

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

REVISED

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

LLS NO. 19-0406.01 Richard Sweetman x4333

SENATE BILL 19-005

SENATE SPONSORSHIP

Rodriguez and Ginal, Bridges, Crowder, Danielson, Donovan, Fields, Foote, Garcia, Gonzales, Lee, Pettersen, Story, Todd

HOUSE SPONSORSHIP

Jaquez Lewis,

Senate Committees

Health & Human Services
Appropriations

House Committees

Health & Insurance
Appropriations

A BILL FOR AN ACT

101 **CONCERNING WHOLESALE IMPORTATION OF PRESCRIPTION**
102 **PHARMACEUTICAL PRODUCTS FROM CANADA FOR RESALE TO**
103 **COLORADO RESIDENTS, AND, IN CONNECTION THEREWITH,**
104 **MAKING AN APPROPRIATION.**

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://leg.colorado.gov>.)

The bill creates the "Colorado Wholesale Importation of Prescription Drugs Act", under which the department of health care policy and financing (department) shall design a program to import

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

HOUSE
Amended 2nd Reading
May 1, 2019

SENATE
3rd Reading Unamended
March 25, 2019

SENATE
Amended 2nd Reading
March 22, 2019

prescription pharmaceutical products from Canada for sale to Colorado consumers. The program design must ensure both drug safety and cost savings for Colorado consumers. The department shall submit the program design to the secretary of the United States department of health and human services and request the secretary's approval of the program, as required by federal law, to import Canadian pharmaceutical products.

If the secretary approves the program, the department shall implement the program. The department shall adopt a funding mechanism to cover the program's administrative costs, and the department shall annually report on the program to the general assembly.

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

SECTION 1. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) United States consumers pay some of the highest prescription drug prices in the world, and it is estimated that United States consumers pay twice as much as the amount Canadian consumers pay for patented prescription drugs and twenty percent more for generic drugs;

(b) Federal law, as codified in 21 U.S.C. sec. 384, authorizes the secretary of the United States department of health and human services to allow wholesale importation of prescription drugs from Canada if such importation is shown to be both safe and less costly for United States consumers;

(c) Although importing prescription drugs would be less costly, there may be risks posed to consumer health and safety if the source, quality, and purity of prescription drugs sold by online pharmacies cannot be verified;

(d) Canada has a rigorous regulatory system to license prescription drugs, equivalent to the licensing system in the United States;

(e) In the United States, Title II of the federal "Drug Quality and Security Act", Pub.L. 113-54, referred to as the "Drug Supply Chain

1 Security Act", has significantly improved drug security and safety through
2 a system of pharmaceutical product track-and-trace procedures; and

3 (f) A wholesale drug importation program for the exclusive
4 benefit of Colorado residents should be designed and implemented to
5 provide Colorado consumers access to safe and less expensive
6 prescription drugs.

7 **SECTION 2.** In Colorado Revised Statutes, 25.5-1-201, **amend**
8 **(1) introductory portion, (1)(f), and (1)(g); and add (1)(h) as follows:**

9 **25.5-1-201. Programs to be administered by the department**
10 **of health care policy and financing. (1) ~~Programs to be administered~~**
11 **and functions to be performed by The department of health care policy**
12 **and financing shall be as follows ADMINISTER THE FOLLOWING PROGRAMS**
13 **AND PERFORM THE FOLLOWING FUNCTIONS:**

14 (f) The old age pension health and medical care program, as
15 specified in section 25.5-2-101; and

16 (g) Programs, services, and supports for persons with intellectual
17 and developmental disabilities, as specified in article 10 of this title TITLE
18 25.5; AND

19 (h) ANY PROGRAM CONCERNING THE WHOLESALE IMPORTATION OF
20 PRESCRIPTION DRUGS PURSUANT TO PART 2 OF ARTICLE 2.5 OF THIS TITLE
21 25.5.

22 **SECTION 3.** In Colorado Revised Statutes, **add** part 2 to article
23 2.5 of title 25.5 as follows:

24 **PART 2**

25 **CANADIAN PRESCRIPTION DRUG**
26 **IMPORTATION PROGRAM**

27 **25.5-2.5-201. Definitions.** AS USED IN THIS PART 2, UNLESS THE

1 CONTEXT OTHERWISE REQUIRES:

2 (1) "CANADIAN SUPPLIER" MEANS A MANUFACTURER, WHOLESALE
3 DISTRIBUTOR, OR PHARMACY THAT IS APPROPRIATELY LICENSED OR
4 PERMITTED UNDER CANADIAN FEDERAL AND PROVINCIAL LAWS AND
5 REGULATIONS TO MANUFACTURE, DISTRIBUTE, OR DISPENSE PRESCRIPTION
6 DRUGS.

