PRESCRIPTION DRUG IMPORTATION PROGRAM

2018 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Norman K. Thurston

Senate Sponsor: Deidre M. Henderson

LONG TITLE

General Description:

This bill requires the Department of Health to design a wholesale Canadian prescription drug importation program, apply for approval of the program by the Secretary of the United States Department of Health and Human Services, and, if the prescription drug importation program is approved, to implement the provisions of the program.

Highlighted Provisions:

This bill:

• defines terms;
• requires the Department of Health to:
  • design a prescription drug importation program;
  • apply for approval of the prescription drug importation program;
  • if the program is approved, implement the provisions of the program; and
  • if approval is denied, study how the state can obtain approval for the program;
• describes the requirements of the prescription drug importation program; and
• modifies the Pharmacy Practice Act and the Utah Antitrust Act to make certain anticompetitive activities illegal.

Money Appropriated in this Bill:

None

Other Special Clauses:

None
Be it enacted by the Legislature of the state of Utah:

Section 1. Section 26-62-101 is enacted to read:

**CHAPTER 62. CANADIAN PRESCRIPTION DRUG IMPORTATION ACT**

**Part 1. General Provisions.**


This chapter is known as the "Canadian Prescription Drug Importation Act."

Section 2. Section 26-62-102 is enacted to read:


As used in this chapter:

(1) "Health insurer" means:

(a) an insurer who offers health care insurance as that term is defined in Section 31A-1-301;

(b) for health benefits offered to state employees under Section 49-20-202, the Public Employees' Benefit and Insurance Program created in Section 49-20-103; or

(c) a workers' compensation insurer;

(i) authorized to provide workers' compensation insurance in the state; or
that is a self-insured employer as defined in Section 34A-2-201.5.

(2) "Prescription drug importation program" means the Canadian Prescription Drug Importation Program established under Section 26-62-301.

(3) "Secretary" means the secretary of the United States Department of Health and Human Services.

Section 3. Section 26-62-201 is enacted to read:


(1) The department shall submit to the secretary:

(a) no later than July 31, 2018, a letter of intent to seek approval for a program to allow for the importation of prescription drugs from Canada into the state under the provisions of 21 U.S.C. Sec. 384(l); and

(b) no later than December 31, 2018, an application for:

(i) the approval of a program to allow for the importation of prescription drugs from Canada into the state under the provisions of 21 U.S.C. Sec. 384(l); and

(ii) certification by the secretary to the United States Congress, in accordance with 21 U.S.C. Sec. 384(l), that importation of Canadian prescription drugs will:

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) The application described in Subsection (1)(b) shall contain:

(a) the findings of the prescription drug importation study described in Section 26-62-202;

(b) a description of the prescription drug importation program designed by the department in accordance with the provisions of this chapter, including measures that will be taken to:

(i) comply with existing state and federal law; and

(ii) reduce the risk to the public's health and safety; and

(c) an estimate of the reduction in the cost of covered products and health insurance premiums to Utah consumers.
(3) If the application for the prescription drug importation program is not approved by
the secretary, the department shall submit a new application in accordance with the
requirements in Subsection (2) on or before December 1 of each year until the earlier of:
(a) approval of the prescription drug importation program by the secretary; or
(b) January 1, 2023.
(4) On or before December 1 of each year that the department submits an application
under Subsection (2) or (3), the department shall submit a written report to the Health and
Human Services Interim Committee regarding the results of the application and any updated
findings and recommendations.

Section 4. Section 26-62-202 is enacted to read:
(1) As funding is available, the department shall study how to gain approval by the
secretary for the state to import certain prescription drugs from Canada for eventual use by
Utah consumers.
(2) The study described in Subsection (1) shall include:
(a) a plan for operating the prescription drug importation program;
(b) a plan to ensure that prescription drugs imported into the state under the
prescription drug importation program meet applicable United States federal and state
standards for safety and effectiveness;
(c) examples of prescription drugs with the highest potential for consumer savings
through importation at the time of the study;
(d) an estimate of the total potential consumer savings attributable to importation of
prescription drugs;
(e) potential wholesalers with whom the state could contract to distribute imported
prescription drugs;
(f) proposed amendments to state law to facilitate importation by the state; and
(g) in coordination with the Office of the Attorney General, proposed amendments to
state law to inhibit pharmaceutical manufacturers from manipulating the pharmaceutical
market in the state or adversely affecting consumer access to pharmaceuticals under the
prescription drug importation program.
(3) The department shall consult with the Utah State Board of Pharmacy,
representatives of the pharmaceutical industry, patient advocates, and others representing persons who could be affected by the prescription drug importation program in conducting the study in this section.

(4) No later than November 1, 2018, the department shall submit a written report to the Health and Human Services Interim Committee on the findings and recommendations of the study described in this section.

