

HOUSE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Insurance.

SB19-005 be amended as follows:

1 Amend reengrossed bill, page 3, strike lines 22 through 27 and substitute:

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

4 PART 2  
5 CANADIAN PRESCRIPTION DRUG  
6 IMPORTATION PROGRAM

7 **25.5-2.5-201. Definitions.** AS USED IN THIS PART 2, UNLESS THE  
8 CONTEXT OTHERWISE REQUIRES:

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

14 (2) "ELIGIBLE IMPORTER" MEANS AN IMPORTER THAT IS DESCRIBED  
15 IN SECTION 25.5-2.5-203 (3).

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

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

22 (5) "PHARMACIST" MEANS A PERSON WHO HOLDS AN ACTIVE AND  
23 UNENCUMBERED LICENSE TO PRACTICE PHARMACY PURSUANT TO SECTION  
24 12-42.5-112.

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

28 (7) "PROGRAM" MEANS THE CANADIAN PRESCRIPTION DRUG  
29 IMPORTATION PROGRAM CREATED IN SECTION 25.5-2.5-202.

30 (8) "VENDOR" MEANS A VENDOR WITH WHICH THE STATE  
31 DEPARTMENT CONTRACTS FOR THE PROVISION OF SERVICES UNDER THE  
32 PROGRAM PURSUANT TO SECTION 25.5-2.5-202 (1).

33 **25.5-2.5-202. Canadian prescription drug importation**  
34 **program - created - importation process - contract with vendor -**  
35 **vendor duties.** (1) THE CANADIAN PRESCRIPTION DRUG IMPORTATION  
36 PROGRAM IS CREATED IN THE STATE DEPARTMENT. ON OR BEFORE  
37 FEBRUARY 1, 2020, THE STATE DEPARTMENT SHALL CONTRACT WITH ONE  
38 OR MORE VENDORS TO PROVIDE SERVICES UNDER THE PROGRAM. FOR  
39 THREE YEARS FOLLOWING THE EFFECTIVE DATE OF THIS PART 2, THE  
40 SELECTION OF ANY VENDOR PURSUANT TO THIS SUBSECTION (1) IS EXEMPT

1 FROM THE REQUIREMENTS OF THE PROCUREMENT CODE, ARTICLES 101 TO  
2 112 OF TITLE 24.

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

14 (b) THE STATE DEPARTMENT SHALL REVIEW THE WHOLESAL  
15 PRESCRIPTION DRUG IMPORTATION LIST AT LEAST EVERY THREE MONTHS  
16 TO ENSURE THAT IT CONTINUES TO MEET THE REQUIREMENTS OF THE  
17 PROGRAM. THE STATE DEPARTMENT MAY DIRECT A VENDOR TO REVISE  
18 THE LIST, AS NECESSARY.

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

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

34 (e) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT WITH  
35 THE ANNUAL REPORT DESCRIBED IN SECTION 25.5-2.5-205 AND PROVIDE  
36 ANY INFORMATION REQUESTED BY THE STATE DEPARTMENT FOR THE  
37 REPORT.

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

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

1 (B) FOR ANY SUBSEQUENT IMPORTED SHIPMENT, ENSURE THAT A  
2 STATISTICALLY VALID SAMPLE OF THE SHIPMENT IS TESTED FOR  
3 AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE  
4 FEDERAL ACT.

5 (II) CERTIFY THAT EACH DRUG:

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

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

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

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

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

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

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

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

36 (7) EACH VENDOR SHALL SUBMIT EVIDENCE OF A SURETY BOND  
37 WITH ANY BID OR INITIAL CONTRACT NEGOTIATION DOCUMENTS AND  
38 SHALL MAINTAIN DOCUMENTATION OF EVIDENCE OF SUCH A BOND WITH  
39 THE STATE DEPARTMENT THROUGHOUT THE CONTRACT TERM. THE SURETY  
40 BOND MAY BE FROM THIS STATE OR ANY OTHER STATE IN THE UNITED  
41 STATES AND MUST BE IN AN AMOUNT OF AT LEAST TWENTY-FIVE  
42 THOUSAND DOLLARS. THE SURETY BOND OR COMPARABLE SECURITY  
43 ARRANGEMENT MUST INCLUDE THE STATE OF COLORADO AS A