7 (2) "ELIGIBLE IMPORTER" MEANS AN IMPORTER THAT IS DESCRIBED
8 IN SECTION 25.5-2.5-203 (3).

9 (3) "FEDERAL ACT" MEANS THE FEDERAL "FOOD, DRUG, AND
10 COSMETIC ACT", 21 U.S.C. 301 ET SEQ.

11 (4) "MEDICAID PHARMACY" MEANS A PHARMACY REGISTERED
12 PURSUANT TO SECTION 12-42.5-117 THAT HAS A PROVIDER AGREEMENT IN
13 EFFECT WITH THE STATE DEPARTMENT AND IS IN GOOD STANDING WITH
14 THE STATE DEPARTMENT.

15 (5) "PHARMACIST" MEANS A PERSON WHO HOLDS AN ACTIVE AND
16 UNENCUMBERED LICENSE TO PRACTICE PHARMACY PURSUANT TO SECTION
17 12-42.5-112.

18 (6) "PRESCRIPTION DRUG" HAS THE SAME MEANING SET FORTH IN
19 SECTION 12-42.5-102 (34); EXCEPT THAT THE TERM INCLUDES ONLY
20 DRUGS THAT ARE INTENDED FOR HUMAN USE.

21 (7) "PROGRAM" MEANS THE CANADIAN PRESCRIPTION DRUG
22 IMPORTATION PROGRAM CREATED IN SECTION 25.5-2.5-202.

23 (8) "VENDOR" MEANS A VENDOR WITH WHICH THE STATE
24 DEPARTMENT CONTRACTS FOR THE PROVISION OF SERVICES UNDER THE
25 PROGRAM PURSUANT TO SECTION 25.5-2.5-202 (1).

26 **25.5-2.5-202. Canadian prescription drug importation**
27 **program - created - importation process - contract with vendor -**

1 **vendor duties.** (1) THE CANADIAN PRESCRIPTION DRUG IMPORTATION
2 PROGRAM IS CREATED IN THE STATE DEPARTMENT. UPON RECEIVING
3 APPROVAL OF THE PROGRAM AS DESCRIBED IN SECTION 25.5-2.5-204 (1),
4 THE STATE DEPARTMENT SHALL CONTRACT WITH ONE OR MORE VENDORS
5 TO PROVIDE SERVICES UNDER THE PROGRAM. FOR THREE YEARS
6 FOLLOWING THE EFFECTIVE DATE OF THIS PART 2, THE SELECTION OF ANY
7 VENDOR PURSUANT TO THIS SUBSECTION (1) IS EXEMPT FROM THE
8 REQUIREMENTS OF THE PROCUREMENT CODE, ARTICLES 101 TO 112 OF
9 TITLE 24.

10 (2) (a) EACH VENDOR, IN CONSULTATION WITH THE STATE
11 DEPARTMENT AND ANY OTHER VENDORS, SHALL ESTABLISH A WHOLESALE
12 PRESCRIPTION DRUG IMPORTATION LIST THAT IDENTIFIES THE
13 PRESCRIPTION DRUGS THAT HAVE THE HIGHEST POTENTIAL FOR COST
14 SAVINGS TO THE STATE. IN DEVELOPING THE LIST, EACH VENDOR SHALL
15 CONSIDER, AT A MINIMUM, WHICH PRESCRIPTION DRUGS WILL PROVIDE THE
16 GREATEST COST SAVINGS TO THE STATE, INCLUDING PRESCRIPTION DRUGS
17 FOR WHICH THERE ARE SHORTAGES, SPECIALTY PRESCRIPTION DRUGS, AND
18 HIGH-VOLUME PRESCRIPTION DRUGS. EACH VENDOR SHALL REVISE THE
19 LIST AT LEAST ANNUALLY AND AT THE DIRECTION OF THE STATE
20 DEPARTMENT PURSUANT TO SUBSECTION (2)(b) OF THIS SECTION.

21 (b) THE STATE DEPARTMENT SHALL REVIEW THE WHOLESALE
22 PRESCRIPTION DRUG IMPORTATION LIST AT LEAST EVERY THREE MONTHS
23 TO ENSURE THAT IT CONTINUES TO MEET THE REQUIREMENTS OF THE
24 PROGRAM. THE STATE DEPARTMENT MAY DIRECT A VENDOR TO REVISE
25 THE LIST, AS NECESSARY.

