CHAPTER 266

HEALTH CARE POLICY AND FINANCING

HOUSE BILL 20-1232

BY REPRESENTATIVE(S) Michaelson Jenet and Liston, Bird, Buentello, Caraveo, Coleman, Cutter, Duran, Esgar, Exum, Gray, Herod, Hooton, Jaquez Lewis, Kipp, Lontine, McCluskie, Mullica, Singer, Sirota, Snyder, Titone, Valdez A., Weissman, Woodrow, Young, Becker;
also SENATOR(S) Todd and Priola, Crowder, Fenberg, Ginal, Hansen, Moreno, Pettersen, Story, Tate, Winter, Zenzinger, Garcia.

AN ACT

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

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;

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Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(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. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.

Approved: July 10, 2020