



General Assembly

February Session, 2022

Amendment

LCO No. 6438



Offered by:

REP. WOOD K., 29th Dist.

REP. PAVALOCK-D'AMATO, 77th Dist.

REP. COOK, 65th Dist.

REP. CARPINO, 32nd Dist.

REP. NUCCIO, 53rd Dist.

REP. COMEY, 102nd Dist.

To: House Bill No. 5400

File No. 302

Cal. No. 232

"AN ACT CONCERNING THE REGULATION OF INSURANCE IN THE STATE."

1 Strike everything after the enacting clause and substitute the
2 following in lieu thereof:

3 "Section 1. Subdivision (1) of subsection (b) of section 38a-510 of the
4 general statutes is repealed and the following is substituted in lieu
5 thereof (*Effective October 1, 2022*):

6 (b) (1) Notwithstanding the sixty-day period set forth in subdivision
7 (2) of subsection (a) of this section, each insurance company, hospital
8 service corporation, medical service corporation, health care center or
9 other entity that uses step therapy for such prescription drugs shall
10 establish and disclose to its health care providers a process by which an
11 insured's treating health care provider may request at any time an
12 override of the use of any step therapy drug regimen. Such disclosure

13 shall be made to health care providers in writing at least once each
14 calendar year, and such health care provider shall display in a
15 conspicuous and prominent location, including the provider's Internet
16 web site and on a bulletin board in the provider's office, information
17 regarding the override process. Any such override process shall be
18 convenient to use by health care providers and an override request shall
19 be expeditiously granted when an insured's treating health care
20 provider demonstrates that the drug regimen required under step
21 therapy (A) has been ineffective in the past for treatment of the insured's
22 medical condition, (B) is expected to be ineffective based on the known
23 relevant physical or mental characteristics of the insured and the known
24 characteristics of the drug regimen, (C) will cause or will likely cause an
25 adverse reaction by or physical harm to the insured, or (D) is not in the
26 best interest of the insured, based on medical necessity. Until October 1,
27 2025, in the case of a prescribed drug for the treatment of schizophrenia,
28 major depressive disorder or bipolar disorder, as defined in the most
29 recent edition of the Diagnostic and Statistical Manual of Mental
30 Disorders, such override request shall be granted not later than twenty-
31 four hours from the time of request.

32 Sec. 2. (*Effective from passage*) (a) There is established a task force to
33 study data collection efforts regarding step therapy. Such study shall
34 include, but need not be limited to, data collection regarding step
35 therapy edits, rejections and appeals of behavioral health drugs and the
36 best methods to collect such data.

37 (b) The task force shall consist of the following members:

38 (1) One appointed by the speaker of the House of Representatives;

39 (2) One appointed by the president pro tempore of the Senate;

40 (3) One appointed by the minority leader of the House of
41 Representatives;

42 (4) The chairpersons and ranking members of the joint standing
43 committees of the General Assembly having cognizance of matters

44 relating to public health and insurance, or their designees;

45 (5) The executive director of the Office of Health Strategy, or the
46 executive director's designee;

47 (6) The Insurance Commissioner, or the Insurance Commissioner's
48 designee;

49 (7) The Commissioner of Consumer Protection, or the commissioner's
50 designee;

51 (8) One representative of the insurance industry, to be appointed by
52 the House chairperson of the joint standing committee of the General
53 Assembly having cognizance of matters relating to insurance;

54 (9) One representative of the pharmaceutical industry, to be
55 appointed by the House ranking member of the joint standing
56 committee of the General Assembly having cognizance of matters
57 relating to insurance;

58 (10) One mental health care provider, to be appointed by the House
59 chairperson of the joint standing committee of the General Assembly
60 having cognizance of matters relating to insurance; and

61 (11) One representative of a mental health advocacy group, who shall
62 be an impacted individual, to be appointed by the House ranking
63 member of the joint standing committee of the General Assembly
64 having cognizance of matters relating to public health.

65 (c) The administrative staff of the joint standing committee of the
66 General Assembly having cognizance of matters relating to public
67 health shall serve as administrative staff of the task force.