26 (c) EACH VENDOR, IN CONSULTATION WITH THE STATE
27 DEPARTMENT, SHALL IDENTIFY CANADIAN SUPPLIERS WHO ARE IN FULL

1 COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS
2 AND REGULATIONS AND WHO HAVE AGREED TO EXPORT PRESCRIPTION
3 DRUGS IDENTIFIED ON THE WHOLESALE PRESCRIPTION DRUG IMPORTATION
4 LIST. EACH VENDOR SHALL VERIFY THAT SUCH CANADIAN SUPPLIERS MEET
5 ALL OF THE REQUIREMENTS OF THE PROGRAM AND WILL EXPORT
6 PRESCRIPTION DRUGS AT PRICES THAT WILL PROVIDE COST SAVINGS TO THE
7 STATE. EACH VENDOR SHALL CONTRACT WITH SUCH ELIGIBLE CANADIAN
8 SUPPLIERS, OR FACILITATE CONTRACTS BETWEEN ELIGIBLE IMPORTERS AND
9 CANADIAN SUPPLIERS, TO IMPORT PRESCRIPTION DRUGS UNDER THE
10 PROGRAM.

11 (d) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT IN
12 DEVELOPING AND ADMINISTERING A DISTRIBUTION PROGRAM WITHIN THE
13 PROGRAM.

14 (e) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT WITH
15 THE ANNUAL REPORT DESCRIBED IN SECTION 25.5-2.5-205 AND PROVIDE
16 ANY INFORMATION REQUESTED BY THE STATE DEPARTMENT FOR THE
17 REPORT.

18 (f) EACH VENDOR SHALL ENSURE THE SAFETY AND QUALITY OF
19 DRUGS IMPORTED UNDER THE PROGRAM, AS FOLLOWS:

20 (I) (A) FOR AN INITIAL IMPORTED SHIPMENT, ENSURE THAT EACH
21 BATCH OF THE DRUG IN THE SHIPMENT IS STATISTICALLY SAMPLED AND
22 TESTED FOR AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT
23 WITH THE FEDERAL ACT; AND

24 (B) FOR ANY SUBSEQUENT IMPORTED SHIPMENT, ENSURE THAT A
25 STATISTICALLY VALID SAMPLE OF THE SHIPMENT IS TESTED FOR
26 AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE
27 FEDERAL ACT.

- 1 (II) CERTIFY THAT EACH DRUG:
- 2 (A) IS APPROVED FOR MARKETING IN THE UNITED STATES AND IS
- 3 NOT ADULTERATED OR MISBRANDED; AND
- 4 (B) MEETS ALL OF THE LABELING REQUIREMENTS UNDER 21 U.S.C.
- 5 SEC. 352.
- 6 (III) MAINTAIN QUALIFIED LABORATORY RECORDS, INCLUDING
- 7 COMPLETE DATA DERIVED FROM ALL TESTS NECESSARY TO ENSURE THAT
- 8 THE DRUG IS IN COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION;
- 9 AND
- 10 (IV) MAINTAIN DOCUMENTATION DEMONSTRATING THAT THE
- 11 TESTING REQUIRED BY THIS SECTION WAS CONDUCTED AT A QUALIFIED
- 12 LABORATORY IN ACCORDANCE WITH THE FEDERAL ACT AND ANY OTHER
- 13 APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS GOVERNING
- 14 LABORATORY QUALIFICATIONS.
- 15 (3) ALL TESTING REQUIRED BY THIS SECTION MUST BE CONDUCTED
- 16 IN A QUALIFIED LABORATORY THAT MEETS THE STANDARDS UNDER THE
- 17 FEDERAL ACT AND ANY OTHER APPLICABLE FEDERAL AND STATE LAWS
- 18 AND REGULATIONS GOVERNING LABORATORY QUALIFICATIONS FOR DRUG
- 19 TESTING.
- 20 (4) EACH VENDOR SHALL MAINTAIN A LIST OF ALL ELIGIBLE
- 21 IMPORTERS THAT PARTICIPATE IN THE PROGRAM.
- 22 (5) EACH VENDOR SHALL ENSURE COMPLIANCE WITH TITLE II OF
- 23 THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB. L. 113-54, BY
- 24 ALL CANADIAN SUPPLIERS, ELIGIBLE IMPORTERS, DISTRIBUTORS, AND
- 25 OTHER PARTICIPANTS IN THE PROGRAM.
- 26 (6) EACH VENDOR SHALL PROVIDE AN ANNUAL FINANCIAL AUDIT
- 27 OF ITS OPERATIONS TO THE STATE DEPARTMENT. EACH VENDOR SHALL

1 ALSO PROVIDE QUARTERLY FINANCIAL REPORTS SPECIFIC TO THE PROGRAM
2 AND SHALL INCLUDE INFORMATION CONCERNING THE PERFORMANCE OF
3 ITS SUBCONTRACTORS AND VENDORS. THE STATE DEPARTMENT SHALL
4 DETERMINE THE FORMAT AND CONTENTS OF THE REPORTS.

