Second Regular Session
Seventy-first General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 18-0509.01 Kip Kolkmeier x4510 **SENATE BILL 18-080**

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A BILL FOR AN ACT

CONCERNING WHOLESALE IMPORTATION OF PHARMACEUTICALS FROM CANADA FOR RESALE TO COLORADO RESIDENTS.

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) must design a program to import prescription pharmaceuticals from Canada for sale to Colorado consumers. The program design must ensure both drug safety and cost savings for Colorado consumers. The department must 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 meeting the requirements of federal law to import Canadian pharmaceutical products.

If the secretary approves the program, the department must implement the program. The department must adopt a funding mechanism to cover the program's administrative costs, and the department must 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) Citizens of the United States pay some of the highest prescription drug prices in the world. It is estimated that United States consumers pay twice as much as Canadian consumers for patented prescription drugs and twenty percent more for generic drugs.

(b) 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. The secretary is authorized to certify a Canadian prescription drug importation program if the program is both safe and less costly for United States consumers.

(c) While importing prescription drugs would be less costly, there are consumer health and safety risks when individuals procure drugs on their own through internet pharmacies. The source, quality, and purity of prescription medications 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. The United States and Canada have had a memorandum of understanding regarding pharmaceutical regulatory cooperation since 1973.

(e) Title II of the federal "Drug Quality and Security Act", Pub.L.

113-54, referred to as the "Drug Supply Chain Security Act", has significantly improved drug security and safety through a system of pharmaceutical product track-and-trace procedures;

(f) The state of Colorado can ensure that wholesale importation of prescription drugs from Canada into Colorado will be safe and less expensive for Colorado consumers; and

(g) A wholesale drug importation program for the exclusive benefit of Colorado residents should be designed and implemented to allow Colorado consumers access to safe and less expensive prescription drugs.

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

PART 2

WHOLESALE IMPORTATION OF PRESCRIPTION DRUGS

25.5-2.5-201. Short title. THE SHORT TITLE OF THIS PART 2 IS THE "COLORADO WHOLESALE IMPORTATION OF PRESCRIPTION DRUGS ACT".

25.5-2.5-202. Definitions. AS USED IN THIS PART 2, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "ACTUAL ACQUISITION COST" MEANS THE PRICE PAID FOR AN IMPORTED PHARMACEUTICAL PRODUCT BY A WHOLESALER UNDER THE IMPORTATION PROGRAM.

(2) "CARRIER" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-102 (8).

(3) "IMPORTATION PROGRAM" MEANS A PROGRAM ADMINISTERED BY THE STATE DEPARTMENT IN ACCORDANCE WITH THIS PART 2 TO IMPORT PRESCRIPTION PHARMACEUTICAL PRODUCTS FROM A LICENSED CANADIAN SUPPLIER SOLELY FOR DISTRIBUTION TO PARTICIPATING IN-STATE

PHARMACIES AND OTHER LICENSED PROVIDERS FOR THE EXCLUSIVE PURPOSE OF DISPENSING TO COLORADO RESIDENTS WITH A VALID PRESCRIPTION.

(4) "SECRETARY" MEANS THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

25.5-2.5-203. Wholesale drug importation program - state department to design program - program requirements. (1) THE STATE DEPARTMENT SHALL DESIGN A WHOLESALE DRUG IMPORTATION PROGRAM. THE STATE DEPARTMENT SHALL CONSULT WITH RELEVANT STAKEHOLDERS AND FEDERAL AGENCIES TO DESIGN AN IMPORTATION PROGRAM THAT ADDRESSES THE REQUIREMENTS OF 21 U.S.C. SEC. 384 AND INCLUDES COMPLETE INFORMATION ON HOW THE IMPORTATION PROGRAM WILL:

(a) ENSURE DRUG SAFETY AND COST SAVINGS FOR COLORADO CONSUMERS;

(b) MEET THE REQUIREMENTS FOR WHOLESALER LICENSES IN ACCORDANCE WITH PART 3 OF ARTICLE 42.5 OF TITLE 12;

(c) SELECT QUALIFIED CANADIAN PHARMACEUTICAL SUPPLIERS LICENSED AND REGULATED UNDER CANADIAN NATIONAL OR PROVINCIAL LAWS;

(d) SAMPLE IMPORTED DRUGS FOR PURITY, CHEMICAL COMPOSITION, AND POTENCY TO THE EXTENT REQUIRED BY FEDERAL LAW;

