104, Colorado Revised Statutes, is amended BY THE ADDITION OF A NEW SUBSECTION to read:

10-16-104. Mandatory coverage provisions - definitions. (20) **Clinical trials and studies.** (a) ALL INDIVIDUAL AND GROUP HEALTH BENEFIT PLANS SHALL PROVIDE COVERAGE FOR ROUTINE PATIENT CARE COSTS THAT A POLICY OR CERTIFICATE HOLDER, OR HIS OR HER DEPENDENT, RECEIVES DURING A CLINICAL TRIAL IF:

(I) THE CLINICAL TRIAL OR STUDY IS APPROVED BY AN INSTITUTIONAL REVIEW BOARD PURSUANT TO 45 CFR 46;

(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 OR STUDY, 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 OR STUDY.

(b) THE COVERAGE REQUIRED PURSUANT TO PARAGRAPH (a) OF THIS SUBSECTION (20) DOES NOT INCLUDE:

(I) ANY PORTION OF THE CLINICAL TRIAL OR STUDY THAT IS 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) EXTRANEOUS EXPENSES RELATED TO PARTICIPATION IN THE CLINICAL TRIAL OR STUDY INCLUDING, BUT NOT LIMITED TO, TRAVEL, HOUSING, AND OTHER EXPENSES THAT A PARTICIPANT OR PERSON ACCOMPANYING A PARTICIPANT MAY INCUR;

(IV) 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

(V) COSTS FOR THE MANAGEMENT OF RESEARCH RELATING TO THE CLINICAL TRIAL OR STUDY.

(c) NOTHING IN THIS SUBSECTION (20) SHALL:

(I) PRECLUDE A CARRIER FROM ASSERTING THE RIGHT TO SEEK REIMBURSEMENT FROM THE CLINICAL TRIAL OR STUDY FOR EXPENSES ARISING FROM COMPLICATIONS CAUSED BY A DRUG OR DEVICE USED IN THE CLINICAL TRIAL OR STUDY;

(II) BE INTERPRETED TO PROVIDE A PRIVATE CAUSE OF ACTION AGAINST A CARRIER FOR DAMAGES ARISING AS A RESULT OF COMPLIANCE WITH THIS SECTION.

(d) FOR THE PURPOSES OF THIS SECTION:

(I) "CLINICAL TRIAL" MEANS AN EXPERIMENT IN WHICH A DRUG OR DEVICE IS ADMINISTERED TO, DISPENSED TO, OR USED BY ONE OR MORE HUMAN SUBJECTS. AN EXPERIMENT MAY INCLUDE THE USE OF A COMBINATION OF DRUGS AS WELL AS THE USE OF A DRUG IN COMBINATION WITH AN ALTERNATIVE THERAPY OR DIETARY SUPPLEMENT.

(II) "ROUTINE PATIENT CARE COST" MEANS 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. IN THE CASE OF A CLINICAL TRIAL INVOLVING THERAPY COMBINED WITH TWO OR MORE DRUGS OR TREATMENTS THAT WOULD NOT NORMALLY BE COVERED IN THAT COMBINATION, 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.

SECTION 2. Act subject to petition - effective date - applicability. (1) This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly that is allowed for submitting a referendum petition pursuant to article V, section 1 (3) of the state constitution, (August 4, 2009, if adjournment sine die is on May 6, 2009); except that, if a referendum petition is filed against this act or an item, section, or part of this act within such period, then the act, item, section, or part, if approved by the people, shall take effect on the date of the official declaration of the vote thereon by proclamation of the governor.

(2) The provisions of this act shall apply to policies, contracts, and certificates of insurance issued or renewed on or after the applicable effective date of this act.