First Regular Session
Seventy-second General Assembly
STATE OF COLORADO

REREVISED
This Version Includes All Amendments Adopted in the Second House

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

SENATE SPONSORSHIP

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Senate Committees
Health & Human Services
Appropriations

House Committees
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A BILL FOR AN ACT

CONCERNING WHOLESALE IMPORTATION OF PRESCRIPTION PHARMACEUTICAL PRODUCTS FROM CANADA FOR RESALE TO COLORADO RESIDENTS, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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

HOUSE Amended 3rd Reading May 2, 2019

HOUSE Amended 2nd Reading May 1, 2019

SENATE 3rd Reading Unamended March 25, 2019

SENATE Amended 2nd Reading March 22, 2019

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, 25.5-1-201, **amend** (1) introductory portion, (1)(f), and (1)(g); and **add** (1)(h) as follows:

25.5-1-201. Programs to be administered by the department of health care policy and financing. (1) ~~Programs to be administered and functions to be performed by~~ The department of health care policy and financing shall ~~be as follows~~ ADMINISTER THE FOLLOWING PROGRAMS AND PERFORM THE FOLLOWING FUNCTIONS:

(f) The old age pension health and medical care program, as specified in section 25.5-2-101; ~~and~~

(g) Programs, services, and supports for persons with intellectual and developmental disabilities, as specified in article 10 of this ~~title~~ TITLE 25.5; AND

(h) ANY PROGRAM CONCERNING THE WHOLESALE IMPORTATION OF PRESCRIPTION DRUGS PURSUANT TO PART 2 OF ARTICLE 2.5 OF THIS TITLE 25.5.

SECTION 3. In Colorado Revised Statutes, **add** part 2 to article 2.5 of title 25.5 as follows:

PART 2

CANADIAN PRESCRIPTION DRUG

IMPORTATION PROGRAM

25.5-2.5-201. Short title. THE SHORT TITLE OF THIS PART 2 IS THE

"DR. IRENE AGUILAR CANADIAN PRESCRIPTION DRUG IMPORTATION ACT".

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

(1) "CANADIAN SUPPLIER" MEANS A MANUFACTURER, WHOLESALE DISTRIBUTOR, OR PHARMACY THAT IS APPROPRIATELY LICENSED OR PERMITTED UNDER CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS TO MANUFACTURE, DISTRIBUTE, OR DISPENSE PRESCRIPTION DRUGS.

(2) "ELIGIBLE IMPORTER" MEANS AN IMPORTER THAT IS DESCRIBED IN SECTION 25.5-2.5-204 (3).

(3) "FEDERAL ACT" MEANS THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. 301 ET SEQ.

(4) "MEDICAID PHARMACY" MEANS A PHARMACY REGISTERED PURSUANT TO SECTION 12-42.5-117 THAT HAS A PROVIDER AGREEMENT IN EFFECT WITH THE STATE DEPARTMENT AND IS IN GOOD STANDING WITH THE STATE DEPARTMENT.

(5) "PHARMACIST" MEANS A PERSON WHO HOLDS AN ACTIVE AND UNENCUMBERED LICENSE TO PRACTICE PHARMACY PURSUANT TO SECTION 12-42.5-112.

(6) "PRESCRIPTION DRUG" HAS THE SAME MEANING SET FORTH IN SECTION 12-42.5-102 (34); EXCEPT THAT THE TERM INCLUDES ONLY DRUGS THAT ARE INTENDED FOR HUMAN USE.

(7) "PROGRAM" MEANS THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM CREATED IN SECTION 25.5-2.5-203.

(8) "VENDOR" MEANS A VENDOR WITH WHICH THE STATE DEPARTMENT CONTRACTS FOR THE PROVISION OF SERVICES UNDER THE

PROGRAM PURSUANT TO SECTION 25.5-2.5-203 (1).

