

First Regular Session
Sixty-fifth General Assembly
STATE OF COLORADO

PREAMENDED

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

LLS NO. 05-0575.01 Michele Hanigsberg

SENATE BILL 05-165

SENATE SPONSORSHIP

Tochtrop, and Hagedorn

HOUSE SPONSORSHIP

Hefley,

Senate Committees
Health and Human Services

House Committees
Health and Human Services

A BILL FOR AN ACT

101 **CONCERNING THE COLORADO CANCER DRUG REPOSITORY PROGRAM.**

Bill Summary

(Note: This summary applies to this bill as introduced and does not necessarily reflect any amendments that may be subsequently adopted.)

Establishes the Colorado cancer drug repository program ("program") in the department of public health and environment for the purpose of allowing a cancer patient or the patient's family to donate unused cancer drugs and medical devices to uninsured and underinsured cancer patients in the state of Colorado.

Allows a cancer patient or the patient's family to donate unused cancer drugs or medical devices to a health care facility, medical clinic, or pharmacy that elects to participate in the program. Authorizes a health care facility, medical clinic, or pharmacy that receives a donated cancer

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
3rd Reading Unamended
February 22, 2005

SENATE
2nd Reading Unamended
February 21, 2005

drug or medical device under the program to distribute the cancer drug to another eligible health care facility, medical clinic, or pharmacy for use under the program. Allows a pharmacist to accept and dispense cancer drugs and medical devices donated under the program to eligible patients if specified requirements are met. Specifies that a cancer drug or medical device donated under the program may not be resold.

Contains rule-making authority.

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

2 **SECTION 1.** Title 25, Colorado Revised Statutes, is amended
3 BY THE ADDITION OF A NEW ARTICLE to read:

4 **ARTICLE 35**

5 **Colorado Cancer Drug Repository Program**

6 **25-35-101. Short title.** THIS ARTICLE SHALL BE KNOWN AND MAY
7 BE CITED AS THE "COLORADO CANCER DRUG REPOSITORY ACT".

8 **25-35-102. Definitions.** AS USED IN THIS ARTICLE, UNLESS THE
9 CONTEXT OTHERWISE REQUIRES:

10 (1) "CANCER DRUG" MEANS A PRESCRIPTION DRUG THAT IS USED
11 TO TREAT CANCER OR THE SIDE EFFECTS OF CANCER.

12 (2) "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH
13 AND ENVIRONMENT.

14 (3) "DISPENSE" SHALL HAVE THE SAME MEANING AS SET FORTH IN
15 SECTION 12-22-102 (9), C.R.S.

16 (4) "ELIGIBLE PATIENT" MEANS AN UNINSURED OR UNDERINSURED
17 CANCER PATIENT WHO MEETS THE ELIGIBILITY CRITERIA ESTABLISHED IN
18 RULE BY THE STATE BOARD.

19 (5) "HEALTH CARE FACILITY" MEANS A HOSPITAL, HOSPICE, OR
20 HOSPITAL UNIT THAT IS REQUIRED TO BE LICENSED PURSUANT TO SECTION
21 25-3-101.

22 (6) "MEDICAL CLINIC" MEANS A COMMUNITY HEALTH CLINIC

1 REQUIRED TO BE LICENSED OR CERTIFIED BY THE DEPARTMENT PURSUANT
2 TO SECTION 25-1.5-103.

3 (7) "MEDICAL DEVICE" MEANS AN INSTRUMENT, APPARATUS,
4 IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR SIMILAR OR RELATED
5 ARTICLE THAT IS REQUIRED UNDER FEDERAL LAW TO BEAR THE LABEL,
6 "CAUTION: FEDERAL LAW REQUIRES DISPENSING BY OR ON THE ORDER
7 OF A PHYSICIAN." "DEVICE" ALSO INCLUDES ANY COMPONENT PART OF,
8 OR ACCESSORY OR ATTACHMENT TO, ANY SUCH ARTICLE, WHETHER OR NOT
9 THE COMPONENT PART, ACCESSORY, OR ATTACHMENT IS SEPARATELY SO
10 LABELED.

