

Second Regular Session
Sixty-ninth General Assembly
STATE OF COLORADO

PREAMENDED

*This Unofficial Version Includes Committee
Amendments Not Yet Adopted on Second Reading*

LLS NO. 14-0892.01 Kristen Forrestal x4217

HOUSE BILL 14-1281

HOUSE SPONSORSHIP

Ginal and Joshi, Wright, Buck, Court, Fields, Holbert, Humphrey, Landgraf, McCann, McNulty, Schafer, Stephens

SENATE SPONSORSHIP

Rivera and Aguilar,

House Committees

Health, Insurance, & Environment

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING THE ALLOWANCE FOR TERMINALLY ILL PATIENTS TO**
102 **HAVE ACCESS TO INVESTIGATIONAL PRODUCTS THAT HAVE NOT**
103 **BEEN APPROVED BY THE FEDERAL FOOD AND DRUG**
104 **ADMINISTRATION THAT OTHER PATIENTS HAVE ACCESS TO**
105 **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/bills summaries>.)

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

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.

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

2 **SECTION 1.** In Colorado Revised Statutes, **add** article 45 to title
3 25 as follows:

4 **ARTICLE 45**

5 **Terminal Patients' Compassionate Care Act**

6 **25-45-101. Short title.** THIS ARTICLE SHALL BE KNOWN AND MAY
7 BE CITED AS THE "RIGHT TO TRY ACT".

8 **25-45-102. Legislative declaration.** (1) THE GENERAL ASSEMBLY
9 FINDS AND DECLARES THAT:

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

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

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

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

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

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

17 **25-45-103. Definitions.** AS USED IN THIS ARTICLE, UNLESS THE
18 CONTEXT OTHERWISE REQUIRES:

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

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

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

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

26 (IV) GIVEN WRITTEN, INFORMED CONSENT FOR THE USE OF THE
27 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR, IF THE

1 PATIENT IS A MINOR OR LACKS THE MENTAL CAPACITY TO PROVIDE
2 INFORMED CONSENT, A PARENT OR LEGAL GUARDIAN HAS GIVEN WRITTEN,
3 INFORMED CONSENT ON THE PATIENT'S BEHALF; AND

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

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

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

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

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

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

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

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

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

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

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

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

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

23 **25-45-104. Drug manufacturers - availability of investigational**
24 **drugs, biological products, or devices - costs - insurance coverage.**

25 (1) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL
26 PRODUCT, OR DEVICE MAY MAKE AVAILABLE THE MANUFACTURER'S
27 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO ELIGIBLE

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

4 (2) A MANUFACTURER MAY:

5 (a) PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT,
6 OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION;
7 OR

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

11 (3) A HEALTH INSURANCE CARRIER MAY, BUT IS NOT REQUIRED TO:

12 (a) PROVIDE COVERAGE FOR THE COST OF AN INVESTIGATIONAL
13 DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

14 (b) PAY FOR ANY CARE OR TREATMENT CONSEQUENT TO THE USE
15 OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT
16 DIFFER FROM THE COSTS OF THE COURSE OF CARE OR TREATMENT THAT
17 WOULD BE COVERED BY THE INSURED'S HEALTH CARE POLICY IN THE
18 ABSENCE OF THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL
19 PRODUCT, OR DEVICE.

20 **25-45-105. Action against health care provider's license or**
21 **medicare certification prohibited.** NOTWITHSTANDING ANY OTHER LAW,
22 A LICENSING BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE
23 ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE ISSUED
24 PURSUANT TO TITLE 12, C.R.S., BASED SOLELY ON THE HEALTH CARE
25 PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING
26 ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL
27 PRODUCT, OR DEVICE. ACTION AGAINST A HEALTH CARE PROVIDER'S

1 MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE
2 PROVIDER'S RECOMMENDATION THAT A PATIENT HAVE ACCESS TO AN
3 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE IS PROHIBITED.

4 **25-45-106. Access to investigational drugs, biological products,**
5 **and devices.** AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE SHALL
6 NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN
7 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. COUNSELING,
8 ADVICE, OR A RECOMMENDATION FROM A LICENSED HEALTH CARE
9 PROVIDER IS NOT A VIOLATION OF THIS SECTION.

10 **25-45-107. No cause of action created.** THIS ARTICLE DOES NOT
11 CREATE A PRIVATE CAUSE OF ACTION AGAINST A MANUFACTURER OF AN
12 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR AGAINST
13 ANY OTHER PERSON OR ENTITY INVOLVED IN THE CARE OF AN ELIGIBLE
14 PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR
15 DEVICE, FOR ANY HARM DONE TO THE ELIGIBLE PATIENT RESULTING FROM
16 THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, SO LONG
17 AS THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN
18 GOOD FAITH WITH THE TERMS OF THIS PART 1.

19 **25-45-108. Affect on health care coverage.** NOTHING IN THIS
20 SECTION AFFECTS THE MANDATORY HEALTH CARE COVERAGE FOR
21 PARTICIPATION IN CLINICAL TRIALS PURSUANT TO SECTION 10-16-106 (20),
22 C.R.S.

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