Second Regular Session Seventy-second General Assembly STATE OF COLORADO

REENGROSSED

This Version Includes All Amendments Adopted in the House of Introduction SENATE BILL 20-119

LLS NO. 20-0742.01 Richard Sweetman x4333

SENATE SPONSORSHIP

Ginal, Bridges, Garcia, Gonzales, Lee, Pettersen, Rodriguez, Winter

Jaquez Lewis,

HOUSE SPONSORSHIP

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

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



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:

SECTION 1. In Colorado Revised Statutes, add 25.5-2.5-208 as

- 3 follows:
- 4

2

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 THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR (a) 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;

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

(d) THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR
PHARMACY IS LOCATED IN A NATION THAT IS APPROVED TO EXPORT
PRESCRIPTION DRUGS INTO COLORADO BY THE UNITED STATES
SECRETARY OF HEALTH AND HUMAN SERVICES OR BY ANOTHER
AUTHORITY THAT IS DESIGNATED FOR SUCH PURPOSE BY FEDERAL <u>LAW</u>;
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 <u>MUST COMPARE THE REGULATIONS FOR:</u>
- 3 <u>(I) SECURING THE SUPPLY CHAIN;</u>
- 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.

SECTION 2. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 5, 2020, if adjournment sine die is on May 6, 2020); except that, if a 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 within such period, then the act, item, section, or part will not take effect
 unless approved by the people at the general election to be held in
 November 2020 and, in such case, will take effect on the date of the
 official declaration of the vote thereon by the governor.