5 (7) EACH VENDOR SHALL SUBMIT EVIDENCE OF A SURETY BOND
6 WITH ANY BID OR INITIAL CONTRACT NEGOTIATION DOCUMENTS AND
7 SHALL MAINTAIN DOCUMENTATION OF EVIDENCE OF SUCH A BOND WITH
8 THE STATE DEPARTMENT THROUGHOUT THE CONTRACT TERM. THE SURETY
9 BOND MAY BE FROM THIS STATE OR ANY OTHER STATE IN THE UNITED
10 STATES AND MUST BE IN AN AMOUNT OF AT LEAST TWENTY-FIVE
11 THOUSAND DOLLARS. THE SURETY BOND OR COMPARABLE SECURITY
12 ARRANGEMENT MUST INCLUDE THE STATE OF COLORADO AS A
13 BENEFICIARY. IN LIEU OF THE SURETY BOND, A VENDOR MAY PROVIDE A
14 COMPARABLE SECURITY AGREEMENT, SUCH AS AN IRREVOCABLE LETTER
15 OF CREDIT OR A DEPOSIT INTO A TRUST ACCOUNT OR FINANCIAL
16 INSTITUTION THAT INCLUDES THE STATE OF COLORADO AS A BENEFICIARY,
17 PAYABLE TO THE STATE OF COLORADO. THE PURPOSES OF THE BOND OR
18 OTHER SECURITY ARRANGEMENT ARE TO:

19 (a) ENSURE PARTICIPATION OF THE VENDOR IN ANY CIVIL OR
20 CRIMINAL LEGAL ACTION BY THE STATE DEPARTMENT, ANY OTHER STATE
21 AGENCY, OR PRIVATE INDIVIDUALS OR ENTITIES AGAINST THE VENDOR
22 BECAUSE OF THE VENDOR'S FAILURE TO PERFORM UNDER THE CONTRACT,
23 INCLUDING BUT NOT LIMITED TO CAUSES OF ACTIONS FOR PERSONAL
24 INJURY, NEGLIGENCE, AND WRONGFUL DEATH;

25 (b) ENSURE PAYMENT BY THE VENDOR THROUGH THE USE OF A
26 BOND OR OTHER COMPARABLE SECURITY ARRANGEMENT OF ANY LEGAL
27 JUDGMENTS AND CLAIMS THAT ARE AWARDED TO THE STATE, OTHER

1 ENTITIES ACTING ON BEHALF OF THE STATE, INDIVIDUALS, OR
2 ORGANIZATIONS IF THE VENDOR IS ASSESSED A FINAL JUDGMENT OR OTHER
3 MONETARY PENALTY IN A COURT OF LAW FOR A CIVIL OR CRIMINAL ACTION
4 UNDER THE PROGRAM. THE BOND OR COMPARABLE SECURITY
5 ARRANGEMENT MAY BE ACCESSED IF THE VENDOR FAILS TO PAY ANY
6 JUDGMENT OR CLAIM WITHIN SIXTY DAYS AFTER FINAL JUDGMENT.

7 (c) ALLOW FOR CIVIL AND CRIMINAL LITIGATION CLAIMS TO BE
8 MADE AGAINST THE BOND OR OTHER COMPARABLE SECURITY
9 ARRANGEMENTS FOR UP TO ONE YEAR AFTER THE VENDOR'S CONTRACT
10 UNDER THE PROGRAM HAS ENDED WITH THE STATE DEPARTMENT, THE
11 VENDOR'S LICENSE IS NO LONGER VALID, OR THE PROGRAM HAS ENDED,
12 WHICHEVER OCCURS LAST.

13 (8) EACH VENDOR SHALL MAINTAIN INFORMATION AND
14 DOCUMENTATION SUBMITTED UNDER THIS SECTION FOR A PERIOD OF AT
15 LEAST SEVEN YEARS.

