



General Assembly

Amendment

February Session, 2024

LCO No. 5835



Offered by:
SEN. LESSER, 9th Dist.

To: Subst. Senate Bill No. 8

File No. 309

Cal. No. 197

"AN ACT CONCERNING DRUG AFFORDABILITY."

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

3 "Section 1. (NEW) (*Effective July 1, 2026*) For the purposes of this
4 section and sections 2 to 11, inclusive, of this act, unless the context
5 otherwise requires:

6 (1) "Canadian supplier" means a manufacturer or wholesale drug
7 distributor that is licensed or permitted under applicable Canadian law
8 to manufacture or distribute prescription drugs;

9 (2) "Canadian prescription drug importation program" or "program"
10 means a program under which the state would seek federal approval to
11 import prescription drugs from Canada that have the highest potential
12 for cost savings in the state.

13 (3) "Drug" means an article that is (A) recognized in the official United
14 States Pharmacopoeia, official Homeopathic Pharmacopoeia of the
15 United States or official National Formulary, or any supplement thereto,

16 (B) intended for use in the diagnosis, cure, mitigation, treatment or
17 prevention of disease in humans, (C) not food and intended to affect the
18 structure or any function of the human body, and (D) not a device and
19 intended for use as a component of any article specified in
20 subparagraphs (A) to (C), inclusive, of this subdivision;

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

23 (5) "Food, Drug and Cosmetic Act" means the federal Food, Drug and
24 Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and
25 Security Act, as both may be amended from time to time;

26 (6) "Qualifying laboratory" has the same meaning as provided in 21
27 CFR 251.2;

28 (7) "Laboratory testing" means a quantitative and qualitative analysis
29 of a drug consistent with the applicable provisions of the official United
30 States Pharmacopoeia;

31 (8) "Medical assistance program" means the state's Medicaid program
32 established under Title XIX of the Social Security Act, as amended from
33 time to time, and the Children's Health Insurance Program established
34 under Title XXI of the Social Security Act, as amended from time to time;

35 (9) "Participating Canadian supplier" means a Canadian supplier that
36 is exporting prescription drugs, in the manufacturer's original
37 container, to a participating wholesaler for distribution in this state
38 under the program;

39 (10) "Participating wholesaler" means a wholesaler that is (A)
40 designated by the Department of Consumer Protection to distribute
41 prescription drugs, in the manufacturer's original container, obtained
42 from a participating Canadian supplier, and (B) participating in the
43 program;

44 (11) "Track-and-trace" means the product tracing process for the
45 components of the pharmaceutical distribution supply chain as

46 described in Title II of the Drug Quality and Security Act; and

47 (12) "Wholesaler" means a wholesaler, as defined in section 21a-70 of
48 the general statutes, that has received a certificate of registration from
49 the Commissioner of Consumer Protection pursuant to said section.

50 Sec. 2. (*Effective July 1, 2026*) (a) The Commissioner of Consumer
51 Protection, in consultation with the executive director of the Office of
52 Health Strategy, shall hire a consultant to study the feasibility of
53 establishing a Canadian prescription drug importation program to
54 reduce prescription drug costs for the medical assistance program. Not
55 later than July 1, 2027, the consultant shall file a report, in accordance
56 with the provisions of section 11-4a of the general statutes, with the
57 commissioner and the joint standing committees of the General
58 Assembly having cognizance of matters relating to appropriations,
59 general law and human services on estimated costs and savings
60 associated with establishing the program and recommendations on
61 whether such program is feasible and how such program could be
62 expanded in the future to reduce prescription drug costs in the state.

63 (b) The commissioner shall, within available resources, spend not
64 more than one hundred twenty-five thousand dollars on hiring such
65 consultant.

66 Sec. 3. (*Effective July 1, 2026*) (a) If the establishment of a Canadian
67 prescription drug importation program is deemed feasible pursuant to
68 section 2 of this act, the Commissioner of Consumer Protection, in
69 consultation with the executive director of the Office of Health Strategy
70 and the task force that may be established pursuant to section 11 of this
71 act, may submit a request to the federal Food and Drug Administration
72 seeking approval for the program under Section 804 of the federal Food,
73 Drug and Cosmetic Act, 21 USC 384(b) to 21 USC 384(h), inclusive, as
74 amended from time to time. If submitted, such request shall, at a
75 minimum:

76 (1) Describe the state's plans for operating the program;

77 (2) Demonstrate that any prescription drug that is imported and
78 distributed in this state under the program:

79 (A) Meets all applicable federal and state standards for safety and
80 effectiveness; and

81 (B) Complies with all federal tracing procedures; and

82 (3) Disclose the costs of implementing the program.

83 (b) (1) If the federal Food and Drug Administration approves the
84 request, the Commissioner of Consumer Protection shall:

85 (A) Submit to the executive director of the Office of Health Strategy
86 and the Commissioner of Social Services a notice disclosing that the
87 federal Food and Drug Administration approved such request;

88 (B) Submit to the joint standing committees of the General Assembly
89 having cognizance of matters relating to appropriations, general law,
90 human services and public health a notice disclosing that the federal
91 Food and Drug Administration approved such request; and

92 (C) Begin operating the program in consultation with the executive
93 director of the Office of Health Strategy and the Commissioner of Social
94 Services not later than one hundred eighty days after the date of such
95 approval.

96 (2) The Commissioner of Consumer Protection shall not operate the
97 program unless the federal Food and Drug Administration approves the
98 request.

99 Sec. 4. (*Effective July 1, 2026*) If the Canadian prescription drug
100 importation program is established, each participating wholesaler may
101 import and distribute a prescription drug in this state from a
102 participating Canadian supplier under the program if:

103 (1) Such drug meets the United States Food and Drug
104 Administration's standards concerning drug safety, effectiveness,

105 misbranding and adulteration;

106 (2) Importing such drug would not violate federal patent laws; and

107 (3) Such drug is not:

108 (A) A controlled substance, as defined in 21 USC 802, as amended
109 from time to time;

110 (B) A biological product, as defined in 42 USC 262, as amended from
111 time to time;

112 (C) An infused drug;

113 (D) An intravenously injected drug;

114 (E) A drug that is inhaled during surgery; or

115 (F) A drug that is a parenteral drug, the importation of which is
116 determined by the federal Secretary of Health and Human Services to
117 pose a threat to the public health.

118 Sec. 5. (*Effective July 1, 2026*) If a Canadian prescription drug
119 importation program is established, participating wholesalers may,
120 subject to the provisions of sections 2 to 9, inclusive, of this act, import
121 and distribute drugs in this state from a participating Canadian supplier
122 under the program to:

123 (1) A pharmacy or institutional pharmacy, as defined in section 20-
124 571 of the general statutes, solely for prescriptions covered under the
125 medical assistance program; and

126 (2) A qualifying laboratory.

127 Sec. 6. (*Effective July 1, 2026*) If a Canadian prescription drug
128 importation program is established, the Commissioner of Consumer
129 Protection shall require that each participating Canadian supplier and
130 participating wholesaler (1) comply with all applicable track-and-trace
131 requirements, and shall not distribute, dispense or sell outside of this

132 state any prescription drug that is imported into this state under the
133 program, and (2) make available to the commissioner all track-and-trace
134 records not later than forty-eight hours after the commissioner requests
135 such records.

