

**Proposed Substitute
Bill No. 5366**

LCO No. 2939

AN ACT CONCERNING THE COST OF PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective January 1, 2021*) No insurer, health care
2 center, hospital service corporation, medical service corporation,
3 fraternal benefit society or other entity that delivers, issues for delivery,
4 renews, amends or continues an individual or group health insurance
5 policy in this state on or after January 1, 2021, that provides coverage of
6 the type specified in subdivisions (1), (2), (4), (11), (12) and (16) of section
7 38a-469 of the general statutes and includes coverage for prescription
8 drugs shall impose coinsurance, copayments, deductibles and out-of-
9 pocket expenses for covered prescription drugs that, in the aggregate,
10 exceed two hundred fifty dollars per insured per month.

11 Sec. 2. (*Effective from passage*) (a) The Insurance Commissioner shall
12 study the feasibility and anticipated impact of capping the annual
13 percentage increase in the wholesale cost of each outpatient prescription
14 drug sold in this state at an amount that is equal to two per cent above
15 the increase in the consumer price index for all urban consumers, as
16 published by the United States Department of Labor, Bureau of Labor
17 Statistics, for the immediately preceding calendar year.

18 (b) Not later than January 1, 2021, the Insurance Commissioner shall
19 submit a report, in accordance with the provisions of section 11-4a of the
20 general statutes, on the commissioner's findings to the joint standing

21 committee of the General Assembly having cognizance of matters
22 relating to insurance.

23 Sec. 3. (NEW) (*Effective July 1, 2020*) For the purposes of this section
24 and sections 4 to 8, inclusive, of this act unless the context otherwise
25 requires:

26 (1) "Drug" means an article that is (A) recognized in the official United
27 States Pharmacopoeia, official Homeopathic Pharmacopoeia of the
28 United States or official National Formulary, or any supplement thereto,
29 (B) intended for use in the diagnosis, cure, mitigation, treatment or
30 prevention of disease in humans, (C) not food and intended to affect the
31 structure or any function of the human body, and (D) not a device and
32 intended for use as a component of any other article specified in
33 subparagraphs (A) to (C), inclusive, of this subdivision;

34 (2) "Drug Quality and Security Act" means the federal Drug Quality
35 and Security Act, 21 USC 351, et seq., as amended from time to time;

36 (3) "Food, Drug and Cosmetic Act" means the Federal Food, Drug and
37 Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and
38 Security Act, as both may be amended from time to time;

39 (4) "Laboratory testing" means a quantitative and qualitative analysis
40 of a prescription drug consistent with the official United States
41 Pharmacopoeia;

42 (5) "Legend drug" means a drug that (A) any applicable federal or
43 state law requires to be (i) dispensed pursuant to a prescription, or (ii)
44 used by a prescribing practitioner, or (B) applicable federal law requires
45 to bear the following legend: "RX ONLY" IN ACCORDANCE WITH
46 GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND
47 COSMETIC ACT;

48 (6) "Participating Canadian supplier" means a manufacturer or
49 wholesale drug distributor that is (A) licensed or permitted under
50 applicable Canadian law to manufacture or distribute prescription

51 drugs, (B) exporting legend drugs, in the manufacturer's original
52 container, to a participating wholesaler for distribution in this state
53 under the program, and (C) properly registered, if such Canadian
54 supplier is required to be registered, with the United States Food and
55 Drug Administration, or any successor agency;

56 (7) "Participating wholesaler" means a wholesaler, as defined in
57 section 21a-70 of the general statutes, that (A) has received a certificate
58 of registration from the Commissioner of Consumer Protection
59 pursuant to said section, and (B) is designated by the commissioner to
60 participate in the program;

61 (8) "Prescription" means a lawful verbal, written or electronic order
62 by a prescribing practitioner for a drug for a specific patient;

63 (9) "Program" means the Canadian legend drug importation program
64 established by the Commissioner of Consumer Protection pursuant to
65 section 4 of this act;

66 (10) "Qualified laboratory" means a laboratory that is (A) adequately
67 equipped and staffed to properly perform laboratory testing on legend
68 drugs, and (B) accredited to International Organization for
69 Standardization (ISO) 17025; and

70 (11) "Track-and-trace" means the product tracing process for the
71 components of the pharmaceutical distribution supply chain, as
72 described in Title II of the Drug Quality and Security Act.

