

**HOUSE BILL No. 2658**

By Representative Ward

2-12

1 AN ACT concerning health and welfare; relating to prescription  
2 medication; establishing the affordable prescription drug importation  
3 program.  
4

5 *Be it enacted by the Legislature of the State of Kansas:*

6 Section 1. Sections 1 through 7, and amendments thereto, shall be  
7 known and may be cited as the affordable prescription drug importation  
8 act.

9 Sec. 2. As used in the affordable prescription drug importation act:

10 (a) "Canadian supplier" means a manufacturer, wholesale distributor  
11 or pharmacy that is appropriately licensed or permitted under Canadian  
12 federal and provincial laws and regulations to manufacture, distribute or  
13 dispense prescription drugs;

14 (b) "department" means the department of health and environment;

15 (c) "eligible importer" means an importer that is described in section  
16 4, and amendments thereto;

17 (d) "federal act" means the federal food, drug, and cosmetic act, 21  
18 U.S.C. § 301 et seq.;

19 (e) "pharmacy" means the same as defined in K.S.A. 65-1626(ww),  
20 and amendments thereto, that has a provider agreement in effect with the  
21 department and is in good standing with the department;

22 (f) "pharmacist" means the same as defined in K.S.A. 65-1626(tt),  
23 and amendments thereto;

24 (g) "prescription drug" means the same as defined in K.S.A. 65-  
25 1626(eee), and amendments thereto, except that "prescription drug"  
26 includes only drugs that are intended for human use;

27 (h) "program" means the affordable prescription drug importation  
28 program;

29 (i) "secretary" means the secretary of health and environment; and

30 (j) "vendor" means a vendor with which the department contracts for  
31 the provision of services under the program.

32 Sec. 3. (a) The affordable prescription drug importation program is  
33 created to be administered by the department. Upon receiving approval of  
34 the program as described in section 5, and amendments thereto, the  
35 department shall contract with one or more vendors to provide services  
36 under the program. On and after July 1, 2020, through June 30, 2023, the

1 selection of any vendor is exempt from the requirements of K.S.A. 75-  
2 3739, and amendments thereto.

3 (b) (1) Each vendor, in consultation with the department and any  
4 other vendors, shall establish a wholesale prescription drug importation list  
5 that identifies the prescription drugs that have the highest potential for cost  
6 savings to the state, including prescription drugs that are in short supply, as  
7 specified by the department, specialty prescription drugs and high-volume  
8 prescription drugs. Each vendor shall revise the list at least annually and at  
9 the direction of the department pursuant to subsection (b)(2).

10 (2) The department shall review each vendor's wholesale prescription  
11 drug importation list at least every three months to ensure that it continues  
12 to meet the requirements of the program. The department may direct a  
13 vendor to revise the list, as necessary.

14 (3) Each vendor, in consultation with the department, shall identify  
15 Canadian suppliers that are in full compliance with relevant Canadian  
16 federal and provincial laws and regulations and that have agreed to export  
17 prescription drugs identified on the wholesale prescription drug  
18 importation list. Each vendor shall verify that such Canadian suppliers  
19 meet all of the requirements of the program and will export prescription  
20 drugs at prices that will provide cost savings to the state. Each vendor shall  
21 contract with such eligible Canadian suppliers, or facilitate contracts  
22 between eligible importers and Canadian suppliers, to import prescription  
23 drugs under the program.

24 (4) Each vendor shall assist the department in developing and  
25 administering a distribution program within the program.

26 (5) Each vendor shall assist the department with the annual report  
27 required by section 6, and amendments thereto, and provide any  
28 information requested by the department for the report.

