

**Second Regular Session
Seventy-second General Assembly
STATE OF COLORADO**

ENGROSSED

*This Version Includes All Amendments Adopted
on Second Reading in the House of Introduction*

LLS NO. 20-0156.01 Brita Darling x2241

HOUSE BILL 20-1232

HOUSE SPONSORSHIP

Michaelson Jenet and Liston,

SENATE SPONSORSHIP

Todd and Priola,

House Committees

Health & Insurance
Appropriations

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING EQUITY IN ACCESS TO CLINICAL TRIALS FOR INDIVIDUALS**

102 **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.

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

HOUSE
Amended 2nd Reading
May 26, 2020

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.

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

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

4 **25.5-5-326. Access to clinical trials - definitions.** (1) AS USED
5 IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

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

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

16 (A) THE NATIONAL INSTITUTES OF HEALTH;

17 (B) THE CENTERS FOR DISEASE CONTROL AND PREVENTION;

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

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

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

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

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

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

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

1 THE SELECTION CRITERIA FOR THE APPROVED CLINICAL TRIAL.

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

19 (II) "ROUTINE COSTS" DO NOT INCLUDE:

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

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

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

25 OR

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

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

6 **SECTION 2. Safety clause.** The general assembly hereby finds,
7 determines, and declares that this act is necessary for the immediate
8 preservation of the public peace, health, or safety.