16 (9) THE STATE DEPARTMENT MAY REQUIRE EACH VENDOR TO
17 COLLECT ANY OTHER INFORMATION NECESSARY TO ENSURE THE
18 PROTECTION OF THE PUBLIC HEALTH.

19 **25.5-2.5-203. Eligible prescription drugs - eligible Canadian**
20 **suppliers - eligible importers - distribution requirements.** (1) AN
21 ELIGIBLE IMPORTER MAY IMPORT A PRESCRIPTION DRUG FROM A
22 CANADIAN SUPPLIER IF:

23 (a) THE DRUG THAT IS TO BE IMPORTED MEETS THE FEDERAL FOOD
24 AND DRUG ADMINISTRATION'S STANDARDS RELATED TO SAFETY,
25 EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

26 (b) IMPORTING THE DRUG WOULD NOT VIOLATE FEDERAL PATENT
27 LAWS;

1 (c) IMPORTING THE DRUG IS EXPECTED TO GENERATE COST
2 SAVINGS; AND

3 (d) THE DRUG IS NOT:

4 (I) A CONTROLLED SUBSTANCE AS DEFINED IN 21 U.S.C. SEC. 802
5 (6);

6 (II) A BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC. 262 (i);

7 (III) AN INFUSED DRUG;

8 (IV) AN INTRAVENOUSLY INJECTED DRUG;

9 (V) A DRUG THAT IS INHALED DURING SURGERY; OR

10 (VI) A DRUG THAT IS A PARENTERAL DRUG, THE IMPORTATION OF
11 WHICH IS DETERMINED BY THE FEDERAL SECRETARY OF HEALTH AND
12 HUMAN SERVICES TO POSE A THREAT TO PUBLIC HEALTH.

13 (2) A CANADIAN SUPPLIER MAY EXPORT PRESCRIPTION DRUGS
14 INTO THE STATE UNDER THE PROGRAM IF THE SUPPLIER:

15 (a) IS IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL
16 AND PROVINCIAL LAWS AND REGULATIONS;

17 (b) IS IDENTIFIED BY THE VENDOR AS ELIGIBLE TO PARTICIPATE IN
18 THE PROGRAM PURSUANT TO SECTION 25.5-2.5-202 (2)(c); AND

19 (c) SUBMITS AN ATTESTATION THAT THE SUPPLIER HAS A
20 REGISTERED AGENT IN THE UNITED STATES, WHICH ATTESTATION
21 INCLUDES THE NAME AND UNITED STATES ADDRESS OF THE REGISTERED
22 AGENT.

23 (3) THE FOLLOWING ENTITIES ARE ELIGIBLE IMPORTERS AND MAY
24 OBTAIN IMPORTED PRESCRIPTION DRUGS:

25 (a) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER
26 CONTRACT WITH A MEDICAID PHARMACY, FOR DISPENSING TO THE
27 PHARMACY'S MEDICAID RECIPIENTS;

1 (b) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER
2 CONTRACT WITH THE DEPARTMENT OF CORRECTIONS, FOR DISPENSING TO
3 INMATES IN THE CUSTODY OF THE DEPARTMENT OF CORRECTIONS;

4 (c) COMMERCIAL PLANS, AS DEFINED BY RULES PROMULGATED BY
5 THE STATE BOARD AND AS APPROVED BY THE FEDERAL GOVERNMENT; AND

6 (d) A LICENSED COLORADO PHARMACIST OR WHOLESALER
7 APPROVED BY THE STATE DEPARTMENT.

8 (4) (a) THE STATE DEPARTMENT SHALL DESIGNATE AN OFFICE OR
9 DIVISION THAT MUST BE A LICENSED PHARMACEUTICAL WHOLESALER OR
10 THAT SHALL CONTRACT WITH A LICENSED PHARMACEUTICAL WHOLESALER
11 LICENSED PURSUANT TO PART 3 OF ARTICLE 42.5 OF TITLE 12.

