Second Regular Session
Sixty-ninth General Assembly
STATE OF COLORADO

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

LLS NO. 14-0892.01 Kristen Forrestal x4217 **HOUSE BILL 14-1281**

HOUSE SPONSORSHIP

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A BILL FOR AN ACT

CONCERNING THE ALLOWANCE FOR TERMINALLY ILL PATIENTS TO HAVE ACCESS TO INVESTIGATIONAL PRODUCTS THAT HAVE NOT BEEN APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION THAT OTHER PATIENTS HAVE ACCESS TO WHEN THEY PARTICIPATE IN CLINICAL TRIALS.

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://www.leg.state.co.us/billsummaries.)

The bill allows, but does not require, eligible patients to participate

HOUSE
3rd Reading Unamended
April 1, 2014

HOUSE
Amended 2nd Reading
March 31, 2014

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.

in clinical trials and use investigational drugs, biological products, and devices. The bill defines an eligible patient as a person who has:

- A terminal illness;
- Considered all other treatment options currently approved by the United States food and drug administration;
- Received a prescription or recommendation from his or her physician;
- Given written, informed consent for the use of the investigational drug, biological product, or device; and
- Documentation from his or her physician that he or she meets the definition of "eligible patient".

The bill clarifies that a health insurance carrier is not required to pay for the investigational drug, biological product, or device.

The bill prohibits any action against a physician's license for his or her recommendations regarding the use of investigational drugs, biological products, or devices.

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

SECTION 1. In Colorado Revised Statutes, **add** article 45 to title 25 as follows:

ARTICLE 45

Access to Treatments for Terminally Ill Patients

25-45-101. Short title. THIS ARTICLE SHALL BE KNOWN AND MAY BE CITED AS THE "RIGHT TO TRY ACT".

25-45-102. Legislative declaration. (1) THE GENERAL ASSEMBLY FINDS AND DECLARES THAT:

(a) THE PROCESS OF APPROVAL FOR INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES IN THE UNITED STATES OFTEN TAKES MANY YEARS;

(b) PATIENTS WHO HAVE A TERMINAL ILLNESS DO NOT HAVE THE LUXURY OF WAITING UNTIL AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE RECEIVES FINAL APPROVAL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(c) PATIENTS WHO HAVE A TERMINAL ILLNESS HAVE A FUNDAMENTAL RIGHT TO ATTEMPT TO PURSUE THE PRESERVATION OF THEIR OWN LIVES BY ACCESSING AVAILABLE INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES;

(d) THE USE OF AVAILABLE INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES IS A DECISION THAT SHOULD BE MADE BY THE PATIENT WITH A TERMINAL ILLNESS IN CONSULTATION WITH THE PATIENT'S HEALTH CARE PROVIDER AND THE PATIENT'S HEALTH CARE TEAM, IF APPLICABLE; AND

(e) THE DECISION TO USE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE SHOULD BE MADE WITH FULL AWARENESS OF THE POTENTIAL RISKS, BENEFITS, AND CONSEQUENCES TO THE PATIENT AND THE PATIENT'S FAMILY.

(2) IT IS THE INTENT OF THE GENERAL ASSEMBLY TO ALLOW FOR TERMINALLY ILL PATIENTS TO USE POTENTIALLY LIFE-SAVING INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

25-45-103. Definitions. AS USED IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) (a) "ELIGIBLE PATIENT" MEANS A PERSON WHO HAS:

(I) A TERMINAL ILLNESS, ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN;

(II) CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

(III) RECEIVED A RECOMMENDATION FROM HIS OR HER PHYSICIAN FOR AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(IV) GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE 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

(V) DOCUMENTATION FROM HIS OR HER PHYSICIAN THAT HE OR SHE MEETS THE REQUIREMENTS OF THIS PARAGRAPH (a).

(b) "ELIGIBLE PATIENT" DOES NOT INCLUDE A PERSON BEING TREATED AS AN INPATIENT IN A HOSPITAL LICENSED OR CERTIFIED PURSUANT TO SECTION 25-3-101.

(2) "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE" MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT HAS SUCCESSFULLY COMPLETED PHASE ONE OF A CLINICAL TRIAL BUT HAS NOT YET BEEN APPROVED FOR GENERAL USE BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND REMAINS UNDER INVESTIGATION IN A UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED CLINICAL TRIAL.