1 BENEFICIARY. IN LIEU OF THE SURETY BOND, A VENDOR MAY PROVIDE A  
2 COMPARABLE SECURITY AGREEMENT, SUCH AS AN IRREVOCABLE LETTER  
3 OF CREDIT OR A DEPOSIT INTO A TRUST ACCOUNT OR FINANCIAL  
4 INSTITUTION THAT INCLUDES THE STATE OF COLORADO AS A BENEFICIARY,  
5 PAYABLE TO THE STATE OF COLORADO. THE PURPOSES OF THE BOND OR  
6 OTHER SECURITY ARRANGEMENT ARE TO:

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

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

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

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

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

34 **25.5-2.5-203. Eligible prescription drugs - eligible Canadian**  
35 **suppliers - eligible importers - distribution requirements.** (1) AN  
36 ELIGIBLE IMPORTER MAY IMPORT A PRESCRIPTION DRUG FROM A  
37 CANADIAN SUPPLIER IF:

38 (a) THE DRUG THAT IS TO BE IMPORTED MEETS THE FEDERAL FOOD  
39 AND DRUG ADMINISTRATION'S STANDARDS RELATED TO SAFETY,  
40 EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

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

43 (c) IMPORTING THE DRUG IS EXPECTED TO GENERATE COST

1 SAVINGS; AND  
2 (d) THE DRUG IS NOT:  
3 (I) A CONTROLLED SUBSTANCE AS DEFINED IN 21 U.S.C. SEC. 802  
4 (6);  
5 (II) A BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC. 262 (i);  
6 (III) AN INFUSED DRUG;  
7 (IV) AN INTRAVENOUSLY INJECTED DRUG;  
8 (V) A DRUG THAT IS INHALED DURING SURGERY; OR  
9 (VI) A DRUG THAT IS A PARENTERAL DRUG, THE IMPORTATION OF  
10 WHICH IS DETERMINED BY THE FEDERAL SECRETARY OF HEALTH AND  
11 HUMAN SERVICES TO POSE A THREAT TO PUBLIC HEALTH.  
12 (2) A CANADIAN SUPPLIER MAY EXPORT PRESCRIPTION DRUGS  
13 INTO THE STATE UNDER THE PROGRAM IF THE SUPPLIER:  
14 (a) IS IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL  
15 AND PROVINCIAL LAWS AND REGULATIONS;  
16 (b) IS IDENTIFIED BY THE VENDOR AS ELIGIBLE TO PARTICIPATE IN  
17 THE PROGRAM PURSUANT TO SECTION 25.5-2.5-202 (2)(c); AND  
18 (c) SUBMITS AN ATTESTATION THAT THE SUPPLIER HAS A  
19 REGISTERED AGENT IN THE UNITED STATES, WHICH ATTESTATION  
20 INCLUDES THE NAME AND UNITED STATES ADDRESS OF THE REGISTERED  
21 AGENT.  
22 (3) THE FOLLOWING ENTITIES ARE ELIGIBLE IMPORTERS AND MAY  
23 OBTAIN IMPORTED PRESCRIPTION DRUGS:  
24 (a) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER  
25 CONTRACT WITH A MEDICAID PHARMACY, FOR DISPENSING TO THE  
26 PHARMACY'S MEDICAID RECIPIENTS;  
27 (b) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER  
28 CONTRACT WITH THE DEPARTMENT OF CORRECTIONS, FOR DISPENSING TO  
29 INMATES IN THE CUSTODY OF THE DEPARTMENT OF CORRECTIONS;  
30 (c) COMMERCIAL PLANS, AS DEFINED BY RULES PROMULGATED BY  
31 THE STATE BOARD AND AS APPROVED BY THE FEDERAL GOVERNMENT; AND  
32 (d) A LICENSED COLORADO PHARMACIST OR WHOLESALER  
33 APPROVED BY THE STATE DEPARTMENT.  
34 (4) (a) THE STATE DEPARTMENT SHALL DESIGNATE AN OFFICE OR  
35 DIVISION THAT MUST BE A LICENSED PHARMACEUTICAL WHOLESALER OR  
36 THAT SHALL CONTRACT WITH A LICENSED PHARMACEUTICAL WHOLESALER  
37 LICENSED PURSUANT TO PART 3 OF ARTICLE 42.5 OF TITLE 12.  
38 (b) THE OFFICE OR DIVISION DESIGNATED BY THE STATE  
39 DEPARTMENT PURSUANT TO SUBSECTION (4)(a) OF THIS SECTION SHALL:  
40 (I) SET A MAXIMUM PROFIT MARGIN SO THAT A WHOLESALER,  
41 DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER PARTICIPATING  
42 IN THE PROGRAM MAINTAINS A PROFIT MARGIN THAT IS NO GREATER THAN  
43 THE PROFIT MARGIN THAT THE WHOLESALER, DISTRIBUTOR, PHARMACY,