12 (b) THE OFFICE OR DIVISION DESIGNATED BY THE STATE
13 DEPARTMENT PURSUANT TO SUBSECTION (4)(a) OF THIS SECTION SHALL:

14 (I) SET A MAXIMUM PROFIT MARGIN SO THAT A WHOLESALER,
15 DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER PARTICIPATING
16 IN THE PROGRAM MAINTAINS A PROFIT MARGIN THAT IS NO GREATER THAN
17 THE PROFIT MARGIN THAT THE WHOLESALER, DISTRIBUTOR, PHARMACY,
18 OR OTHER LICENSED PROVIDER WOULD HAVE EARNED ON THE EQUIVALENT
19 NONIMPORTED DRUG;

20 (II) EXCLUDE GENERIC PRODUCTS IF THE IMPORTATION OF THE
21 PRODUCTS WOULD VIOLATE UNITED STATES PATENT LAWS APPLICABLE TO
22 UNITED STATES-BRANDED PRODUCTS;

23 (III) COMPLY WITH THE REQUIREMENTS OF 21 U.S.C. SEC. 360eee
24 TO 360eee-4 AS ENACTED IN TITLE II OF THE FEDERAL "DRUG QUALITY
25 AND SECURITY ACT"; AND

26 (IV) DETERMINE A METHOD FOR COVERING THE ADMINISTRATIVE
27 COSTS OF THE PROGRAM, WHICH METHOD MAY INCLUDE A FEE IMPOSED ON

1 EACH PRESCRIPTION PHARMACEUTICAL PRODUCT SOLD THROUGH THE
2 PROGRAM OR ANY OTHER APPROPRIATE METHOD AS DETERMINED BY THE
3 STATE DEPARTMENT, BUT THE STATE DEPARTMENT SHALL NOT REQUIRE A
4 FEE IN AN AMOUNT THE STATE DEPARTMENT DETERMINES WOULD
5 SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

6 (5) CANADIAN SUPPLIERS AND ELIGIBLE IMPORTERS PARTICIPATING
7 UNDER THE PROGRAM:

8 (a) SHALL COMPLY WITH THE TRACKING AND TRACING
9 REQUIREMENTS OF 21 U.S.C. SEC. 360eee ET SEQ.; AND

10 (b) SHALL NOT DISTRIBUTE, DISPENSE, OR SELL PRESCRIPTION
11 DRUGS IMPORTED UNDER THE PROGRAM OUTSIDE OF THE STATE.

12 (6) A PARTICIPATING ELIGIBLE IMPORTER SHALL SUBMIT TO THE
13 VENDOR ALL OF FOLLOWING INFORMATION ABOUT EACH DRUG TO BE
14 ACQUIRED BY THE IMPORTER UNDER THE PROGRAM:

15 (a) THE NAME AND QUANTITY OF THE ACTIVE INGREDIENT OF THE
16 DRUG;

17 (b) A DESCRIPTION OF THE DOSAGE FORM OF THE DRUG;

18 (c) THE DATE ON WHICH THE DRUG IS RECEIVED;

19 (d) THE QUANTITY OF THE DRUG THAT IS RECEIVED;

20 (e) THE POINT OF ORIGIN AND DESTINATION OF THE DRUG; AND

21 (f) THE PRICE PAID BY THE IMPORTER FOR THE DRUG.

22 (7) A PARTICIPATING CANADIAN SUPPLIER SHALL SUBMIT TO THE
23 VENDOR THE FOLLOWING INFORMATION ABOUT EACH DRUG TO BE
24 SUPPLIED BY THE CANADIAN SUPPLIER UNDER THE PROGRAM:

25 (a) THE ORIGINAL SOURCE OF THE DRUG, INCLUDING:

26 (I) THE NAME OF THE MANUFACTURER OF THE DRUG;

27 (II) THE DATE ON WHICH THE DRUG WAS MANUFACTURED; AND

1 (III) THE COUNTRY, STATE OR PROVINCE, AND CITY WHERE THE
2 DRUG WAS MANUFACTURED;

3 (b) THE DATE ON WHICH THE DRUG IS SHIPPED;

4 (c) THE QUANTITY OF THE DRUG THAT IS SHIPPED;

5 (d) THE QUANTITY OF EACH LOT OF THE DRUG ORIGINALLY
6 RECEIVED AND THE SOURCE OF THE LOT; AND

7 (e) THE LOT OR CONTROL NUMBER AND THE BATCH NUMBER
8 ASSIGNED TO THE DRUG BY THE MANUFACTURER.

9 (8) THE STATE DEPARTMENT SHALL IMMEDIATELY SUSPEND THE
10 IMPORTATION OF A SPECIFIC DRUG OR THE IMPORTATION OF DRUGS BY A
11 SPECIFIC ELIGIBLE IMPORTER IF IT DISCOVERS THAT ANY DRUG OR
12 ACTIVITY IS IN VIOLATION OF THIS SECTION OR ANY FEDERAL OR STATE
13 LAW OR REGULATION. THE STATE DEPARTMENT MAY REVOKE THE
14 SUSPENSION IF, AFTER CONDUCTING AN INVESTIGATION, IT DETERMINES
15 THAT THE PUBLIC IS ADEQUATELY PROTECTED FROM COUNTERFEIT OR
16 UNSAFE DRUGS BEING IMPORTED INTO THIS STATE.