136 Sec. 7. (*Effective July 1, 2026*) (a) A participating wholesaler in any
137 approved Canadian prescription drug importation program shall
138 ensure the safety and quality of all drugs that may be imported and
139 distributed in this state under the program. The participating
140 wholesaler shall, if such program is established:

141 (1) For each initial shipment of a drug that is imported into this state
142 by a participating wholesaler, ensure that a qualifying laboratory
143 engaged by the participating wholesaler tests a statistically valid sample
144 size for each batch of each drug in such shipment for authenticity and
145 degradation in a manner that is consistent with the Food, Drug and
146 Cosmetic Act;

147 (2) For each shipment of a drug that is imported into this state by a
148 participating wholesaler and has been sampled and tested pursuant to
149 subdivision (1) of this subsection, ensure that a qualifying laboratory
150 engaged by the participating wholesaler tests a statistically valid sample
151 of such shipment for authenticity and degradation in a manner that is
152 consistent with the Food, Drug and Cosmetic Act;

153 (3) Only import drugs into this state that are (A) approved for
154 marketing in the United States, (B) not adulterated or misbranded, and
155 (C) meet all of the labeling requirements under 21 USC 352, as amended
156 from time to time;

157 (4) Maintain qualifying laboratory records, including, but not limited
158 to, complete data derived from all tests necessary to ensure that each
159 drug imported into this state under the program is in compliance with
160 the requirements of this section; and

161 (5) Maintain documentation demonstrating that the testing required
162 by this section was conducted at a qualifying laboratory in accordance

163 with the Food, Drug and Cosmetic Act and all other applicable federal
164 and state laws and regulations concerning qualifying laboratory
165 qualifications.

166 (b) The participating wholesaler shall maintain all information and
167 documentation pursuant to this section for a period of not less than three
168 years from the date of submission.

169 (c) Each participating wholesaler shall maintain all of the following
170 information for each drug that such participating wholesaler imports
171 and distributes in this state under the program, and submit such
172 information to the Commissioner of Consumer Protection upon request
173 by the commissioner:

174 (1) The name and quantity of the active ingredient of such drug;

175 (2) A description of the dosage form of such drug;

176 (3) The date on which such participating wholesaler received such
177 drug;

178 (4) The quantity of such drug that such participating wholesaler
179 received;

180 (5) The point of origin and destination of such drug;

181 (6) The price paid by such participating wholesaler for such drug;

182 (7) A report for any drug that fails qualifying laboratory testing; and

183 (8) Such additional information and documentation that the
184 commissioner deems necessary to ensure the protection of the public
185 health.

186 (d) The Commissioner of Consumer Protection shall require each
187 participating Canadian supplier in any approved Canadian prescription
188 drug importation program to maintain the following information and
189 documentation and, upon request by the commissioner, submit such
190 information and documentation to the commissioner for each drug that

191 such participating Canadian supplier exports into this state under the
192 program:

193 (1) The original source of such drug, including, but not limited to:

194 (A) The name of the manufacturer of such drug;

195 (B) The date on which such drug was manufactured; and

196 (C) The location where such drug was manufactured;

197 (2) The date on which such drug was shipped;

198 (3) The quantity of such drug that was shipped;

199 (4) The quantity of each lot of such drug originally received and the
200 source of such lot;

201 (5) The lot or control number and the batch number assigned to such
202 drug by the manufacturer; and

203 (6) Such additional information and documentation that the
204 Commissioner of Consumer Protection, in consultation with the
205 executive director of the Office of Health Strategy and the
206 Commissioner of Social Services, deems necessary to ensure the
207 protection of the public health.

208 Sec. 8. (*Effective July 1, 2026*) (a) If a Canadian prescription drug
209 importation program is established, the Commissioner of Consumer
210 Protection shall issue a written order:

211 (1) Suspending importation and distribution of a drug under the
212 program if the commissioner discovers that such distribution or
213 importation violates any provision of sections 2 to 9, inclusive, of this
214 act or any other applicable state or federal law or regulation;

215 (2) Suspending all importation and distribution of drugs by a
216 participating wholesaler under the program if the commissioner
217 discovers that the participating wholesaler has violated any provision

218 of sections 2 to 9, inclusive, of this act or any other applicable state or
219 federal law or regulation;

220 (3) Suspending all importation and distribution of drugs by a
221 participating Canadian supplier under the program if the commissioner
222 discovers that the participating Canadian supplier has violated any
223 provision of sections 2 to 9, inclusive, of this act or any other applicable
224 state or federal law or regulation; or

225 (4) Requiring the recall or seizure of any drug that was imported and
226 distributed under the program and has been identified as adulterated,
227 within the meaning of section 21a-105 of the general statutes, or
228 misbranded.

229 (b) The commissioner shall send a notice to each participating
230 Canadian supplier and participating wholesaler affected by any order
231 issued pursuant to subsection (a) of this section notifying such
232 participating Canadian supplier or participating wholesaler that:

233 (1) The commissioner has issued such order, and provide the legal
234 and factual basis for such order; and

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

239 (c) If a hearing is timely requested pursuant to subsection (b) of this
240 section, the commissioner shall, not later than thirty days after the
241 receipt of the request, convene the hearing as a contested case in
242 accordance with the provisions of chapter 54 of the general statutes. The
243 commissioner shall issue a final decision vacating, modifying or
244 affirming the order not later than ninety days after the close of evidence
245 or the due date for the filing of briefs, whichever is later. The
246 participating Canadian supplier or participating wholesaler aggrieved
247 by such final decision may appeal such decision in accordance with the
248 provisions of section 4-183 of the general statutes.

249 Sec. 9. (*Effective July 1, 2026*) If a Canadian prescription drug
250 importation program is established, the Commissioner of Consumer
251 Protection, in consultation with the executive director of the Office of
252 Health Strategy and the Commissioner of Social Services, may adopt
253 regulations in accordance with the provisions of chapter 54 of the
254 general statutes to implement the provisions of sections 2 to 9, inclusive,
255 of this act.

256 Sec. 10. (*Effective July 1, 2026*) Not later than one hundred eighty days
257 after any Canadian prescription drug importation program begins, and
258 annually thereafter, the Commissioner of Consumer Protection, in
259 consultation with the executive director of the Office of Health Strategy,
260 shall submit a report, in accordance with the provisions of section 11-4a
261 of the general statutes, to the joint standing committees of the General
262 Assembly having cognizance of matters relating to appropriations,
263 general law and human services. Such report shall describe (1) the
264 operations of the program, if established, (2) any violation of sections 2
265 to 9, inclusive, of this act that resulted in any action taken by the
266 commissioner pursuant to section 8 of this act and the status of the
267 investigation into such violation, and (3) recommendations for
268 expanding the program to other state-funded and privately funded
269 health care programs.

