



General Assembly

**Amendment**

February Session, 2022

LCO No. 6461



Offered by:

REP. WOOD K., 29<sup>th</sup> Dist.

REP. PAVALOCK-D'AMATO, 77<sup>th</sup> Dist.

REP. COOK, 65<sup>th</sup> Dist.

REP. CARPINO, 32<sup>nd</sup> Dist.

REP. NUCCIO, 53<sup>rd</sup> Dist.

REP. COMEY, 102<sup>nd</sup> 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4 general statutes is repealed and the following is substituted in lieu  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) One appointed by the minority leader of the Senate;

43 (5) The chairpersons and ranking members of the joint standing  
44 committees of the General Assembly having cognizance of matters  
45 relating to public health and insurance, or their designees;

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

48 (7) The Insurance Commissioner, or the Insurance Commissioner's  
49 designee;

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

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

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

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

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

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

69 (d) Not later than July 1, 2023, the task force shall submit a report on  
70 its findings and recommendations to the joint standing committees of  
71 the General Assembly having cognizance of matters relating to

72 insurance and public health, in accordance with the provisions of  
73 section 11-4a of the general statutes. The task force shall terminate on  
74 the date that it submits such report or on July 1, 2023, whichever is  
75 earlier.

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

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

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

103 Sec. 4. Section 38a-477gg of the 2022 supplement to the general

104 statutes is repealed and the following is substituted in lieu thereof  
105 (*Effective from passage and applicable to contracts entered into on or after*  
106 *January 1, 2022*):

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

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

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

134 (a) For any contract delivered, issued for delivery, renewed, amended  
135 or continued in this state on or after January 1, 2022, each managed care

136 organization shall, when calculating an enrollee's liability for a  
137 coinsurance, copayment, deductible or other out-of-pocket expense for  
138 a covered benefit, give credit for any discount provided or payment  
139 made by a third party for the amount of, or any portion of the amount  
140 of, the coinsurance, copayment, deductible or other out-of-pocket  
141 expense for the covered benefit.

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

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

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

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

168 (c) If payment of a specific premium or subscription fee is required to  
169 provide coverage for a child, the policy or contract may require that  
170 notification of birth of such newly born child and payment of the  
171 required premium or fees shall be furnished to the insurer, hospital  
172 service corporation, medical service corporation or health care center  
173 not later than [sixty-one] ninety-one days after the date of birth in order  
174 to continue coverage beyond such [sixty-one-day] period, provided  
175 failure to furnish such notice or pay such premium or fees shall not  
176 prejudice any claim originating within such [sixty-one-day] period.

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

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

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

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

199 Sec. 8 (NEW) (*Effective July 1, 2022*) For the purposes of this section

200 and sections 9 to 13, inclusive, of this act unless the context otherwise  
201 requires:

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

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

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

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

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

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

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

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



230 AND COSMETIC ACT;

231 (9) "Manufacturer" means (A) an applicant as defined in 21 CFR 314.3,  
232 as amended from time to time, (B) a person who owns or operates an  
233 establishment that manufactures an eligible prescription drug, or (C) a  
234 holder of a drug master file containing information necessary to conduct  
235 the Statutory Testing, prepare the manufacturer's attestation and  
236 information statement, or comply with Section 804 of the Food, Drug  
237 and Cosmetic Act, 21 USC 360(b), as amended from time to time;

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

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

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

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

261 (14) "Qualified laboratory" means a laboratory in this state that has  
262 been approved by the United States Food and Drug Administration for  
263 the purposes of Section 804 of the Food, Drug and Cosmetic Act, 21 USC  
264 360(b), as amended from time to time;

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

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

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

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

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

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

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

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

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

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

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

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

299 (D) Meet all review and authorization criteria as set forth in 21 CFR  
300 251.4, as amended from time to time; and

301 (E) Satisfy all pre-importation requirements as set forth in 21 CFR  
302 251.5.