17 **25.5-2.5-204. Federal approval.** (1) ON OR BEFORE SEPTEMBER
18 1, 2020, THE STATE DEPARTMENT SHALL SUBMIT A REQUEST TO THE
19 UNITED STATES SECRETARY OF HEALTH AND HUMAN SERVICES FOR
20 APPROVAL OF THE PROGRAM UNDER 21 U.S.C. SEC. 384. THE STATE
21 DEPARTMENT SHALL BEGIN OPERATING THE PROGRAM NOT LATER THAN
22 SIX MONTHS AFTER RECEIVING SUCH APPROVAL. THE REQUEST MUST, AT
23 A MINIMUM:

24 (a) DESCRIBE THE STATE DEPARTMENT'S PLAN FOR OPERATING THE
25 PROGRAM;

26 (b) DEMONSTRATE HOW THE PRESCRIPTION DRUGS IMPORTED INTO
27 THE STATE UNDER THE PROGRAM WILL MEET THE APPLICABLE FEDERAL

1 AND STATE STANDARDS FOR SAFETY, EFFECTIVENESS, MISBRANDING, AND
2 ADULTERATION;

3 (c) INCLUDE A LIST OF PRESCRIPTION DRUGS THAT HAVE THE
4 HIGHEST POTENTIAL FOR COST SAVINGS TO THE STATE THROUGH
5 IMPORTATION AT THE TIME THAT THE REQUEST IS SUBMITTED;

6 (d) ESTIMATE THE TOTAL COST SAVINGS ATTRIBUTABLE TO THE
7 PROGRAM; AND

8 (e) INCLUDE A LIST OF POTENTIAL CANADIAN SUPPLIERS FROM
9 WHICH THE STATE WOULD IMPORT PRESCRIPTION DRUGS AND
10 DEMONSTRATE THAT THE SUPPLIERS ARE IN FULL COMPLIANCE WITH
11 RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND
12 REGULATIONS.

13 (2) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE
14 CONTRARY, THE STATE DEPARTMENT MAY EXPEND MONEY FOR THE
15 PURPOSE OF REQUESTING APPROVAL OF THE PROGRAM AS DESCRIBED IN
16 SUBSECTION (1) OF THIS SECTION BUT THE STATE DEPARTMENT SHALL NOT
17 SPEND ANY OTHER MONEY TO IMPLEMENT THE PROGRAM UNTIL THE STATE
18 DEPARTMENT RECEIVES APPROVAL OF THE PROGRAM AS DESCRIBED IN
19 SAID SUBSECTION (1).

20 (3) UPON RECEIPT OF FEDERAL APPROVAL OF THE PROGRAM, THE
21 STATE DEPARTMENT SHALL NOTIFY THE PRESIDENT OF THE SENATE AND
22 THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AS WELL AS THE
23 HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE
24 HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES,
25 OR ANY SUCCESSOR COMMITTEES. AFTER APPROVAL IS RECEIVED AND
26 BEFORE THE START OF THE NEXT REGULAR SESSION OF THE GENERAL
27 ASSEMBLY IN WHICH THE PROPOSAL COULD BE FUNDED, THE STATE

1 DEPARTMENT SHALL SUBMIT TO ALL PARTIES SPECIFIED IN THIS
2 SUBSECTION (3) A PROPOSAL FOR PROGRAM IMPLEMENTATION AND
3 PROGRAM FUNDING.

4 **25.5-2.5-205. Reports.** (1) NOTWITHSTANDING SECTION 24-1-136
5 (11)(a)(I), ON OR BEFORE DECEMBER 1, 2021, AND ON OR BEFORE
6 DECEMBER 1 EACH YEAR THEREAFTER, THE STATE DEPARTMENT SHALL
7 SUBMIT A REPORT TO THE GOVERNOR, THE PRESIDENT OF THE SENATE, AND
8 THE SPEAKER OF THE HOUSE OF REPRESENTATIVES CONCERNING THE
9 OPERATION OF THE PROGRAM DURING THE PREVIOUS FISCAL YEAR. THE
10 REPORT MUST INCLUDE, AT A MINIMUM:

11 (a) A LIST OF THE PRESCRIPTION DRUGS THAT WERE IMPORTED
12 UNDER THE PROGRAM;