68 (d) Not later than July 1, 2023, the task force shall submit a report on
69 its findings and recommendations to the joint standing committees of
70 the General Assembly having cognizance of matters relating to
71 insurance and public health, in accordance with the provisions of
72 section 11-4a of the general statutes. The task force shall terminate on

73 the date that it submits such report or on July 1, 2023, whichever is
74 earlier.

75 Sec. 3. Section 38a-477ff of the 2022 supplement to the general statutes
76 is repealed and the following is substituted in lieu thereof (*Effective from*
77 *passage and applicable to policies delivered, issued for delivery, renewed,*
78 *amended or continued on or after January 1, 2022*):

79 (a) Each insurer, health care center, hospital service corporation,
80 medical service corporation, fraternal benefit society or other entity that
81 delivers, issues for delivery, renews, amends or continues an individual
82 or group health insurance policy in this state on or after January 1, 2022,
83 providing coverage of the type specified in subdivisions (1), (2), (4), (11)
84 and (12) of section 38a-469 shall, when calculating an insured's liability
85 for a coinsurance, copayment, deductible or other out-of-pocket expense
86 for a covered benefit, give credit for any discount provided or payment
87 made by a third party for the amount of, or any portion of the amount
88 of, the coinsurance, copayment, deductible or other out-of-pocket
89 expense for the covered benefit.

90 (b) If, under federal law, application of subsection (a) of this section
91 would result in health savings account ineligibility under Section 223 of
92 the Internal Revenue Code of 1986, or any subsequent corresponding
93 internal revenue code of the United States, as amended from time to
94 time, this requirement shall apply for health savings account-qualified,
95 high deductible health plans with respect to the deductible of such a
96 plan after the enrollee has satisfied the minimum deductible under
97 Section 223 of said internal revenue code, except for items or services
98 that are preventive care pursuant to Section 223(c)(2)(C) of said internal
99 revenue code, in which case the requirements of subsection (a) of this
100 section shall apply regardless of whether the minimum deductible
101 under Section 223 of said internal revenue code is satisfied.

102 Sec. 4. Section 38a-477gg of the 2022 supplement to the general
103 statutes is repealed and the following is substituted in lieu thereof
104 (*Effective from passage and applicable to contracts entered into on or after*

105 *January 1, 2022):*

106 (a) On and after January 1, 2022, each contract entered into between
107 a health carrier, as defined in section 38a-591a, and a pharmacy benefits
108 manager, as defined in section 38a-479aaa, for the administration of the
109 pharmacy benefit portion of a health benefit plan in this state on behalf
110 of plan sponsors shall require that the pharmacy benefits manager,
111 when calculating an insured's or enrollee's liability for a coinsurance,
112 copayment, deductible or other out-of-pocket expense for a covered
113 prescription drug benefit, give credit for any discount provided or
114 payment made by a third party for the amount of, or any portion of the
115 amount of, the coinsurance, copayment, deductible or other out-of-
116 pocket expense for the covered prescription drug benefit.

117 (b) If, under federal law, application of subsection (a) of this section
118 would result in health savings account ineligibility under Section 223 of
119 the Internal Revenue Code of 1986, or any subsequent corresponding
120 internal revenue code of the United States, as amended from time to
121 time, this requirement shall apply for health savings account-qualified,
122 high deductible health plans with respect to the deductible of such a
123 plan after the enrollee has satisfied the minimum deductible under
124 Section 223 of said internal revenue code, except for items or services
125 that are preventive care pursuant to Section 223(c)(2)(C) of said internal
126 revenue code, in which case the requirements of subsection (a) of this
127 section shall apply regardless of whether the minimum deductible
128 under Section 223 of said internal revenue code is satisfied.

129 Sec. 5. Section 38a-478w of the 2022 supplement to the general
130 statutes is repealed and the following is substituted in lieu thereof
131 (*Effective from passage and applicable to contracts delivered, issued for*
132 *delivery, renewed, amended or continued on or after January 1, 2022):*

133 (a) For any contract delivered, issued for delivery, renewed, amended
134 or continued in this state on or after January 1, 2022, each managed care
135 organization shall, when calculating an enrollee's liability for a
136 coinsurance, copayment, deductible or other out-of-pocket expense for

137 a covered benefit, give credit for any discount provided or payment
138 made by a third party for the amount of, or any portion of the amount
139 of, the coinsurance, copayment, deductible or other out-of-pocket
140 expense for the covered benefit.

