First Regular Session
Seventy-fifth General Assembly
STATE OF COLORADO

REREVISED
This Version Includes All Amendments Adopted in the Second House

LLS NO. 25-0747.01 Brita Darling x2241

HOUSE BILL 25-1270

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SENATE
3rd Reading Unamended
April 14, 2025

SENATE
2nd Reading Unamended
April 11, 2025

HOUSE
3rd Reading Unamended
March 14, 2025

HOUSE
2nd Reading Unamended
March 13, 2025

A BILL FOR AN ACT

CONCERNING GRANTING ELIGIBLE PATIENTS THE RIGHT TO TRY INDIVIDUALIZED INVESTIGATIONAL MEDICAL TREATMENTS.

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 allows, but does not require, an eligible patient to request from a manufacturer the manufacturer's individualized investigational drug, biological product, or device, which is a drug, biological product, or device that is unique and produced exclusively for use by an individual patient based on the patient's own genetic profile. The manufacturer must be operating within an institution that operates under federal rules for the

protection of human subjects. An eligible patient is an individual who has:

- A life-threatening or severely debilitating illness, as attested to by the patient's treating physician;
- Considered all other treatment options currently approved by the United States food and drug administration;
- Received a recommendation from the patient's treating physician;
- Given written, informed consent for the use of the individualized investigational drug, biological product, or device; and
- Documentation from the treating physician that the individual meets the definition of "eligible patient".

The bill authorizes, but does not require, a manufacturer to make the individualized investigational drug, biological product, or device available to an eligible patient at no charge, but the manufacturer may require payment to cover the cost.

If any harm is caused to the eligible patient resulting from the use of the individualized investigational drug, biological product, or device, a private right of action cannot be brought against the manufacturer or against any other individual or entity involved in the care of the eligible patient with regard to the eligible patient's use of the individualized investigational drug, biological product, or device, so long as the manufacturer, individual, or entity complied with the law and exercised reasonable care.

The bill prohibits any action against a health-care provider's license based on the health-care provider's recommendations regarding the use of the individualized investigational drug, biological product, or device.

Nothing in the bill affects a health-care insurer's obligation under current law relating to coverage for an insured's participation in a clinical trial.

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

SECTION 1. In Colorado Revised Statutes, 25-45-102, **amend** (1) introductory portion and (2) as follows:

25-45-102. Legislative declaration. (1) FOR PURPOSES OF THIS PART 1, the general assembly finds and declares that:

(2) It is the intent of the general assembly FOR THIS PART 1 to allow for terminally ill patients to use potentially life-saving

investigational drugs, biological products, and devices.

SECTION 2. In Colorado Revised Statutes, 25-45-103, **amend** the introductory portion as follows:

25-45-103. Definitions. As used in this ~~article~~ PART 1, unless the context otherwise requires:

SECTION 3. In Colorado Revised Statutes, 25-45-104, **amend** (1) and (3)(a) as follows:

25-45-104. Drug manufacturers - availability of investigational drugs, biological products, or devices - costs - insurance coverage. (1) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients pursuant to this ~~article~~ PART 1. This ~~article~~ PART 1 does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(3) (a) Nothing in this ~~article~~ PART 1 expands the coverage provided in ~~sections~~ SECTION 10-16-104 (20) or 10-16-104.6. ~~C.R.S.~~

SECTION 4. In Colorado Revised Statutes, **amend** 25-45-107 as follows:

25-45-107. No cause of action created. This ~~article~~ PART 1 does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this ~~article~~ PART 1, unless

there was a failure to exercise reasonable care.

SECTION 5. In Colorado Revised Statutes, **add** part 2 to article 45 of title 25 as follows:

PART 2

INDIVIDUALIZED TREATMENTS

25-45-201. Legislative declaration. (1) FOR PURPOSES OF THIS PART 2, THE GENERAL ASSEMBLY FINDS AND DETERMINES THAT:

(a) SOME PUBLIC AND PRIVATE ENTITIES OPERATING UNDER FEDERAL STANDARDS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH DEVELOP INDIVIDUALIZED INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES THAT ARE UNIQUE AND PRODUCED EXCLUSIVELY FOR USE BY AN INDIVIDUAL PATIENT BASED ON THE PATIENT'S GENETIC PROFILE, INCLUDING INDIVIDUAL GENE THERAPY, ANTISENSE OLIGONUCLEOTIDES, AND INDIVIDUALIZED NEOANTIGEN VACCINES; AND

(b) A PATIENT WHO HAS A LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS MAY BENEFIT FROM THESE INDIVIDUALIZED TREATMENTS.

