Second Regular Session
Seventy-second General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 20-0156.01 Brita Darling x2241 **HOUSE BILL 20-1232**

HOUSE SPONSORSHIP

Michaelson Jenet and Liston,

SENATE SPONSORSHIP

Todd,

House Committees
Health & Insurance
Appropriations

Senate Committees

A BILL FOR AN ACT

CONCERNING EQUITY IN ACCESS TO CLINICAL TRIALS FOR INDIVIDUALS ENROLLED IN THE MEDICAL ASSISTANCE PROGRAM.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

The bill authorizes the state medical assistance program (medicaid) to cover routine costs associated with phase I through phase IV clinical trials involving the prevention, detection, diagnosis, or treatment of life-threatening or debilitating diseases or conditions. The medicaid recipient's (recipient's) treating physician must determine that the recipient has a qualifying disease or condition and that the recipient meets the selection criteria for the clinical trial.

The clinical trial must be an approved clinical trial, as described in the bill, and must be conducted by agencies and organizations specified in the bill.

"Routine costs", as defined in the bill, include medically necessary items or services included under the medicaid program for a recipient, to the extent that the provision of such items or services to the individual outside the course of such participation would otherwise be covered under the medical assistance program, without regard to whether the recipient is participating in a clinical trial. Routine costs do not include items specified in the bill, including the investigational item, device, or service itself; items and services provided solely to satisfy data collection and analysis needed for the clinical trial; and items, drugs, or services that would otherwise be provided by the clinical trial or provided for free to any individual participating in the clinical trial.

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

SECTION 1. In Colorado Revised Statutes, **add** 25.5-5-326 as follows:

25.5-5-326. Access to clinical trials - definitions. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "APPROVED CLINICAL TRIAL" MEANS A PHASE I, II, III, OR IV CLINICAL TRIAL INVOLVING THE PREVENTION, DETECTION, DIAGNOSIS, OR TREATMENT OF A LIFE-THREATENING OR DEBILITATING DISEASE OR CONDITION IF ANY ONE OF THE FOLLOWING CONDITIONS APPLY:

(I) THE CLINICAL TRIAL IS CONDUCTED UNDER AN INVESTIGATIONAL NEW DRUG APPLICATION OR AN INVESTIGATIONAL DEVICE EXEMPTION REVIEWED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION, OR IS EXEMPTED FROM REVIEW BY THE FEDERAL FOOD AND DRUG ADMINISTRATION; OR

(II) THE CLINICAL TRIAL IS APPROVED OR FUNDED BY:

(A) THE NATIONAL INSTITUTES OF HEALTH;

(B) THE CENTERS FOR DISEASE CONTROL AND PREVENTION;

(C) THE AGENCY FOR HEALTH CARE RESEARCH AND QUALITY;

(D) THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES;

(E) A COOPERATIVE GROUP OR CENTER OF ANY OF THE ENTITIES DESCRIBED IN SUBSECTIONS (1)(a)(II)(A) TO (1)(a)(II)(D) OF THIS SECTION, THE FEDERAL DEPARTMENT OF DEFENSE, OR THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

(F) A QUALIFIED NONGOVERNMENTAL RESEARCH ENTITY IDENTIFIED IN GUIDELINES ISSUED BY THE NATIONAL INSTITUTES OF HEALTH FOR CENTER SUPPORT GRANTS; OR

(G) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS, THE FEDERAL DEPARTMENT OF DEFENSE, OR THE FEDERAL DEPARTMENT OF ENERGY, PROVIDED THAT REVIEW AND APPROVAL OF THE CLINICAL TRIAL OCCURS THROUGH A SYSTEM OF PEER REVIEW THAT IS COMPARABLE TO THE PEER REVIEW OF CLINICAL TRIALS PERFORMED BY THE NATIONAL INSTITUTES OF HEALTH, INCLUDING AN UNBIASED REVIEW OF THE HIGHEST SCIENTIFIC STANDARDS BY QUALIFIED INDIVIDUALS WHO HAVE NO INTEREST IN THE OUTCOME OF THE REVIEW.