73 Sec. 4. (NEW) (*Effective July 1, 2020*) (a) The Commissioner of
74 Consumer Protection shall establish a program to be known as the
75 "Canadian legend drug importation program". Under such program,
76 the commissioner shall, notwithstanding any contrary provision of the
77 general statutes:

78 (1) Provide for the importation of safe and effective legend drugs
79 from Canada that have the highest potential for cost savings in this state;
80 and

81 (2) Designate one or more participating wholesalers to distribute
82 legend drugs in this state:

83 (A) In the manufacturer's original container;

84 (B) From a participating Canadian supplier; and

85 (C) To a pharmacy or institutional pharmacy, as both terms are
86 defined in section 20-571 of the general statutes, or a qualified
87 laboratory.

88 (b) (1) Not later than July 1, 2021, the Commissioner of Consumer
89 Protection shall submit a request to the federal Secretary of Health and
90 Human Services seeking approval for the program under 21 USC 384,
91 as amended from time to time. Such request shall, at a minimum:

92 (A) Describe the commissioner's plans for operating the program;

93 (B) Demonstrate that the legend drugs that will be imported and
94 distributed in this state under the program shall:

95 (i) Meet all applicable federal and state standards for safety and
96 effectiveness; and

97 (ii) Comply with all federal tracing procedures; and

98 (C) Disclose the costs of implementing the program.

99 (2) (A) If the federal Secretary of Health and Human Services
100 approves the commissioner's request, the commissioner shall:

101 (i) Submit to the Commissioner of Public Health a notice disclosing
102 that the federal Secretary of Health and Human Services has approved
103 such request;

104 (ii) Submit to the joint standing committees of the General Assembly
105 having cognizance of matters relating to appropriations, general law,
106 human services and public health a notice disclosing that the federal

107 Secretary of Health and Human Services has approved such request;
108 and

109 (iii) Begin operating the program not later than one hundred eighty
110 days after the date of such approval.

111 (B) Except as otherwise provided in this subsection, the
112 Commissioner of Consumer Protection shall not operate the program
113 unless the federal Secretary of Health and Human Services approves the
114 commissioner's request.

115 Sec. 5. (NEW) (*Effective July 1, 2020*) (a) Each participating wholesaler
116 may, subject to the provisions of this section and sections 4 and 7 of this
117 act, import into this state a legend drug from a participating Canadian
118 supplier, and distribute such legend drug to a pharmacy or institutional
119 pharmacy, as both terms are defined in section 20-571 of the general
120 statutes, or a qualified laboratory in this state, under the program if:

121 (1) Such participating wholesaler:

122 (A) Is registered with the federal Secretary of Health and Human
123 Services pursuant to Section 510(b) of the Food, Drug and Cosmetic Act,
124 21 USC 360(b), as amended from time to time; and

125 (B) Holds a valid labeler code that has been issued to such
126 participating wholesaler by the United States Food and Drug
127 Administration, or any successor agency; and

128 (2) Such legend drug:

129 (A) May be imported into this state in accordance with applicable
130 federal patent laws;

131 (B) Meets the United States Food and Drug Administration's, or any
132 successor agency's, standards concerning drug safety, effectiveness,
133 misbranding and adulteration; and

134 (C) Is not:

135 (i) A controlled substance, as defined in 21 USC 802, as amended from
136 time to time;

137 (ii) A biological product, as defined in 42 USC 262, as amended from
138 time to time;

139 (iii) An infused drug;

140 (iv) An intravenously injected drug;

141 (v) A drug that is inhaled during surgery; or

142 (vi) A drug that is a parenteral drug, the importation of which is
143 determined by the federal Secretary of Health and Human Services to
144 pose a threat to the public health.

145 (b) Each participating wholesaler shall:

146 (1) Comply with all applicable track-and-trace requirements, and
147 make available to the Commissioner of Consumer Protection all track-
148 and-trace records not later than forty-eight hours after the commissioner
149 requests such records;

150 (2) Not import, distribute, dispense or sell in this state any legend
151 drugs under the program except in accordance with the provisions of
152 this section and sections 4 and 7 of this act;

153 (3) Not distribute, dispense or sell outside of this state any legend
154 drugs that are imported into this state under the program;

155 (4) Ensure the safety and quality of the legend drugs that are
156 imported and distributed in this state under the program;

157 (5) For each initial shipment of a legend drug that is imported into
158 this state by such participating wholesaler, ensure that a qualified
159 laboratory engaged by such participating wholesaler tests a statistically
160 valid sample size for each batch of such legend drug in such shipment
161 for authenticity and degradation in a manner that is consistent with the

