

Second Regular Session  
Sixty-ninth General Assembly  
STATE OF COLORADO

REVISED

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

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

Health & Human Services

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.

SENATE  
Amended 2nd Reading  
May 2, 2014

HOUSE  
3rd Reading Unamended  
April 1, 2014

HOUSE  
Amended 2nd Reading  
March 31, 2014

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.

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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 **Access to Treatments for Terminally Ill Patients**

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 PROTECTS  
12 FUTURE PATIENTS FROM PREMATURE, INEFFECTIVE, AND UNSAFE  
13 MEDICATIONS AND TREATMENTS OVER THE LONG RUN, BUT THE PROCESS  
14 OFTEN TAKES MANY YEARS;

15 (b) PATIENTS WHO HAVE A TERMINAL ILLNESS DO NOT HAVE THE  
16 LUXURY OF WAITING UNTIL AN INVESTIGATIONAL DRUG, BIOLOGICAL

1 PRODUCT, OR DEVICE RECEIVES FINAL APPROVAL FROM THE UNITED  
2 STATES FOOD AND DRUG ADMINISTRATION;

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

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

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

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

19 **25-45-103. Definitions.** AS USED IN THIS ARTICLE, UNLESS THE  
20 CONTEXT OTHERWISE REQUIRES:

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

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

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

26 (III) BEEN UNABLE TO PARTICIPATE IN A CLINICAL TRIAL FOR THE  
27 TERMINAL ILLNESS WITHIN ONE HUNDRED MILES OF THE PATIENT'S HOME

1 ADDRESS FOR THE TERMINAL ILLNESS, OR NOT BEEN ACCEPTED TO THE  
2 CLINICAL TRIAL WITHIN ONE WEEK OF COMPLETION OF THE CLINICAL TRIAL  
3 APPLICATION PROCESS;

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

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

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

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

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

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

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

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

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

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

11 (d) DESCRIBES THE POTENTIALLY BEST AND WORST OUTCOMES OF  
12 USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE  
13 WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME,  
14 INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR  
15 WORSE SYMPTOMS MIGHT RESULT, AND THAT DEATH COULD BE HASTENED  
16 BY THE PROPOSED TREATMENT, BASED ON THE PHYSICIAN'S KNOWLEDGE  
17 OF THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF  
18 THE PATIENT'S CONDITION;

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

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

27 (g) MAKES CLEAR THAT IN-HOME HEALTH CARE   MAY BE DENIED

1 IF TREATMENT BEGINS; AND

2 (h) STATES THAT THE PATIENT UNDERSTANDS THAT HE OR SHE IS  
3 LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE  
4 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT  
5 THIS LIABILITY EXTENDS TO THE PATIENT'S ESTATE, UNLESS A CONTRACT  
6 BETWEEN THE PATIENT AND THE MANUFACTURER OF THE DRUG,  
7 BIOLOGICAL PRODUCT, OR DEVICE STATES OTHERWISE.

8 **25-45-104. Drug manufacturers - availability of investigational**  
9 **drugs, biological products, or devices - costs - insurance coverage.**

10 (1) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL  
11 PRODUCT, OR DEVICE MAY MAKE AVAILABLE THE MANUFACTURER'S  
12 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE TO ELIGIBLE  
13 PATIENTS PURSUANT TO THIS ARTICLE. THIS ARTICLE DOES NOT REQUIRE  
14 THAT A MANUFACTURER MAKE AVAILABLE AN INVESTIGATIONAL DRUG,  
15 BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT.

16 (2) A MANUFACTURER MAY:

17 (a) PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT,  
18 OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION;  
19 OR

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

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

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

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

10 (4) IF A PATIENT DIES WHILE BEING TREATED BY AN  
11 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE PATIENT'S  
12 HEIRS ARE NOT LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE  
13 TREATMENT OR LACK OF INSURANCE DUE TO THE TREATMENT.

14 **25-45-105. Action against health care provider's license or**  
15 **medicare certification prohibited.** NOTWITHSTANDING ANY OTHER LAW,  
16 A LICENSING BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND, OR TAKE  
17 ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE ISSUED  
18 PURSUANT TO TITLE 12, C.R.S., BASED SOLELY ON THE HEALTH CARE  
19 PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING  
20 ACCESS TO OR TREATMENT WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL  
21 PRODUCT, OR DEVICE, AS LONG AS THE RECOMMENDATIONS ARE  
22 CONSISTENT WITH MEDICAL STANDARDS OF CARE. ACTION AGAINST A  
23 HEALTH CARE PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON  
24 THE HEALTH CARE PROVIDER'S RECOMMENDATION THAT A PATIENT HAVE  
25 ACCESS TO AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE  
26 IS PROHIBITED.

27 **25-45-106. Access to investigational drugs, biological products,**

1 **and devices.** AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE SHALL  
2 NOT BLOCK OR ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN  
3 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. COUNSELING,  
4 ADVICE, OR A RECOMMENDATION CONSISTENT WITH MEDICAL STANDARDS  
5 OF CARE FROM A LICENSED HEALTH CARE PROVIDER IS NOT A VIOLATION  
6 OF THIS SECTION.

7 **25-45-107. No cause of action created.** THIS ARTICLE DOES NOT  
8 CREATE A PRIVATE CAUSE OF ACTION AGAINST A MANUFACTURER OF AN  
9 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR AGAINST  
10 ANY OTHER PERSON OR ENTITY INVOLVED IN THE CARE OF AN ELIGIBLE  
11 PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR  
12 DEVICE, FOR ANY HARM DONE TO THE ELIGIBLE PATIENT RESULTING FROM  
13 THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, SO LONG  
14 AS THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN  
15 GOOD FAITH WITH THE TERMS OF THIS PART 1, UNLESS THERE WAS A  
16 FAILURE TO EXERCISE REASONABLE CARE.

17 **25-45-108. Affect on health care coverage.** NOTHING IN THIS  
18 SECTION AFFECTS THE MANDATORY HEALTH CARE COVERAGE FOR  
19 PARTICIPATION IN CLINICAL TRIALS PURSUANT TO SECTION 10-16-106(20),  
20 C.R.S.

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