

1                   **PRESCRIPTION DRUG IMPORTATION PROGRAM**

2                                   2018 GENERAL SESSION

3                                   STATE OF UTAH

4                           **Chief Sponsor: Norman K. Thurston**

5                           Senate Sponsor: Deidre M. Henderson

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7   **LONG TITLE**

8   **General Description:**

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

13 **Highlighted Provisions:**

14       This bill:

- 15       ▶ defines terms;
- 16       ▶ requires the Department of Health to:
  - 17       • design a prescription drug importation program;
  - 18       • apply for approval of the prescription drug importation program;
  - 19       • if the program is approved, implement the provisions of the program; and
  - 20       • if approval is denied, study how the state can obtain approval for the program;
- 21       ▶ describes the requirements of the prescription drug importation program; and
- 22       ▶ modifies the Pharmacy Practice Act and the Utah Antitrust Act to make certain

23 anticompétitive activities illegal.

24 **Money Appropriated in this Bill:**

25       None

26 **Other Special Clauses:**

27       None



28 **Utah Code Sections Affected:**

29 AMENDS:

30 [76-10-3104](#), as renumbered and amended by Laws of Utah 2013, Chapter 187

31 ENACTS:

32 [26-62-101](#), Utah Code Annotated 1953

33 [26-62-102](#), Utah Code Annotated 1953

34 [26-62-201](#), Utah Code Annotated 1953

35 [26-62-202](#), Utah Code Annotated 1953

36 [26-62-301](#), Utah Code Annotated 1953

37 [26-62-302](#), Utah Code Annotated 1953

38 [26-62-303](#), Utah Code Annotated 1953

39 [26-62-304](#), Utah Code Annotated 1953

40 [26-62-305](#), Utah Code Annotated 1953

41 [58-17b-626](#), Utah Code Annotated 1953



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

44 Section 1. Section [26-62-101](#) is enacted to read:

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

46 **Part 1. General Provisions.**

47 **26-62-101. Title.**

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

49 Section 2. Section [26-62-102](#) is enacted to read:

50 **26-62-102. Definitions.**

51 As used in this chapter:

52 (1) "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 (2) "Prescription drug importation program" means the Canadian Prescription Drug  
61 Importation Program established under Section [26-62-301](#).

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

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

65 **Part 2. Application and Certification.**

66 **26-62-201. Application for approval of prescription drug importation program**  
67 **and certification of Canadian drug importation.**

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

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

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

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

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

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

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

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

81 (a) the findings of the prescription drug importation study described in Section  
82 [26-62-202](#);

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

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

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

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

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

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

94 (b) January 1, 2023.

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

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

100 **26-62-202. Prescription drug importation study.**

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

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

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

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

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

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

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

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

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

120 (3) The department shall consult with the Utah State Board of Pharmacy,

121 representatives of the pharmaceutical industry, patient advocates, and others representing  
122 persons who could be affected by the prescription drug importation program in conducting the  
123 study in this section.

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

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

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

129 **26-62-301. Canadian Prescription Drug Importation Program.**

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

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

133 **26-62-302. Program requirements.**

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

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

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

139 (3) specify the actions that the department, the Insurance Department, and the  
140 Department of Commerce will take if market competition and routine health plan

141 administration does not result in significant savings for Utah consumers;

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

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

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

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

151 (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:

172 **26-62-303. Pharmaceutical importation list.**

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

183 (b) may not include a prescription drug that is:  
184 (i) a controlled substance, as that term is defined in 21 U.S.C. Sec. 802;  
185 (ii) a biological product, as that term is defined in 42 U.S.C. Sec. 262;  
186 (iii) an infused drug, including a peritoneal dialysis solution;  
187 (iv) an intravenously injected drug;  
188 (v) a drug that is inhaled during surgery; or  
189 (vi) a drug that may not be imported under applicable United States federal and state  
190 law.

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

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

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

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

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

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

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

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

207 (d) may not contain personally identifiable personal health care information that is  
208 protected by the Health Insurance Portability and Accountability Act as defined in Section  
209 [31A-1-301](#).

210 (5) The department shall:

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

213 (b) establish policies and procedures by rule made in accordance with Title 63G,

214 Chapter 3, Utah Administrative Rulemaking Act, for updating the pharmaceutical importation  
215 list in accordance with Subsection (5)(a).

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

217 **26-62-304. Audits.**

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

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

222 (a) include a review of the:

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

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

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

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

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

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

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

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

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

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



245 (vi) the prescription drug importation program does not put consumers at a higher  
246 health and safety risk than if the program did not exist;  
247 (vii) the prescription drug importation program continues to provide Utah consumers  
248 with substantial savings on imported prescription drugs; and  
249 (viii) a participating pharmacy's ability to negotiate professional fees is not impeded.  
250 (2) The department shall coordinate with the Insurance Department and the  
251 Department of Commerce to conduct audits in accordance with this section and to enforce the  
252 provisions of this chapter.

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

254 **26-62-305. Implementation.**

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

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

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

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

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

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

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

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

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

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

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

274 (b) The fees in Subsection (3)(a) may not exceed the amount necessary to cover the  
275 cost the department incurs to implement this chapter.

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

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

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

280 (i) design the prescription drug importation program; and

281 (ii) negotiate with wholesalers in Canada and the United States regarding the potential  
282 implementation of the prescription drug importation program; and

283 (b) may not:

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

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

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

288 **58-17b-626. Pharmaceutical manufacturer -- Prohibited conduct -- Penalties.**

289 (1) A pharmaceutical manufacturer may not:

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

293 (b) discriminate against a pharmaceutical supplier, distributor, or dispenser based on  
294 whether the supplier, distributor, or dispenser participates in the prescription drug importation  
295 program established under Section [26-62-301](#).

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

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

299 **76-10-3104. Illegal anticompetitive activities.**

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

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

305 (3) For purposes of the importation of prescription drugs under Title 26, Chapter 62,  
306 Canadian Prescription Drug Importation Act, in addition to the activities described in

307 Subsections (1) and (2), a unilateral act in the form of a trust or otherwise, in restraint of trade  
308 or commerce, is unlawful.

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**Legislative Review Note**  
**Office of Legislative Research and General Counsel**