162 Food, Drug and Cosmetic Act;

163 (6) For each shipment of a legend drug that is imported into this state
164 by such participating wholesaler, and sampled and tested pursuant to
165 subdivision (5) of this subsection, ensure that a qualified laboratory
166 engaged by such participating wholesaler tests a statistically valid
167 sample of such legend drug in such shipment for authenticity and
168 degradation in a manner that is consistent with the Food, Drug and
169 Cosmetic Act;

170 (7) Certify to the Commissioner of Consumer Protection that each
171 legend drug imported into this state under the program:

172 (A) Is approved for marketing in the United States and not
173 adulterated or misbranded; and

174 (B) Meets all labeling requirements under 21 USC 352, as amended
175 from time to time;

176 (8) Maintain laboratory records, including, but not limited to,
177 complete data derived from all tests necessary to ensure that each
178 legend drug imported into this state under the program satisfies the
179 requirements of subdivisions (5) and (6) of this subsection;

180 (9) Maintain documentation demonstrating that the testing required
181 by subdivisions (5) and (6) of this subsection was conducted at a
182 qualified laboratory in accordance with the Food, Drug and Cosmetic
183 Act and all other applicable federal and state laws and regulations
184 concerning laboratory qualifications;

185 (10) Maintain the following information for each legend drug that
186 such participating wholesaler imports and distributes in this state under
187 the program, and submit such information to the Commissioner of
188 Consumer Protection upon request by the commissioner:

189 (A) The name and quantity of the active ingredient of such legend
190 drug;

- 191 (B) A description of the dosage form of such legend drug;
- 192 (C) The date on which such participating wholesaler received such
193 legend drug;
- 194 (D) The quantity of such legend drug that such participating
195 wholesaler received;
- 196 (E) The point of origin and destination of such legend drug;
- 197 (F) The price paid by such participating wholesaler for such legend
198 drug;
- 199 (G) A report for any legend drug that fails laboratory testing under
200 subdivision (5) or (6) of this subsection; and
- 201 (H) Such additional information and documentation that the
202 commissioner deems necessary to ensure the protection of the public
203 health; and
- 204 (11) Maintain all information and documentation that is submitted to
205 the Commissioner of Consumer Protection pursuant to this subsection
206 for a period of not less than three years.
- 207 Sec. 6. (NEW) (*Effective July 1, 2020*) Each participating Canadian
208 supplier shall:
- 209 (1) Comply with all applicable track-and-trace requirements;
- 210 (2) Not distribute, dispense or sell outside of this state any legend
211 drugs that are imported into this state under the program; and
- 212 (3) Maintain the following information and documentation and,
213 upon request by the Commissioner of Consumer Protection, submit
214 such information and documentation to the commissioner for each
215 legend drug that such participating Canadian supplier exports into this
216 state under the program:

217 (A) The original source of such legend drug, including, but not
218 limited to:

219 (i) The name of the manufacturer of such legend drug;

220 (ii) The date on which such legend drug was manufactured; and

221 (iii) The location where such legend drug was manufactured;

222 (B) The date on which such legend drug was shipped to a
223 participating wholesaler;

224 (C) The quantity of such legend drug that was shipped to a
225 participating wholesaler;

226 (D) The quantity of each lot of such legend drug that such
227 participating Canadian supplier originally received and the source of
228 such lot;

229 (E) The lot or control number and the batch number assigned to such
230 legend drug by the manufacturer; and

231 (F) Such additional information and documentation that the
232 commissioner deems necessary to ensure the protection of the public
233 health.

234 Sec. 7. (NEW) (*Effective July 1, 2020*) (a) The Commissioner of
235 Consumer Protection shall issue a written order:

236 (1) Suspending importation and distribution of a legend drug under
237 the program if the commissioner discovers that such distribution or
238 importation violates any provision of sections 4 to 6, inclusive, of this
239 act or any other applicable state or federal law or regulation;

240 (2) Suspending all importation and distribution of legend drugs by a
241 participating wholesaler under the program if the commissioner
242 discovers that the participating wholesaler has violated any provision
243 of section 4 or 5 of this act or any other applicable state or federal law or

244 regulation;

245 (3) Suspending all importation and distribution of legend drugs by a
246 participating Canadian supplier under the program if the commissioner
247 discovers that the participating Canadian supplier has violated any
248 provision of section 4 or 6 of this act or any other applicable state or
249 federal law or regulation; or

250 (4) Requiring the recall or seizure of any legend drug that was
251 imported and distributed under the program and has been identified as
252 adulterated, within the meaning of section 21a-105 of the general
253 statutes, or misbranded.