25.5-2.5-203. Canadian prescription drug importation program - created - importation process - contract with vendor - vendor duties. (1) THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM IS CREATED IN THE STATE DEPARTMENT. UPON RECEIVING APPROVAL OF THE PROGRAM AS DESCRIBED IN SECTION 25.5-2.5-205 (1), THE STATE DEPARTMENT SHALL CONTRACT WITH ONE OR MORE VENDORS TO PROVIDE SERVICES UNDER THE PROGRAM. FOR THREE YEARS FOLLOWING THE EFFECTIVE DATE OF THIS PART 2, THE SELECTION OF ANY VENDOR PURSUANT TO THIS SUBSECTION (1) IS EXEMPT FROM THE REQUIREMENTS OF THE PROCUREMENT CODE, ARTICLES 101 TO 112 OF TITLE 24.

(2) (a) EACH VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT AND ANY OTHER VENDORS, SHALL ESTABLISH A WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST THAT IDENTIFIES THE PRESCRIPTION DRUGS THAT HAVE THE HIGHEST POTENTIAL FOR COST SAVINGS TO THE STATE. IN DEVELOPING THE LIST, EACH VENDOR SHALL CONSIDER, AT A MINIMUM, WHICH PRESCRIPTION DRUGS WILL PROVIDE THE GREATEST COST SAVINGS TO THE STATE, INCLUDING PRESCRIPTION DRUGS FOR WHICH THERE ARE SHORTAGES, SPECIALTY PRESCRIPTION DRUGS, AND HIGH-VOLUME PRESCRIPTION DRUGS. EACH VENDOR SHALL REVISE THE LIST AT LEAST ANNUALLY AND AT THE DIRECTION OF THE STATE DEPARTMENT PURSUANT TO SUBSECTION (2)(b) OF THIS SECTION.

(b) THE STATE DEPARTMENT SHALL REVIEW THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST AT LEAST EVERY THREE MONTHS TO ENSURE THAT IT CONTINUES TO MEET THE REQUIREMENTS OF THE PROGRAM. THE STATE DEPARTMENT MAY DIRECT A VENDOR TO REVISE

THE LIST, AS NECESSARY.

(c) EACH VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT, SHALL IDENTIFY CANADIAN SUPPLIERS WHO ARE IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS AND WHO HAVE AGREED TO EXPORT PRESCRIPTION DRUGS IDENTIFIED ON THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST. EACH VENDOR SHALL VERIFY THAT SUCH CANADIAN SUPPLIERS MEET ALL OF THE REQUIREMENTS OF THE PROGRAM AND WILL EXPORT PRESCRIPTION DRUGS AT PRICES THAT WILL PROVIDE COST SAVINGS TO THE STATE. EACH VENDOR SHALL CONTRACT WITH SUCH ELIGIBLE CANADIAN SUPPLIERS, OR FACILITATE CONTRACTS BETWEEN ELIGIBLE IMPORTERS AND CANADIAN SUPPLIERS, TO IMPORT PRESCRIPTION DRUGS UNDER THE PROGRAM.

(d) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT IN DEVELOPING AND ADMINISTERING A DISTRIBUTION PROGRAM WITHIN THE PROGRAM.

(e) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT WITH THE ANNUAL REPORT DESCRIBED IN SECTION 25.5-2.5-206 AND PROVIDE ANY INFORMATION REQUESTED BY THE STATE DEPARTMENT FOR THE REPORT.

(f) EACH VENDOR SHALL ENSURE THE SAFETY AND QUALITY OF DRUGS IMPORTED UNDER THE PROGRAM, AS FOLLOWS:

(I) (A) FOR AN INITIAL IMPORTED SHIPMENT, ENSURE THAT EACH BATCH OF THE DRUG IN THE SHIPMENT IS STATISTICALLY SAMPLED AND TESTED FOR AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE FEDERAL ACT; AND

(B) FOR ANY SUBSEQUENT IMPORTED SHIPMENT, ENSURE THAT A

STATISTICALLY VALID SAMPLE OF THE SHIPMENT IS TESTED FOR AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE FEDERAL ACT.