270 Sec. 11. (*Effective January 1, 2026*) (a) If the Commissioner of Consumer
271 Protection decides to apply for federal approval for a Canadian
272 prescription drug importation program based on the results of the study
273 completed pursuant to section 2 of this act, there shall be established a
274 task force to provide recommendations to the commissioner on such
275 program. The task force shall be within the Department of Consumer
276 Protection for administrative purposes only.

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

278 (1) Two appointed by the speaker of the House of Representatives,
279 who shall be representatives of an organization that represents
280 pharmacies;

281 (2) Two appointed by the president pro tempore of the Senate, one of
282 whom shall be a representative of an organization representing
283 pharmacy benefit managers and one of whom shall be an academic with
284 expertise in consumer access to prescription drugs;

285 (3) One appointed by the majority leader of the House of
286 Representatives;

287 (4) One appointed by the majority leader of the Senate;

288 (5) One appointed by the minority leader of the House of
289 Representatives;

290 (6) One appointed by the minority leader of the Senate; and

291 (7) Two persons appointed by the Governor.

292 (c) All initial appointments to the task force shall be made not later
293 than thirty days after the Commissioner of Consumer Protection notifies
294 the speaker of the House of Representatives and the president pro
295 tempore of the Senate that the commissioner plans to seek federal
296 approval of a Canadian prescription drug program. Any vacancy shall
297 be filled by the appointing authority.

298 (d) The speaker of the House of Representatives and the president
299 pro tempore of the Senate shall select the chairpersons of the task force
300 from among the members of the task force. Such chairpersons shall
301 schedule the first meeting of the task force, which shall be held not later
302 thirty days after initial appointments are made pursuant to subsection
303 (c) of this section.

304 (e) The administrative staff of the joint standing committee of the
305 General Assembly having cognizance of matters relating to general law
306 shall serve as administrative staff of the task force.

307 (f) Not later than one hundred eighty days after it is established, the
308 task force shall submit an interim report on its findings and
309 recommendations concerning the Canadian prescription drug

310 importation program to the Commissioner of Consumer Protection and
311 the joint standing committees of the General Assembly having
312 cognizance of matters relating to general law, human services and
313 public health, in accordance with the provisions of section 11-4a of the
314 general statutes. The task force shall issue a final report not later than
315 one year after it is established. The task force shall terminate on the date
316 that it submits such report or one year after it is established, whichever
317 is earlier.

318 Sec. 12. (NEW) (*Effective July 1, 2024*) (a) There is established the
319 Prescription Drug Affordability Board to advise the executive director
320 of the Office of Health Strategy on decisions regarding the affordability
321 of prescription drugs. The board shall be within the Office of Health
322 Strategy for administrative purposes only.

323 (b) The purposes of the Prescription Drug Affordability Board shall
324 be to (1) explore strategies to reduce out-of-pocket drug costs to
325 consumers while supporting innovations in biotechnology and scientific
326 discovery, (2) study the prescription drug supply chain and
327 pharmaceutical pricing strategies to identify opportunities for consumer
328 savings, (3) monitor prescription drug prices in the state, (4) promote
329 innovative strategies for the use of more affordable drugs, (5) take into
330 consideration recommendations of a stakeholder council established
331 pursuant to section 13 of this act, (6) recommend a range of options of
332 prescription drug cost affordability tools to the executive director of the
333 Office of Health Strategy, and (7) recommend strategies to support
334 Connecticut's biopharmaceutical industry.

335 (c) The board shall consist of five members, each of whom shall have
336 an advanced degree and experience or expertise in a relevant field,
337 including, but not limited to, health care economics, health services
338 research, pharmacoeconomics, pharmacology or clinical medicine. At
339 least one such member shall have direct experience with consumer
340 advocacy and health equity. The members shall be appointed by the
341 Governor with the advice and consent of either house of the General
342 Assembly. The Governor shall make all initial appointments not later

343 than January 1, 2025. Any vacancy shall be filled for the remainder of
344 the unexpired term by the Governor.

345 (d) Each member of the board shall serve a term of three years, except
346 as to the terms of the members who are first appointed to the board.
347 Two such members shall serve an initial term of three years, two such
348 members shall serve an initial term of two years and one such member
349 shall serve an initial term of one year, to be determined by the Governor.
350 The Governor may remove any appointed member of the board for
351 malfeasance in office, failure to regularly attend meetings or any cause
352 that renders the member incapable or unfit to discharge the duties of the
353 member's office. Any such removal is not subject to review. No board
354 member shall serve for more than three full terms, or nine years in total,
355 including partial terms.

356 (e) The Governor shall designate one member of the board to serve as
357 the chairperson of the board. Such chairperson shall schedule the first
358 meeting of the board, which shall be held not later than February 1, 2025.

359 (f) The board may employ staff and engage in contracts necessary to
360 carry out its purposes as set forth in subsection (b) of this section. The
361 board shall meet not less than quarterly. A majority of the board shall
362 constitute a quorum. The concurrence of a majority of the board present
363 at any meeting on a matter within the board's powers and duties is
364 required for any determination made by the board. Any conflict of
365 interest involving a member of the board shall be disclosed not later
366 than at the next board meeting after the conflict is identified.

367 (g) Not later than December 31, 2025, and annually thereafter, the
368 board shall report, in accordance with the provisions of section 11-4a of
369 the general statutes, to the joint standing committees of the General
370 Assembly having cognizance of matters relating to aging, general law,
371 human services and insurance. The report shall include, but need not be
372 limited to: (1) Strategies for identifying and eliminating pricing or
373 business practices that raise prices without supporting or enhancing
374 innovation in drug development, (2) price trends and affordability

375 strategies for any drug identified pursuant to subsection (b) or (c) of
376 section 15 of this act, (3) any recommendations the board may have for
377 legislation needed to make prescription drug products more affordable
378 in the state while supporting and enhancing innovation in drug
379 development, (4) purchasing strategies, cost effectiveness evaluations
380 and the development of new technologies and drugs that increase
381 affordability, (5) any violation resulting in penalties pursuant to section
382 16 of this act, and (6) a summary and evaluation of the Prescription Drug
383 Affordability Board's activities and recommendations.

384 (h) Members of the board may engage in private employment, or in
385 a profession or business, subject to any applicable laws and regulations
386 of the state regarding official ethics or conflict of interest. As used in this
387 subsection, (1) "conflict of interest" means (A) an association of a board
388 member, including a financial or personal association, that has the
389 potential to bias or appear to bias a board member's decisions in matters
390 related to the board, and (B) any instance in which a board member, a
391 staff member of the board or an immediate family member of a board
392 member has received or could receive (i) a financial benefit of any
393 amount derived from the results or findings of a study or determination
394 that is reached by or for the board, or (ii) a financial benefit from an
395 individual or company that owns or manufactures a prescription drug,
396 service or item that is being or will be studied by the board; and (2)
397 "financial benefit" means honoraria, fees, stock or any other form of
398 compensation, including increases to the value of existing stock
399 holdings.