(2) THEREFORE, THE GENERAL ASSEMBLY DECLARES THAT, IN ACCORDANCE WITH THE RECOMMENDATION OF THE PATIENT'S TREATING PHYSICIAN AND WITH THE SAFEGUARDS DESCRIBED IN THIS PART 2, A PATIENT SHOULD HAVE THE RIGHT TO TRY AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THE TREATING PHYSICIAN AND MANUFACTURER THAT PROVIDES THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, ACTING IN ACCORDANCE WITH THIS PART 2, SHOULD BE PROTECTED FROM ADVERSE CONSEQUENCES RESULTING FROM THE

PATIENT'S DECISION TO TRY THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

25-45-202. Definitions. AS USED IN THIS PART 2, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "ELIGIBLE FACILITY" MEANS AN INSTITUTION OPERATING UNDER THE FEDERALWIDE ASSURANCE FOR THE PROTECTION OF HUMAN SUBJECTS IN ACCORDANCE WITH 45 CFR 46 AND 42 U.S.C. SEC. 289a.

(2) "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WHO HAS:

(a) A LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS, AS ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN;

(b) IN CONSULTATION WITH THE TREATING PHYSICIAN, CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(c) RECEIVED A RECOMMENDATION FROM THE TREATING PHYSICIAN FOR USE OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FOR TREATMENT OF THE LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS;

(d) GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, OR, IF THE PATIENT IS A MINOR OR LACKS THE MENTAL CAPACITY TO PROVIDE INFORMED CONSENT, A PARENT OR LEGAL GUARDIAN HAS GIVEN WRITTEN, INFORMED CONSENT ON THE PATIENT'S BEHALF; AND

(e) DOCUMENTATION FROM THE TREATING PHYSICIAN THAT THE PATIENT MEETS THE REQUIREMENTS OF THIS SUBSECTION (2), INCLUDING ATTESTATION FROM THE TREATING PHYSICIAN THAT THE TREATING PHYSICIAN WAS CONSULTED IN THE CREATION OF THE WRITTEN, INFORMED CONSENT GIVEN UNDER THIS PART 2.

(3) "INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE" MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT IS UNIQUE AND PRODUCED EXCLUSIVELY FOR USE BY AN ELIGIBLE PATIENT, BASED ON THE PATIENT'S OWN GENETIC PROFILE, INCLUDING INDIVIDUALIZED GENE THERAPY, ANTISENSE OLIGONUCLEOTIDES, AND INDIVIDUALIZED NEOANTIGEN VACCINES.

(4) "INSTITUTION" HAS THE MEANING SET FORTH IN 45 CFR 46.102 (f).

(5) "LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS" HAS THE MEANING SET FORTH IN 21 CFR 312.81.

(6) "MINOR" MEANS AN INDIVIDUAL WHO IS UNDER EIGHTEEN YEARS OF AGE.

(7) "WRITTEN, INFORMED CONSENT" MEANS A WRITTEN DOCUMENT SIGNED BY AN ELIGIBLE PATIENT; BY A PARENT OR LEGAL GUARDIAN, IF THE PATIENT IS A MINOR; OR BY A DESIGNATED HEALTH-CARE AGENT PURSUANT TO A HEALTH-CARE POWER OF ATTORNEY, IF THE PATIENT IS INCAPACITATED, THAT, AT A MINIMUM:

(a) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS FROM WHICH THE ELIGIBLE PATIENT SUFFERS;

(b) ATTESTS THAT THE ELIGIBLE PATIENT CONCURS WITH THE TREATING PHYSICIAN'S BELIEF THAT ALL CURRENTLY APPROVED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE;

(c) CLEARLY IDENTIFIES THE SPECIFIC INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE PROPOSED FOR TREATMENT OF THE ELIGIBLE PATIENT'S LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS;

(d) DESCRIBES THE POTENTIAL BEST AND WORST OUTCOMES RESULTING FROM USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR WORSE SYMPTOMS MIGHT RESULT AND THAT DEATH COULD BE HASTENED BY THE PROPOSED TREATMENT, BASED ON THE PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE ELIGIBLE PATIENT'S CONDITION;

(e) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY BE WITHDRAWN IF THE ELIGIBLE PATIENT BEGINS TREATMENT OF THE LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT HOSPICE CARE MAY BE REINSTATED IF SUCH TREATMENT ENDS AND THE PATIENT AGAIN MEETS HOSPICE CARE ELIGIBILITY REQUIREMENTS;

(f) MAKES CLEAR THAT IN-HOME HEALTH CARE MAY BE DENIED IF TREATMENT BEGINS;