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

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

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

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

318 Sec. 10. (NEW) (*Effective July 1, 2022*) (a) Each participating

319 wholesaler may, subject to the provisions of this section and sections 9  
320 and 12 of this act, import into this state a legend drug from a  
321 participating Canadian supplier, and distribute such legend drug to a  
322 licensed pharmacy or institutional pharmacy, or a qualified laboratory  
323 in this state, under the importation program if:

324 (1) Such participating wholesaler:

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

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

330 (2) Such legend drug:

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

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

336 (C) Is not:

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

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

341 (iii) An infused drug;

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

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

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

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

349 (b) Each participating wholesaler shall:

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

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

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

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

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

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

369 (7) For each subsequent shipment of a legend drug that is imported  
370 into this state by such participating wholesaler, and sampled and tested  
371 pursuant to subdivision (6) of this subsection, ensure that a qualified  
372 laboratory engaged by such participating wholesaler tests a statistically  
373 valid sample of such legend drug in such shipment for authenticity and

374 degradation in a manner that is consistent with the Food, Drug and  
375 Cosmetic Act and 21 CFR 251.16, as both may be amended from time to  
376 time, and quarantine such shipment until the results of such test  
377 conducted pursuant to this subdivision indicate that such legend drug  
378 is consistent with its labeling;

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

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

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

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

387 (9) Either:

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

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

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

402 (11) Maintain documentation demonstrating that the testing required

403 by subdivisions (6) and (7) of this subsection was conducted at a  
404 qualified laboratory in accordance with the Food, Drug and Cosmetic  
405 Act, and all other applicable federal and state laws and regulations  
406 concerning laboratory qualifications;

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

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

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

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

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

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

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

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

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

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

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

431 than three years.

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

434 (1) Comply with all applicable track-and-trace requirements;

435 (2) Not distribute, dispense or sell outside of this state any legend  
436 drugs that are imported into this state under the importation program;  
437 and

438 (3) Maintain the following information and documentation and,  
439 upon request by the commissioner, submit such information and  
440 documentation to the commissioner for each legend drug that such  
441 participating Canadian supplier exports into this state under the  
442 importation program:

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

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

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

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

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

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

452 (D) The quantity of each lot of such legend drug that such  
453 participating Canadian supplier originally received and the source of  
454 such lot;

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



457 (F) Such additional information and documentation that the  
458 commissioner deems necessary to ensure the protection of the public  
459 health.

460 Sec. 12. (NEW) (*Effective July 1, 2022*) (a) The commissioner shall issue  
461 a written order:

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

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

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

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

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

486 (b) The commissioner shall send a notice to each participating

487 Canadian supplier and participating wholesaler affected by an order  
488 issued pursuant to subsection (a) of this section notifying such  
489 participating Canadian supplier or participating wholesaler that:

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

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

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

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

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

519       Sec. 15. (*Effective from passage*) Not later than January 1, 2023, the State  
520 Comptroller shall prepare and submit a report, in accordance with  
521 section 11-4a of the general statutes, to the joint standing committee of  
522 the General Assembly having cognizance of matters relating to  
523 insurance. Such report shall include an analysis of state purchasing  
524 pools for prescription drugs and health care supplies, and shall describe:  
525 (1) Whether current pool purchasing arrangements with other states are  
526 resulting in cost savings in the state; and (2) whether other potential  
527 pool purchasing relationships may result in lower prescription drug and  
528 health care costs.

529       Sec. 16. Subdivision (1) of subsection (b) of section 38a-544 of the  
530 general statutes is repealed and the following is substituted in lieu  
531 thereof (*Effective October 1, 2022*):

532       (b) (1) Notwithstanding the sixty-day period set forth in subdivision  
533 (2) of subsection (a) of this section, each insurance company, hospital  
534 service corporation, medical service corporation, health care center or  
535 other entity that uses step therapy for such prescription drugs shall  
536 establish and disclose to its health care providers a process by which an  
537 insured's treating health care provider may request at any time an  
538 override of the use of any step therapy drug regimen. Such disclosure  
539 shall be made to health care providers in writing at least once each  
540 calendar year, and such health care provider shall display in a  
541 conspicuous and prominent location, including on the provider's  
542 Internet web site and on a bulletin board in the provider's office,  
543 information regarding the override process. Any such override process  
544 shall be convenient to use by health care providers and an override  
545 request shall be expeditiously granted when an insured's treating health  
546 care provider demonstrates that the drug regimen required under step  
547 therapy (A) has been ineffective in the past for treatment of the insured's  
548 medical condition, (B) is expected to be ineffective based on the known  
549 relevant physical or mental characteristics of the insured and the known  
550 characteristics of the drug regimen, (C) will cause or will likely cause an  
551 adverse reaction by or physical harm to the insured, or (D) is not in the  
552 best interest of the insured, based on medical necessity. Until October 1,

553 2025, in the case of a prescribed drug for the treatment of schizophrenia,  
 554 major depressive disorder or bipolar disorder, as defined in the most  
 555 recent edition of the Diagnostic and Statistical Manual of Mental  
 556 Disorders, such override request shall be granted not later than twenty-  
 557 four hours from the time of the request."

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
Sec. 16	<i>October 1, 2022</i>	38a-544(b)(1)