(3) "TERMINAL ILLNESS" MEANS A DISEASE THAT, WITHOUT LIFE-SUSTAINING PROCEDURES, WILL SOON RESULT IN DEATH OR A STATE OF PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY.

(4) "WRITTEN, INFORMED CONSENT" MEANS A WRITTEN DOCUMENT SIGNED BY THE PATIENT AND ATTESTED TO BY THE PATIENT'S PHYSICIAN AND A WITNESS THAT, AT A MINIMUM:

(a) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS;

(b) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH HIS OR HER PHYSICIAN IN BELIEVING THAT ALL CURRENTLY APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE;

(c) CLEARLY IDENTIFIES THE SPECIFIC PROPOSED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT THE PATIENT IS SEEKING TO USE;

(d) DESCRIBES THE POTENTIALLY BEST AND WORST OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, BASED ON THE PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION;

(e) MAKES CLEAR THAT THE PATIENT'S HEALTH INSURER AND PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR TREATMENTS CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

(f) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT AND CARE MAY BE REINSTATED IF THE CURATIVE TREATMENT ENDS AND THE PATIENT MEETS HOSPICE ELIGIBILITY REQUIREMENTS;

(g) MAKES CLEAR THAT IN-HOME HEALTH CARE AND INPATIENT SERVICES MAY BE DENIED IF TREATMENT BEGINS; AND

(h) STATES THAT THE PATIENT UNDERSTANDS THAT HE OR SHE IS LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT THIS LIABILITY EXTENDS TO THE PATIENT'S SUCCESSORS AND ESTATE.

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. THIS ARTICLE DOES NOT REQUIRE THAT A MANUFACTURER MAKE AVAILABLE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT.

(2) A MANUFACTURER MAY:

(a) PROVIDE AN 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 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(3) (a) NOTHING IN THIS ARTICLE EXPANDS THE COVERAGE PROVIDED IN SECTIONS 10-16-104 (20) OR 10-16-104.6, C.R.S.

(b) A HEALTH INSURANCE CARRIER MAY, BUT IS NOT REQUIRED TO, PROVIDE COVERAGE FOR THE COST OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(c) AN INSURER MAY DENY COVERAGE TO AN ELIGIBLE PATIENT FROM THE TIME THE ELIGIBLE PATIENT BEGINS USE OF THE INVESTIGATIONAL DRUG, BIOLOGIC PRODUCT, OR DEVICE THROUGH A PERIOD NOT TO EXCEED SIX MONTHS FROM THE TIME THE INVESTIGATIONAL DRUG, BIOLOGIC PRODUCT, OR DEVICE IS NO LONGER USED BY THE ELIGIBLE PATIENT; EXCEPT THAT COVERAGE MAY NOT BE DENIED FOR A PREEXISTING CONDITION AND FOR COVERAGE FOR BENEFITS WHICH COMMENCED PRIOR TO THE TIME THE ELIGIBLE PATIENT BEGINS USE OF SUCH DRUG, BIOLOGIC PRODUCT OR DEVICE.

(4) IF A PATIENT DIES WHILE BEING TREATED BY AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE PATIENT'S HEIRS ARE NOT LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE

TREATMENT OR LACK OF INSURANCE DUE TO THE TREATMENT.

25-45-105. Action against health care provider's license or medicare certification prohibited. NOTWITHSTANDING ANY OTHER LAW, A LICENSING BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE ISSUED PURSUANT TO TITLE 12, C.R.S., BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. ACTION AGAINST A HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION THAT A PATIENT HAVE ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE IS PROHIBITED.

25-45-106. Access to investigational drugs, biological products, and devices. AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE SHALL NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. COUNSELING, ADVICE, OR A RECOMMENDATION FROM A LICENSED HEALTH CARE PROVIDER IS NOT A VIOLATION OF THIS SECTION.

25-45-107. No cause of action created. THIS ARTICLE 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 PART 1.

25-45-108. Affect on health care coverage. NOTHING IN THIS SECTION AFFECTS THE MANDATORY HEALTH CARE COVERAGE FOR PARTICIPATION IN CLINICAL TRIALS PURSUANT TO SECTION 10-16-106 (20), C.R.S.

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, and safety.