400 (i) In carrying out its purposes, the board shall:

401 (1) Collect and review publicly available information and
402 information available via private subscriptions regarding prescription
403 drug pricing and business practices of health carriers, health
404 maintenance organizations, managed care organizations,
405 manufacturers, wholesale distributors and pharmacy benefit managers,
406 including, but not limited to, the annual report by pharmacy benefit
407 managers required pursuant to section 38a-479ppp of the general

408 statutes;

409 (2) Identify innovative strategies that may reduce the cost of
410 prescription drugs to consumers, including importation of certain
411 prescription drugs from Canada and other foreign countries and
412 jurisdictions; and

413 (3) Identify states with innovative programs to lower prescription
414 drug costs and, if relevant and approved by the board, (A) enter into
415 memoranda of understanding with such states to aid in the collection of
416 transparency data for prescription drug products or any other
417 information needed to establish similar programs in this state, and (B)
418 recommend multistate compacts the state can join to lower prescription
419 drug costs.

420 (j) The board may receive and accept aid or contributions from any
421 source of money, property, labor or other things of value, to be held,
422 used and applied to carry out the purposes of the board, provided
423 acceptance of such aid or contributions does not present a conflict of
424 interest for any board member or any purpose of the board.

425 Sec. 13. (NEW) (*Effective July 1, 2024*) (a) There is established a
426 Prescription Drug Affordability Stakeholder Advisory Council to advise
427 the Prescription Drug Affordability Board established pursuant to
428 section 12 of this act on decisions regarding the affordability of
429 prescription drugs.

430 (b) Members of the council shall serve for three years and shall consist
431 of:

432 (1) Two appointed by the speaker of the House of Representatives;

433 (2) Two appointed by the president pro tempore of the Senate;

434 (3) One appointed by the majority leader of the House of
435 Representative;

436 (4) One appointed by the majority leader of the Senate;

437 (5) One appointed by the minority leader of the House of
438 Representatives;

439 (6) One appointed by the minority leader of the Senate;

440 (7) One appointed by the Governor;

441 (8) The Commissioner of Social Services, or the commissioner's
442 designee;

443 (9) The Commissioner of Consumer Protection, or the commissioner's
444 designee;

445 (10) The executive director of the Office of Health Strategy, or the
446 executive director's designee; and

447 (11) The Healthcare Advocate, or the Healthcare Advocate's
448 designee.

449 (c) All initial appointments to the council shall be made not later than
450 November 1, 2024. Any vacancy shall be filled by the appointing
451 authority.

452 (d) The speaker of the House of Representatives and the president
453 pro tempore of the Senate shall select the chairpersons of the council
454 from among the members of the council. Such chairpersons shall
455 schedule the first meeting of the council, which shall be held not later
456 than December 1, 2024.

457 (e) The administrative staff of the joint standing committee of the
458 General Assembly having cognizance of matters relating to insurance
459 shall serve as administrative staff of the council.

460 (f) Not later than September 1, 2025, and annually thereafter, the
461 council shall submit a report to the board, in accordance with the
462 provisions of section 11-4a of the general statutes, on its
463 recommendations concerning prescription drug prices. The council
464 shall also provide recommendations to the board at any time the board

465 requests such recommendations.

466 Sec. 14. (NEW) (*Effective July 1, 2024*) As used in this section and
467 sections 15 and 16 of this act:

468 (1) "Biologic" means a drug licensed under 42 USC 262, as amended
469 from time to time;

470 (2) "Biosimilar" means a drug that is highly similar to a biologic and
471 is produced or distributed in accordance with a biologics license
472 application approved under 42 USC 262(k), as amended from time to
473 time;

474 (3) "Board" means the Prescription Drug Affordability Board
475 established pursuant to section 12 of this act;

476 (4) "Brand-name drug" means a drug that is produced or distributed
477 in accordance with an original new drug application approved under 21
478 USC 355, as amended from time to time, but does not include an
479 authorized generic drug as defined in 42 CFR 447.502, as amended from
480 time to time;

481 (5) "Generic drug" means (A) a prescription drug product that is
482 marketed or distributed in accordance with an abbreviated new drug
483 application approved under 21 USC 355, as amended from time to time,
484 (B) an authorized generic drug as defined in 42 CFR 447.502, as
485 amended from time to time, or (C) a drug that entered the market before
486 calendar year 1962 that was not originally marketed under a new
487 prescription drug product application;

488 (6) "Manufacturer" means an entity that (A) engages in the
489 manufacture of a drug product, or (B) enters into a lease with another
490 manufacturer to market and distribute a prescription drug product
491 under the entity's own name and sets or changes the wholesale
492 acquisition cost of the prescription drug product it manufactures or
493 markets;

494 (7) "Prescription drug product" means a brand-name drug, a generic

495 drug, a biologic or biosimilar;

496 (8) "Upper payment limit" means the maximum rate above which
497 purchasers throughout the state may not pay for prescription drug
498 products exclusive of any reasonable fee charged by a pharmacy for
499 dispensing or delivering such products; and

500 (9) "Wholesale acquisition cost" means the price of a medication set
501 by a pharmaceutical manufacturer in the United States when selling to
502 a wholesaler.

503 Sec. 15. (NEW) (*Effective July 1, 2024*) (a) To the extent practicable, the
504 Prescription Drug Affordability Board established pursuant to section
505 12 of this act may assess pricing information for prescription drug
506 products by: (1) Entering into a memorandum of understanding with
507 another state to which a manufacturer reports pricing information, (2)
508 assessing spending for the drug in Connecticut, (3) utilizing data and
509 findings, including consumer affordability strategies, developed by
510 another state's board, (4) utilizing data and findings, including cost
511 containment strategies, developed by any other state or federal entity,
512 (5) utilizing the maximum fair price for a prescription drug for persons
513 eligible for Medicare established pursuant to the federal Inflation
514 Reduction Act of 2022, P.L. No. 117-169, as amended from time to time,
515 and (6) assessing any other available pricing information.

516 (b) On and after July 1, 2025, the board shall review the following
517 prescription drug products:

518 (1) Any outpatient prescription drug listed by the Office of Health
519 Strategy pursuant to section 19a-754b of the general statutes;

520 (2) Any drug designated by another state's prescription drug
521 affordability board as unaffordable or that will be subject to an
522 affordability review;

523 (3) Any drug selected by the Centers for Medicare and Medicaid
524 Services for price negotiation under Medicare Part D; and

525 (4) Insulin drugs as defined in section 20-616 of the general statutes
526 and noninsulin drugs as defined in section 38a-492d of the general
527 statutes, as amended by this act.

528 (c) On and after July 1, 2025, the board shall identify any other
529 prescription drug products or pricing practices that may create
530 affordability challenges, such as increasing prices or decreasing access,
531 for the health care system in the state or patients, including, but not
532 limited to, drugs needed to address significant public health priorities.

533 (d) After identifying prescription drug products as required by
534 subsections (b) and (c) of this section, the board may conduct a review
535 for any identified prescription drug product or pricing practice if, after
536 (1) seeking input from the Prescription Drug Affordability Stakeholder
537 Advisory Council established pursuant to section 13 of this act, and (2)
538 considering the average patient cost share of the prescription drug
539 product, the board determines such review is in the interest of
540 consumers.

