

**Representative Brad R. Wilson** proposes the following substitute bill:

**PRESCRIPTION DRUG AMENDMENTS**

2018 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Norman K. Thurston**

Senate Sponsor: Deidre M. Henderson

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**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 Utah Antitrust Act to make certain anticompetitive activities illegal.

**Money Appropriated in this Bill:**

None

**Other Special Clauses:**



26 None

27 **Utah Code Sections Affected:**

28 AMENDS:

29 **76-10-3104**, as renumbered and amended by Laws of Utah 2013, Chapter 187

30 ENACTS:

31 **26-62-101**, Utah Code Annotated 1953

32 **26-62-102**, Utah Code Annotated 1953

33 **26-62-201**, Utah Code Annotated 1953

34 **26-62-202**, Utah Code Annotated 1953

35 **26-62-301**, Utah Code Annotated 1953

36 **26-62-302**, Utah Code Annotated 1953

37 **26-62-303**, Utah Code Annotated 1953

38 **26-62-304**, Utah Code Annotated 1953

39 **26-62-305**, Utah Code Annotated 1953

40 **26-62-401**, Utah Code Annotated 1953



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

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

44 **CHAPTER 62. PRESCRIPTION DRUG AFFORDABILITY ACT**

45 **Part 1. General Provisions.**

46 **26-62-101. Title.**

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

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

49 **26-62-102. Definitions.**

50 As used in this chapter:

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

52 (2) "Health insurer" means:

53 (a) an insurer who offers health care insurance as that term is defined in Section

54 [31A-1-301](#);

55 (b) for health benefits offered to state employees under Section [49-20-202](#), the Public

56 Employees' Benefit and Insurance Program created in Section [49-20-103](#); or

57 (c) a workers' compensation insurer:  
58 (i) authorized to provide workers' compensation insurance in the state; or  
59 (ii) that is a self-insured employer as defined in Section [34A-2-201.5](#).

60 (3) "Pharmaceutical manufacturer" means:  
61 (a) a person that is engaged in the manufacturing of drugs or pharmaceutical devices  
62 that are available for purchase by residents of the state; or

63 (b) a person that is responsible for setting the price of a drug or device that is available  
64 for purchase by residents of the state of Utah on behalf of a person described in Subsection  
65 (2)(a).

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

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

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

71 **Part 2. Application and Certification.**

72 **26-62-201. Application for approval of prescription drug importation program**  
73 **and certification of Canadian drug importation.**

74 (1) The department shall submit to the secretary:

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

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

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

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

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

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

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

87 (a) the findings of the prescription drug importation study described in Section

88 [26-62-202](#);

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

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

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

94 (c) an estimate of the reduction in the cost of covered products and health insurance  
95 premiums to Utah consumers.

96 (3) If the application for the prescription drug importation program is not approved by  
97 the secretary, the department shall submit a new application in accordance with the  
98 requirements in Subsection (2) on or before December 1 of each year until the earlier of:

99 (a) approval of the prescription drug importation program by the secretary; or

100 (b) January 1, 2023.

101 (4) On or before December 1 of each year that the department submits an application  
102 under Subsection (2) or (3), the department shall submit a written report to the Health and  
103 Human Services Interim Committee regarding the results of the application and any updated  
104 findings and recommendations.

105 Section 4. Section **26-62-202** is enacted to read:

106 **26-62-202. Prescription drug importation study.**

107 (1) As funding is available, the department shall study how to gain approval by the  
108 secretary for the state to import certain prescription drugs from Canada for eventual use by  
109 Utah consumers.

110 (2) The study described in Subsection (1) shall include:

111 (a) a plan for operating the prescription drug importation program;

112 (b) a plan to ensure that prescription drugs imported into the state under the  
113 prescription drug importation program meet applicable United States federal and state  
114 standards for safety and effectiveness;

115 (c) examples of prescription drugs with the highest potential for consumer savings  
116 through importation at the time of the study;

117 (d) an estimate of the total potential consumer savings attributable to importation of  
118 prescription drugs;

119 (e) potential wholesalers with whom the state could contract to distribute imported  
120 prescription drugs;

121 (f) proposed amendments to state law to facilitate importation by the state; and

122 (g) in coordination with the Office of the Attorney General, proposed amendments to  
123 state law to inhibit pharmaceutical manufacturers from manipulating the pharmaceutical  
124 market in the state or adversely affecting consumer access to pharmaceuticals under the  
125 prescription drug importation program.

126 (3) The department shall consult with the Utah State Board of Pharmacy,  
127 representatives of the pharmaceutical industry, patient advocates, health insurers, and others  
128 representing persons who could be affected by the prescription drug importation program in  
129 conducting the study in this section.

