### First Regular Session Seventy-second General Assembly STATE OF COLORADO

# ENGROSSED

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

LLS NO. 19-0116.01 Kristen Forrestal x4217

SENATE BILL 19-081

SENATE SPONSORSHIP

Zenzinger, Moreno

Hooton, Arndt

### HOUSE SPONSORSHIP

Senate Committees Health & Human Services **House Committees** 

# A BILL FOR AN ACT

- 101 CONCERNING THE REPEAL OF THE "COLORADO CANCER DRUG
- 102 **Repository Act".**

### **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 <u>http://leg.colorado.gov/</u>.)

**Statutory Revision Committee.** The bill repeals the "Colorado Cancer Drug Repository Act".

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



| 1  | SECTION 1. Legislative declaration. The general assembly                     |
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| 2  | declares that the purpose of this act is to repeal statutory provisions that |
| 3  | are duplicative of another program within the Colorado department of         |
| 4  | public health and environment. The general assembly further declares that    |
| 5  | repealing these statutory provisions does not alter the scope or             |
| 6  | applicability of the remaining statutes.                                     |
| 7  | SECTION 2. In Colorado Revised Statutes, repeal article 35 of                |
| 8  | title 25 as follows:   |
| 9  | ARTICLE 35   |
| 10 | <b>Colorado Cancer Drug Repository Program</b>                               |
| 11 | 25-35-101. Short title. This article shall be known and may be               |
| 12 | cited as the "Colorado Cancer Drug Repository Act".                          |
| 13 | 25-35-102. Definitions. As used in this article, unless the context          |
| 14 | otherwise requires:  |
| 15 | (1) "Cancer drug" means a prescription drug that is used to treat            |
| 16 | cancer or the side effects of cancer.  |
| 17 | (2) "Department" means the department of public health and                   |
| 18 | environment.   |
| 19 | (3) "Dispense" shall have the same meaning as set forth in section           |
| 20 | <del>12-42.5-102 (11), C.R.S.</del>  |
| 21 | (4) "Eligible patient" means an uninsured or underinsured cancer             |
| 22 | patient who meets the eligibility criteria established in rule by the state  |
| 23 | <del>board.</del>  |
| 24 | (5) "Health care facility" means a hospital, hospice, or hospital            |
| 25 | unit that is required to be licensed pursuant to section 25-3-101.           |
| 26 | (6) "Medical clinic" means a community health clinic required to             |
| 27 | be licensed or certified by the department pursuant to section 25-1.5-103.   |

(7) "Medical device" means an instrument, apparatus, implement,
 machine, contrivance, implant, in vitro reagent, or other similar or related
 article, including a component, part, or accessary that is:

4 (a) Recognized in the official national formulary, or the United
5 States pharmacopoeia, or any supplement;

6 (b) Intended for use in the diagnosis of disease or other
7 conditions, or in the cure, mitigation, treatment, or prevention of disease,
8 in humans or animals; or

9 (c) Intended to affect the structure or any function of the human 10 body or animals, that does not achieve any of its primary intended 11 purposes through chemical action within or on the human body or 12 animals, and that is not dependent upon being metabolized for the 13 achievement of any of its primary intended purposes.

14 (8) "Pharmacist" means an individual licensed by this state
15 pursuant to article 42.5 of title 12, C.R.S., to engage in the practice of
16 pharmacy.

17 (9) "Program" means the Colorado cancer drug repository
 18 program created in section 25-35-103.

19 (10) "State board" means the state board of health.

20 25-35-103. Cancer drug repository - administration - donation
 21 - dispensing - cancer drugs - medical devices. (1) There is hereby
 22 established the Colorado cancer drug repository program for the purpose
 23 of allowing a cancer patient or the patient's family to donate unused
 24 cancer drugs and medical devices to uninsured and underinsured cancer
 25 patients in the state of Colorado. The program shall be administered by
 26 the department.

27 (2) The program shall allow 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. A
 health care facility, medical clinic, or pharmacy that receives a donated
 cancer drug or medical device under the program may distribute the
 cancer drug to another eligible health care facility, medical clinic, or
 pharmacy for use under the program.

7 (3) A pharmacist may accept and dispense cancer drugs and
8 medical devices donated under the program to eligible patients if all of
9 the following requirements are met:

(a) (I) The cancer drug or medical device is in its original,
 unopened, sealed, and tamper-evident packaging or, if packaged in
 single-unit doses, the single-unit-dose packaging is unopened; or

(II) The pharmacist has determined that the cancer drug or
 medical device is safe for redistribution;

(b) The cancer drug bears an expiration date that has not expired;
 (c) The cancer drug or medical device is not adulterated or
 misbranded, as determined by a pharmacist; and

(d) The cancer drug or medical device is prescribed by a
 practitioner, as defined in section 12-42.5-102 (32), C.R.S., for use by an
 eligible patient and is dispensed by a pharmacist.

(4) A cancer drug or medical device donated under the program
 may not be resold. A health care facility, medical clinic, or pharmacy may
 charge an eligible patient a handling fee to receive a donated cancer drug
 or medical device, which fee may not exceed the amount specified in rule
 by the state board.

26 (5) Nothing in this section requires a health care facility, medical
 27 clinic, or pharmacy to participate in the program.

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| 1  | (6) A health care facility, medical clinic, or pharmacy that elects            |
|----|--|
| 2  | to participate in the program shall establish eligibility criteria for         |
| 3  | individuals to receive donated cancer drugs or medical devices.                |
| 4  | Dispensation shall be prioritized to cancer patients who are uninsured or      |
| 5  | underinsured. Dispensation to other cancer patients shall be permitted if      |
| 6  | an uninsured or underinsured cancer patient is not available.                  |
| 7  | 25-35-104. Rules. (1) The state board, in consultation with the                |
| 8  | state board of pharmacy, shall promulgate any rules necessary for the          |
| 9  | implementation and administration of the program. The rules shall              |
| 10 | include, at a minimum:   |
| 11 | (a) Requirements for health care facilities, medical clinics, and              |
| 12 | pharmacies to accept and dispense donated cancer drugs and medical             |
| 13 | devices under the program, including but not limited to:                       |
| 14 | (I) Eligibility criteria; and  |
| 15 | (II) Standards and procedures for a health care facility, medical              |
| 16 | clinic, or pharmacy to accept, safely store, and dispense donated cancer       |
| 17 | drugs and medical devices.   |
| 18 | (b) and (c) Repealed.  |
| 19 | (d) The maximum handling fee that a health care facility, medical              |
| 20 | clinic, or pharmacy may charge for distributing or dispensing donated          |
| 21 | cancer drugs or medical devices.   |
| 22 | (e) Repealed.  |
| 23 | 25-35-105. Liability - prescription drug manufacturers.                        |
| 24 | Nothing in this article shall be construed to create or abrogate any liability |
| 25 | on behalf of a prescription drug manufacturer for the storage, donation,       |
| 26 | acceptance, or dispensing of a cancer drug or medical device, or to create     |
| 27 | any civil cause of action against a prescription drug manufacturer, in         |

1 addition to that which is available under applicable law.

2 SECTION 3. Act subject to petition - effective date. This act 3 takes effect at 12:01 a.m. on the day following the expiration of the 4 ninety-day period after final adjournment of the general assembly (August 5 2, 2019, if adjournment sine die is on May 3, 2019); except that, if a 6 referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act 7 8 within such period, then the act, item, section, or part will not take effect 9 unless approved by the people at the general election to be held in 10 November 2020 and, in such case, will take effect on the date of the 11 official declaration of the vote thereon by the governor.