HOUSE BILL No. 2658

By Representative Ward

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

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

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

Sec. 2. As used in the affordable prescription drug importation act:
(a) "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;
(b) "department" means the department of health and environment;
(c) "eligible importer" means an importer that is described in section 4, and amendments thereto;
(d) "federal act" means the federal food, drug, and cosmetic act, 21 U.S.C. § 301 et seq.;
(e) "pharmacy" means the same as defined in K.S.A. 65-1626(ww), and amendments thereto, that has a provider agreement in effect with the department and is in good standing with the department;
(f) "pharmacist" means the same as defined in K.S.A. 65-1626(tt), and amendments thereto;
(g) "prescription drug" means the same as defined in K.S.A. 65-1626(eee), and amendments thereto, except that "prescription drug" includes only drugs that are intended for human use;
(h) "program" means the affordable prescription drug importation program;
(i) "secretary" means the secretary of health and environment; and
(j) "vendor" means a vendor with which the department contracts for the provision of services under the program.

Sec. 3. (a) The affordable prescription drug importation program is created to be administered by the department. Upon receiving approval of the program as described in section 5, and amendments thereto, the department shall contract with one or more vendors to provide services under the program. On and after July 1, 2020, through June 30, 2023, the
selection of any vendor is exempt from the requirements of K.S.A. 75-3739, and amendments thereto.

(b) (1) Each vendor, in consultation with the 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, including prescription drugs that are in short supply, as specified by the department, specialty prescription drugs and high-volume prescription drugs. Each vendor shall revise the list at least annually and at the direction of the department pursuant to subsection (b)(2).

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

(3) Each vendor, in consultation with the department, shall identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and that 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.

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

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

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

(A) (i) 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

(ii) 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;

(B) certify that each drug:

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

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

(C) 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

(D) 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.

(7) All testing required by this section shall 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.

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

(9) 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.

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

(11) 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 department throughout the contract term. The surety bond may be from this state or any other state in the United States and shall be in an amount of at least $25,000. The surety bond shall include the state of Kansas 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 Kansas as a beneficiary, payable to the state of Kansas. The purposes of the bond or other security arrangement are to:

(A) Ensure participation of the vendor in any civil or criminal action by the department, any other state agency, 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 action 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 60 days after final judgment; and
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
department, the vendor's license is no longer valid or the program has
ended, whichever occurs last.

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

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

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

(1) The drug that is to be imported meets the federal food and drug
administration's standards related to safety, effectiveness, misbranding and
adulteration;
(2) importing the drug would not violate federal patent laws;
(3) importing the drug is expected to generate cost savings; and
(4) the drug is not:
   (A) A controlled substance as defined in 21 U.S.C. § 802(6), as in
effect on July 1, 2020;
   (B) a biological product as defined in 42 U.S.C. § 262(i), as in effect
on July 1, 2020;
   (C) an infused drug;
   (D) an intravenously injected drug;
   (E) a drug that is inhaled during surgery; or
   (F) 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.

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

(1) is in full compliance with relevant Canadian federal and
provincial laws and regulations;
(2) is identified by the vendor as eligible to participate in the
program; and
(3) 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.

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

(1) A pharmacist or wholesaler employed by or under contract with a
medicaid pharmacy for dispensing to the pharmacy's medicaid recipients;
(2) 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; and
(3) a licensed Kansas pharmacist or wholesaler approved by the
department.
(d) (1) The department shall designate an office or division that shall
be a licensed pharmaceutical wholesaler or that shall contract with a
licensed pharmaceutical wholesaler.
(2) The office or division designated by the department pursuant to
subsection (d)(1) shall:
(A) 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 not greater than the profit margin that the
wholesaler, distributor, pharmacy or other licensed provider would earn on
the equivalent nonimported drug;
(B) exclude generic products if the importation of the products would
violate United States patent laws applicable to branded products in the
United States;
(C) comply with the requirements of 21 U.S.C. §§ 360eee through
360eee-4 as enacted in title II of the federal drug quality and security act,
as in effect on July 1, 2020; and
(D) 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 department, except that the department shall
not require a fee in an amount the department determines would
significantly reduce consumer savings.
(e) Canadian suppliers and eligible importers participating under the
program shall:
(1) Comply with the tracking and tracing requirements of 21 U.S.C. §
360eee et seq., as in effect on July 1, 2020; and
(2) not distribute, dispense or sell prescription drugs imported under
the program outside of this state.
(f) A participating eligible importer shall submit to the vendor all of
the following information about each drug to be acquired by the importer
under the program:
(1) The name and quantity of the active ingredient of the drug;
(2) a description of the dosage form of the drug;
(3) the date on which the drug is received;
(4) the quantity of the drug that is received;
(5) the point of origin and destination of the drug; and
(6) the price paid by the importer for the drug.
(g) 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:
(1) The original source of the drug, including:
(A) The name of the manufacturer of the drug;
(B) the date on which the drug was manufactured; and
(C) the country, state or province and city where the drug was manufactured;
(2) the date on which the drug is shipped;
(3) the quantity of the drug that is shipped;
(4) the quantity of each lot of the drug originally received and the source of the lot; and
(5) the lot or control number and the batch number assigned to the drug by the manufacturer.

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

Sec. 5. (a) On or before September 1, 2021, the 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. § 384. The department shall begin operating the program not later than six months after receiving such approval. The request shall, at a minimum:
(1) Describe the department's plan for operating the program;
(2) demonstrate how the prescription drugs imported into this state under the program will meet the applicable federal and state standards for safety, effectiveness, misbranding and adulteration;
(3) include a list of prescription drugs that have the highest potential for cost savings to this state through importation at the time that the request is submitted;
(4) estimate the total cost savings attributable to the program; and
(5) include a list of potential Canadian suppliers from which this state would import prescription drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

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

(c) Upon receipt of federal approval of the program, the secretary shall submit a report notifying the president of the senate, the speaker of the house of representatives, the committee on public health and welfare of the senate and the committee on health and human services of the house of
representatives, or any successor committees, of such approval. Before the
start of the regular session of the legislature that commences after the
approval is received, the secretary shall submit to all parties specified in
this subsection a proposal for program implementation and funding.

Sec. 6. On or before December 1, 2022, and on or before December 1
of each year thereafter, the secretary 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 shall 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 2, and amendments thereto;
and
(f) documentation demonstrating how the program ensures that:
(1) The vendor verifies that Canadian suppliers participating in the
program are in full compliance with relevant Canadian federal and
provincial laws and regulations;
(2) prescription drugs imported under the program are not shipped,
sold or dispensed outside of this state once in the possession of the eligible
importer;
(3) prescription drugs imported under the program are pure,
unadulterated, potent and safe;
(4) the program does not put consumers at a higher health and safety
risk than if the program did not exist; and
(5) the program provides cost savings to this state on imported
prescription drugs.

Sec. 7. (a) The secretary shall approve a method of financing the
administrative costs of the prescription drug importation program and may
include methods such as imposing a fee on each prescription
pharmaceutical product sold through the program or any other appropriate
method determined by the department to finance administrative costs. The
department shall not require a fee in an amount that the department
determines would significantly reduce consumer savings.
(b) The secretary shall adopt rules and regulations as necessary for
the administration of the program. Such rules and regulations shall be
adopted not later than July 1, 2021.
Sec. 8. This act shall take effect and be in force from and after its publication in the statute book.