First Regular Session
Seventy-second General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 19-0406.01 Richard Sweetman x4333 **SENATE BILL 19-005**

SENATE SPONSORSHIP

Rodriguez and Ginal,

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Jaquez Lewis,

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

CONCERNING WHOLESALE IMPORTATION OF PRESCRIPTION PHARMACEUTICAL PRODUCTS 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) shall design a program to import 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 Security Act", has significantly improved drug security and safety through

a system of pharmaceutical product track-and-trace procedures; and

(f) A wholesale drug importation program for the exclusive benefit of Colorado residents should be designed and implemented to provide 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 PRESCRIPTION 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.

(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) ON OR BEFORE JANUARY 1, 2020, THE STATE DEPARTMENT, IN CONSULTATION WITH RELEVANT STAKEHOLDERS AND FEDERAL AGENCIES, SHALL DESIGN AN IMPORTATION PROGRAM TO IMPORT PRESCRIPTION PHARMACEUTICAL

PRODUCTS FROM ONE OR MORE LICENSED CANADIAN SUPPLIERS SOLELY FOR DISTRIBUTION TO PARTICIPATING IN-STATE PHARMACIES AND OTHER LICENSED PROVIDERS FOR THE EXCLUSIVE PURPOSE OF DISPENSING PRESCRIPTION PHARMACEUTICAL PRODUCTS TO COLORADO RESIDENTS WITH VALID PRESCRIPTIONS. IN DESIGNING THE IMPORTATION PROGRAM, THE STATE DEPARTMENT SHALL ENSURE THAT THE IMPORTATION PROGRAM SATISFIES THE REQUIREMENTS OF 21 U.S.C. SEC. 384. THE STATE DEPARTMENT SHALL INCLUDE IN THE DESIGN OF THE IMPORTATION PROGRAM INFORMATION INDICATING 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 THAT ARE LICENSED AND REGULATED UNDER CANADIAN NATIONAL OR PROVINCIAL LAWS;

(d) SAMPLE IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCTS 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 EQUIVALENT UNITED STATES-LICENSED PRESCRIPTION PHARMACEUTICAL PRODUCTS;

(f) ENSURE THAT IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCTS ARE NOT DISTRIBUTED, DISPENSED, OR SOLD OUTSIDE OF

COLORADO;

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

(h) ENSURE THAT EACH PAYMENT MADE BY A CARRIER FOR REIMBURSEMENT OF THE PRODUCT COMPONENT OF ANY CLAIM DOES NOT EXCEED THE LIMIT ESTABLISHED BY THE STATE DEPARTMENT FOR THE IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCT FOR WHICH THE PAYMENT IS MADE;

(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 EACH IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCT;

(k) ENSURE THAT PARTICIPATING CARRIERS DEMONSTRATE TO THE STATE DEPARTMENT HOW SAVINGS ON IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCTS ARE REFLECTED IN 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, WHICH METHOD MAY INCLUDE A FEE IMPOSED ON EACH PRESCRIPTION PHARMACEUTICAL PRODUCT SOLD THROUGH THE PROGRAM 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; AND

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

25.5-2.5-204. Draft report - public hearings - final report - repeal. (1) ON OR BEFORE JANUARY 1, 2020, THE STATE DEPARTMENT SHALL:

(a) PREPARE AND PUBLICLY RELEASE A DRAFT REPORT THAT FULLY DESCRIBES THE PROPOSED IMPORTATION PROGRAM; AND

(b) POST THE DRAFT REPORT ON ITS WEBSITE AND SUBMIT THE DRAFT REPORT TO THE JOINT BUDGET COMMITTEE, 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 AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

(2) NOT LESS THAN FIFTEEN DAYS NOR MORE THAN FORTY-FIVE

DAYS AFTER THE DATE THE STATE DEPARTMENT POSTS THE REPORT ON THE STATE DEPARTMENT'S WEBSITE, THE STATE DEPARTMENT SHALL HOLD AT LEAST TWO PUBLIC HEARINGS TO RECEIVE COMMENTS ON THE DRAFT REPORT. AT LEAST ONE HEARING MUST BE HELD IN THE DENVER METROPOLITAN AREA, AND AT LEAST ONE HEARING MUST BE HELD IN WESTERN COLORADO.