(e) DETERMINE WHICH PRESCRIPTION PHARMACEUTICAL PRODUCTS WILL BE IMPORTED AND ENSURE THAT ALL IMPORTED PRODUCTS ARE SIGNIFICANTLY LESS COSTLY TO COLORADO CONSUMERS THAN THE UNITED STATES-LICENSED EQUIVALENT PHARMACEUTICAL PRODUCTS;

(f) ENSURE THAT IMPORTED PRODUCTS WILL NOT BE DISTRIBUTED,

DISPENSED, OR SOLD OUTSIDE OF COLORADO;

(g) ENSURE THAT PARTICIPATING PHARMACIES AND OTHER LICENSED PROVIDERS CHARGE INDIVIDUAL CONSUMERS, CARRIERS, AND OTHER PAYORS NO MORE THAN THE LIMIT ESTABLISHED BY THE STATE DEPARTMENT FOR THE IMPORTED PHARMACEUTICAL PRODUCT;

(h) ENSURE THAT PAYMENTS BY CARRIERS FOR REIMBURSEMENT OF THE PRODUCT COMPONENT OF ANY CLAIM IS NO MORE THAN THE LIMIT ESTABLISHED BY THE STATE DEPARTMENT FOR THE IMPORTED PHARMACEUTICAL PRODUCT;

(i) ENSURE THAT CARRIERS MAINTAIN UP-TO-DATE FORMULARIES AND CLAIMS PAYMENT SYSTEMS FOR THEIR PARTICIPATING HEALTH PLANS CONSISTENT WITH THE IMPORTATION PROGRAM;

(j) ENSURE THAT PARTICIPATING CARRIERS BASE THEIR HEALTH PLAN COINSURANCE AND PATIENT COST-SHARING ON PRICES THAT ARE NO HIGHER THAN THE LIMIT ESTABLISHED BY THE STATE DEPARTMENT FOR THE IMPORTED PHARMACEUTICAL PRODUCT;

(k) ENSURE THAT PARTICIPATING CARRIERS DEMONSTRATE TO THE STATE DEPARTMENT HOW SAVINGS ON IMPORTED DRUGS ARE REFLECTED IN CUSTOMER PREMIUMS FOR THE CARRIERS' HEALTH PLANS;

(l) SET A MAXIMUM PROFIT MARGIN, STATED IN TERMS OF A PERCENTAGE ABOVE THE ACTUAL ACQUISITION COST, THAT WHOLESALERS, DISTRIBUTORS, AND PHARMACIES PARTICIPATING IN THE IMPORTATION PROGRAM MAY EARN;

(m) EXCLUDE GENERIC PRODUCTS IF THE IMPORTATION OF THE PRODUCTS WOULD VIOLATE UNITED STATES PATENT LAWS APPLICABLE TO UNITED STATES BRANDED PRODUCTS;

(n) COMPLY WITH THE REQUIREMENTS OF 21 U.S.C. SEC. 360eee

TO 360eee-4 PERTAINING TO THE TRACK-AND-TRACE REQUIREMENTS AS ENACTED IN TITLE II OF THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB.L. 113-54;

(o) DETERMINE A METHOD FOR COVERING THE ADMINISTRATIVE COSTS OF THE IMPORTATION PROGRAM. THE METHOD MAY BE A FEE ON EACH PRESCRIPTION OR ANY OTHER APPROPRIATE METHOD AS DETERMINED BY THE STATE DEPARTMENT, BUT THE STATE DEPARTMENT SHALL NOT REQUIRE A FEE IN AN AMOUNT THAT THE STATE DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

(p) DETERMINE THE MOST COST-EFFECTIVE PRODUCTS TO INCLUDE IN THE IMPORTATION PROGRAM.

25.5-2.5-204. Draft report - public hearings - final report. (1) NO LATER THAN JANUARY 1, 2019, THE STATE DEPARTMENT SHALL PREPARE A DRAFT REPORT THAT FULLY DESCRIBES THE PROPOSED WHOLESALE DRUG IMPORTATION PROGRAM. NO LATER THAN JANUARY 1, 2019, THE STATE DEPARTMENT SHALL POST THE DRAFT REPORT ON ITS WEBSITE AND SUBMIT THE DRAFT REPORT TO THE JOINT BUDGET COMMITTEE OF THE GENERAL ASSEMBLY, THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, THE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

(2) THE STATE DEPARTMENT SHALL HOLD AT LEAST TWO PUBLIC HEARINGS TO RECEIVE COMMENTS ON THE DRAFT REPORT. THE HEARINGS MUST BE HELD NO LESS THAN FIFTEEN DAYS, NOR MORE THAN FORTY-FIVE DAYS, AFTER THE DATE THE STATE DEPARTMENT POSTED THE REPORT ON THE STATE DEPARTMENT'S WEBSITE. THE STATE DEPARTMENT SHALL HOLD

AT LEAST ONE HEARING IN THE DENVER METROPOLITAN AREA AND AT LEAST ONE HEARING IN WESTERN COLORADO.