Section 5. Section 26-62-301 is enacted to read:

**Part 3. Prescription Drug Importation Program.**

**26-62-301. Canadian Prescription Drug Importation Program.**

The department shall establish a Canadian Prescription Drug Importation Program in accordance with the provisions in this chapter.

Section 6. Section 26-62-302 is enacted to read:

**26-62-302. Program requirements.**

The prescription drug importation program established under Section 26-62-301 shall:

(1) only allow for the importation of prescription drugs that have been identified by the department in the pharmaceutical importation list described in Section 26-62-303;

(2) monitor consumer prices to ensure that market competition and routine health plan administration provide significant savings for Utah consumers;

(3) specify the actions that the department, the Insurance Department, and the Department of Commerce will take if market competition and routine health plan administration does not result in significant savings for Utah consumers;

(4) only use Canadian suppliers regulated under relevant Canadian federal or provincial laws;

(5) if required by the secretary, establish a process to ensure the purity, chemical composition, and potency of imported products;

(6) ensure that imported prescription drugs will not be distributed, dispensed, or sold outside of the state;

(7) ensure that a participating health insurer keeps formularies and claims payment systems up to date with the prescription drugs provided through the prescription drug importation program;

(8) ensure that a participating health insurer bases patient cost sharing on a reasonable
152 commercial price for imported prescription drugs;
153 (9) require that a participating health insurer demonstrate to the Insurance Department
154 how savings on imported prescription drugs are reflected in premiums;
155 (10) ensure that the program does not import a generic prescription drug that would
156 violate United States patent laws;
157 (11) comply with the track and trace requirements in Title II of the Drug Security and
158 Quality Act, 4 U.S.C. Sec. 360eee, et seq., before imported prescription drugs come into
159 possession of the wholesaler;
160 (12) ensure that the supply and distribution chain is in compliance with applicable
161 United States federal and state law after imported prescription drugs are in the possession of
162 the wholesaler;
163 (13) ensure that the prescription drug importation program is adequately financed
164 through an efficient approach that does not jeopardize significant consumer savings;
165 (14) require publication of the wholesalers' acquisition cost of each imported
166 prescription drug;
167 (15) for an imported prescription drug, require a participating pharmacy to disclose
168 upon request the price of the drug that the participating pharmacy will charge to a patient who
169 is not covered by a health plan or contract; and
170 (16) include an audit function described in Section 26-62-304.
171 Section 7. Section 26-62-303 is enacted to read:
173 (1) (a) The department shall coordinate with the Utah State Board of Pharmacy to
174 develop and periodically revise a pharmaceutical importation list in accordance with this
175 section.
176 (b) The department may coordinate with a working group created under the direction of
177 the Utah State Board of Pharmacy to satisfy the requirement in Subsection (1)(a).
178 (2) The pharmaceutical importation list described in Subsection (1)(a):
179 (a) shall include prescription drugs that:
180 (i) may be imported from Canada under applicable United States federal and state law;
181 and
182 (ii) are expected to generate substantial savings for Utah consumers; and
(b) may not include a prescription drug that is:

(i) a controlled substance, as that term is defined in 21 U.S.C. Sec. 802;

(ii) a biological product, as that term is defined in 42 U.S.C. Sec. 262;

(iii) an infused drug, including a peritoneal dialysis solution;

(iv) an intravenously injected drug;

(v) a drug that is inhaled during surgery; or

(vi) a drug that may not be imported under applicable United States federal and state law.

(3) A health insurer shall provide the department and the Utah State Board of Pharmacy or the designees of the Utah State Board of Pharmacy with any information requested by the department regarding:

(a) the cost of a prescription drug to the health insurer, including the amount of any discount or rebate;

(b) the quantity of a prescription drug that is dispensed to covered individuals, regardless of whether the health insurer pays for the prescription drug; and

(c) the amount of any co-pay or other charge that a health insurer imposes on a covered individual for the prescription drug.

(4) The information described in Subsection (3):

(a) shall only be used for the purpose of developing the pharmaceutical importation list or enforcing provisions of this chapter;

(b) is proprietary information that the department, the Utah State Board of Pharmacy, or a designee of the Utah State Board of Pharmacy may not disclose to any person;

(c) is a private record for the purpose of Title 63G, Chapter 2, Government Records Access and Management Act; and

(d) may not contain personally identifiable personal health care information that is protected by the Health Insurance Portability and Accountability Act as defined in Section 31A-1-301.

(5) The department shall:

(a) review the pharmaceutical importation list every three months to ensure that the pharmaceutical importation list continues to meet the requirements in Subsection (2); and

(b) establish policies and procedures by rule made in accordance with Title 63G.
Chapter 3, Utah Administrative Rulemaking Act, for updating the pharmaceutical importation list in accordance with Subsection (5)(a).

Section 8. Section 26-62-304 is enacted to read:


(1) The prescription drug importation program established under Section 26-62-301 shall include regular audits of suppliers, importers, wholesalers, retail pharmacies, health insurers, and other persons who participate in the prescription drug importation program.