(II) CERTIFY THAT EACH DRUG:

(A) IS APPROVED FOR MARKETING IN THE UNITED STATES AND IS NOT ADULTERATED OR MISBRANDED; AND

(B) MEETS ALL OF THE LABELING REQUIREMENTS UNDER 21 U.S.C. SEC. 352.

(III) MAINTAIN QUALIFIED LABORATORY RECORDS, INCLUDING COMPLETE DATA DERIVED FROM ALL TESTS NECESSARY TO ENSURE THAT THE DRUG IS IN COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION; AND

(IV) MAINTAIN DOCUMENTATION DEMONSTRATING THAT THE TESTING REQUIRED BY THIS SECTION WAS CONDUCTED AT A QUALIFIED LABORATORY IN ACCORDANCE WITH THE FEDERAL ACT AND ANY OTHER APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS GOVERNING LABORATORY QUALIFICATIONS.

(3) ALL TESTING REQUIRED BY THIS SECTION MUST BE CONDUCTED IN A QUALIFIED LABORATORY THAT MEETS THE STANDARDS UNDER THE FEDERAL ACT AND ANY OTHER APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS GOVERNING LABORATORY QUALIFICATIONS FOR DRUG TESTING.

(4) EACH VENDOR SHALL MAINTAIN A LIST OF ALL ELIGIBLE IMPORTERS THAT PARTICIPATE IN THE PROGRAM.

(5) EACH VENDOR SHALL ENSURE COMPLIANCE WITH TITLE II OF THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB. L. 113-54, BY ALL CANADIAN SUPPLIERS, ELIGIBLE IMPORTERS, DISTRIBUTORS, AND

OTHER PARTICIPANTS IN THE PROGRAM.

(6) EACH VENDOR SHALL PROVIDE AN ANNUAL FINANCIAL AUDIT OF ITS OPERATIONS TO THE STATE DEPARTMENT. EACH VENDOR SHALL ALSO PROVIDE QUARTERLY FINANCIAL REPORTS SPECIFIC TO THE PROGRAM AND SHALL INCLUDE INFORMATION CONCERNING THE PERFORMANCE OF ITS SUBCONTRACTORS AND VENDORS. THE STATE DEPARTMENT SHALL DETERMINE THE FORMAT AND CONTENTS OF THE REPORTS.

(7) EACH VENDOR SHALL SUBMIT EVIDENCE OF A SURETY BOND WITH ANY BID OR INITIAL CONTRACT NEGOTIATION DOCUMENTS AND SHALL MAINTAIN DOCUMENTATION OF EVIDENCE OF SUCH A BOND WITH THE STATE DEPARTMENT THROUGHOUT THE CONTRACT TERM. THE SURETY BOND MAY BE FROM THIS STATE OR ANY OTHER STATE IN THE UNITED STATES AND MUST BE IN AN AMOUNT OF AT LEAST TWENTY-FIVE THOUSAND DOLLARS. THE SURETY BOND OR COMPARABLE SECURITY ARRANGEMENT MUST INCLUDE THE STATE OF COLORADO AS A BENEFICIARY. IN LIEU OF THE SURETY BOND, A VENDOR MAY PROVIDE A COMPARABLE SECURITY AGREEMENT, SUCH AS AN IRREVOCABLE LETTER OF CREDIT OR A DEPOSIT INTO A TRUST ACCOUNT OR FINANCIAL INSTITUTION THAT INCLUDES THE STATE OF COLORADO AS A BENEFICIARY, PAYABLE TO THE STATE OF COLORADO. THE PURPOSES OF THE BOND OR OTHER SECURITY ARRANGEMENT ARE TO:

(a) ENSURE PARTICIPATION OF THE VENDOR IN ANY CIVIL OR CRIMINAL LEGAL ACTION BY THE STATE DEPARTMENT, ANY OTHER STATE AGENCY, OR PRIVATE INDIVIDUALS OR ENTITIES AGAINST THE VENDOR BECAUSE OF THE VENDOR'S FAILURE TO PERFORM UNDER THE CONTRACT, INCLUDING BUT NOT LIMITED TO CAUSES OF ACTIONS FOR PERSONAL INJURY, NEGLIGENCE, AND WRONGFUL DEATH;

(b) ENSURE PAYMENT BY THE VENDOR THROUGH THE USE OF A BOND OR OTHER COMPARABLE SECURITY ARRANGEMENT OF ANY LEGAL JUDGMENTS AND CLAIMS THAT ARE AWARDED TO THE STATE, OTHER ENTITIES ACTING ON BEHALF OF THE STATE, INDIVIDUALS, OR ORGANIZATIONS IF THE VENDOR IS ASSESSED A FINAL JUDGMENT OR OTHER MONETARY PENALTY IN A COURT OF LAW FOR A CIVIL OR CRIMINAL ACTION UNDER THE PROGRAM. THE BOND OR COMPARABLE SECURITY ARRANGEMENT MAY BE ACCESSED IF THE VENDOR FAILS TO PAY ANY JUDGMENT OR CLAIM WITHIN SIXTY DAYS AFTER FINAL JUDGMENT.

(c) ALLOW FOR CIVIL AND CRIMINAL LITIGATION CLAIMS TO BE MADE AGAINST THE BOND OR OTHER COMPARABLE SECURITY ARRANGEMENTS FOR UP TO ONE YEAR AFTER THE VENDOR'S CONTRACT UNDER THE PROGRAM HAS ENDED WITH THE STATE DEPARTMENT, THE VENDOR'S LICENSE IS NO LONGER VALID, OR THE PROGRAM HAS ENDED, WHICHEVER OCCURS LAST.

(8) EACH VENDOR SHALL MAINTAIN INFORMATION AND DOCUMENTATION SUBMITTED UNDER THIS SECTION FOR A PERIOD OF AT LEAST SEVEN YEARS.

(9) THE STATE DEPARTMENT MAY REQUIRE EACH VENDOR TO COLLECT ANY OTHER INFORMATION NECESSARY TO ENSURE THE PROTECTION OF THE PUBLIC HEALTH.

25.5-2.5-204. Eligible prescription drugs - eligible Canadian suppliers - eligible importers - distribution requirements. (1) AN ELIGIBLE IMPORTER MAY IMPORT A PRESCRIPTION DRUG FROM A CANADIAN SUPPLIER IF:

(a) THE DRUG THAT IS TO BE IMPORTED MEETS THE FEDERAL FOOD AND DRUG ADMINISTRATION'S STANDARDS RELATED TO SAFETY,

EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

(b) IMPORTING THE DRUG WOULD NOT VIOLATE FEDERAL PATENT LAWS;

(c) IMPORTING THE DRUG IS EXPECTED TO GENERATE COST SAVINGS; AND

(d) THE DRUG IS NOT:

(I) A CONTROLLED SUBSTANCE AS DEFINED IN 21 U.S.C. SEC. 802 (6);

(II) A BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC. 262 (i);

(III) AN INFUSED DRUG;

(IV) AN INTRAVENOUSLY INJECTED DRUG;

(V) A DRUG THAT IS INHALED DURING SURGERY; OR

(VI) A DRUG THAT IS A PARENTERAL DRUG, THE IMPORTATION OF WHICH IS DETERMINED BY THE FEDERAL SECRETARY OF HEALTH AND HUMAN SERVICES TO POSE A THREAT TO PUBLIC HEALTH.

(2) A CANADIAN SUPPLIER MAY EXPORT PRESCRIPTION DRUGS INTO THE STATE UNDER THE PROGRAM IF THE SUPPLIER:

(a) IS IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS;

(b) IS IDENTIFIED BY THE VENDOR AS ELIGIBLE TO PARTICIPATE IN THE PROGRAM PURSUANT TO SECTION 25.5-2.5-203 (2)(c); AND

(c) SUBMITS AN ATTESTATION THAT THE SUPPLIER HAS A REGISTERED AGENT IN THE UNITED STATES, WHICH ATTESTATION INCLUDES THE NAME AND UNITED STATES ADDRESS OF THE REGISTERED AGENT.