(b) "LIFE-THREATENING OR DEBILITATING DISEASE OR CONDITION" MEANS A DISEASE OR CONDITION FROM WHICH THE LIKELIHOOD OF DEATH IS PROBABLE, OR THE DISEASE OR CONDITION IS PROGRESSIVE OR SIGNIFICANTLY DEBILITATING, UNLESS THE COURSE OF THE DISEASE OR CONDITION IS INTERRUPTED.

(c) "QUALIFIED INDIVIDUAL" MEANS AN INDIVIDUAL WHO IS ELIGIBLE FOR AND ENROLLED IN THE STATE MEDICAL ASSISTANCE PROGRAM AND WHO A TREATING PHYSICIAN DETERMINES HAS A LIFE-THREATENING OR DEBILITATING DISEASE OR CONDITION AND MEETS

THE SELECTION CRITERIA FOR THE APPROVED CLINICAL TRIAL.

(d) (I) "ROUTINE COSTS" MEANS MEDICALLY NECESSARY ITEMS AND SERVICES THAT ARE INCLUDED UNDER THE MEDICAL ASSISTANCE PROGRAM FOR A MEDICAL ASSISTANCE RECIPIENT, TO THE EXTENT THAT THE PROVISION OF SUCH ITEMS OR SERVICES TO THE INDIVIDUAL OUTSIDE THE COURSE OF SUCH PARTICIPATION WOULD OTHERWISE BE COVERED UNDER THE MEDICAL ASSISTANCE PROGRAM, WITHOUT REGARD TO WHETHER THE RECIPIENT IS ENROLLED IN A CLINICAL TRIAL. FOR MEDICAL ASSISTANCE RECIPIENTS PARTICIPATING IN AN APPROVED CLINICAL TRIAL, "ROUTINE COSTS" INCLUDE MEDICALLY NECESSARY ITEMS AND SERVICES THAT ARE NOT OTHERWISE EXCLUDED PURSUANT TO SUBSECTION (1)(d)(II)(D) OF THIS SECTION, RELATING TO THE DETECTION AND TREATMENT OF COMPLICATIONS ARISING FROM THE MEDICAL ASSISTANCE RECIPIENT'S MEDICAL CARE, INCLUDING COMPLICATIONS RELATING TO PARTICIPATION IN THE CLINICAL TRIAL, TO THE EXTENT THAT THE PROVISION OF SUCH ITEMS OR SERVICES TO THE INDIVIDUAL OUTSIDE THE COURSE OF SUCH PARTICIPATION WOULD OTHERWISE BE INCLUDED UNDER THE MEDICAL ASSISTANCE PROGRAM.

(II) "ROUTINE COSTS" DO NOT INCLUDE:

(A) THE INVESTIGATIONAL ITEM, DEVICE, OR SERVICE ITSELF;

(B) ITEMS AND SERVICES PROVIDED SOLELY TO SATISFY THE DATA COLLECTION AND ANALYSIS NEEDS OF THE CLINICAL TRIAL;

(C) ITEMS, DRUGS, OR SERVICES CUSTOMARILY PROVIDED FREE OF CHARGE TO ANY QUALIFIED INDIVIDUAL ENROLLED IN THE CLINICAL TRIAL; OR

(D) ITEMS, DRUGS, OR SERVICES THAT THE CLINICAL TRIAL IS REQUIRED TO PROVIDE.

(2) THE MEDICAL ASSISTANCE PROGRAM ESTABLISHED PURSUANT TO THIS ARTICLE 5 AND ARTICLES 4 AND 6 OF THIS TITLE 25.5 MUST INCLUDE COVERAGE AND PAYMENT FOR THE ROUTINE COSTS ASSOCIATED WITH PARTICIPATION IN AN APPROVED CLINICAL TRIAL FOR A QUALIFIED INDIVIDUAL.

SECTION 2. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 5, 2020, if adjournment sine die is on May 6, 2020); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2020 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.