541 (e) In conducting a review of prescription drugs, the board shall
542 examine any document and research related to the pricing of the
543 prescription drug product, including, but not limited to, (1) net average
544 price in the state, (2) market competition and context, (3) projected
545 revenue to the manufacturer, (4) the estimated value or cost
546 effectiveness, (5) whether and how the prescription drug product
547 represents an innovative therapy or is likely to improve health or health
548 outcomes for the target consumer, and (6) any rebates, discounts, patient
549 access programs or other cost mitigation strategies relevant to the
550 prescription drug product.

551 (f) The board shall determine whether use of the prescription drug
552 product, consistent with the labeling approved by the federal Food and
553 Drug Administration or standard medical practice, has led or will lead
554 to affordability challenges, such as increasing prices or decreasing
555 access, for the health care system in the state or for patients. In
556 determining whether a prescription drug product has led or will lead to

557 an affordability challenge, the board may consider the following factors:

558 (1) The wholesale acquisition cost for the prescription drug product
559 sold in the state;

560 (2) The average monetary price concession, discount or rebate
561 provided or expected to be provided to health plans in the state as
562 reported by manufacturers and health plans, expressed as a percentage
563 of the wholesale acquisition cost for the prescription drug product
564 under review;

565 (3) The total amount of the price concession, discount or rebate the
566 manufacturer provides to each pharmacy benefits manager operating in
567 the state for the prescription drug product under review, as reported by
568 manufacturers and pharmacy benefits managers, expressed as a
569 percentage of the wholesale acquisition costs;

570 (4) The price at which therapeutic alternatives have been sold in the
571 state;

572 (5) The average monetary concession, discount or rebate the
573 manufacturer provides or is expected to provide to health plan payors
574 and pharmacy benefits managers in the state for therapeutic
575 alternatives;

576 (6) The costs to health plans based on patient access consistent with
577 United States Food and Drug Administration labeled indications and
578 recognized standard medical practice;

579 (7) The impact on patient access resulting from the cost of the
580 prescription drug product relative to health plan benefit design;

581 (8) The current or expected dollar value of drug-specific patient
582 access programs that are supported by the manufacturer;

583 (9) The relative financial impacts to health, medical or social services
584 costs as may be quantified and compared to baseline effects of existing
585 therapeutic alternatives;

586 (10) The average patient copayment or other cost sharing for the
587 prescription drug product in the state;

588 (11) Any information a manufacturer chooses to provide; and

589 (12) Any other factors as determined by the board.

590 (g) If the board finds that the spending on a prescription drug
591 product reviewed under this section has led or will lead to an
592 affordability challenge, such as increasing prices or decreasing access to
593 such drug, and determines that at least three other states with a
594 combined population above fifteen million have also examined the
595 affordability of said prescription drug product, the board shall
596 coordinate with other states and may join a multistate compact to set an
597 upper payment limit on such drug products. The board shall
598 recommend the establishment of an upper payment limit for such drug
599 product and any such compact it deems would benefit the state to the
600 executive director of the Office of Health Strategy and the
601 Commissioner of Consumer Protection after considering: (1) The cost of
602 administering the drug, (2) the cost of delivering the drug to patients,
603 and (3) other relevant administrative costs related to the drug. In its
604 recommendations, the board may utilize (A) upper payment limits set
605 by similar boards in other states, provided the board finds that the other
606 entity's price justification process is at least as rigorous as the process set
607 forth in state law, (B) upper payment limits set by any other state or
608 federal entity, provided the board finds that the other entity's price
609 justification process is at least as rigorous as the process set forth in state
610 law, and (C) the Medicare maximum fair price for a prescription drug
611 established pursuant to the federal Inflation Reduction Act of 2022, P.L.
612 No. 117-169.

613 (h) The executive director of the Office of Health Strategy shall adopt
614 regulations in accordance with chapter 54 of the general statutes
615 governing the adoption of an upper payment limit recommendation
616 from the board.

617 Sec. 16. (NEW) (*Effective July 1, 2025*) (a) As used in this section and

618 section 17 of this act, (1) "participating ERISA plan" means an employee
619 welfare benefit plan subject to the Employee Retirement Income
620 Security Act of 1974, as amended from time to time, that elects to
621 participate in the provisions of this section and section 17 of this act; (2)
622 "health benefit plan" has the same meaning as provided in section 38a-
623 472f of the general statutes; and (3) "state entity" means any state agency,
624 or any person acting on the state's behalf that purchases a prescription
625 drug for an individual with a health benefit plan provided by the state,
626 including a health benefit plan offered by local, state or federal agencies
627 or through organizations licensed in the state.

628 (b) It shall be a violation of this section for a state entity, health benefit
629 plan or participating ERISA plan to purchase prescription drugs with
630 an established upper payment limit to be dispensed or delivered to a
631 consumer in the state, whether directly or through a distributor, for a
632 cost higher than the upper payment limit as determined pursuant to
633 subsection (g) of section 15 of this act. Contracts entered into by a state
634 entity, health benefit plan or participating ERISA plan and a third party
635 for the purchase of prescription drugs shall expressly provide that rates
636 paid for drugs may not exceed the upper payment limit.

637 (c) It shall be a violation of this section for a retail pharmacy licensed
638 in this state to purchase for sale or distribution to a person whose health
639 care is provided by a state entity, health benefit plan or participating
640 ERISA plan a drug for a cost that exceeds the upper payment limit as
641 determined pursuant to subsection (g) of section 15 of this act. A
642 pharmacy may set reasonable costs for dispensing or delivering a
643 prescription drug subject to an upper payment limit.

644 (d) The Commissioner of Consumer Protection, in consultation with
645 the executive director of the Office of Health Strategy, shall enforce the
646 provisions of this section and may, subject to notice and an opportunity
647 for a hearing pursuant to chapter 54 of the general statutes, issue civil
648 penalties not exceeding fifty thousand dollars per violation. The
649 commissioner shall adopt regulations, in accordance with chapter 54 of
650 the general statutes, to implement the provisions of this section.

651 Sec. 17. (NEW) (*Effective July 1, 2025*) Any savings generated by a state
652 entity, health benefit plan or participating ERISA plan that are
653 attributable to the implementation of an upper payment limit
654 established upon recommendation of the Prescription Drug
655 Affordability Board shall be used to reduce health care costs to
656 consumers, prioritizing the reduction of out-of-pocket costs for
657 prescription drugs. Not later than April 1, 2026, and annually thereafter,
658 each state entity, health benefit plan and participating ERISA plan shall
659 submit to the board and to the executive director of the Office of Health
660 Strategy a report, in a form prescribed by the executive director,
661 detailing the total volume and price paid for any drug subject to an
662 upper payment limit. Not later than July 1, 2026, and annually
663 thereafter, the executive director, in accordance with the provisions of
664 section 11-4a of the general statutes, shall file a report with the joint
665 standing committees of the General Assembly having cognizance of
666 matters relating to appropriations, general law, human services,
667 insurance and public health. The report shall include savings achieved
668 as a result of implementing upper payment limits, how those savings
669 were passed on to the consumer, and the executive director's
670 recommendations concerning additional savings that may be achieved
671 and supporting strategies to ensure those savings are passed on to the
672 consumer.