29 (6) Each vendor shall ensure the safety and quality of drugs imported  
30 under the program, as follows:

31 (A) (i) For an initial imported shipment, ensure that each batch of the  
32 drug in the shipment is statistically sampled and tested for authenticity and  
33 degradation in a manner consistent with the federal act; and

34 (ii) for any subsequent imported shipment, ensure that a statistically  
35 valid sample of the shipment is tested for authenticity and degradation in a  
36 manner consistent with the federal act;

37 (B) certify that each drug:

38 (i) Is approved for marketing in the United States and is not  
39 adulterated or misbranded; and

40 (ii) meets all of the labeling requirements under 21 U.S.C. § 352, as  
41 in effect on July 1, 2020;

42 (C) maintain qualified laboratory records, including complete data  
43 derived from all tests necessary to ensure that the drug is in compliance

1 with the requirements of this section; and

2 (D) maintain documentation demonstrating that the testing required  
3 by this section was conducted at a qualified laboratory in accordance with  
4 the federal act and any other applicable federal and state laws and  
5 regulations governing laboratory qualifications.

6 (7) All testing required by this section shall be conducted in a  
7 qualified laboratory that meets the standards under the federal act and any  
8 other applicable federal and state laws and regulations governing  
9 laboratory qualifications for drug testing.

10 (8) Each vendor shall maintain a list of all eligible importers that  
11 participate in the program.

12 (9) Each vendor shall ensure compliance with title II of the federal  
13 drug quality and security act, Pub.L. 113-54, by all Canadian suppliers,  
14 eligible importers, distributors and other participants in the program.

15 (10) Each vendor shall provide an annual financial audit of its  
16 operations to the department. Each vendor shall provide quarterly financial  
17 reports specific to the program and shall include information concerning  
18 the performance of its subcontractors and vendors. The department shall  
19 determine the format and contents of the reports.

20 (11) Each vendor shall submit evidence of a surety bond with any bid  
21 or initial contract negotiation documents and shall maintain documentation  
22 of evidence of such a bond with the department throughout the contract  
23 term. The surety bond may be from this state or any other state in the  
24 United States and shall be in an amount of at least \$25,000. The surety  
25 bond shall include the state of Kansas as a beneficiary. In lieu of the surety  
26 bond, a vendor may provide a comparable security agreement, such as an  
27 irrevocable letter of credit or a deposit into a trust account or financial  
28 institution that includes the state of Kansas as a beneficiary, payable to the  
29 state of Kansas. The purposes of the bond or other security arrangement  
30 are to:

31 (A) Ensure participation of the vendor in any civil or criminal action  
32 by the department, any other state agency, private individuals or entities  
33 against the vendor because of the vendor's failure to perform under the  
34 contract, including, but not limited to, causes of action for personal injury,  
35 negligence and wrongful death;

36 (B) ensure payment by the vendor through the use of a bond or other  
37 comparable security arrangement of any legal judgments and claims that  
38 are awarded to the state, other entities acting on behalf of the state,  
39 individuals or organizations if the vendor is assessed a final judgment or  
40 other monetary penalty in a court of law for a civil or criminal action  
41 under the program. The bond or comparable security arrangement may be  
42 accessed if the vendor fails to pay any judgment or claim within 60 days  
43 after final judgment; and

1 (C) allow for civil and criminal litigation claims to be made against  
2 the bond or other comparable security arrangements for up to one year  
3 after the vendor's contract under the program has ended with the  
4 department, the vendor's license is no longer valid or the program has  
5 ended, whichever occurs last.

6 (12) Each vendor shall maintain information and documentation  
7 submitted under this section for a period of at least seven years.

8 (13) The department may require each vendor to collect any other  
9 information necessary to ensure the protection of the public health.

10 Sec. 4. (a) An eligible importer may import a prescription drug from a  
11 Canadian supplier if:

12 (1) The drug that is to be imported meets the federal food and drug  
13 administration's standards related to safety, effectiveness, misbranding and  
14 adulteration;

15 (2) importing the drug would not violate federal patent laws;

16 (3) importing the drug is expected to generate cost savings; and

17 (4) the drug is not:

18 (A) A controlled substance as defined in 21 U.S.C. § 802(6), as in  
19 effect on July 1, 2020;

20 (B) a biological product as defined in 42 U.S.C. § 262(i), as in effect  
21 on July 1, 2020;

22 (C) an infused drug;

23 (D) an intravenously injected drug;

24 (E) a drug that is inhaled during surgery; or

25 (F) a drug that is a parenteral drug, the importation of which is  
26 determined by the federal secretary of health and human services to pose a  
27 threat to public health.