(3) FOLLOWING THE PUBLIC HEARINGS REQUIRED BY SUBSECTION (2) OF THIS SECTION, AND NO LATER THAN APRIL 15, 2020, THE STATE DEPARTMENT SHALL PREPARE AND PUBLICLY RELEASE A FINAL REPORT THAT FULLY DESCRIBES THE IMPORTATION PROGRAM. THE STATE DEPARTMENT SHALL POST THE FINAL REPORT ON ITS WEBSITE AND SUBMIT THE FINAL REPORT TO THE JOINT BUDGET COMMITTEE, 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 AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

(4) THIS SECTION IS REPEALED, EFFECTIVE MAY 1, 2020.

25.5-2.5-205. Request for secretary's approval - effect of approval - notice to revisor of statutes. (1) ON OR BEFORE MAY 1, 2020, 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 MAY MODIFY THE IMPORTATION PROGRAM DESIGN AS 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 IMPORTATION 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 ON:

(a) THE DATE SPECIFIED IN THE EXECUTIVE DIRECTOR'S NOTICE TO THE REVISOR OF STATUTES THAT THE SECRETARY HAS APPROVED THE IMPORTATION PROGRAM; OR

(b) THE DATE OF SAID NOTICE IF THE NOTICE DOES NOT SPECIFY A DIFFERENT DATE.

25.5-2.5-206. Importation program authorized - rules. (1) UPON APPROVAL BY THE SECRETARY, IN ACCORDANCE WITH SECTION 25.5-2.5-205, 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 IMPOSING A FEE ON EACH PRESCRIPTION PHARMACEUTICAL PRODUCT 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 PROPOSALS FROM ONE OR MORE PHARMACEUTICAL 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 WHOLESALERS BEST SUITED TO IMPORT PRESCRIPTION PHARMACEUTICAL PRODUCTS UNDER THE IMPORTATION PROGRAM. IN ADDITION TO ANY OTHER TERMS REQUIRED BY THE STATE DEPARTMENT, A WHOLESALER SHALL AGREE TO:

(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, 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 WHOLESALERS SELECTED BY THE STATE DEPARTMENT;

(c) REQUIRE PARTICIPATING CANADIAN SUPPLIERS TO CONTRACT DIRECTLY WITH THE PHARMACEUTICAL WHOLESALERS SELECTED BY THE STATE DEPARTMENT; AND

(d) ESTABLISH AND MAKE PUBLICLY AVAILABLE THE INITIAL LIST OF IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCTS COVERED BY THE IMPORTATION PROGRAM AND THE ACTUAL ACQUISITION COST FOR EACH LISTED PRESCRIPTION PHARMACEUTICAL PRODUCT. AT ANY TIME, THE STATE DEPARTMENT MAY ADD TO OR REMOVE FROM THE IMPORTATION PROGRAM PRESCRIPTION PHARMACEUTICAL PRODUCTS. THE STATE DEPARTMENT 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, 2022, AND EACH JANUARY 1 THEREAFTER, THE EXECUTIVE DIRECTOR SHALL SUBMIT A REPORT TO THE JOINT BUDGET COMMITTEE, 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 AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

(2) THE REPORT DESCRIBED IN SUBSECTION (1) OF THIS SECTION MUST INCLUDE THE FOLLOWING:

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

(b) THE NUMBER OF WHOLESALERS, DISTRIBUTORS, PHARMACIES AND OTHER LICENSED PROVIDERS, AND CARRIERS THAT ARE PARTICIPATING IN THE IMPORTATION PROGRAM;

(c) THE NUMBER OF IMPORTED PRESCRIPTION PHARMACEUTICAL PRODUCTS DISPENSED AND SOLD THROUGH THE IMPORTATION PROGRAM;

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

(e) THE INFORMATION COLLECTED PURSUANT TO 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 THE PHARMACEUTICAL INDUSTRY AND OTHER HEALTH CARE INDUSTRIES THAT ARE AFFECTED BY THE IMPORTATION PROGRAM. THE STATE DEPARTMENT SHALL INCLUDE INFORMATION CONCERNING POTENTIAL ANTICOMPETITIVE BEHAVIOR IN THE REPORT REQUIRED BY SECTION 25.5-2.5-208.

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 PUBLIC health CARE and human services ~~committees~~ COMMITTEE of the house of representatives and THE HEALTH AND HUMAN SERVICES COMMITTEE OF 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 2, 2019, if adjournment sine die is on May 3, 2019); 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.