(2) The audit function in Subsection (1) shall:

(a) include a review of the:

(i) methodology used to determine the prescription drugs with the greatest potential for savings;

(ii) process used to ensure that Canadian suppliers are of high quality, high performance, and in full compliance with Canadian laws;

(iii) methods used to ensure that imported prescription drugs under the prescription drug importation program are not shipped, sold, or dispensed outside the state once in the possession of the wholesaler or the wholesaler's contractors; and

(iv) processes used to ensure that imported prescription drugs are pure, unadulterated, potent, and safe; and

(b) ensure that Utah consumers benefit from significant savings by verifying that:

(i) participating pharmacies and administering providers are not charging rates that jeopardize significant consumer savings to any consumer or participating health plan;

(ii) a participating health insurer bases formularies and claims processing systems remain up to date with all relevant aspects of the prescription drug importation program;

(iii) a participating health insurer bases patient coinsurance and other cost sharing on a commercially reasonable rate for covered, imported prescription drugs that does not jeopardize significant consumer savings;

(iv) a participating health insurer reimburses participating pharmacies and administering providers no more than a commercially reasonable rate for imported, dispensed prescription drugs;

(v) the prescription drug importation program is adequately financed to support all administrative functions while generating significant consumer savings;
(vi) the prescription drug importation program does not put consumers at a higher health and safety risk than if the program did not exist;
(vii) the prescription drug importation program continues to provide Utah consumers with substantial savings on imported prescription drugs; and
(viii) a participating pharmacy's ability to negotiate professional fees is not impeded.

(2) The department shall coordinate with the Insurance Department and the Department of Commerce to conduct audits in accordance with this section and to enforce the provisions of this chapter.

Section 9. Section 26-62-305 is enacted to read:


(1) The department is responsible for implementing the provisions of the prescription drug importation program upon:
   (a) certification by the secretary to the United States Congress, in accordance with 21 U.S.C. Sec. 384(l), that importation of Canadian prescription drugs will:
      (i) pose no additional risk to the public's health and safety; and
      (ii) result in a significant reduction in the cost of covered products to the American consumer;
   (b) approval by the secretary of the prescription drug importation program; and
   (c) satisfying any other requirements of state and federal law for the importation of prescription drugs from Canada.

(2) The department shall implement the prescription drug importation program by contracting with any wholesale pharmacy that:
   (a) is licensed to operate in the state as a class C pharmacy under Section 58-17b-302;
   (b) complies with the program requirements described in Section 26-62-302; and
   (c) agrees to any additional conditions of participation that may be established by the department in accordance with the requirements of federal law and this chapter.

(3) (a) The department may establish fees, in accordance with Section 63J-1-504, on an entity that participates in the prescription drug importation program for the importation of prescription drugs.
    (b) The fees in Subsection (3)(a) may not exceed the amount necessary to cover the cost the department incurs to implement this chapter.
(c) The department shall deposit in the General Fund the fees described in Subsection (3)(a) as a dedicated credit to be used solely to pay for the cost of implementing this chapter.

(4) Before the conditions described in Subsection (1) are satisfied, the department:
(a) may, to the extent allowed under United State federal and state law:
(i) design the prescription drug importation program; and
(ii) negotiate with wholesalers in Canada and the United States regarding the potential implementation of the prescription drug importation program; and
(b) may not:
(i) allow the importation of any prescription drugs under this chapter; or
(ii) implement any provisions of the prescription drug importation program that would violate United States federal or state law.

Section 10. Section 58-17b-626 is enacted to read:

58-17b-626. Pharmaceutical manufacturer -- Prohibited conduct -- Penalties.
(1) A pharmaceutical manufacturer may not:
(a) take any action, by agreement, unilaterally, or otherwise, that has the effect of fixing or otherwise controlling the price that a pharmaceutical supplier, distributor, or dispenser charges or advertises for pharmaceuticals in the drug importation program; or
(b) discriminate against a pharmaceutical supplier, distributor, or dispenser based on whether the supplier, distributor, or dispenser participates in the prescription drug importation program established under Section 26-62-301.
(2) The attorney general may bring a civil action or seek an injunction against any person who violates a provision of this section.

Section 11. Section 76-10-3104 is amended to read:

76-10-3104. Illegal anticompetitive activities.
(1) Every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce is declared to be illegal.
(2) It shall be unlawful for any person to monopolize, or attempt to monopolize, or combine or conspire with any other person or persons to monopolize, any part of trade or commerce.
(3) For purposes of the importation of prescription drugs under Title 26, Chapter 62, Canadian Prescription Drug Importation Act, in addition to the activities described in
Subsections (1) and (2), a unilateral act in the form of a trust or otherwise, in restraint of trade or commerce, is unlawful.

Legislative Review Note
Office of Legislative Research and General Counsel