First Regular Session
Sixty-seventh General Assembly
STATE OF COLORADO

REENGROSSED
This Version Includes All Amendments
Adopted in the House of Introduction

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

HOUSE SPONSORSHIP

Primavera,

SENATE SPONSORSHIP

Carroll M.,

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.

HOUSE
3rd Reading Unamended
February 16, 2009

HOUSE
Amended 2nd Reading
February 13, 2009

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

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 COVERED PERSON'S TREATING PHYSICIAN, WHO IS PROVIDING COVERED HEALTH CARE SERVICES TO THE PERSON UNDER THE HEALTH BENEFIT PLAN CONTRACT, RECOMMENDS PARTICIPATION IN THE CLINICAL TRIAL AFTER DETERMINING THAT PARTICIPATION IN THE CLINICAL TRIAL HAS THE POTENTIAL TO PROVIDE A THERAPEUTIC HEALTH BENEFIT TO THE COVERED PERSON;

(II) THE CLINICAL TRIAL OR STUDY IS APPROVED UNDER THE SEPTEMBER 19, 2000, MEDICARE NATIONAL COVERAGE DECISION REGARDING CLINICAL TRIALS, AS AMENDED;

(III) 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;

(IV) PRIOR TO PARTICIPATION IN A CLINICAL TRIAL OR STUDY, THE COVERED PERSON HAS SIGNED A STATEMENT OF CONSENT INDICATING THAT THE COVERED PERSON HAS BEEN INFORMED OF THE PROCEDURE TO BE UNDERTAKEN, ALTERNATIVE METHODS OF TREATMENT, THE GENERAL

NATURE AND EXTENT OF THE RISKS ASSOCIATED WITH PARTICIPATION IN THE CLINICAL TRIAL OR STUDY, THE COVERAGE PROVIDED BY AN INDIVIDUAL OR GROUP HEALTH BENEFIT PLAN WILL BE CONSISTENT WITH THE COVERAGE PROVIDED IN THE COVERED PERSON'S HEALTH BENEFIT PLAN, AND ALL OUT-OF-NETWORK RATES WILL APPLY; AND

(V) THE COVERED PERSON SUFFERS FROM A CONDITION THAT IS DISABLING, PROGRESSIVE, OR LIFE-THREATENING.

(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;

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

(VI) 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 COVERED PERSON'S

HEALTH PLAN.

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

(I) PRECLUDE A CARRIER FROM ASSERTING THE RIGHT TO SEEK REIMBURSEMENT FROM THE ENTITY CONDUCTING 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 ALL ITEMS AND SERVICES THAT ARE A BENEFIT UNDER A HEALTH COVERAGE PLAN THAT WOULD BE COVERED IF THE COVERED PERSON WERE NOT INVOLVED IN EITHER THE EXPERIMENTAL OR THE CONTROL ARMS OF A CLINICAL TRIAL; EXCEPT THE INVESTIGATIONAL ITEM OR SERVICE, ITSELF; ITEMS AND SERVICES PROVIDED SOLELY TO SATISFY DATA COLLECTION AND ANALYSIS NEEDS AND THAT ARE NOT USED IN THE DIRECT CLINICAL MANAGEMENT OF THE PATIENT; ITEMS AND SERVICES CUSTOMARILY PROVIDED BY THE RESEARCH SPONSORS FREE OF CHARGE FOR ANY ENROLLEE IN THE TRIAL; ROUTINE COSTS IN CLINICAL TRIALS INCLUDE ITEMS OR SERVICES THAT ARE TYPICALLY PROVIDED ABSENT A CLINICAL TRIAL; ITEMS OR SERVICES REQUIRED SOLELY FOR THE PROVISION OF THE INVESTIGATIONAL ITEMS OR

SERVICES, THE CLINICALLY APPROPRIATE MONITORING OF THE EFFECTS OF THE ITEM OF SERVICE, OR THE PREVENTION OF COMPLICATIONS; AND ITEMS OR SERVICES NEEDED FOR REASONABLE AND NECESSARY CARE ARISING FROM THE PROVISION OF AN INVESTIGATIONAL ITEM OR SERVICE, INCLUDING THE DIAGNOSIS OR TREATMENT OF COMPLICATIONS.

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.