(3) THE FOLLOWING ENTITIES ARE ELIGIBLE IMPORTERS AND MAY OBTAIN IMPORTED PRESCRIPTION DRUGS:

(a) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER CONTRACT WITH A MEDICAID PHARMACY, FOR DISPENSING TO THE PHARMACY'S MEDICAID RECIPIENTS;

(b) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER CONTRACT WITH THE DEPARTMENT OF CORRECTIONS, FOR DISPENSING TO INMATES IN THE CUSTODY OF THE DEPARTMENT OF CORRECTIONS;

(c) COMMERCIAL PLANS, AS DEFINED BY RULES PROMULGATED BY THE STATE BOARD AND AS APPROVED BY THE FEDERAL GOVERNMENT; AND

(d) A LICENSED COLORADO PHARMACIST OR WHOLESALER APPROVED BY THE STATE DEPARTMENT.

(4) (a) THE STATE DEPARTMENT SHALL DESIGNATE AN OFFICE OR DIVISION THAT MUST BE A LICENSED PHARMACEUTICAL WHOLESALER OR THAT SHALL CONTRACT WITH A LICENSED PHARMACEUTICAL WHOLESALER LICENSED PURSUANT TO PART 3 OF ARTICLE 42.5 OF TITLE 12.

(b) THE OFFICE OR DIVISION DESIGNATED BY THE STATE DEPARTMENT PURSUANT TO SUBSECTION (4)(a) OF THIS SECTION SHALL:

(I) SET A MAXIMUM PROFIT MARGIN SO THAT A WHOLESALER, DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER PARTICIPATING IN THE PROGRAM MAINTAINS A PROFIT MARGIN THAT IS NO GREATER THAN THE PROFIT MARGIN THAT THE WHOLESALER, DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER WOULD HAVE EARNED ON THE EQUIVALENT NONIMPORTED DRUG;

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

(III) COMPLY WITH THE REQUIREMENTS OF 21 U.S.C. SEC. 360eee TO 360eee-4 AS ENACTED IN TITLE II OF THE FEDERAL "DRUG QUALITY

AND SECURITY ACT"; AND

(IV) DETERMINE A METHOD FOR COVERING THE ADMINISTRATIVE COSTS OF THE 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 THE STATE DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

(5) CANADIAN SUPPLIERS AND ELIGIBLE IMPORTERS PARTICIPATING UNDER THE PROGRAM:

(a) SHALL COMPLY WITH THE TRACKING AND TRACING REQUIREMENTS OF 21 U.S.C. SEC. 360eee ET SEQ.; AND

(b) SHALL NOT DISTRIBUTE, DISPENSE, OR SELL PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM OUTSIDE OF THE STATE.

(6) A PARTICIPATING ELIGIBLE IMPORTER SHALL SUBMIT TO THE VENDOR ALL OF FOLLOWING INFORMATION ABOUT EACH DRUG TO BE ACQUIRED BY THE IMPORTER UNDER THE PROGRAM:

(a) THE NAME AND QUANTITY OF THE ACTIVE INGREDIENT OF THE DRUG;

(b) A DESCRIPTION OF THE DOSAGE FORM OF THE DRUG;

(c) THE DATE ON WHICH THE DRUG IS RECEIVED;

(d) THE QUANTITY OF THE DRUG THAT IS RECEIVED;

(e) THE POINT OF ORIGIN AND DESTINATION OF THE DRUG; AND

(f) THE PRICE PAID BY THE IMPORTER FOR THE DRUG.

