

1 **PRESCRIPTION DRUG IMPORTATION PROGRAM**

2 2019 GENERAL SESSION

3 STATE OF UTAH

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

5 Senate Sponsor: Curtis S. Bramble

7 **LONG TITLE**

8 **General Description:**

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

11 **Highlighted Provisions:**

12 This bill:

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

21 and

- 22 ▶ creates a sunset date for the provisions of this bill.

23 **Money Appropriated in this Bill:**

24 None

25 **Other Special Clauses:**

26 None

27 **Utah Code Sections Affected:**



28 AMENDS:

29 [63I-1-226](#), as last amended by Laws of Utah 2018, Chapters 180, 281, 384, 430, and
30 468

31 [63I-1-276](#), as enacted by Laws of Utah 2014, Chapter 226

32 [76-10-3104](#), as renumbered and amended by Laws of Utah 2013, Chapter 187

33 ENACTS:

34 [26-66-101](#), Utah Code Annotated 1953

35 [26-66-102](#), Utah Code Annotated 1953

36 [26-66-201](#), Utah Code Annotated 1953

37 [26-66-202](#), Utah Code Annotated 1953

38 [26-66-301](#), Utah Code Annotated 1953

39 [26-66-302](#), Utah Code Annotated 1953

40 [26-66-303](#), Utah Code Annotated 1953

41 [26-66-304](#), Utah Code Annotated 1953

42 [26-66-305](#), Utah Code Annotated 1953

43 [26-66-401](#), Utah Code Annotated 1953



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

46 Section 1. Section [26-66-101](#) is enacted to read:

47 **CHAPTER 66. PRESCRIPTION DRUG AFFORDABILITY ACT**

48 **Part 1. General Provisions**

49 **[26-66-101](#). Title.**

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

51 Section 2. Section [26-66-102](#) is enacted to read:

52 **[26-66-102](#). Definitions.**

53 As used in this chapter:

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

55 (2) "Health insurer" means:

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

57 [31A-1-301](#);

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

59 Employees' Benefit and Insurance Program created in Section 49-20-103; or

60 (c) a workers' compensation insurer:

61 (i) authorized to provide workers' compensation insurance in the state; or

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

63 (3) "Pharmaceutical manufacturer" means:

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

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

68 (4) "Prescription drug importation program" means the Canadian Prescription Drug
69 Importation Program established under Section 26-66-301.

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

72 Section 3. Section 26-66-201 is enacted to read:

73 **Part 2. Application and Certification**

74 **26-66-201. Application for approval of prescription drug importation program**
75 **and certification of Canadian drug importation.**

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

77 (a) no later than July 31, 2019, a brief letter of intent to seek approval for a program to
78 allow for the importation of prescription drugs from Canada into the state under the provisions
79 of 21 U.S.C. Sec. 384(l); and

80 (b) no later than December 31, 2019, an application for:

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

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

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

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

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

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

90 [26-66-202](#);

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

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

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

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

98 (3) If the department does not believe that the department will be able to submit the
99 application described in Subsection (1)(b) before December 31, 2019, the department shall
100 report to the Health and Human Services Interim Committee before December 31, 2019, on:

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

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

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

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

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

108 (b) January 1, 2024.

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

113 Section 4. Section **26-66-202** is enacted to read:

114 **26-66-202. Prescription drug importation study.**

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

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

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

120 (b) a plan to ensure that prescription drugs imported into the state under the

121 prescription drug importation program meet applicable United States federal and state
122 standards for safety and effectiveness;

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

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

127 (e) a list of potential wholesalers with whom the state could contract to distribute
128 imported prescription drugs;

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

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

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

138 (4) No later than November 1, 2019, the department shall submit a written report to the
139 Health and Human Services Interim Committee on the findings and recommendations of the
140 study described in this section.

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

143 Section 5. Section **26-66-301** is enacted to read:

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

145 **26-66-301. Canadian Prescription Drug Importation Program.**

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

148 Section 6. Section **26-66-302** is enacted to read:

149 **26-66-302. Program requirements.**

150 The prescription drug importation program established under Section [26-66-301](#) shall:

151 (1) only allow for the importation of prescription drugs that have been identified by the

- 152 department in the pharmaceutical importation list described in Section [26-66-303](#);
153 (2) monitor consumer prices to ensure that market competition and routine health plan
154 administration provide significant savings for Utah consumers;
155 (3) specify the actions that the department, the Insurance Department, and the
156 Department of Commerce will take if market competition and routine health plan
157 administration does not result in significant savings for Utah consumers;
158 (4) only use Canadian suppliers regulated under relevant Canadian federal or provincial
159 laws;
160 (5) if required by the secretary, establish a process to ensure the purity, chemical
161 composition, and potency of imported products;
162 (6) ensure that imported prescription drugs will not be distributed, dispensed, or sold
163 outside of the state;
164 (7) ensure that the program does not import a generic prescription drug that would
165 violate United States patent laws;
166 (8) comply with the track and trace requirements in Title II of the Drug Security and
167 Quality Act, 4 U.S.C. Sec. 360eee, et seq., before imported prescription drugs come into
168 possession of the wholesaler;
169 (9) ensure that the supply and distribution chain is in compliance with applicable
170 United States federal and state law after imported prescription drugs are in the possession of
171 the wholesaler;
172 (10) ensure that the prescription drug importation program is adequately financed
173 through an efficient approach that does not jeopardize significant consumer savings;
174 (11) require publication of a wholesaler's acquisition cost of each imported prescription
175 drug;
176 (12) for an imported prescription drug, require a participating pharmacy to disclose
177 upon request the price of the drug that the participating pharmacy will charge to a patient who
178 is not covered by a health plan or contract;
179 (13) include an audit function described in Section [26-66-304](#); and
180 (14) ensure that participation by a wholesaler, health insurer, health care provider, or
181 consumer is voluntary.
182 Section 7. Section **26-66-303** is enacted to read:

183 **26-66-303. Pharmaceutical importation list.**

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

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

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

190 (a) shall include prescription drugs that:

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

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

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

196 (3) A participating health insurer shall provide the department and the Utah State
197 Board of Pharmacy or the designees of the Utah State Board of Pharmacy with any information
198 requested by the department regarding the net per unit cost of the health insurer's top 20
199 high-cost drugs and the quantity of those drugs dispensed by the health insurer to covered
200 individuals.

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

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

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

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

208 (d) may not contain personally identifiable personal health care information that is
209 protected by the Health Insurance Portability and Accountability Act as defined in Section
210 [31A-1-301](#).

211 (5) The department shall:

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

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

217 Section 8. Section **26-66-304** is enacted to read:

218 **26-66-304. Audits.**

219 (1) The prescription drug importation program established under Section [26-66-301](#)
220 shall include audits of suppliers, importers, wholesalers, retail pharmacies, health insurers, and
221 other persons who participate in the prescription drug importation program as appropriate and
222 necessary.

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

224 (a) include a review of the:

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

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

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

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

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

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

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

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

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

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

244 (3) The department shall coordinate with the Insurance Department and the

245 Department of Commerce to conduct audits in accordance with this section and to enforce the
246 provisions of this chapter.

247 Section 9. Section **26-66-305** is enacted to read:

248 **26-66-305. Implementation.**

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

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

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

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

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

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

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

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

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

264 (b) complies with the program requirements described in Section [26-66-302](#); and

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

267 (3) (a) The department shall establish fees, in accordance with Section [63J-1-504](#), on
268 an entity that participates in the prescription drug importation program to cover all startup and
269 implementation costs of the prescription drug program.

270 (b) The Insurance Department may establish fees, in accordance with Section
271 [63J-1-504](#), on an insurer that participates in the prescription drug importation program to take
272 an action specified by the department under Subsection [26-66-302](#)(3) or Subsection
273 [26-66-304](#)(3).

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

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

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

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

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

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

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

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

288 (b) may not:

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

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

292 Section 10. Section **26-66-401** is enacted to read:

293 **26-66-401. Pharmaceutical manufacturer -- Prohibited conduct -- Penalties.**

294 (1) A pharmaceutical manufacturer may not:

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

298 (b) discriminate against a pharmaceutical supplier, distributor, or dispenser based on
299 whether the supplier, distributor, or dispenser participates in the prescription drug importation
300 program.

301 (2) The attorney general may bring a civil action or seek an injunction against any
302 person who violates a provision of this section, and may seek any remedy available to the
303 attorney general for violations of Title 76, Chapter 10, Part 31, Utah Antitrust Act.

304 Section 11. Section **63I-1-226** is amended to read:

305 **63I-1-226. Repeal dates, Title 26.**

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

307 (2) Title 26, Chapter 9f, Utah Digital Health Service Commission Act, is repealed July
308 1, 2025.

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

310 (4) Subsection 26-18-417(3) is repealed July 1, 2020.

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

312 (6) Title 26, Chapter 36b, Inpatient Hospital Assessment Act, is repealed July 1, 2024.

313 (7) Title 26, Chapter 36c, Medicaid Expansion Hospital Assessment Act, is repealed
314 July 1, 2024.

315 (8) Title 26, Chapter 36d, Hospital Provider Assessment Act, is repealed July 1, 2019.

316 (9) Title 26, Chapter 56, Hemp Extract Registration Act, is repealed January 1, 2019.

317 (10) Title 26, Chapter 63, Nurse Home Visiting Pay-for-Success Program, is repealed
318 July 1, 2026.

319 (11) Title 26, Chapter 66, Prescription Drug Affordability Act, is repealed July 1, 2029.
320 Section 12. Section 63I-1-276 is amended to read:

321 **63I-1-276. Repeal dates, Title 76.**

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

323 (2) Subsection 76-10-3104(3), referencing anticompetitive activities regarding
324 prescription drugs, is repealed July 1, 2029.

325 Section 13. Section 76-10-3104 is amended to read:

326 **76-10-3104. Illegal anticompetitive activities.**

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

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

332 (3) For purposes of the importation of prescription drugs under Title 26, Chapter 66,
333 Prescription Drug Affordability Act, in addition to the activities described in Subsections (1)
334 and (2), a unilateral act in the form of a trust or otherwise, in restraint of trade or commerce, is
335 unlawful.

336