28 (b) A Canadian supplier may export prescription drugs into the state  
29 under the program if the supplier:

30 (1) Is in full compliance with relevant Canadian federal and  
31 provincial laws and regulations;

32 (2) is identified by the vendor as eligible to participate in the  
33 program; and

34 (3) submits an attestation that the supplier has a registered agent in  
35 the United States, which attestation includes the name and United States  
36 address of the registered agent.

37 (c) The following entities are eligible importers and may obtain  
38 imported prescription drugs:

39 (1) A pharmacist or wholesaler employed by or under contract with a  
40 medicaid pharmacy for dispensing to the pharmacy's medicaid recipients;

41 (2) a pharmacist or wholesaler employed by or under contract with  
42 the department of corrections for dispensing to inmates in the custody of  
43 the department of corrections; and

1 (3) a licensed Kansas pharmacist or wholesaler approved by the  
2 department.

3 (d) (1) The department shall designate an office or division that shall  
4 be a licensed pharmaceutical wholesaler or that shall contract with a  
5 licensed pharmaceutical wholesaler.

6 (2) The office or division designated by the department pursuant to  
7 subsection (d)(1) shall:

8 (A) Set a maximum profit margin so that a wholesaler, distributor,  
9 pharmacy or other licensed provider participating in the program maintains  
10 a profit margin that is not greater than the profit margin that the  
11 wholesaler, distributor, pharmacy or other licensed provider would earn on  
12 the equivalent nonimported drug;

13 (B) exclude generic products if the importation of the products would  
14 violate United States patent laws applicable to branded products in the  
15 United States;

16 (C) comply with the requirements of 21 U.S.C. §§ 360eee through  
17 360eee-4 as enacted in title II of the federal drug quality and security act,  
18 as in effect on July 1, 2020; and

19 (D) determine a method for covering the administrative costs of the  
20 program, which method may include a fee imposed on each prescription  
21 pharmaceutical product sold through the program or any other appropriate  
22 method as determined by the department, except that the department shall  
23 not require a fee in an amount the department determines would  
24 significantly reduce consumer savings.

25 (e) Canadian suppliers and eligible importers participating under the  
26 program shall:

27 (1) Comply with the tracking and tracing requirements of 21 U.S.C. §  
28 360eee et seq., as in effect on July 1, 2020; and

29 (2) not distribute, dispense or sell prescription drugs imported under  
30 the program outside of this state.

31 (f) A participating eligible importer shall submit to the vendor all of  
32 the following information about each drug to be acquired by the importer  
33 under the program:

34 (1) The name and quantity of the active ingredient of the drug;

35 (2) a description of the dosage form of the drug;

36 (3) the date on which the drug is received;

37 (4) the quantity of the drug that is received;

38 (5) the point of origin and destination of the drug; and

39 (6) the price paid by the importer for the drug.

40 (g) A participating Canadian supplier shall submit to the vendor the  
41 following information about each drug to be supplied by the Canadian  
42 supplier under the program:

43 (1) The original source of the drug, including:

- 1 (A) The name of the manufacturer of the drug;  
2 (B) the date on which the drug was manufactured; and  
3 (C) the country, state or province and city where the drug was  
4 manufactured;
- 5 (2) the date on which the drug is shipped;  
6 (3) the quantity of the drug that is shipped;  
7 (4) the quantity of each lot of the drug originally received and the  
8 source of the lot; and

9 (5) the lot or control number and the batch number assigned to the  
10 drug by the manufacturer.