11 (8) "PHARMACIST" MEANS AN INDIVIDUAL LICENSED BY THIS STATE
12 PURSUANT TO THE PROVISIONS OF ARTICLE 22 OF TITLE 12, C.R.S, TO
13 ENGAGE IN THE PRACTICE OF PHARMACY.

14 (9) "PROGRAM" MEANS THE COLORADO CANCER DRUG
15 REPOSITORY PROGRAM CREATED IN SECTION 25-35-103.

16 (10) "STATE BOARD" MEANS THE STATE BOARD OF HEALTH.

17 **25-35-103. Cancer drug repository - administration - donation**
18 **- dispensing - cancer drugs - medical devices.** (1) THERE IS HEREBY
19 ESTABLISHED THE COLORADO CANCER DRUG REPOSITORY PROGRAM FOR
20 THE PURPOSE OF ALLOWING A CANCER PATIENT OR THE PATIENT'S FAMILY
21 TO DONATE UNUSED CANCER DRUGS AND MEDICAL DEVICES TO UNINSURED
22 AND UNDERINSURED CANCER PATIENTS IN THE STATE OF COLORADO. THE
23 PROGRAM SHALL BE ADMINISTERED BY THE DEPARTMENT.

24 (2) THE PROGRAM SHALL ALLOW A CANCER PATIENT OR THE
25 PATIENT'S FAMILY TO DONATE UNUSED CANCER DRUGS OR MEDICAL
26 DEVICES TO A HEALTH CARE FACILITY, MEDICAL CLINIC, OR PHARMACY
27 THAT ELECTS TO PARTICIPATE IN THE PROGRAM. A HEALTH CARE FACILITY,

1 MEDICAL CLINIC, OR PHARMACY THAT RECEIVES A DONATED CANCER DRUG
2 OR MEDICAL DEVICE UNDER THE PROGRAM MAY DISTRIBUTE THE CANCER
3 DRUG TO ANOTHER ELIGIBLE HEALTH CARE FACILITY, MEDICAL CLINIC, OR
4 PHARMACY FOR USE UNDER THE PROGRAM.

5 (3) A PHARMACIST MAY ACCEPT AND DISPENSE CANCER DRUGS
6 AND MEDICAL DEVICES DONATED UNDER THE PROGRAM TO ELIGIBLE
7 PATIENTS IF ALL OF THE FOLLOWING REQUIREMENTS ARE MET:

8 (a) THE CANCER DRUG IS IN ITS ORIGINAL, UNOPENED, SEALED, AND
9 TAMPER-EVIDENT UNIT DOSE PACKAGING OR, IF PACKAGED IN SINGLE-UNIT
10 DOSES, THE SINGLE-UNIT-DOSE PACKAGING IS UNOPENED;

11 (b) THE CANCER DRUG BEARS AN EXPIRATION DATE THAT IS LATER
12 THAN SIX MONTHS AFTER THE DATE THE DRUG WAS DONATED;

13 (c) THE CANCER DRUG OR MEDICAL DEVICE IS NOT ADULTERATED
14 OR MISBRANDED, AS DETERMINED BY A PHARMACIST EMPLOYED BY OR
15 UNDER CONTRACT WITH THE HEALTH CARE FACILITY, MEDICAL CLINIC, OR
16 PHARMACY; AND

17 (d) THE CANCER DRUG OR MEDICAL DEVICE IS PRESCRIBED BY A
18 PRACTITIONER, AS DEFINED IN SECTION 12-22-102 (27), C.R.S., FOR USE
19 BY AN ELIGIBLE PATIENT AND IS DISPENSED BY A PHARMACIST.

20 (4) A CANCER DRUG OR MEDICAL DEVICE DONATED UNDER THE
21 PROGRAM MAY NOT BE RESOLD. A HEALTH CARE FACILITY, MEDICAL
22 CLINIC, OR PHARMACY MAY CHARGE AN ELIGIBLE PATIENT A HANDLING FEE
23 TO RECEIVE A DONATED CANCER DRUG OR MEDICAL DEVICE, WHICH FEE
24 MAY NOT EXCEED THE AMOUNT SPECIFIED IN RULE BY THE STATE BOARD.