673 Sec. 18. (NEW) (*Effective July 1, 2025*) (a) As used in this section,
674 "manufacturer" means an entity that (1) engages in the manufacture of
675 a drug product, or (2) enters into a lease with another manufacturer to
676 market and distribute a prescription drug product under the entity's
677 own name and sets or changes the wholesale acquisition cost of the
678 prescription drug product it manufactures or markets. Any
679 manufacturer that intends to withdraw from sale or distribution within
680 the state, or change pricing or availability to the point that access is
681 impaired or restricted, of a prescription drug for which the Prescription
682 Drug Affordability Board has recommended an upper payment limit
683 shall provide a notice of withdrawal in writing at least six months before
684 the date of the intended withdrawal of such prescription drug to the

685 board, the executive director of the Office of Health Strategy, the
686 Commissioner of Consumer Protection, the Insurance Commissioner,
687 the Attorney General and any entity in the state with which the
688 manufacturer has a contract for the sale or distribution of the drug.

689 (b) The Commissioner of Consumer Protection may assess a civil
690 penalty not to exceed five hundred thousand dollars if the board
691 determines that a manufacturer failed to provide the notice required by
692 subsection (a) of this section before withdrawing from sale or
693 distribution, or changing pricing or availability to the point that access
694 is impaired or restricted, of a prescription drug within the state for
695 which an upper payment limit has been established in accordance with
696 subsection (g) of section 15 of this act. Any such penalty shall be
697 assessed only after notice to a manufacturer and an opportunity for a
698 hearing pursuant to the provisions of chapter 54 of the general statutes.
699 The commissioner shall adopt regulations, in accordance with chapter
700 54 of the general statutes, to implement the provisions of this section.

701 (c) A representative of a manufacturer that reasonably foresees an
702 impending shortage of a prescription drug such manufacturer sells or
703 distributes in the state shall notify the board in the same form and
704 manner a manufacturer is required to notify the federal Food and Drug
705 Administration of such shortage in accordance with the notification
706 provisions of the Coronavirus Aid, Relief, and Economic Security Act
707 (CARES Act), P.L. 116-136, as amended from time to time. The
708 Commissioner of Consumer Protection may assess a civil penalty of not
709 more than fifty thousand dollars for each violation of the provisions of
710 this subsection after notice and an opportunity for a hearing in
711 accordance with the provisions of chapter 54 of the general statutes. The
712 commissioner shall adopt regulations, in accordance with the
713 provisions of chapter 54 of the general statutes, to implement the
714 provisions of this section. A penalty shall not be assessed under this
715 subsection if a manufacturer provides evidence satisfactory to the
716 commissioner that a drug shortage was caused by unforeseen
717 circumstances, such as an accident or disaster affecting a manufacturing
718 facility or supply network.

- 719 Sec. 19. (NEW) (*Effective January 1, 2025*) (a) As used in this section:
- 720 (1) "Health benefit plan" has the same meaning as provided in section
721 38a-472f of the general statutes;
- 722 (2) "Insulin" means an insulin product, including, but not limited to,
723 an insulin pen or vial, that is licensed under 42 USC 262(a) or 42 USC
724 262(k), as amended from time to time;
- 725 (3) "Eligible insulin product" means an insulin product for which at
726 least two licenses have been issued and continues to be marketed
727 pursuant to such licensure;
- 728 (4) "Net cost" means the cost of an insulin product taking into account
729 rebates or discounts for that specific product, excluding (A) rebates or
730 discounts required by state or federal law, including Medicaid,
731 Medicare and section 340B of the Public Health Service Act, 42 USC
732 256b, as amended from time to time, and (B) rebates or discounts related
733 to portfolio agreements that relate to purchase of multiple insulin
734 products or other drugs;
- 735 (5) "State entity" means any state agency, or any person acting on
736 behalf of the state, that purchases a prescription drug for an individual
737 with health insurance paid for by the state, including health insurance
738 offered by local, state, or federal agencies or through organizations
739 licensed in the state;
- 740 (6) "Wholesale acquisition cost" means the price of a medication set
741 by a pharmaceutical manufacturer in the United States when selling to
742 a wholesaler; and
- 743 (7) "Wholesaler" means a wholesaler, as defined in section 21a-70 of
744 the general statutes, that has received a certificate of registration from
745 the Commissioner of Consumer Protection pursuant to said section.
- 746 (b) A state entity and health benefit plan shall, except as otherwise
747 required in any collective bargaining agreement affecting the state
748 employee health plan established pursuant to section 5-259 of the

749 general statutes, make available in a preferred tier with no copayment
750 or out-of-pocket cost an eligible insulin product at the lowest wholesale
751 acquisition cost to a beneficiary. Notwithstanding the provisions of this
752 section, if a state entity or health benefit plan determines that another
753 eligible insulin product has a lower net cost than the lowest wholesale
754 acquisition cost, such entity or health plan may offer that product with
755 no out-of-pocket payment to a beneficiary of such state entity or health
756 benefit plan. Nothing in this section shall prevent such entity or health
757 benefit plan from covering more than one eligible insulin product in a
758 preferred tier with no copayment or out-of-pocket cost to a beneficiary
759 of such entity or health benefit plan.

760 Sec. 20. Section 38a-492d of the general statutes is repealed and the
761 following is substituted in lieu thereof (*Effective January 1, 2025*):

762 (a) For the purposes of this section:

763 (1) "Diabetes device" has the same meaning as provided in section 20-
764 616;

765 (2) "Diabetic ketoacidosis device" has the same meaning as provided
766 in section 20-616;

767 (3) "Glucagon drug" has the same meaning as provided in section 20-
768 616;

769 (4) "High deductible health plan" has the same meaning as that term
770 is used in subsection (f) of section 38a-493;

771 (5) "Insulin drug" has the same meaning as provided in section 20-
772 616;

773 (6) "Noninsulin drug" means a drug, including, but not limited to, a
774 glucagon drug, glucose tablet or glucose gel, that does not contain
775 insulin and is approved by the federal Food and Drug Administration
776 to treat diabetes; and

777 (7) "Prescribing practitioner" has the same meaning as provided in

778 section 20-571.

779 (b) Notwithstanding the provisions of section 38a-492a, each
780 individual health insurance policy providing coverage of the type
781 specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469
782 delivered, issued for delivery, renewed, amended or continued in this
783 state shall provide coverage for the treatment of all types of diabetes.
784 Such coverage shall include, but need not be limited to, coverage for
785 medically necessary:

786 (1) Laboratory and diagnostic testing and screening, including, but
787 not limited to, hemoglobin A1c testing and retinopathy screening, for
788 all types of diabetes;

789 (2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B)
790 prescribed and dispensed pursuant to subsection (d) of section 20-616
791 once during a policy year;

792 (3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or
793 (B) prescribed and dispensed pursuant to subsection (d) of section 20-
794 616 once during a policy year if the noninsulin drug is a glucagon drug;

795 (4) Diabetes devices in accordance with the insured's diabetes
796 treatment plan, including, but not limited to, diabetes devices
797 prescribed and dispensed pursuant to subsection (d) of section 20-616
798 once during a policy year; and

799 (5) Diabetic ketoacidosis devices in accordance with the insured's
800 diabetes treatment plan, including, but not limited to, diabetic
801 ketoacidosis devices prescribed and dispensed pursuant to subsection
802 (d) of section 20-616 once during a policy year.

