SENATE BILL 21-123

BY SENATOR(S) Ginal and Coram, Buckner, Danielson, Fields, Gonzales, Jaquez Lewis, Kolker, Lee, Pettersen, Priola, Story, Winter, Garcia; also REPRESENTATIVE(S) McCormick and Lynch, Bernett, Bockenfeld, Cutter, Daugherty, Duran, Esgar, Exum, Gonzales-Gutierrez, Herod, Hooton, Jackson, Jodeh, Kennedy, Kipp, Lontine, McCluskie, Michaelson Jenet, Mullica, Ortiz, Ricks, Roberts, Sirota, Titone, Valdez A., Woodrow, Young.

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

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

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

(a) The people of the United States pay the highest prescription drug prices in the world, to the detriment of Colorado consumers, employers, and the state;

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(b) The cost of prescription drugs continues to rise faster than any other major component of health care, contributing to the affordability challenge faced by Colorado consumers, employers, and the state;

(c) Given the COVID-19 pandemic and the resulting economic downturn, the affordability of prescription drugs is more important than ever in the state of Colorado;

(d) In 2019, the general assembly enacted, and the governor subsequently signed into law, Senate Bill 19-005, which created the Canadian prescription drug importation program in the department of health care policy and financing, which program requires the department, upon approval of the program by the United States secretary of health and human services, to access lower-priced prescription drugs in Canada; and

(e) Many other countries have even lower prescription drug prices than Canada, as well as different supplies of specific drugs.

(2) Therefore, the general assembly declares that by accessing additional countries' drug supplies through Colorado's drug importation program, Colorado could even further increase access and cost savings associated with the program.

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

25.5-2.5-208. Expansion of program to include additional foreign suppliers - federal action required - notice to general assembly. (1) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE CONTRARY, THE STATE 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:

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

(b) A VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT,

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HAS IDENTIFIED THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR PHARMACY AS A SUPPLIER THAT SATISFIES THE REQUIREMENTS OF THE PROGRAM AND THAT WILL EXPORT PRESCRIPTION DRUGS AT PRICES THAT WILL PROVIDE COST SAVINGS TO THE STATE;

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

(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 LAW; AND

(e) THE STATE DEPARTMENT SUBMITS EVIDENCE TO THE PRESIDENT OF THE SENATE, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES, WHICH EVIDENCE COMPARES THE EXPORTING NATION'S REGULATORY SYSTEM FOR PRESCRIPTION DRUGS TO THE REGULATORY SYSTEM FOR PRESCRIPTION DRUGS ADMINISTERED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO THE FEDERAL ACT AND DEMONSTRATES THAT THE EXPORTING NATION'S REGULATORY SYSTEM IS AS STRINGENT AS THE SYSTEM IN THE UNITED STATES OR OTHERWISE ENSURES THE SAFETY, PURITY, AND POTENCY OF THE PRESCRIPTION DRUGS FROM THE EXPORTING NATION. THE EVIDENCE MUST COMPARE THE REGULATIONS FOR:

(I) SECURING THE SUPPLY CHAIN FOR PRESCRIPTION DRUGS;

(II) PRESCRIPTION DRUG MANUFACTURING;

(III) PRESCRIPTION DRUG LABELING; AND

(IV) PRESCRIPTION DRUG TRACKING AND TRACING.

(2) IF, UPON THE SATISFACTION OF THE CONDITIONS DESCRIBED IN SUBSECTION (1) OF THIS SECTION, THE STATE DEPARTMENT DECIDES TO

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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, THE EXECUTIVE DIRECTOR SHALL NOTIFY THE PRESIDENT OF THE SENATE, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AND 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 STATE DEPARTMENT'S INTENT TO DO SO. THE EXECUTIVE DIRECTOR SHALL PROVIDE THE NOTICE AT LEAST THIRTY DAYS BEFORE THE PROGRAM IS EXPANDED, AND THE NOTICE MAY INCLUDE ANY RECOMMENDATIONS OF THE STATE DEPARTMENT FOR LEGISLATION TO AMEND THIS PART 2 TO REFLECT THE EXPANSION OF THE PROGRAM.

(3) IF THE STATE DEPARTMENT EXPANDS THE PROGRAM IN ACCORDANCE WITH THIS SECTION, AN ELIGIBLE IMPORTER MAY IMPORT A PRESCRIPTION DRUG FROM A FOREIGN SUPPLIER PURSUANT TO THIS SECTION IF THE DRUG THAT IS TO BE IMPORTED IS A PRESCRIPTION DRUG, AS DEFINED IN 21 U.S.C. SEC. 384 (a)(3).

SECTION 3. 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; 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 2022 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Leroy M. Garcia PRESIDENT OF THE SENATE

Alec Garnett SPEAKER OF THE HOUSE OF REPRESENTATIVES

le'd-Markweep **Robin Jones**

Cindi L. Markwell SECRETARY OF THE SENATE

CHIEF CLERK OF THE HOUSE OF REPRESENTATIVES

26,2021 at APPROVE 12:25pm (Date and Time) Jared & Polis GOVERNOR OF THE \$TATE OF COLORADO