(g) MAKES CLEAR THAT THE ELIGIBLE PATIENT'S HEALTH INSURANCE PROVIDER OR HEALTH-CARE PROVIDER IS NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS CONSEQUENT TO THE USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE UNLESS SPECIFICALLY REQUIRED BY LAW OR CONTRACT;

(h) STATES THAT THE PATIENT UNDERSTANDS THAT THEY ARE LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT THIS LIABILITY EXTENDS TO THE PATIENT'S ESTATE,

UNLESS A CONTRACT BETWEEN THE PATIENT AND THE MANUFACTURER OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE STATES OTHERWISE; AND

(i) STATES THAT THE ELIGIBLE PATIENT, OR, FOR AN ELIGIBLE PATIENT WHO IS A MINOR OR WHO LACKS CAPACITY TO PROVIDE INFORMED CONSENT, THE PARENT OR LEGAL GUARDIAN, CONSENTS TO THE USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FOR TREATMENT OF THE LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS.

25-45-203. Drug manufacturers - authorized access to and use of individualized investigational drugs, biological products, or devices - costs. (1) A MANUFACTURER OPERATING WITHIN AN ELIGIBLE FACILITY AND IN ACCORDANCE WITH APPLICABLE FEDERAL LAW MAY MAKE AVAILABLE TO AN ELIGIBLE PATIENT, AND AN ELIGIBLE PATIENT MAY REQUEST, THE MANUFACTURER'S INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE FROM THE ELIGIBLE FACILITY OR MANUFACTURER OPERATING WITHIN THE ELIGIBLE FACILITY.

(2) A MANUFACTURER OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY:

(a) PROVIDE THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION; OR

(b) REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF, OR THE COSTS ASSOCIATED WITH, THE MANUFACTURE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(3) NOTHING IN THIS PART 2 REQUIRES A MANUFACTURER OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR

DEVICE TO MAKE THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AVAILABLE TO AN ELIGIBLE PATIENT.

(4) IF A PATIENT DIES WHILE BEING TREATED WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE PATIENT'S HEIRS ARE NOT LIABLE FOR OUTSTANDING DEBT RELATED TO THE TREATMENT, INCLUDING COSTS ATTRIBUTED TO LACK OF INSURANCE COVERAGE FOR THE TREATMENT.

25-45-204. Action against health-care provider's license or medicare certification prohibited. NOTWITHSTANDING ANY OTHER LAW, A LICENSING BOARD SHALL NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE OTHER ACTION AGAINST A HEALTH-CARE PROVIDER'S LICENSE ISSUED PURSUANT TO TITLE 12 BASED SOLELY ON THE HEALTH-CARE PROVIDER'S RECOMMENDATION TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, SO LONG AS THE RECOMMENDATION IS CONSISTENT WITH MEDICAL STANDARDS OF CARE. ACTION AGAINST A HEALTH-CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH-CARE PROVIDER'S RECOMMENDATION THAT AN ELIGIBLE PATIENT HAVE ACCESS TO AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE IS PROHIBITED.

25-45-205. Access to individualized investigational drugs, biological products, and devices - prohibition on state action. AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE SHALL NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. COUNSELING, ADVICE, OR A RECOMMENDATION CONSISTENT WITH MEDICAL STANDARDS OF CARE FROM A LICENSED HEALTH-CARE PROVIDER IS NOT A VIOLATION

OF THIS SECTION.

25-45-206. No cause of action created. THIS PART 2 DOES NOT CREATE A PRIVATE RIGHT OF ACTION AGAINST A MANUFACTURER OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, OR AGAINST AN INDIVIDUAL OR ENTITY INVOLVED IN THE CARE OF AN ELIGIBLE PATIENT USING AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, FOR ANY HARM CAUSED TO THE ELIGIBLE PATIENT RESULTING FROM USE OF THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, SO LONG AS THE MANUFACTURER OR INDIVIDUAL OR ENTITY HAS MADE A GOOD FAITH EFFORT TO COMPLY WITH THE PROVISIONS OF THIS PART 2 AND HAS EXERCISED REASONABLE CARE IN ACTIONS TAKEN PURSUANT TO THIS PART 2.

25-45-207. Effect on health-care coverage. NOTHING IN THIS PART 2 AFFECTS A HEALTH INSURANCE PROVIDER'S OBLIGATION TO PROVIDE COVERAGE FOR AN INSURED'S PARTICIPATION IN A CLINICAL TRIAL PURSUANT TO SECTION 10-16-104 (20).

SECTION 6. Safety clause. The general assembly finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety or for appropriations for the support and maintenance of the departments of the state and state institutions.