1 OR OTHER LICENSED PROVIDER WOULD HAVE EARNED ON THE EQUIVALENT  
2 NONIMPORTED DRUG;

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

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

9 (IV) DETERMINE A METHOD FOR COVERING THE ADMINISTRATIVE  
10 COSTS OF THE PROGRAM, WHICH METHOD MAY INCLUDE A FEE IMPOSED ON  
11 EACH PRESCRIPTION PHARMACEUTICAL PRODUCT SOLD THROUGH THE  
12 PROGRAM OR ANY OTHER APPROPRIATE METHOD AS DETERMINED BY THE  
13 STATE DEPARTMENT, BUT THE STATE DEPARTMENT SHALL NOT REQUIRE A  
14 FEE IN AN AMOUNT THE STATE DEPARTMENT DETERMINES WOULD  
15 SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **25.5-2.5-204. Federal approval.** (1) ON OR BEFORE SEPTEMBER  
12 1, 2020, THE STATE DEPARTMENT SHALL SUBMIT A REQUEST TO THE  
13 UNITED STATES SECRETARY OF HEALTH AND HUMAN SERVICES FOR  
14 APPROVAL OF THE PROGRAM UNDER 21 U.S.C. SEC. 384. THE STATE  
15 DEPARTMENT SHALL BEGIN OPERATING THE PROGRAM NOT LATER THAN  
16 SIX MONTHS AFTER RECEIVING SUCH APPROVAL. THE REQUEST MUST, AT  
17 A MINIMUM:

18 (a) DESCRIBE THE STATE DEPARTMENT'S PLAN FOR OPERATING THE  
19 PROGRAM;

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

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

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

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

34 (2) UPON RECEIPT OF FEDERAL APPROVAL OF THE PROGRAM, THE  
35 STATE DEPARTMENT SHALL NOTIFY THE PRESIDENT OF THE SENATE AND  
36 THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AS WELL AS THE  
37 HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE  
38 HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES,  
39 OR ANY SUCCESSOR COMMITTEES. AFTER APPROVAL IS RECEIVED AND  
40 BEFORE THE START OF THE NEXT REGULAR SESSION OF THE GENERAL  
41 ASSEMBLY IN WHICH THE PROPOSAL COULD BE FUNDED, THE STATE  
42 DEPARTMENT SHALL SUBMIT TO ALL PARTIES SPECIFIED IN THIS  
43 SUBSECTION (2) A PROPOSAL FOR PROGRAM IMPLEMENTATION AND

1 PROGRAM FUNDING.

2 **25.5-2.5-205. Reports.** (1) NOTWITHSTANDING SECTION 24-1-136  
3 (11)(a)(I), ON OR BEFORE DECEMBER 1, 2021, AND ON OR BEFORE  
4 DECEMBER 1 EACH YEAR THEREAFTER, THE STATE DEPARTMENT SHALL  
5 SUBMIT A REPORT TO THE GOVERNOR, THE PRESIDENT OF THE SENATE, AND  
6 THE SPEAKER OF THE HOUSE OF REPRESENTATIVES CONCERNING THE  
7 OPERATION OF THE PROGRAM DURING THE PREVIOUS FISCAL YEAR. THE  
8 REPORT MUST INCLUDE, AT A MINIMUM:

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

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

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

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

17 (e) A DESCRIPTION OF THE METHODOLOGY USED TO DETERMINE  
18 WHICH PRESCRIPTION DRUGS SHOULD BE INCLUDED ON THE WHOLESALE  
19 PRESCRIPTION DRUG IMPORTATION LIST ESTABLISHED PURSUANT TO  
20 SECTION 25.5-2.5-202 (2)(a); AND

21 (f) DOCUMENTATION DEMONSTRATING HOW THE PROGRAM  
22 ENSURES THAT:

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

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

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

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

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

36 Strike pages 4 through 8.

37 Page 9, strike lines 1 through 10.

38 Page 9, strike line 27.

39 Strike pages 10 and 11.



- 1 Page 12, strike lines 1 through 9.
- 2 Page 12, strike lines 14 through 21.
- 3 Renumber succeeding sections accordingly.

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