803 (c) Notwithstanding the provisions of section 38a-492a, no policy
804 described in subsection (b) of this section shall impose coinsurance,
805 copayments, deductibles and other out-of-pocket expenses on an
806 insured that exceed:

807 (1) Twenty-five dollars for each thirty-day supply of a medically

808 necessary covered insulin drug (A) prescribed to the insured by a
809 prescribing practitioner, or (B) prescribed and dispensed pursuant to
810 subsection (d) of section 20-616 once during a policy year;

811 (2) Twenty-five dollars for each thirty-day supply of a medically
812 necessary covered noninsulin drug (A) prescribed to the insured by a
813 prescribing practitioner, or (B) prescribed and dispensed pursuant to
814 subsection (d) of section 20-616 once during a policy year if such
815 noninsulin drug is a glucagon drug;

816 (3) One hundred dollars for a thirty-day supply of all medically
817 necessary covered diabetes devices and diabetic ketoacidosis devices for
818 such insured that are in accordance with such insured's diabetes
819 treatment plan, including, but not limited to, diabetes devices and
820 diabetic ketoacidosis devices prescribed and dispensed pursuant to
821 subsection (d) of section 20-616 once during a policy year.

822 (d) Notwithstanding the provisions of section 38a-492a and
823 subsection (c) of this section, on and after January 1, 2025, any policy
824 described in subsection (b) of this section shall make available in a
825 preferred tier with no copayment or out-of-pocket cost an eligible
826 insulin product, as defined in section 19 of this act, at the lowest
827 wholesale acquisition cost in accordance with section 19 of this act.

828 [(d)] (e) The provisions of [subsection (c)] subsections (c) and (d) of
829 this section shall apply to a high deductible health plan to the maximum
830 extent permitted by federal law, except if such plan is used to establish
831 a medical savings account or an Archer MSA pursuant to Section 220 of
832 the Internal Revenue Code of 1986, or any subsequent corresponding
833 internal revenue code of the United States, as amended from time to
834 time, or a health savings account pursuant to Section 223 of said Internal
835 Revenue Code, as amended from time to time, the provisions of said
836 [subsection (c)] subsections shall apply to such plan to the maximum
837 extent that (1) is permitted by federal law, and (2) does not disqualify
838 such account for the deduction allowed under said Section 220 or 223,
839 as applicable.

840 Sec. 21. Section 38a-518d of the general statutes is repealed and the
841 following is substituted in lieu thereof (*Effective January 1, 2025*):

842 (a) For the purposes of this section:

843 (1) "Diabetes device" has the same meaning as provided in section 20-
844 616;

845 (2) "Diabetic ketoacidosis device" has the same meaning as provided
846 in section 20-616;

847 (3) "Glucagon drug" has the same meaning as provided in section 20-
848 616;

849 (4) "High deductible health plan" has the same meaning as that term
850 is used in subsection (f) of section 38a-520;

851 (5) "Insulin drug" has the same meaning as provided in section 20-
852 616;

853 (6) "Noninsulin drug" means a drug, including, but not limited to, a
854 glucagon drug, glucose tablet or glucose gel, that does not contain
855 insulin and is approved by the federal Food and Drug Administration
856 to treat diabetes; and

857 (7) "Prescribing practitioner" has the same meaning as provided in
858 section 20-571.

859 (b) Notwithstanding the provisions of section 38a-518a, each group
860 health insurance policy providing coverage of the type specified in
861 subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered,
862 issued for delivery, renewed, amended or continued in this state shall
863 provide coverage for the treatment of all types of diabetes. Such
864 coverage shall include, but need not be limited to, coverage for
865 medically necessary:

866 (1) Laboratory and diagnostic testing and screening, including, but
867 not limited to, hemoglobin A1c testing and retinopathy screening, for

868 all types of diabetes;

869 (2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B)
870 prescribed and dispensed pursuant to subsection (d) of section 20-616
871 once during a policy year;

872 (3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or
873 (B) prescribed and dispensed pursuant to subsection (d) of section 20-
874 616 once during a policy year if the noninsulin drug is a glucagon drug;

875 (4) Diabetes devices in accordance with the insured's diabetes
876 treatment plan, including, but not limited to, diabetes devices
877 prescribed and dispensed pursuant to subsection (d) of section 20-616
878 once during a policy year; and

879 (5) Diabetic ketoacidosis devices in accordance with the insured's
880 diabetes treatment plan, including, but not limited to, diabetic
881 ketoacidosis devices prescribed and dispensed pursuant to subsection
882 (d) of section 20-616 once during a policy year.

883 (c) Notwithstanding the provisions of section 38a-518a, no policy
884 described in subsection (b) of this section shall impose coinsurance,
885 copayments, deductibles and other out-of-pocket expenses on an
886 insured that exceed:

887 (1) Twenty-five dollars for each thirty-day supply of a medically
888 necessary covered insulin drug (A) prescribed to the insured by a
889 prescribing practitioner, or (B) prescribed and dispensed pursuant to
890 subsection (d) of section 20-616 once during a policy year;

891 (2) Twenty-five dollars for each thirty-day supply of a medically
892 necessary covered noninsulin drug (A) prescribed to the insured by a
893 prescribing practitioner, or (B) prescribed and dispensed pursuant to
894 subsection (d) of section 20-616 once during a policy year if such
895 noninsulin drug is a glucagon drug;

896 (3) One hundred dollars for a thirty-day supply of all medically
897 necessary covered diabetes devices and diabetic ketoacidosis devices for

898 such insured that are in accordance with such insured's diabetes
899 treatment plan, including, but not limited to, diabetes devices and
900 diabetic ketoacidosis devices prescribed and dispensed pursuant to
901 subsection (d) of section 20-616 once during a policy year.

902 (d) Notwithstanding the provisions of section 38a-518a and
903 subsection (c) of this section, on and after January 1, 2025, any policy
904 described in subsection (b) of this section shall make available in a
905 preferred tier with no copayment or out-of-pocket cost an eligible
906 insulin product, as defined in section 19 of this act, at the lowest
907 wholesale acquisition cost in accordance with section 19 of this act.

908 [(d)] (e) The provisions of [subsection (c)] subsections (c) and (d) of
909 this section shall apply to a high deductible health plan to the maximum
910 extent permitted by federal law, except if such plan is used to establish
911 a medical savings account or an Archer MSA pursuant to Section 220 of
912 the Internal Revenue Code of 1986, or any subsequent corresponding
913 internal revenue code of the United States, as amended from time to
914 time, or a health savings account pursuant to Section 223 of said Internal
915 Revenue Code, as amended from time to time, the provisions of said
916 [subsection (c)] subsections shall apply to such plan to the maximum
917 extent that (1) is permitted by federal law, and (2) does not disqualify
918 such account for the deduction allowed under said Section 220 or 223,
919 as applicable.