11 (h) The department shall immediately suspend the importation of a  
12 specific drug or the importation of drugs by a specific eligible importer if  
13 the department discovers that any drug or activity is in violation of this  
14 section or any federal or state law or regulation. The department may  
15 revoke the suspension if, after conducting an investigation, the department  
16 determines that the public is adequately protected from counterfeit or  
17 unsafe drugs being imported into this state.

18 Sec. 5. (a) On or before September 1, 2021, the department shall  
19 submit a request to the United States secretary of health and human  
20 services for approval of the program under 21 U.S.C. § 384. The  
21 department shall begin operating the program not later than six months  
22 after receiving such approval. The request shall, at a minimum:

- 23 (1) Describe the department's plan for operating the program;  
24 (2) demonstrate how the prescription drugs imported into this state  
25 under the program will meet the applicable federal and state standards for  
26 safety, effectiveness, misbranding and adulteration;  
27 (3) include a list of prescription drugs that have the highest potential  
28 for cost savings to this state through importation at the time that the  
29 request is submitted;
- 30 (4) estimate the total cost savings attributable to the program; and  
31 (5) include a list of potential Canadian suppliers from which this state  
32 would import prescription drugs and demonstrate that the suppliers are in  
33 full compliance with relevant Canadian federal and provincial laws and  
34 regulations.

35 (b) Notwithstanding any provision of this subsection to the contrary,  
36 the department may expend moneys for the purpose of requesting approval  
37 of the program as described in subsection (a), except that the department  
38 shall not expend moneys to implement the program until the department  
39 receives approval of the program from the federal government.

40 (c) Upon receipt of federal approval of the program, the secretary  
41 shall submit a report notifying the president of the senate, the speaker of  
42 the house of representatives, the committee on public health and welfare of  
43 the senate and the committee on health and human services of the house of

1 representatives, or any successor committees, of such approval. Before the  
2 start of the regular session of the legislature that commences after the  
3 approval is received, the secretary shall submit to all parties specified in  
4 this subsection a proposal for program implementation and funding.

5 Sec. 6. On or before December 1, 2022, and on or before December 1  
6 of each year thereafter, the secretary shall submit a report to the governor,  
7 the president of the senate and the speaker of the house of representatives  
8 concerning the operation of the program during the previous fiscal year.  
9 The report shall include, at a minimum:

10 (a) A list of the prescription drugs that were imported under the  
11 program;

12 (b) the number of participating Canadian suppliers and eligible  
13 importers;

14 (c) the number of prescriptions dispensed through the program;

15 (d) the estimated cost savings during the previous fiscal year and to  
16 date;

17 (e) a description of the methodology used to determine which  
18 prescription drugs should be included on the wholesale prescription drug  
19 importation list established pursuant to section 2, and amendments thereto;  
20 and

21 (f) documentation demonstrating how the program ensures that:

22 (1) The vendor verifies that Canadian suppliers participating in the  
23 program are in full compliance with relevant Canadian federal and  
24 provincial laws and regulations;

25 (2) prescription drugs imported under the program are not shipped,  
26 sold or dispensed outside of this state once in the possession of the eligible  
27 importer;

28 (3) prescription drugs imported under the program are pure,  
29 unadulterated, potent and safe;

30 (4) the program does not put consumers at a higher health and safety  
31 risk than if the program did not exist; and

32 (5) the program provides cost savings to this state on imported  
33 prescription drugs.

34 Sec. 7. (a) The secretary shall approve a method of financing the  
35 administrative costs of the prescription drug importation program and may  
36 include methods such as imposing a fee on each prescription  
37 pharmaceutical product sold through the program or any other appropriate  
38 method determined by the department to finance administrative costs. The  
39 department shall not require a fee in an amount that the department  
40 determines would significantly reduce consumer savings.

41 (b) The secretary shall adopt rules and regulations as necessary for  
42 the administration of the program. Such rules and regulations shall be  
43 adopted not later than July 1, 2021.

1       Sec. 8. This act shall take effect and be in force from and after its  
2       publication in the statute book.