141 (b) If, under federal law, application of subsection (a) of this section
142 would result in health savings account ineligibility under Section 223 of
143 the Internal Revenue Code of 1986, or any subsequent corresponding
144 internal revenue code of the United States, as amended from time to
145 time, this requirement shall apply for health savings account-qualified,
146 high deductible health plans with respect to the deductible of such a
147 plan after the enrollee has satisfied the minimum deductible under
148 Section 223 of said internal revenue code, except for items or services
149 that are preventive care pursuant to Section 223(c)(2)(C) of said internal
150 revenue code, in which case the requirements of subsection (a) of this
151 section shall apply regardless of whether the minimum deductible
152 under Section 223 of said internal revenue code is satisfied.

153 Sec. 6. Section 38a-490 of the general statutes is repealed and the
154 following is substituted in lieu thereof (*Effective January 1, 2023*):

155 (a) Each individual health insurance policy delivered, issued for
156 delivery, renewed, amended or continued in this state providing
157 coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11)
158 and (12) of section 38a-469 for a family member of the insured or
159 subscriber shall, as to such family member's coverage, also provide that
160 the health insurance benefits applicable for children shall be payable
161 with respect to a newly born child of the insured or subscriber from the
162 moment of birth.

163 (b) Coverage for such newly born child shall consist of coverage for
164 injury and sickness including necessary care and treatment of medically
165 diagnosed congenital defects and birth abnormalities within the limits
166 of the policy.

167 (c) If payment of a specific premium or subscription fee is required to
168 provide coverage for a child, the policy or contract may require that

169 notification of birth of such newly born child and payment of the
170 required premium or fees shall be furnished to the insurer, hospital
171 service corporation, medical service corporation or health care center
172 not later than [sixty-one] ninety-one days after the date of birth in order
173 to continue coverage beyond such [sixty-one-day] period, provided
174 failure to furnish such notice or pay such premium or fees shall not
175 prejudice any claim originating within such [sixty-one-day] period.

176 Sec. 7. Section 38a-516 of the general statutes is repealed and the
177 following is substituted in lieu thereof (*Effective January 1, 2023*):

178 (a) Each group health insurance policy delivered, issued for delivery,
179 renewed, amended or continued in this state providing coverage of the
180 type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-
181 469 for a family member of the insured or subscriber shall, as to such
182 family member's coverage, also provide that the health insurance
183 benefits applicable for children shall be payable with respect to a newly
184 born child of the insured or subscriber from the moment of birth.

185 (b) Coverage for such newly born child shall consist of coverage for
186 injury and sickness including necessary care and treatment of medically
187 diagnosed congenital defects and birth abnormalities within the limits
188 of the policy.

189 (c) If payment of a specific premium fee is required to provide
190 coverage for a child, the policy may require that notification of birth of
191 such newly born child and payment of the required premium or fees
192 shall be furnished to the insurer, hospital service corporation, medical
193 service corporation or health care center not later than [sixty-one]
194 ninety-one days after the date of birth in order to continue coverage
195 beyond such [sixty-one-day] period, provided failure to furnish such
196 notice or pay such premium shall not prejudice any claim originating
197 within such [sixty-one-day] period.

198 Sec. 8 (NEW) (*Effective July 1, 2022*) For the purposes of this section
199 and sections 9 to 13, inclusive, of this act unless the context otherwise
200 requires:

201 (1) "Commissioner" means the Commissioner of Consumer
202 Protection;

203 (2) "Drug" means an article that is (A) recognized in the official United
204 States Pharmacopoeia, official Homeopathic Pharmacopoeia of the
205 United States or official National Formulary, or any supplement thereto,
206 (B) intended for use in the diagnosis, cure, mitigation, treatment or
207 prevention of disease in humans, (C) not food and intended to affect the
208 structure or any function of the human body, and (D) not a device and
209 intended for use as a component of any other article specified in
210 subparagraphs (A) to (C), inclusive, of this subdivision;

211 (3) "Drug Quality and Security Act" means the Drug Quality and
212 Security Act, 21 USC 351, et seq., as amended from time to time;

213 (4) "Food, Drug and Cosmetic Act" means the Food, Drug and
214 Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and
215 Security Act, as both may be amended from time to time;