(3) FOLLOWING THE PUBLIC HEARINGS REQUIRED BY THIS SECTION, AND NO LATER THAN APRIL 15, 2019, THE STATE DEPARTMENT SHALL PREPARE A FINAL REPORT THAT FULLY DESCRIBES THE IMPORTATION PROGRAM, POST THE FINAL REPORT ON ITS WEBSITE, AND SUBMIT THE FINAL REPORT TO THE JOINT BUDGET COMMITTEE OF THE GENERAL ASSEMBLY, THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, THE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

25.5-2.5-205. Request for secretary's approval - effect of approval - notice to revisor of statutes. (1) NO LATER THAN MAY 1, 2019, THE EXECUTIVE DIRECTOR SHALL SUBMIT A FORMAL REQUEST TO THE SECRETARY FOR REVIEW AND APPROVAL OF THE IMPORTATION PROGRAM. THE EXECUTIVE DIRECTOR SHALL PROVIDE INFORMATION REQUESTED BY THE SECRETARY DURING THE SECRETARY'S REVIEW. THE EXECUTIVE DIRECTOR IS AUTHORIZED TO MODIFY THE IMPORTATION PROGRAM DESIGN IF REQUIRED BY THE SECRETARY SO LONG AS THE MODIFICATIONS ARE CONSISTENT WITH THIS PART 2.

(2) SECTIONS 25.5-2.5-206 TO 25.5-2.5-209 TAKE EFFECT IF THE SECRETARY APPROVES THE IMPORTATION PROGRAM BY DETERMINING THAT THE PROGRAM COMPLIES WITH 21 U.S.C. SEC. 384. THE EXECUTIVE DIRECTOR SHALL NOTIFY THE REVISOR OF STATUTES IN WRITING THAT THE SECRETARY HAS APPROVED THE IMPORTATION PROGRAM BY E-MAILING THE NOTICE TO REVISOROFSTATUTES.GA@STATE.CO.US. SECTIONS

25.5-2.5-206 TO 25.5-2.5-209 TAKE EFFECT UPON:

(a) THE DATE IDENTIFIED IN THE NOTICE THAT THE SECRETARY HAS APPROVED THE IMPORTATION PROGRAM; OR

(b) THE DATE OF THE NOTICE TO THE REVISOR OF STATUTES IF THE NOTICE DOES NOT SPECIFY A DIFFERENT DATE.

25.5-2.5-206. Importation program authorized - rules. (1) UPON APPROVAL BY THE SECRETARY, THE STATE DEPARTMENT SHALL ADMINISTER AN IMPORTATION PROGRAM.

(2) THE STATE DEPARTMENT SHALL APPROVE A METHOD OF FINANCING THE ADMINISTRATIVE COSTS OF THE IMPORTATION PROGRAM, WHICH METHOD MAY INCLUDE REQUIRING A FEE ON EACH PRESCRIPTION SOLD THROUGH THE IMPORTATION PROGRAM OR ANY OTHER APPROPRIATE METHOD DETERMINED BY THE STATE DEPARTMENT TO FINANCE ADMINISTRATIVE COSTS. THE STATE DEPARTMENT SHALL NOT REQUIRE A FEE IN AN AMOUNT THAT THE STATE DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

(3) THE EXECUTIVE DIRECTOR SHALL PROMULGATE RULES, IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, AS NECESSARY FOR THE ADMINISTRATION OF THIS PART 2.

25.5-2.5-207. Importation program implementation. (1) TO IMPLEMENT THE IMPORTATION PROGRAM, THE STATE DEPARTMENT SHALL:

(a) BASED ON THE RELEVANT CRITERIA CONTAINED IN THE IMPORTATION PROGRAM DESIGN, DEVELOP AND ISSUE A REQUEST FOR COMPETITIVE BIDS TO SELECT A PHARMACEUTICAL WHOLESALER OR WHOLESALERS LICENSED BY THE STATE BOARD OF PHARMACY IN ACCORDANCE WITH PART 3 OF ARTICLE 42.5 OF TITLE 12. THE STATE DEPARTMENT SHALL SELECT THE LICENSED PHARMACEUTICAL

