

Second 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. 20-0742.01 Richard Sweetman x4333

SENATE BILL 20-119

SENATE SPONSORSHIP

Ginal,

HOUSE SPONSORSHIP

Jaquez Lewis,

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 **CONCERNING EXPANDING THE CANADIAN PRESCRIPTION DRUG**
102 **IMPORTATION PROGRAM TO INCLUDE PRESCRIPTION DRUG**
103 **SUPPLIERS FROM NATIONS OTHER THAN CANADA UPON THE**
104 **ENACTMENT OF LEGISLATION BY THE UNITED STATES CONGRESS**
105 **AUTHORIZING SUCH PRACTICE.**

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>.)

In 2019, the Colorado general assembly enacted, and the governor subsequently signed into law, the Canadian prescription drug importation

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.

SENATE
Amended 2nd Reading
February 26, 2020

program (program) in the department of health care policy and financing (department). The department is directed to request approval of the program on or before September 1, 2020, from the United States secretary of health and human services and to implement the program upon receipt of approval.

The bill states that the department may expand the program to allow a manufacturer, wholesale distributor, or pharmacy from a nation other than Canada to export prescription drugs into the state under the program if certain conditions are met.

If, upon the satisfaction of these conditions, the department decides to expand the program, the executive director of the department shall notify the president of the senate and the speaker of the house of representatives, as well as the health and human services committee of the senate and the health and insurance committee of the house of representatives, or any successor committees, of the department's intent to do so. The executive director shall provide the notice at least 30 days before the program is expanded, and the notice may include any recommendations of the department for legislation to amend the program to reflect its expansion.

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

2 **SECTION 1.** In Colorado Revised Statutes, **add** 25.5-2.5-208 as
3 follows:

4 **25.5-2.5-208. Expansion of program to include additional**
5 **foreign suppliers - federal action required - notice to general**
6 **assembly.** (1) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE
7 CONTRARY, THE STATE DEPARTMENT MAY EXPAND THE PROGRAM TO
8 ALLOW A MANUFACTURER, WHOLESALE DISTRIBUTOR, OR PHARMACY
9 FROM A NATION OTHER THAN CANADA TO EXPORT PRESCRIPTION DRUGS
10 INTO THE STATE UNDER THE PROGRAM IF:

11 (a) THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR
12 PHARMACY IS APPROPRIATELY LICENSED OR PERMITTED UNDER THAT
13 NATION'S LAWS AND REGULATIONS PERTAINING TO THE MANUFACTURING,
14 DISTRIBUTION, OR DISPENSING OF PRESCRIPTION DRUGS;

1 (b) THE MANUFACTURER, WHOLESAL E DISTRIBUTOR, OR
2 PHARMACY HAS BEEN IDENTIFIED BY A VENDOR WITH WHICH THE STATE
3 DEPARTMENT HAS CONTRACTED PURSUANT TO SECTION 25.5-2.5-203 (1)
4 AS A SUPPLIER THAT SATISFIES THE REQUIREMENTS OF THE PROGRAM AND
5 WILL EXPORT PRESCRIPTION DRUGS AT PRICES THAT WILL PROVIDE COST
6 SAVINGS TO THE STATE;

7 (c) THE UNITED STATES CONGRESS ENACTS LEGISLATION TO
8 AMEND 21 U.S.C. SEC. 384 OR OTHERWISE ENACTS LEGISLATION TO
9 PERMIT STATES, INCLUDING COLORADO, TO IMPORT PRESCRIPTION DRUGS
10 FROM FOREIGN COUNTRIES OTHER THAN CANADA;

11 (d) THE MANUFACTURER, WHOLESAL E DISTRIBUTOR, OR
12 PHARMACY IS LOCATED IN A NATION THAT IS APPROVED TO EXPORT
13 PRESCRIPTION DRUGS INTO COLORADO BY THE UNITED STATES
14 SECRETARY OF HEALTH AND HUMAN SERVICES OR BY ANOTHER
15 AUTHORITY THAT IS DESIGNATED FOR SUCH PURPOSE BY FEDERAL LAW;
16 AND

17 (e) THE STATE DEPARTMENT SUBMITS EVIDENCE TO THE PRESIDENT
18 OF THE SENATE, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, THE
19 HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, AND THE
20 HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES,
21 OR ANY SUCCESSOR COMMITTEES, WHICH EVIDENCE COMPARES THE
22 EXPORTING NATION'S REGULATORY SYSTEM FOR PRESCRIPTION DRUGS TO
23 THE REGULATORY SYSTEM FOR PRESCRIPTION DRUGS ADMINISTERED BY
24 THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO THE
25 FEDERAL ACT AND DEMONSTRATES THAT THE EXPORTING NATION'S
26 REGULATORY SYSTEM IS AS STRINGENT AS THE SYSTEM IN THE UNITED
27 STATES OR OTHERWISE ENSURES THE SAFETY, PURITY, AND POTENCY OF

1 THE PRESCRIPTION DRUGS FROM THE EXPORTING NATION. THE EVIDENCE
2 MUST COMPARE THE REGULATIONS FOR:

3 (I) SECURING THE SUPPLY CHAIN;

4 (II) PRESCRIPTION DRUG MANUFACTURING;

5 (III) PRESCRIPTION DRUG LABELING; AND

6 (IV) PRESCRIPTION DRUG TRACKING AND TRACING.

7 (2) IF, UPON THE SATISFACTION OF THE CONDITIONS DESCRIBED IN
8 SUBSECTION (1) OF THIS SECTION, THE STATE DEPARTMENT DECIDES TO
9 EXPAND THE PROGRAM TO ALLOW A MANUFACTURER, WHOLESALE
10 DISTRIBUTOR, OR PHARMACY FROM A NATION OTHER THAN CANADA TO
11 EXPORT PRESCRIPTION DRUGS INTO THE STATE UNDER THE PROGRAM, THE
12 EXECUTIVE DIRECTOR OF THE STATE DEPARTMENT SHALL NOTIFY THE
13 PRESIDENT OF THE SENATE AND THE SPEAKER OF THE HOUSE OF
14 REPRESENTATIVES, AS WELL AS THE HEALTH AND HUMAN SERVICES
15 COMMITTEE OF THE SENATE AND THE HEALTH AND INSURANCE COMMITTEE
16 OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES, OF
17 THE STATE DEPARTMENT'S INTENT TO DO SO. THE EXECUTIVE DIRECTOR
18 SHALL PROVIDE THE NOTICE AT LEAST THIRTY DAYS BEFORE THE PROGRAM
19 IS EXPANDED, AND THE NOTICE MAY INCLUDE ANY RECOMMENDATIONS OF
20 THE STATE DEPARTMENT FOR LEGISLATION TO AMEND THIS PART 2 TO
21 REFLECT THE EXPANSION OF THE PROGRAM.

22 **SECTION 2. Act subject to petition - effective date.** This act
23 takes effect at 12:01 a.m. on the day following the expiration of the
24 ninety-day period after final adjournment of the general assembly (August
25 5, 2020, if adjournment sine die is on May 6, 2020); except that, if a
26 referendum petition is filed pursuant to section 1 (3) of article V of the
27 state constitution against this act or an item, section, or part of this act

1 within such period, then the act, item, section, or part will not take effect
2 unless approved by the people at the general election to be held in
3 November 2020 and, in such case, will take effect on the date of the
4 official declaration of the vote thereon by the governor.