216 (5) "Importation program" means the Canadian legend drug
217 importation program established by the commissioner pursuant to
218 section 9 of this act;

219 (6) "Institutional pharmacy" has the same meaning as provided in
220 section 20-571 of the general statutes;

221 (7) "Laboratory testing" means a quantitative and qualitative analysis
222 of a prescription drug consistent with the official United States
223 Pharmacopoeia;

224 (8) "Legend drug" means a drug that (A) any applicable federal or
225 state law provides shall only be (i) dispensed pursuant to a prescription,
226 or (ii) used by a prescribing practitioner, or (B) applicable federal law
227 requires to bear the following legend: "RX ONLY" IN ACCORDANCE
228 WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG
229 AND COSMETIC ACT;

230 (9) "Manufacturer" means (A) an applicant as defined in 21 CFR 314.3,

231 as amended from time to time, (B) a person who owns or operates an
232 establishment that manufactures an eligible prescription drug, or (C) a
233 holder of a drug master file containing information necessary to conduct
234 the Statutory Testing, prepare the manufacturer's attestation and
235 information statement, or comply with Section 804 of the Food, Drug
236 and Cosmetic Act, 21 USC 360(b), as amended from time to time;

237 (10) "Participating Canadian supplier" means a manufacturer or
238 wholesale drug distributor within Canada that (A) holds an active Drug
239 Establishment License to wholesale drugs by Health Canada, (B) is
240 registered with provincial regulatory authorities to distribute HPFB-
241 approved drugs, (C) is not licensed by a provincial regulatory authority
242 with an international pharmacy license that allows it to distribute drugs
243 that are approved by countries other than Canada and that are not
244 HPFB-approved for distribution in Canada, (D) is properly registered,
245 if such Canadian supplier is required to be registered, with the United
246 States Food and Drug Administration, or any successor agency, and (E)
247 exports legend drugs, in the manufacturer's original container, to a
248 participating wholesaler for distribution in this state under the
249 importation program;

250 (11) "Participating wholesaler" means a wholesaler as defined in 21
251 CFR 251.2, as amended from time to time, that is designated by the
252 commissioner to participate in the importation program in this state.
253 Participating wholesaler does not include a person authorized to import
254 drugs under Section 801 (d) (1) of the Food, Drug and Cosmetic Act, 21
255 USC 381, as amended from time to time;

256 (12) "Pharmacy" has the same meaning as provided in section 20-571
257 of the general statutes;

258 (13) "Prescription" means a lawful oral, written or electronic order by
259 a prescribing practitioner for a drug for a specific patient;

260 (14) "Qualified laboratory" means a laboratory in this state that has
261 been approved by the United States Food and Drug Administration for
262 the purposes of Section 804 of the Food, Drug and Cosmetic Act, 21 USC

263 360(b), as amended from time to time;

264 (15) "Qualified wholesaler" means a wholesaler, as defined in section
265 21a-70 of the general statutes, that has received a certificate of
266 registration from the commissioner pursuant to said section; and

267 (16) "Track-and-trace" means the product tracing process for the
268 components of the pharmaceutical distribution supply chain, as
269 described in Title II of the Drug Quality and Security Act.

270 Sec. 9. (NEW) (*Effective July 1, 2022*) (a) The commissioner shall
271 establish a program to be known as the "Canadian legend drug
272 importation program". Under such importation program, the
273 commissioner shall, notwithstanding any provision of the general
274 statutes:

275 (1) Provide for the importation from Canada of safe and effective
276 legend drugs that have the highest potential for cost savings for patients
277 in this state;

278 (2) Develop and implement an application and approval process for
279 qualified wholesalers to be designated as participating wholesalers; and

280 (3) Designate one or more participating wholesalers to distribute in
281 this state legend drugs, imported from Canada, from a participating
282 Canadian supplier and in the manufacturer's original container, to a
283 licensed pharmacy or institutional pharmacy or a qualified laboratory.