13 (b) THE NUMBER OF PARTICIPATING CANADIAN SUPPLIERS AND
14 ELIGIBLE IMPORTERS;

15 (c) THE NUMBER OF PRESCRIPTIONS DISPENSED THROUGH THE
16 PROGRAM;

17 (d) THE ESTIMATED COST SAVINGS DURING THE PREVIOUS FISCAL
18 YEAR AND TO DATE;

19 (e) A DESCRIPTION OF THE METHODOLOGY USED TO DETERMINE
20 WHICH PRESCRIPTION DRUGS SHOULD BE INCLUDED ON THE WHOLESAL
21 PRESCRIPTION DRUG IMPORTATION LIST ESTABLISHED PURSUANT TO
22 SECTION 25.5-2.5-202 (2)(a); AND

23 (f) DOCUMENTATION DEMONSTRATING HOW THE PROGRAM
24 ENSURES THAT:

25 (I) THE VENDOR VERIFIES THAT CANADIAN SUPPLIERS
26 PARTICIPATING IN THE PROGRAM ARE IN FULL COMPLIANCE WITH
27 RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND

1 REGULATIONS;

2 (II) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE
3 NOT SHIPPED, SOLD, OR DISPENSED OUTSIDE OF THE STATE ONCE IN THE
4 POSSESSION OF THE ELIGIBLE IMPORTER;

5 (III) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE
6 PURE, UNADULTERATED, POTENT, AND SAFE;

7 (IV) THE PROGRAM DOES NOT PUT CONSUMERS AT A HIGHER
8 HEALTH AND SAFETY RISK THAN IF THE PROGRAM DID NOT EXIST; AND

9 (V) THE PROGRAM PROVIDES COST SAVINGS TO THE STATE ON
10 IMPORTED PRESCRIPTION DRUGS.

11

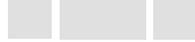
12 **25.5-2.5-206. Importation program authorized - rules.**

13 (1) UPON APPROVAL BY THE SECRETARY, IN ACCORDANCE WITH SECTION
14 25.5-2.5-205, THE STATE DEPARTMENT SHALL ADMINISTER AN
15 IMPORTATION PROGRAM.

16 (2) THE STATE DEPARTMENT SHALL APPROVE A METHOD OF
17 FINANCING THE ADMINISTRATIVE COSTS OF THE IMPORTATION PROGRAM,
18 WHICH METHOD MAY INCLUDE IMPOSING A FEE ON EACH PRESCRIPTION
19 PHARMACEUTICAL PRODUCT SOLD THROUGH THE IMPORTATION PROGRAM
20 OR ANY OTHER APPROPRIATE METHOD DETERMINED BY THE STATE
21 DEPARTMENT TO FINANCE ADMINISTRATIVE COSTS. THE STATE
22 DEPARTMENT SHALL NOT REQUIRE A FEE IN AN AMOUNT THAT THE STATE
23 DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER
24 SAVINGS.

25 (3) THE EXECUTIVE DIRECTOR SHALL PROMULGATE RULES, IN
26 ACCORDANCE WITH ARTICLE 4 OF TITLE 24 AND SECTION 25.5-1-108, AS
27 NECESSARY FOR THE ADMINISTRATION OF THIS PART 2.

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SECTION 4. In Colorado Revised Statutes, **amend** 25.5-2.5-101 as follows:

25.5-2.5-101. Short title. THE SHORT TITLE OF this ~~article shall be known and may be cited as~~ PART 1 IS the "Colorado Cares Rx Act".



SECTION 5. Appropriation - adjustments to 2019 long bill.

(1) For the 2019-20 state fiscal year, \$1,041,802 is appropriated to the department of health care policy and financing. This appropriation is from the general fund. To implement this act, the department may use this appropriation as follows:

(a) \$469,293 for use by the executive director's office for personal services, which amount is based on an assumption that the department will require an additional 4.1 FTE;

(b) \$27,790 for use by the executive director's office for operating expenses;

(c) \$134,719 for legal services; and

(e) \$410,000 for general professional services and special projects.

(2) For the 2019-20 state fiscal year, \$134,719 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of health care policy and financing under subsection (1)(c) of this section and is based on an assumption that the department of law will require an additional 0.7 FTE. To implement this act, the department of law may use this appropriation to provide legal services for the department of health care policy and financing.

(3) The appropriation in subsection (1)(a) of this section is based

1 on the assumption that the anticipated amount of federal funds received
2 for the 2019-20 state fiscal year by the department of health care policy
3 and financing for personal services will decrease by \$70,000. ■■■

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