920 Sec. 22. (NEW) (*Effective July 1, 2024*) (a) As used in this section:

921 (1) "Eligible drug" means an injectable drug product approved under
922 Section 505(j) or 505(b)(2) of the federal Food, Drug and Cosmetic Act,
923 as amended from time to time, that is on the drug shortage list, or has
924 been on such list during the prior five-year period, established under
925 Section 506E of the federal Food, Drug and Cosmetic Act, 21 USC 356e,
926 as amended from time to time, or which has otherwise been identified
927 as being at risk of shortage;

928 (2) "Drug purchasing agency" means the Departments of Correction,
929 Social Services and Mental Health and Addiction Services; and

930 (3) "Hospital" means a hospital licensed pursuant to chapter 368v of
931 the general statutes.

932 (b) Each hospital or drug purchasing agency shall consider, as part of
933 its drug shortage mitigation strategy for eligible drugs, whether
934 working with an entity that provides such hospital or drug purchasing
935 agency with a physical reserve inventory would assist in addressing
936 drug shortages.

937 Sec. 23. (NEW) (*Effective from passage*) As used in this section and
938 section 24 of this act:

939 (1) "340B drug" means a drug that (A) is a covered outpatient drug
940 within the meaning of 42 USC 256b; (B) has been subject to any offer for
941 reduced prices by a manufacturer under 42 USC 256b(a)(1); and (C) is
942 purchased by a covered entity. "340B drug" includes a drug that would
943 have been purchased but for the restriction or limitation described in
944 subsection (a) of section 24 of this act;

945 (2) "Biologic" has the same meaning as provided in section 21a-70d of
946 the general statutes;

947 (3) "Covered entity" has the same meaning as provided in Section
948 340B of the Public Health Service Act, 42 USC 256b, as amended from
949 time to time;

950 (4) "Manufacturer" has the same meaning as provided in section 21a-
951 70 of the general statutes, except that such definition shall include
952 manufacturers of biologics;

953 (5) "Package" has the same meaning as provided in 21 USC
954 360eee(11)(A); and

955 (6) "Pharmacy" has the same meaning as provided in section 20-571
956 of the general statutes.

957 Sec. 24. (NEW) (*Effective from passage*) (a) A manufacturer, or an agent
958 or affiliate of such manufacturer, shall not, either directly or indirectly:

959 (1) Deny, restrict, prohibit, discriminate against or otherwise limit the
960 acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy
961 that is under contract with, or otherwise authorized by, a covered entity
962 to receive 340B drugs on behalf of the covered entity unless such receipt
963 is prohibited under federal law; or

964 (2) Require a covered entity, or a pharmacy that is under contract
965 with a covered entity, to submit any claims or utilization data as a
966 condition for allowing the acquisition of a 340B drug by, or delivery of
967 a 340B drug to, a covered entity, or a pharmacy that is under contract
968 with a covered entity, unless the claims or utilization data sharing is
969 required by the United States Department of Health and Human
970 Services.

971 (b) (1) On and after July 1, 2024, if the Commissioner of Consumer
972 Protection receives information and has a reasonable belief, after
973 evaluating such information, that any manufacturer, or an agent or
974 affiliate of such manufacturer, has acted in violation of any provision of
975 this section, or regulation adopted thereunder, such manufacturer, or an
976 agent or affiliate of such manufacturer, shall be subject to a civil penalty
977 of not more than fifty thousand dollars for each violation. The
978 commissioner shall issue a notice of violation and civil penalty and may
979 issue such notice by first-class mail or personal service. Such notice shall
980 include: (A) A reference to the section of the general statutes, or
981 regulation of Connecticut state agencies believed or alleged to have been
982 violated; (B) a short and plain language statement of the matters
983 asserted or charged; (C) a description of the activity to cease; (D) a
984 statement of the amount of the civil penalty or penalties that may be
985 imposed; (E) a statement concerning the right to a hearing; and (F) a
986 statement that such manufacturer, or an agent or affiliate of such
987 manufacturer, may, not later than ten business days after receipt of such
988 notice, make a request for a hearing on the matters asserted.

989 (2) The manufacturer, or an agent or affiliate of such manufacturer,
990 to whom such notice is provided pursuant to subparagraph (A) of
991 subdivision (1) of this subsection may, not later than ten business days

992 after receipt of such notice, make written application to the Department
 993 of Consumer Protection to request a hearing to demonstrate that such
 994 violation did not occur. The failure to make a timely request for a
 995 hearing shall result in the issuance of a cease and desist order or
 996 imposition of a civil penalty by the department. All hearings held under
 997 this subsection shall be conducted in accordance with the provisions for
 998 contested cases under chapter 54 of the general statutes.

999 (3) Following any hearing before the Department of Consumer
 1000 Protection pursuant to subdivision (2) of this subsection, if the
 1001 department finds, by a preponderance of the evidence, that any
 1002 manufacturer, or an agent or affiliate of such manufacturer, violated or
 1003 is violating any provision of this subsection, any regulation adopted
 1004 thereunder or any order issued by the department, the department shall
 1005 issue a final cease and desist order in addition to any civil penalty the
 1006 department imposes.

1007 (c) Nothing in this section shall be construed or applied to be in
 1008 conflict with or less restrictive than:

1009 (1) Applicable federal law and related regulations, including 21 USC
 1010 355-1, as amended from time to time; or

1011 (2) Other laws of this state to the extent such laws are compatible with
 1012 applicable federal law.

1013 (d) The Commissioner of Consumer Protection shall adopt
 1014 regulations in accordance with the provisions of chapter 54 of the
 1015 general statutes to implement the provisions of this section."

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2026	New section
Sec. 2	July 1, 2026	New section
Sec. 3	July 1, 2026	New section
Sec. 4	July 1, 2026	New section
Sec. 5	July 1, 2026	New section

Sec. 6	<i>July 1, 2026</i>	New section
Sec. 7	<i>July 1, 2026</i>	New section
Sec. 8	<i>July 1, 2026</i>	New section
Sec. 9	<i>July 1, 2026</i>	New section
Sec. 10	<i>July 1, 2026</i>	New section
Sec. 11	<i>January 1, 2026</i>	New section
Sec. 12	<i>July 1, 2024</i>	New section
Sec. 13	<i>July 1, 2024</i>	New section
Sec. 14	<i>July 1, 2024</i>	New section
Sec. 15	<i>July 1, 2024</i>	New section
Sec. 16	<i>July 1, 2025</i>	New section
Sec. 17	<i>July 1, 2025</i>	New section
Sec. 18	<i>July 1, 2025</i>	New section
Sec. 19	<i>January 1, 2025</i>	New section
Sec. 20	<i>January 1, 2025</i>	38a-492d
Sec. 21	<i>January 1, 2025</i>	38a-518d
Sec. 22	<i>July 1, 2024</i>	New section
Sec. 23	<i>from passage</i>	New section
Sec. 24	<i>from passage</i>	New section