LEGISLATIVE GENERAL COUNSEL
₵ Approved for Filing: D.M. Cheung ₵
₵ 02-13-18 10:01 AM ₵

H.B. 163
2nd Sub. (Gray)

Representative Norman K. Thurston proposes the following substitute bill:

PRESCRIPTION DRUG AMENDMENTS

2018 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Norman K. Thurston

Senate Sponsor: Deidre M. Henderson

LONG TITLE

General Description:

This bill creates a program and reporting requirements relating to prescription drugs and the importation of prescription drugs.

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;
- requires pharmaceutical manufacturers to provide information to the state about certain price increases for prescription drugs;
- modifies the Utah Antitrust Act to make certain anticompetitive activities illegal; and
- creates a sunset date for the provisions of this bill.

Money Appropriated in this Bill:

2nd Sub. H.B. 163

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

63I-1-226, as last amended by Laws of Utah 2017, Chapters 177 and 443

63I-1-276, as enacted by Laws of Utah 2014, Chapter 226

76-10-3104, as renumbered and amended by Laws of Utah 2013, Chapter 187

ENACTS:

26-62-101, Utah Code Annotated 1953

26-62-102, Utah Code Annotated 1953

26-62-201, Utah Code Annotated 1953

26-62-202, Utah Code Annotated 1953

26-62-301, Utah Code Annotated 1953

26-62-302, Utah Code Annotated 1953

26-62-303, Utah Code Annotated 1953

26-62-304, Utah Code Annotated 1953

26-62-305, Utah Code Annotated 1953

26-62-401, Utah Code Annotated 1953

26-62-402, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

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

CHAPTER 62. PRESCRIPTION DRUG AFFORDABILITY ACT

Part 1. General Provisions.

26-62-101. Title.

This chapter is known as the "Prescription Drug Affordability Act."

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

26-62-102. Definitions.

As used in this chapter:

(1) "Drug" means the same as that term is defined in Section 58-17b-102.

(2) "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

(ii) that is a self-insured employer as defined in Section 34A-2-201.5.

(3) "Pharmaceutical manufacturer" means:

(a) a person that is engaged in the manufacturing of drugs or pharmaceutical devices that are available for purchase by residents of the state; or

(b) a person that is responsible for setting the price of a drug or device that is available for purchase by residents of the state on behalf of a person described in this Subsection (3).

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

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

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

Part 2. Application and Certification.

26-62-201. Application for approval of prescription drug importation program and certification of Canadian drug importation.

(1) The department shall submit to the secretary:

(a) no later than July 31, 2018, a brief 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 department does not believe that the department will be able to submit the application described in Subsection (1)(b) before December 31, 2018, the department shall report to the Health and Human Services Interim Committee before December 31, 2018, on:

(a) the reason for the delay in submitting the application;

(b) any steps that the department has taken to prepare the application; and

(c) when the department believes that the application will be ready for submission.

(4) 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.

(5) On or before December 1 of each year that the department submits an application under Subsection (2) or (4), 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:

26-62-202. Prescription drug importation study.

(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, health insurers, 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.

(5) The department shall seek grant funding to conduct the study described in this section.

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

Part 3. Canadian 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 the program does not import a generic prescription drug that would violate United States patent laws;

(8) comply with the track and trace requirements in Title II of the Drug Security and Quality Act, 4 U.S.C. Sec. 360eee, et seq., before imported prescription drugs come into possession of the wholesaler;

(9) ensure that the supply and distribution chain is in compliance with applicable United States federal and state law after imported prescription drugs are in the possession of the wholesaler;

(10) ensure that the prescription drug importation program is adequately financed through an efficient approach that does not jeopardize significant consumer savings;

(11) require publication of a wholesaler's acquisition cost of each imported prescription drug;

(12) for an imported prescription drug, require a participating pharmacy to disclose upon request the price of the drug that the participating pharmacy will charge to a patient who is not covered by a health plan or contract;

(13) include an audit function described in Section 26-62-304; and

(14) ensure that participation by a wholesaler, health insurer, health care provider, or consumer is voluntary.

Section 7. Section **26-62-303** is enacted to read:

26-62-303. Pharmaceutical importation list.

(1) (a) The department shall coordinate with the Utah State Board of Pharmacy to develop and periodically revise a pharmaceutical importation list in accordance with this section.

(b) The department may coordinate with a working group created under the direction of the Utah State Board of Pharmacy to satisfy the requirement in Subsection (1)(a).

(2) The pharmaceutical importation list described in Subsection (1)(a):

(a) shall include prescription drugs that:

(i) may be imported from Canada under applicable United States federal and state law; and

(ii) are expected to generate substantial savings for Utah consumers; and

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

(3) A participating 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 the net per unit cost of the health insurer's top 20 high-cost drugs and the quantity of those drugs dispensed by the health insurer to covered individuals.