WHOLESALER OR WHOLESALERS BEST SUITED TO IMPORT AND DISTRIBUTE DRUGS UNDER THE IMPORTATION PROGRAM. IN ADDITION TO ANY OTHER TERMS REQUIRED BY THE STATE DEPARTMENT, A WHOLESALER MUST AGREE TO DO THE FOLLOWING:

(I) DEVELOP A REGISTRATION SYSTEM TO ENROLL DISTRIBUTORS, PHARMACIES AND OTHER LICENSED PROVIDERS, AND CARRIERS IN THE IMPORTATION PROGRAM;

(II) ESTABLISH AN OUTREACH AND MARKETING PLAN TO FOSTER PUBLIC AWARENESS OF THE IMPORTATION PROGRAM; AND

(III) ESTABLISH A TELEPHONE HOTLINE AND CREATE AN INTERNET PORTAL TO ADDRESS QUESTIONS REGARDING THE IMPORTATION PROGRAM AND TO ASSIST PHARMACIES AND OTHER LICENSED PROVIDERS AND CARRIERS IN REGISTERING FOR THE IMPORTATION PROGRAM.

(b) REQUIRE PARTICIPATING PHARMACIES OR OTHER LICENSED PROVIDERS TO CONTRACT DIRECTLY WITH THE PHARMACEUTICAL WHOLESALER OR WHOLESALERS SELECTED BY THE STATE DEPARTMENT.

(c) REQUIRE PARTICIPATING CANADIAN SUPPLIERS TO CONTRACT DIRECTLY WITH THE PHARMACEUTICAL WHOLESALER OR WHOLESALERS SELECTED BY THE STATE DEPARTMENT.

(d) ESTABLISH AND MAKE PUBLICLY AVAILABLE THE INITIAL LIST OF IMPORTED PHARMACEUTICAL PRODUCTS COVERED BY THE IMPORTATION PROGRAM AND THE ACTUAL ACQUISITION COST FOR EACH LISTED PHARMACEUTICAL PRODUCT. THE STATE DEPARTMENT MAY ADD OR REMOVE PHARMACEUTICAL PRODUCTS FROM THE IMPORTATION PROGRAM AT ANY TIME AND SHALL UPDATE THE PUBLIC LIST OF INCLUDED PRODUCTS AT LEAST QUARTERLY.

25.5-2.5-208. Report to the general assembly.

(1) NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), ON OR BEFORE JANUARY 1, 2021, AND EACH JANUARY 1 THEREAFTER, THE EXECUTIVE DIRECTOR SHALL SUBMIT A REPORT TO THE JOINT BUDGET COMMITTEE OF THE GENERAL ASSEMBLY, THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, THE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES. THE REPORT MUST INCLUDE THE FOLLOWING:

(a) THE SPECIFIC PHARMACEUTICAL PRODUCTS IMPORTED THROUGH THE IMPORTATION PROGRAM;

(b) THE NUMBER OF PARTICIPATING WHOLESALERS, DISTRIBUTORS, PHARMACIES AND OTHER LICENSED PROVIDERS, AND CARRIERS;

(c) THE NUMBER OF PRESCRIPTIONS DISPENSED THROUGH THE IMPORTATION PROGRAM;

(d) THE ESTIMATED SAVINGS TO CONSUMERS, CARRIERS, AND EMPLOYERS RESULTING FROM THE IMPORTATION PROGRAM;

(e) INFORMATION REQUIRED TO BE COLLECTED BY SECTION 25.5-2.5-209; AND

(f) ANY OTHER INFORMATION THE STATE DEPARTMENT DEEMS RELEVANT.

25.5-2.5-209. Monitoring anticompetitive behavior. THE STATE DEPARTMENT SHALL, IN CONSULTATION WITH THE ATTORNEY GENERAL, IDENTIFY THE POTENTIAL FOR ANTICOMPETITIVE BEHAVIOR IN INDUSTRIES THAT WOULD BE AFFECTED BY THE IMPORTATION PROGRAM. THE STATE DEPARTMENT SHALL INCLUDE INFORMATION ON POTENTIAL ANTICOMPETITIVE BEHAVIOR IN THE REPORT REQUIRED BY SECTION

25.5-2.5-208 (1).

SECTION 3. 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 4. In Colorado Revised Statutes, 25.5-2.5-103, **amend** (3) as follows:

25.5-2.5-103. Lower-cost prescription drugs - information - research - reporting. (3) The state department shall report annually to the health and human services committees of the house of representatives and the senate, or any successor committees, concerning the provisions of this ~~article~~ PART 1.

SECTION 5. 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 8, 2018, if adjournment sine die is on May 9, 2018); 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 2018 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.