(7) A PARTICIPATING CANADIAN SUPPLIER SHALL SUBMIT TO THE VENDOR THE FOLLOWING INFORMATION ABOUT EACH DRUG TO BE SUPPLIED BY THE CANADIAN SUPPLIER UNDER THE PROGRAM:

(a) THE ORIGINAL SOURCE OF THE DRUG, INCLUDING:

(I) THE NAME OF THE MANUFACTURER OF THE DRUG;

(II) THE DATE ON WHICH THE DRUG WAS MANUFACTURED; AND

(III) THE COUNTRY, STATE OR PROVINCE, AND CITY WHERE THE DRUG WAS MANUFACTURED;

(b) THE DATE ON WHICH THE DRUG IS SHIPPED;

(c) THE QUANTITY OF THE DRUG THAT IS SHIPPED;

(d) THE QUANTITY OF EACH LOT OF THE DRUG ORIGINALLY RECEIVED AND THE SOURCE OF THE LOT; AND

(e) THE LOT OR CONTROL NUMBER AND THE BATCH NUMBER ASSIGNED TO THE DRUG BY THE MANUFACTURER.

(8) THE STATE DEPARTMENT SHALL IMMEDIATELY SUSPEND THE IMPORTATION OF A SPECIFIC DRUG OR THE IMPORTATION OF DRUGS BY A SPECIFIC ELIGIBLE IMPORTER IF IT DISCOVERS THAT ANY DRUG OR ACTIVITY IS IN VIOLATION OF THIS SECTION OR ANY FEDERAL OR STATE LAW OR REGULATION. THE STATE DEPARTMENT MAY REVOKE THE SUSPENSION IF, AFTER CONDUCTING AN INVESTIGATION, IT DETERMINES THAT THE PUBLIC IS ADEQUATELY PROTECTED FROM COUNTERFEIT OR UNSAFE DRUGS BEING IMPORTED INTO THIS STATE.

25.5-2.5-205. Federal approval. (1) ON OR BEFORE SEPTEMBER 1, 2020, THE STATE DEPARTMENT SHALL SUBMIT A REQUEST TO THE UNITED STATES SECRETARY OF HEALTH AND HUMAN SERVICES FOR APPROVAL OF THE PROGRAM UNDER 21 U.S.C. SEC. 384. THE STATE DEPARTMENT SHALL BEGIN OPERATING THE PROGRAM NOT LATER THAN SIX MONTHS AFTER RECEIVING SUCH APPROVAL. THE REQUEST MUST, AT A MINIMUM:

(a) DESCRIBE THE STATE DEPARTMENT'S PLAN FOR OPERATING THE

PROGRAM;

(b) DEMONSTRATE HOW THE PRESCRIPTION DRUGS IMPORTED INTO THE STATE UNDER THE PROGRAM WILL MEET THE APPLICABLE FEDERAL AND STATE STANDARDS FOR SAFETY, EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

(c) INCLUDE A LIST OF PRESCRIPTION DRUGS THAT HAVE THE HIGHEST POTENTIAL FOR COST SAVINGS TO THE STATE THROUGH IMPORTATION AT THE TIME THAT THE REQUEST IS SUBMITTED;

(d) ESTIMATE THE TOTAL COST SAVINGS ATTRIBUTABLE TO THE PROGRAM; AND

(e) INCLUDE A LIST OF POTENTIAL CANADIAN SUPPLIERS FROM WHICH THE STATE WOULD IMPORT PRESCRIPTION DRUGS AND DEMONSTRATE THAT THE SUPPLIERS ARE IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS.

(2) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE CONTRARY, THE STATE DEPARTMENT MAY EXPEND MONEY FOR THE PURPOSE OF REQUESTING APPROVAL OF THE PROGRAM AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION BUT THE STATE DEPARTMENT SHALL NOT SPEND ANY OTHER MONEY TO IMPLEMENT THE PROGRAM UNTIL THE STATE DEPARTMENT RECEIVES APPROVAL OF THE PROGRAM AS DESCRIBED IN SAID SUBSECTION (1).