284 (b) (1) Not later than July 1, 2023, the commissioner shall submit a
285 request to the federal Secretary of Health and Human Services seeking
286 approval for the importation program under 21 USC 384, as amended
287 from time to time. Such request shall, at a minimum:

288 (A) Describe the commissioner's plans for operating the importation
289 program;

290 (B) Demonstrate that the legend drugs to be imported and distributed
291 in this state under the importation program shall:

292 (i) Meet all applicable federal and state standards for safety and
293 effectiveness; and

294 (ii) Comply with all federal tracing procedures and federal supply
295 chain security requirements as set forth in 21 CFR 251.14, as amended
296 from time to time;

297 (C) Disclose the costs of implementing the importation program;

298 (D) Meet all review and authorization criteria as set forth in 21 CFR
299 251.4, as amended from time to time; and

300 (E) Satisfy all pre-importation requirements as set forth in 21 CFR
301 251.5.

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

304 (i) Submit to (I) the Commissioner of Public Health a notice disclosing
305 that the federal Secretary of Health and Human Services has approved
306 such request, and (II) the joint standing committees of the General
307 Assembly having cognizance of matters relating to appropriations,
308 general law, human services, insurance and public health a notice
309 disclosing that the federal Secretary of Health and Human Services has
310 approved such request; and

311 (ii) Begin operating the importation program not later than one
312 hundred eighty days after the date of such approval.

313 (B) Except as otherwise provided in this subsection, the
314 commissioner shall not operate the importation program unless the
315 federal Secretary of Health and Human Services approves the
316 commissioner's request.

317 Sec. 10. (NEW) (*Effective July 1, 2022*) (a) Each participating
318 wholesaler may, subject to the provisions of this section and sections 9
319 and 12 of this act, import into this state a legend drug from a
320 participating Canadian supplier, and distribute such legend drug to a

321 licensed pharmacy or institutional pharmacy, or a qualified laboratory
322 in this state, under the importation program if:

323 (1) Such participating wholesaler:

324 (A) Is registered with the federal Secretary of Health and Human
325 Services pursuant to 21 CFR 251, as amended from time to time; and

326 (B) Holds a valid labeler code that was issued to such participating
327 wholesaler by the United States Food and Drug Administration, or any
328 successor agency; and

329 (2) Such legend drug:

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

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

335 (C) Is not:

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

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

340 (iii) An infused drug;

341 (iv) An intravenously, intradermally, intrathecally, intramuscularly
342 or subcutaneously injected drug;

343 (v) A drug that is inhaled during surgery;

344 (vi) A drug that is a parenteral drug, the importation of which is
345 determined by the federal Secretary of Health and Human Services to
346 pose a threat to the public health; or

347 (vii) A drug that is a compound which is not commercially available.

348 (b) Each participating wholesaler shall:

349 (1) Comply with all applicable track-and-trace requirements, and
350 make available to the commissioner all track-and-trace records not later
351 than forty-eight hours after said commissioner requests such records;

352 (2) Not import into, or distribute, dispense or sell, in this state any
353 legend drugs under the importation program except in accordance with
354 the provisions of this section and sections 9 and 12 of this act;

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

357 (4) Ensure the safety and quality of each legend drug that is imported
358 and distributed in this state under the importation program;

359 (5) Comply with federal pre-importation request requirements as set
360 forth in 21 CFR 251.5, as amended from time to time;

361 (6) For each initial shipment of any legend drug that is imported into
362 this state by such participating wholesaler, ensure that a qualified
363 laboratory engaged by such participating wholesaler tests a statistically
364 valid sample size for each batch of such legend drug in such shipment
365 for authenticity and degradation in a manner that is consistent with the
366 Food, Drug and Cosmetic Act and 21 CFR 251.16, as both may be
367 amended from time to time;

368 (7) For each subsequent shipment of a legend drug that is imported
369 into this state by such participating wholesaler, and sampled and tested
370 pursuant to subdivision (6) of this subsection, ensure that a qualified
371 laboratory engaged by such participating wholesaler tests a statistically
372 valid sample of such legend drug in such shipment for authenticity and
373 degradation in a manner that is consistent with the Food, Drug and
374 Cosmetic Act and 21 CFR 251.16, as both may be amended from time to
375 time, and quarantine such shipment until the results of such test
376 conducted pursuant to this subdivision indicate that such legend drug

377 is consistent with its labeling;

378 (8) Certify to the commissioner that each legend drug imported into
379 this state under the importation program:

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

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

384 (C) Meets all labeling requirements as set forth in 21 CFR 251.12, 21
385 CFR 251.13 and 21 CFR 251.14, as amended from time to time;

386 (9) Either:

387 (A) Propose a national drug code for each drug imported into this
388 state in accordance with sections 8 to 13, inclusive, of this act, pursuant
389 to the procedures under 21 CFR 207.33, as amended from time to time,
390 and list such drug pursuant to the procedures set forth in 21 CFR 207.53,
391 as amended from time to time; or

392 (B) Ensure that the entity performing relabeling on such wholesaler's
393 behalf lists each eligible prescription drug and incorporates the national
394 drug code such wholesaler proposed for assignment in accordance with
395 the labeling requirements set forth in 21 CFR 207, as amended from time
396 to time;

397 (10) Maintain laboratory records, including, but not limited to,
398 complete data derived from all tests necessary to ensure that each
399 legend drug imported into this state under the importation program
400 satisfies the requirements of subdivisions (6) and (7) of this subsection;

401 (11) Maintain documentation demonstrating that the testing required
402 by subdivisions (6) and (7) of this subsection was conducted at a
403 qualified laboratory in accordance with the Food, Drug and Cosmetic
404 Act, and all other applicable federal and state laws and regulations
405 concerning laboratory qualifications;

406 (12) Maintain the following information for each legend drug that
407 such participating wholesaler imports and distributes in this state under
408 the importation program, and submit such information to the
409 commissioner upon request by the commissioner:

410 (A) The name and quantity of the active ingredient of such legend
411 drug;

412 (B) A description of the dosage form of such legend drug;

413 (C) The date on which such participating wholesaler received such
414 legend drug;

415 (D) The quantity of such legend drug that such participating
416 wholesaler received;

417 (E) The point of origin and destination of such legend drug;

418 (F) The price paid by such participating wholesaler for such legend
419 drug;

420 (G) A report for each legend drug that fails laboratory testing under
421 subdivision (6) or (7) of this subsection; and

422 (H) Such additional information and documentation that the
423 commissioner deems necessary to ensure the protection of the public
424 health;

425 (13) Ensure that any legend drug that fails laboratory testing under
426 subdivision (6) or (7) of this subsection is appropriately quarantined and
427 destroyed; and

428 (14) Maintain all information and documentation that is submitted to
429 the commissioner pursuant to this subsection for a period of not less
430 than three years.

431 Sec. 11. (NEW) (*Effective July 1, 2022*) Each participating Canadian
432 supplier shall:

- 433 (1) Comply with all applicable track-and-trace requirements;
- 434 (2) Not distribute, dispense or sell outside of this state any legend
435 drugs that are imported into this state under the importation program;
436 and
- 437 (3) Maintain the following information and documentation and,
438 upon request by the commissioner, submit such information and
439 documentation to the commissioner for each legend drug that such
440 participating Canadian supplier exports into this state under the
441 importation program:
- 442 (A) The original source of such legend drug, including, but not
443 limited to:
- 444 (i) The name of the manufacturer of such legend drug;
- 445 (ii) The date on which such legend drug was manufactured; and
- 446 (iii) The location where such legend drug was manufactured;
- 447 (B) The date on which such legend drug was shipped to a
448 participating wholesaler;
- 449 (C) The quantity of such legend drug that was shipped to a
450 participating wholesaler;
- 451 (D) The quantity of each lot of such legend drug that such
452 participating Canadian supplier originally received and the source of
453 such lot;
- 454 (E) The lot or control number and the batch number assigned to such
455 legend drug by the manufacturer; and
- 456 (F) Such additional information and documentation that the
457 commissioner deems necessary to ensure the protection of the public
458 health.
- 459 Sec. 12. (NEW) (*Effective July 1, 2022*) (a) The commissioner shall issue

460 a written order:

461 (1) Suspending importation and distribution of a legend drug under
462 the importation program if the commissioner discovers that such
463 importation or distribution violates any provision of sections 9 to 11,
464 inclusive, of this act or any other applicable state or federal law or
465 regulation, including post importation requirements as set forth in 21
466 CFR 251.18;