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

(a) shall only be requested and 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:

26-62-304. Audits.

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

(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) the prescription drug importation program is adequately financed to support all administrative functions while generating significant consumer savings;

(iii) the prescription drug importation program does not put consumers at a higher health and safety risk than if the program did not exist;

(iv) the prescription drug importation program continues to provide Utah consumers with substantial savings on imported prescription drugs; and

(v) a participating pharmacy's ability to negotiate professional fees is not impeded.

(3) 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:

26-62-305. Implementation.

(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;

(c) satisfying any other requirements of state and federal law for the importation of prescription drugs from Canada; and

(d) collecting fees under Subsection (3)(a) sufficient to cover the startup costs of the prescription drug program.

(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 shall establish fees, in accordance with Section 63J-1-504, on an entity that participates in the prescription drug importation program to cover all startup and implementation costs of the prescription drug program.

(b) The Insurance Department may establish fees, in accordance with Section 63J-1-504, on an insurer that participates in the prescription drug importation program to take

an action specified by the department under Subsection 26-62-302(3) or Subsection 26-62-304(3).

(c) (i) A fee collected by the department under Subsection (3)(a) is a dedicated credit for use by the department to implement this chapter.

(ii) A fee collected by the Insurance Department under Subsection (3)(b) is a dedicated credit for use by the Insurance Department to perform the functions described in Subsection (3)(b).

(d) The fees in Subsections (3)(a) and (b) may not exceed the amount necessary to cover the cost the department incurs to implement this chapter.

(e) 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 **26-62-401** is enacted to read:

26-62-401. 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.

(2) The attorney general may bring a civil action or seek an injunction against any person who violates a provision of this section, and may seek any remedy available to the

attorney general for violations of Title 76, Chapter 10, Part 31, Utah Antitrust Act.

Section 11. Section **26-62-402** is enacted to read:

26-62-402. Pharmaceutical manufacturer -- Report required.

(1) For each drug that has an annual wholesale acquisition cost of $10,000 or more, a pharmaceutical manufacturer shall submit a report to the department if a price increase for that drug will result in an increase in the wholesale acquisition cost that is equal to:

(a) 7.5% or more over a period of 12 months; or

(b) 18% or more over a period of 36 months.

(2) The report described in Subsection (1) shall:

(a) be submitted to the department no later than 30 days before the day on which the price increase takes effect; and

(b) include, for each drug for which a report is required under Subsection (1):

(i) the increase in the cost of the drug, expressed as a percentage increase based on the price of the drug before the cost increase;

(ii) a justification for each price increase;

(iii) the date on which each price increase takes effect;

(iv) the total profit derived from sales of the drug, expressed in total dollars and as a percentage of the pharmaceutical manufacturer's total profits for that calendar year;

(v) the total expenditures of the pharmaceutical manufacturer on materials and manufacturing for the drug;

(vi) the total research and development costs paid by the pharmaceutical manufacturer for the development and production of the drug;

(vii) the total administrative, marketing, and advertising costs for the drug; and

(viii) costs associated with direct-to-consumer coupons and patient assistance programs for the drug.

(3) (a) The department shall publish information submitted to the department under this section:

(i) at least once in every three month period; and

(ii) in a manner that allows the information to be identified separately for each drug.

(b) Notwithstanding Subsection (3)(a), the department may not disclose a trade secret, as defined in Section 13-24-2, under this section.

(4) Information submitted to the department under this section is a private record for the purpose of Title 63G, Chapter 2, Government Records Access and Management Act.

Section 12. Section **63I-1-226** is amended to read:

63I-1-226. Repeal dates, Title 26.

(1) Section 26-1-40 is repealed July 1, 2019.

(2) Title 26, Chapter 9f, Utah Digital Health Service Commission Act, is repealed July 1, 2025.

(3) Section 26-10-11 is repealed July 1, 2020.

(4) Title 26, Chapter 33a, Utah Health Data Authority Act, is repealed July 1, 2024.

(5) Title 26, Chapter 36a, Hospital Provider Assessment Act, is repealed July 1, 2019.

(6) Title 26, Chapter 36b, Inpatient Hospital Assessment Act, is repealed July 1, 2021.

[~~(7) Section 26-38-2.5 is repealed July 1, 2017.~~]

[~~(8) Section 26-38-2.6 is repealed July 1, 2017.~~]

[~~(9)~~] (7) Title 26, Chapter 56, Hemp Extract Registration Act, is repealed July 1, 2021.

(8) Title 26, Chapter 62, Prescription Drug Affordability Act, is repealed July 1, 2028.

Section 13. Section **63I-1-276** is amended to read:

63I-1-276. Repeal dates, Title 76.

(1) Subsection 76-10-526(15) is repealed July 1, 2018.

(2) Subsection 76-10-3104(3) is repealed July 1, 2028.

Section 14. 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, Prescription Drug Affordability 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.