25 (5) NOTHING IN THIS SECTION REQUIRES A HEALTH CARE FACILITY,
26 MEDICAL CLINIC, OR PHARMACY TO PARTICIPATE IN THE PROGRAM.

27 **25-35-104. Rules.** (1) THE STATE BOARD, IN CONSULTATION WITH

1 THE STATE BOARD OF PHARMACY, SHALL PROMULGATE ANY RULES
2 NECESSARY FOR THE IMPLEMENTATION AND ADMINISTRATION OF THE
3 PROGRAM. THE RULES SHALL INCLUDE, AT A MINIMUM:

4 (a) REQUIREMENTS FOR HEALTH CARE FACILITIES, MEDICAL
5 CLINICS, AND PHARMACIES TO ACCEPT AND DISPENSE DONATED CANCER
6 DRUGS AND MEDICAL DEVICES UNDER THE PROGRAM, INCLUDING BUT NOT
7 LIMITED TO:

8 (I) ELIGIBILITY CRITERIA; AND

9 (II) STANDARDS AND PROCEDURES FOR A HEALTH CARE FACILITY,
10 MEDICAL CLINIC, OR PHARMACY TO ACCEPT, SAFELY STORE, AND DISPENSE
11 DONATED CANCER DRUGS AND MEDICAL DEVICES.

12 (b) ELIGIBILITY CRITERIA FOR INDIVIDUALS TO RECEIVE DONATED
13 CANCER DRUGS OR MEDICAL DEVICES DISPENSED UNDER THE PROGRAM.
14 THE CRITERIA SHALL PRIORITIZE DISPENSATION TO CANCER PATIENTS WHO
15 ARE UNINSURED OR UNDERINSURED, BUT SHALL PERMIT DISPENSATION TO
16 OTHER CANCER PATIENTS IF AN UNINSURED OR UNDERINSURED CANCER
17 PATIENT IS NOT AVAILABLE.

18 (c) A MEANS BY WHICH AN ELIGIBLE PATIENT MAY INDICATE THE
19 INDIVIDUAL'S ELIGIBILITY UNDER THE PROGRAM;

20 (d) THE MAXIMUM HANDLING FEE THAT A HEALTH CARE FACILITY,
21 MEDICAL CLINIC, OR PHARMACY MAY CHARGE FOR DISTRIBUTING OR
22 DISPENSING DONATED CANCER DRUGS OR MEDICAL DEVICES; AND

23 (e) A LIST OF CANCER DRUGS, ARRANGED BY CATEGORY OR
24 INDIVIDUAL CANCER DRUG, THAT THE PROGRAM WILL ACCEPT AND WILL
25 NOT ACCEPT FOR DISPENSING. THE LIST OF CANCER DRUGS THE PROGRAM
26 WILL NOT ACCEPT SHALL INCLUDE THE REASON A CANCER DRUG IS
27 INELIGIBLE FOR DONATION.

1 **25-35-105. Liability - prescription drug manufacturers.**

2 NOTHING IN THIS ARTICLE SHALL BE CONSTRUED TO CREATE OR ABROGATE
3 ANY LIABILITY ON BEHALF OF A PRESCRIPTION DRUG MANUFACTURER FOR
4 THE STORAGE, DONATION, ACCEPTANCE, OR DISPENSING OF A CANCER
5 DRUG OR MEDICAL DEVICE, OR TO CREATE ANY CIVIL CAUSE OF ACTION
6 AGAINST A PRESCRIPTION DRUG MANUFACTURER, IN ADDITION TO THAT
7 WHICH IS AVAILABLE UNDER APPLICABLE LAW.

8 **SECTION 2. Effective date.** This act shall take effect at 12:01
9 a.m. on the day following the expiration of the ninety-day period after
10 final adjournment of the general assembly that is allowed for submitting
11 a referendum petition pursuant to article V, section 1 (3) of the state
12 constitution (August 10, 2005, if adjournment sine die is on May 11,
13 2005); except that, if a referendum petition is filed against this act or an
14 item, section, or part of this act within such period, then the act, item,
15 section, or part, if approved by the people, shall take effect on the date of
16 the official declaration of the vote thereon by proclamation of the
17 governor.