467 (2) Suspending all importation and distribution of legend drugs by a
468 participating wholesaler under the importation program if the
469 commissioner discovers that the participating wholesaler has violated
470 any provision of section 9 or 10 of this act or any other applicable state
471 or federal law or regulation;

472 (3) Suspending all importation and distribution of legend drugs by a
473 participating Canadian supplier under the importation program if the
474 commissioner discovers that the participating Canadian supplier has
475 violated any provision of section 9 or 11 of this act or any other
476 applicable state or federal law or regulation;

477 (4) Requiring the quarantine, recall or seizure of any legend drug that
478 was imported and distributed under the importation program if such
479 legend drug has been identified as adulterated, within the meaning of
480 section 21a-105 of the general statutes, or misbranded; or

481 (5) Requiring retesting, at the expense of the participating wholesaler
482 and by a laboratory approved by the commissioner, of any legend drug
483 distributed by the participating wholesaler if the commissioner deems
484 such retesting necessary.

485 (b) The commissioner shall send a notice to each participating
486 Canadian supplier and participating wholesaler affected by an order
487 issued pursuant to subsection (a) of this section notifying such
488 participating Canadian supplier or participating wholesaler that:

489 (1) The commissioner has issued such order, and providing the legal

490 and factual basis for such order; and

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

495 (c) If a participating Canadian supplier or participating wholesaler
496 timely requests a hearing pursuant to subsection (b) of this section, the
497 commissioner shall, not later than thirty days after the receipt of the
498 request, convene the hearing as a contested case in accordance with the
499 provisions of chapter 54 of the general statutes. Not later than sixty days
500 after the receipt of such request, the commissioner shall issue a final
501 decision vacating, modifying or affirming the commissioner's order. If
502 the participating Canadian supplier or participating wholesaler is
503 aggrieved by such final decision, such participating Canadian supplier
504 or participating wholesaler may appeal such decision in accordance
505 with the provisions of section 4-183 of the general statutes.

506 Sec. 13. (NEW) (*Effective July 1, 2022*) The commissioner may, in
507 consultation with the Commissioner of Public Health, adopt regulations
508 in accordance with the provisions of chapter 54 of the general statutes
509 to implement the provisions of sections 8 to 12, inclusive, of this act.

510 Sec. 14. (*Effective from passage*) Not later than January 1, 2023, the
511 Office of Health Strategy shall prepare and submit a report, in
512 accordance with section 11-4a of the general statutes, to the joint
513 standing committee of the General Assembly having cognizance of
514 matters relating to insurance. Such report shall include, but need not be
515 limited to, an analysis of pharmacy benefit manager distribution of
516 prescription drug practices regarding spread pricing arrangements,
517 manufacturing rebates and transparency and accountability.

518 Sec. 15. (*Effective from passage*) Not later than January 1, 2023, the State
519 Comptroller shall prepare and submit a report, in accordance with
520 section 11-4a of the general statutes, to the joint standing committee of
521 the General Assembly having cognizance of matters relating to

522 insurance. Such report shall include an analysis of state purchasing
 523 pools for prescription drugs and health care supplies, and shall describe:
 524 (1) Whether current pool purchasing arrangements with other states are
 525 resulting in cost savings in the state; and (2) whether other potential
 526 pool purchasing relationships may result in lower prescription drug and
 527 health care costs."

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2022</i>	38a-510(b)(1)
Sec. 2	<i>from passage</i>	New section
Sec. 3	<i>from passage and applicable to policies delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022</i>	38a-477ff
Sec. 4	<i>from passage and applicable to contracts entered into on or after January 1, 2022</i>	38a-477gg
Sec. 5	<i>from passage and applicable to contracts delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022</i>	38a-478w
Sec. 6	<i>January 1, 2023</i>	38a-490
Sec. 7	<i>January 1, 2023</i>	38a-516
Sec. 8	<i>July 1, 2022</i>	New section
Sec. 9	<i>July 1, 2022</i>	New section
Sec. 10	<i>July 1, 2022</i>	New section
Sec. 11	<i>July 1, 2022</i>	New section
Sec. 12	<i>July 1, 2022</i>	New section
Sec. 13	<i>July 1, 2022</i>	New section
Sec. 14	<i>from passage</i>	New section
Sec. 15	<i>from passage</i>	New section