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

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

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

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

137 **26-62-301. Canadian Prescription Drug Importation Program.**

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

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

141 **26-62-302. Program requirements.**

142 The prescription drug importation program established under Section [26-62-301](#) shall:

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

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

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

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

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

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

156 (7) ensure that the program does not import a generic prescription drug that would  
157 violate United States patent laws;

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

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

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

166 (11) require publication of the wholesalers' acquisition cost of each imported  
167 prescription drug;

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

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

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

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

175 **26-62-303. Pharmaceutical importation list.**

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

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

- 181 (2) The pharmaceutical importation list described in Subsection (1)(a):  
182 (a) shall include prescription drugs that:  
183 (i) may be imported from Canada under applicable United States federal and state law;  
184 and  
185 (ii) are expected to generate substantial savings for Utah consumers; and  
186 (b) may not include a prescription drug that may not be imported under applicable  
187 United States federal and state law.
- 188 (3) A participating health insurer shall provide the department and the Utah State  
189 Board of Pharmacy or the designees of the Utah State Board of Pharmacy with any information  
190 requested by the department regarding the net per unit cost of the health insurer's top twenty  
191 high-cost drugs and the quantity of those drugs dispensed by the health insurer to covered  
192 individuals.
- 193 (4) The information described in Subsection (3):  
194 (a) shall only be requested and used for the purpose of developing the pharmaceutical  
195 importation list or enforcing provisions of this chapter;  
196 (b) is proprietary information that the department, the Utah State Board of Pharmacy,  
197 or a designee of the Utah State Board of Pharmacy may not disclose to any person;  
198 (c) is a private record for the purpose of Title 63G, Chapter 2, Government Records  
199 Access and Management Act; and  
200 (d) may not contain personally identifiable personal health care information that is  
201 protected by the Health Insurance Portability and Accountability Act as defined in Section  
202 [31A-1-301](#).
- 203 (5) The department shall:  
204 (a) review the pharmaceutical importation list every three months to ensure that the  
205 pharmaceutical importation list continues to meet the requirements in Subsection (2); and  
206 (b) establish policies and procedures by rule made in accordance with Title 63G,  
207 Chapter 3, Utah Administrative Rulemaking Act, for updating the pharmaceutical importation  
208 list in accordance with Subsection (5)(a).
- 209 Section 8. Section **26-62-304** is enacted to read:  
210 **26-62-304. Audits.**  
211 (1) The prescription drug importation program established under Section [26-62-301](#)

212 shall include audits of suppliers, importers, wholesalers, retail pharmacies, health insurers, and  
213 other persons who participate in the prescription drug importation program as appropriate and  
214 necessary.

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

216 (a) include a review of the:

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

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

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

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

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

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

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

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

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

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

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

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

240 **26-62-305. Implementation.**

241 (1) The department is responsible for implementing the provisions of the prescription  
242 drug importation program upon:



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

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

246 (ii) result in a significant reduction in the cost of covered products to the American  
247 consumer;

248 (b) approval by the secretary of the prescription drug importation program; and

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

251 (2) The department shall implement the prescription drug importation program by  
252 contracting with any wholesale pharmacy that:

253 (a) is licensed to operate in the state as a class C pharmacy under Section [58-17b-302](#);

254 (b) complies with the program requirements described in Section [26-62-302](#); and

255 (c) agrees to any additional conditions of participation that may be established by the  
256 department in accordance with the requirements of federal law and this chapter.

257 (3) (a) The department may establish fees, in accordance with Section [63J-1-504](#), on an  
258 entity that participates in the prescription drug importation program for the importation of  
259 prescription drugs.

260 (b) The Insurance Department may establish fees, in accordance with Section  
261 [63J-1-504](#), on an insurer that participates in the prescription drug importation program to take  
262 any actions specified by the department under Subsection [26-62-302](#)(3).

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

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

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

270 (c) The department shall deposit in the General Fund the fees described in Subsection  
271 (3)(a) as a dedicated credit to be used solely to pay for the cost of implementing this chapter.

272 (4) Before the conditions described in Subsection (1) are satisfied, the department:

273 (a) may, to the extent allowed under United State federal and state law:

274 (i) design the prescription drug importation program; and  
275 (ii) negotiate with wholesalers in Canada and the United States regarding the potential  
276 implementation of the prescription drug importation program; and

277 (b) may not:

278 (i) allow the importation of any prescription drugs under this chapter; or

279 (ii) implement any provisions of the prescription drug importation program that would  
280 violate United States federal or state law.

281 Section 10. Section **26-62-401** is enacted to read:

282 **26-62-401. Pharmaceutical manufacturer -- Prohibited conduct -- Penalties.**

283 (1) A pharmaceutical manufacturer may not:

284 (a) take any action, by agreement, unilaterally, or otherwise, that has the effect of  
285 fixing or otherwise controlling the price that a pharmaceutical supplier, distributor, or dispenser  
286 charges or advertises for pharmaceuticals in the drug importation program; or

287 (b) discriminate against a pharmaceutical supplier, distributor, or dispenser based on  
288 whether the supplier, distributor, or dispenser participates in the prescription drug importation  
289 program.

290 (2) The attorney general may bring a civil action or seek an injunction against any  
291 person who violates a provision of this section.

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

293 **76-10-3104. Illegal anticompetitive activities.**

294 (1) Every contract, combination in the form of trust or otherwise, or conspiracy in  
295 restraint of trade or commerce is declared to be illegal.

296 (2) It shall be unlawful for any person to monopolize, or attempt to monopolize, or  
297 combine or conspire with any other person or persons to monopolize, any part of trade or  
298 commerce.

299 (3) For purposes of the importation of prescription drugs under Title 26, Chapter 62,  
300 Canadian Prescription Drug Importation Act, in addition to the activities described in  
301 Subsections (1) and (2), a unilateral act in the form of a trust or otherwise, in restraint of trade  
302 or commerce, is unlawful.