254 (b) The Commissioner of Consumer Protection shall send a notice to
255 each participating Canadian supplier and participating wholesaler
256 affected by an order issued pursuant to subsection (a) of this section
257 notifying such participating Canadian supplier or participating
258 wholesaler that:

259 (1) The commissioner has issued such order, and providing the legal
260 and factual basis for such order; and

261 (2) Such participating Canadian supplier or participating wholesaler
262 may request, in writing, a hearing before the commissioner, provided
263 such request is received by the commissioner not later than thirty days
264 after the date of such notice.

265 (c) If a participating Canadian supplier or participating wholesaler
266 timely requests a hearing pursuant to subsection (b) of this section, the
267 Commissioner of Consumer Protection shall, not later than thirty days
268 after the receipt of the request, convene the hearing as a contested case
269 in accordance with the provisions of chapter 54 of the general statutes.
270 Not later than sixty days after the receipt of such request, the
271 commissioner shall issue a final decision vacating, modifying or
272 affirming the commissioner's order. A participating Canadian supplier
273 or participating wholesaler aggrieved by a final decision may appeal

274 such decision in accordance with the provisions of section 4-183 of the
275 general statutes.

276 Sec. 8. (NEW) (*Effective July 1, 2020*) The Commissioner of Consumer
277 Protection may, in consultation with the Commissioner of Public
278 Health, adopt regulations in accordance with the provisions of chapter
279 54 of the general statutes to implement the provisions of sections 3 to 7,
280 inclusive, of this act.

281 Sec. 9. (NEW) (*Effective October 1, 2020*) (a) Each pharmaceutical
282 manufacturer doing business in this state that manufactures a brand
283 name prescription drug and enters into an agreement with another
284 pharmaceutical manufacturer for the purpose of delaying or preventing
285 such other manufacturer from introducing a generic substitute for such
286 drug into the marketplace shall, not later than thirty days after entering
287 into such agreement, send notice to the Insurance Commissioner, in a
288 form and manner prescribed by the commissioner, disclosing the name
289 of such drug.

290 (b) (1) The commissioner shall, not later than thirty days after
291 receiving a notice pursuant to subsection (a) of this section, send notice
292 to each health carrier, as defined in section 38a-1080 of the general
293 statutes, and pharmacy benefits manager, as defined in section 38a-
294 479aaa of the general statutes, doing business in this state. Such notice
295 shall, at a minimum:

296 (A) Disclose the name of the brand name prescription drug that is the
297 subject of the notice the commissioner received pursuant to subsection
298 (a) of this section; and

299 (B) Instruct such health carrier, if such health carrier includes such
300 drug on such health carrier's drug formulary or list of covered drugs, or
301 pharmacy benefits manager, if such pharmacy benefits manager
302 administers a prescription drug benefit that includes such drug, to
303 immediately reduce the cost of such drug to covered individuals by an
304 amount that is equal to fifty per cent of the manufacturer's wholesale list

305 price for such drug.

306 (2) For the purposes of this subsection, "manufacturer's wholesale list
307 price" has the same meaning as provided in section 21a-126 of the
308 general statutes.

309 (c) The provisions of this section shall apply to the maximum extent
310 permitted by applicable law.

311 (d) The commissioner may adopt regulations, in accordance with
312 chapter 54 of the general statutes, to implement the provisions of this
313 section.

314 Sec. 10. (NEW) (*Effective October 1, 2020*) (a) There is established a
315 Critical Drug Shortage Review Board, which shall be part of the
316 Executive Department.

317 (b) The board shall consist of the following members:

318 (1) The Commissioner of Correction;

319 (2) The Commissioner of Mental Health and Addiction Services;

320 (3) The Commissioner of Social Services; and

321 (4) The executive director of the Office of Health Strategy, established
322 under section 19a-754a of the general statutes.

323 (b) A majority of the board shall constitute a quorum for the
324 transaction of any business.

325 (c) The members of the board shall serve without compensation, but
326 shall, within the limits of available funds, be reimbursed for expenses
327 necessarily incurred in the performance of their duties.