(3) UPON RECEIPT OF FEDERAL APPROVAL OF THE PROGRAM, THE STATE 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. AFTER APPROVAL IS RECEIVED AND BEFORE THE START OF THE NEXT REGULAR SESSION OF THE GENERAL ASSEMBLY IN WHICH THE PROPOSAL COULD BE FUNDED, THE STATE DEPARTMENT SHALL SUBMIT TO ALL PARTIES SPECIFIED IN THIS SUBSECTION (3) A PROPOSAL FOR PROGRAM IMPLEMENTATION AND PROGRAM FUNDING.

25.5-2.5-206. Reports. (1) NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), ON OR BEFORE DECEMBER 1, 2021, AND ON OR BEFORE DECEMBER 1 EACH YEAR THEREAFTER, THE STATE DEPARTMENT SHALL SUBMIT A REPORT TO THE GOVERNOR, THE PRESIDENT OF THE SENATE, AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES CONCERNING THE OPERATION OF THE PROGRAM DURING THE PREVIOUS FISCAL YEAR. THE REPORT MUST INCLUDE, AT A MINIMUM:

(a) A LIST OF THE PRESCRIPTION DRUGS THAT WERE IMPORTED UNDER THE PROGRAM;

(b) THE NUMBER OF PARTICIPATING CANADIAN SUPPLIERS AND ELIGIBLE IMPORTERS;

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

(d) THE ESTIMATED COST SAVINGS DURING THE PREVIOUS FISCAL YEAR AND TO DATE;

(e) A DESCRIPTION OF THE METHODOLOGY USED TO DETERMINE WHICH PRESCRIPTION DRUGS SHOULD BE INCLUDED ON THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST ESTABLISHED PURSUANT TO SECTION 25.5-2.5-203 (2)(a); AND

(f) DOCUMENTATION DEMONSTRATING HOW THE PROGRAM ENSURES THAT:

(I) THE VENDOR VERIFIES THAT CANADIAN SUPPLIERS PARTICIPATING IN THE PROGRAM ARE IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS;

(II) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE NOT SHIPPED, SOLD, OR DISPENSED OUTSIDE OF THE STATE ONCE IN THE POSSESSION OF THE ELIGIBLE IMPORTER;

(III) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE PURE, UNADULTERATED, POTENT, AND SAFE;

(IV) THE PROGRAM DOES NOT PUT CONSUMERS AT A HIGHER HEALTH AND SAFETY RISK THAN IF THE PROGRAM DID NOT EXIST; AND

(V) THE PROGRAM PROVIDES COST SAVINGS TO THE STATE ON IMPORTED PRESCRIPTION DRUGS.

25.5-2.5-207. Importation program authorized - rules. (1) UPON APPROVAL BY THE SECRETARY, IN ACCORDANCE WITH SECTION 25.5-2.5-206, 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 AND SECTION 25.5-1-108, AS NECESSARY FOR THE ADMINISTRATION OF THIS PART 2.

SECTION 4. 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 5. Appropriation - adjustments to 2019 long bill. (1) For the 2019-20 state fiscal year, $1,041,802 is appropriated to the department of health care policy and financing. This appropriation is from the general fund. To implement this act, the department may use this appropriation as follows:

(a) $469,293 for use by the executive director's office for personal services, which amount is based on an assumption that the department will require an additional 4.1 FTE;

(b) $27,790 for use by the executive director's office for operating expenses;

(c) $134,719 for legal services; and

(e) $410,000 for general professional services and special projects.

(2) For the 2019-20 state fiscal year, $134,719 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of health care policy and financing under subsection (1)(c) of this section and is based on an assumption that the department of law will require an additional 0.7 FTE. To implement this

act, the department of law may use this appropriation to provide legal services for the department of health care policy and financing.

(3) The appropriation in subsection (1)(a) of this section is based on the assumption that the anticipated amount of federal funds received for the 2019-20 state fiscal year by the department of health care policy and financing for personal services will decrease by $70,000.

SECTION 6. 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.