328 (d) The board shall have the following powers and duties: (1) To
329 evaluate the cost of prescription drugs in this state; (2) to declare a
330 prescription drug pricing emergency and recommend that the

331 Commissioner of Public Health request that the federal government
332 exercise its powers under 28 USC 1498; (3) obtain from any executive
333 department, board, commission or other agency of the state such
334 assistance and data as necessary and available to carry out the purposes
335 of this section; (4) accept any gift, donation or bequest for the purpose
336 of performing the duties described in this section; and (5) perform such
337 other acts as may be necessary and appropriate to carry out the duties
338 described in this section.

339 (e) The board shall meet as often as deemed necessary by a majority
340 of the board.

341 (f) The board may enter into such contractual agreements as may be
342 necessary for the discharge of its duties, within the limits of its
343 appropriated funds and in accordance with established procedures.

344 Sec. 11. (NEW) (*Effective January 1, 2021*) (a) For the purposes of this
345 section:

346 (1) "Affordable Care Act" has the same meaning as provided in
347 section 38a-1080 of the general statutes;

348 (2) "Health benefit plan" has the same meaning as provided in section
349 38a-1080 of the general statutes, except that such term shall not include
350 a grandfathered health plan as such term is used in the Affordable Care
351 Act; and

352 (3) "Health carrier" has the same meaning as provided in section 38a-
353 1080 of the general statutes.

354 (b) Notwithstanding any provision of the general statutes and except
355 as provided in subsection (c) of this section, no health carrier offering a
356 health benefit plan in this state on or after January 1, 2021, that includes
357 a pharmacy benefit and uses a drug formulary or list of covered drugs
358 may:

359 (1) Remove a prescription drug from the drug formulary or list of

360 covered drugs during a plan year; or

361 (2) Move a prescription drug from a cost-sharing tier that imposes a
362 lesser coinsurance, copayment or deductible for the prescription drug to
363 a cost-sharing tier that imposes a greater coinsurance, copayment or
364 deductible for the prescription drug during a plan year, unless the
365 prescription drug is subject to an in-network coinsurance, copayment or
366 deductible that is not greater than forty dollars per prescription per
367 month in any tier.

368 (c) A health carrier offering a health benefit plan in this state on or
369 after January 1, 2021, that includes a pharmacy benefit and uses a drug
370 formulary or list of covered drugs may:

371 (1) Remove a prescription drug from the drug formulary or list of
372 covered drugs, upon at least ninety days' advance notice to a covered
373 person and the covered person's treating physician, if:

374 (A) The federal Food and Drug Administration issues an
375 announcement, guidance, notice, warning or statement concerning the
376 prescription drug that calls into question the clinical safety of the
377 prescription drug, unless the covered person's treating physician states,
378 in writing, that the prescription drug remains medically necessary
379 despite such announcement, guidance, notice, warning or statement; or

380 (B) The prescription drug is approved by the federal Food and Drug
381 Administration for use without a prescription; and

382 (2) Move a brand name prescription drug from a cost-sharing tier that
383 imposes a lesser coinsurance, copayment or deductible for the brand
384 name prescription drug to a cost-sharing tier that imposes a greater
385 coinsurance, copayment or deductible for the brand name prescription
386 drug if the health carrier adds to the drug formulary or list of covered
387 drugs a generic prescription drug that is:

388 (A) Approved by the federal Food and Drug Administration for use
389 as an alternative to such brand name prescription drug; and

390 (B) In a cost-sharing tier that imposes a coinsurance, copayment or
391 deductible for the generic prescription drug that is lesser than the
392 coinsurance, copayment or deductible that is imposed for such brand
393 name prescription drug.

394 (d) Nothing in this section shall prevent or prohibit a health carrier
395 from adding a prescription drug to a formulary or list of covered drugs
396 at any time.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>January 1, 2021</i>	New section
Sec. 2	<i>from passage</i>	New section
Sec. 3	<i>July 1, 2020</i>	New section
Sec. 4	<i>July 1, 2020</i>	New section
Sec. 5	<i>July 1, 2020</i>	New section
Sec. 6	<i>July 1, 2020</i>	New section
Sec. 7	<i>July 1, 2020</i>	New section
Sec. 8	<i>July 1, 2020</i>	New section
Sec. 9	<i>October 1, 2020</i>	New section
Sec. 10	<i>October 1, 2020</i>	New section
Sec. 11	<i>January 1, 2021</i>	New section