



General Assembly

Substitute Bill No. 13

February Session, 2022



AN ACT REDUCING PRESCRIPTION DRUG PRICES.

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

1 Section 1. (NEW) (*Effective July 1, 2022*) There is established an
2 account to be known as the "Covered Connecticut account" which shall
3 be a separate, nonlapsing account within the General Fund. The account
4 shall be administered by the Office of Health Strategy, established under
5 section 19a-754a of the general statutes, and contain any moneys
6 required by law to be deposited in the account. Moneys in the account
7 shall be expended by the (1) Office of Health Strategy for the purpose of
8 supporting the Covered Connecticut program established under section
9 19a-754c of the general statutes, and (2) Department of Social Services
10 for the purpose of supporting the state medical assistance program
11 administered by the department.

12 Sec. 2. (NEW) (*Effective July 1, 2022*) For the purposes of this section
13 and sections 3 and 4 of this act:

14 (1) "Commissioner" means the Commissioner of Revenue Services;

15 (2) "Consumer price index" means the consumer price index, annual
16 average, for all urban consumers: United States city average, all items,
17 published by the United States Department of Labor, Bureau of Labor
18 Statistics, or its successor, or, if the index is discontinued, an equivalent

19 index published by a federal authority, or, if no such index is published,
20 a comparable index published by the United States Department of
21 Labor, Bureau of Labor Statistics;

22 (3) "Covered Connecticut account" means the Covered Connecticut
23 account established under section 1 of this act;

24 (4) "Identified prescription drug" means a prescription drug that is
25 sold at a price that exceeds the sum calculated under subdivision (1) of
26 subsection (a) of section 3 of this act for such drug;

27 (5) "Legend drug" has the same meaning as provided in section 20-
28 571 of the general statutes;

29 (6) "Office of Health Strategy" means the Office of Health Strategy
30 established under section 19a-754a of the general statutes;

31 (7) "Person" has the same meaning as provided in section 12-1 of the
32 general statutes;

33 (8) "Pharmaceutical manufacturer" means a person that
34 manufactures a prescription drug and sells, directly or through another
35 person, the prescription drug for distribution in this state;

36 (9) "Prescription drug" means a legend drug approved by the federal
37 Food and Drug Administration, or any successor agency, and
38 prescribed by a health care provider to an individual in this state;

39 (10) "Reference price" means the wholesale acquisition cost of a drug
40 (A) on January 1, 2022, or (B) on the date such drug is first commercially
41 marketed in the United States if such drug is first commercially
42 marketed in the United States after January 1, 2022; and

43 (11) "Wholesale acquisition cost" has the same meaning as provided
44 in 42 USC 1395w-3a, as amended from time to time.

45 Sec. 3. (NEW) (*Effective July 1, 2022*) (a) (1) Notwithstanding any
46 provision of the general statutes and except as provided in subdivision

47 (2) of this subsection, no pharmaceutical manufacturer shall, on or after
48 January 1, 2023, sell a prescription drug with a wholesale acquisition
49 cost equal to or greater than one hundred dollars in this state at a price
50 that exceeds the sum of:

51 (A) The reference price for the prescription drug, adjusted for any
52 increase or decrease in the consumer price index; and

53 (B) Two per cent of the reference price for the prescription drug for
54 each twelve-month period that has elapsed since the date on which the
55 reference price for such prescription drug was determined,
56 compounded annually on the anniversary of such date.

57 (2) A pharmaceutical manufacturer may sell a prescription drug in
58 this state at a price that exceeds the sum calculated for the prescription
59 drug under subdivision (1) of this subsection if the federal Secretary of
60 Health and Human Services determines, pursuant to 21 USC 356e, as
61 amended from time to time, that such prescription drug is in shortage
62 in the United States.

63 (b) (1) Except as provided in subdivision (2) of this subsection, any
64 pharmaceutical manufacturer that violates the provisions of subsection
65 (a) of this section shall be liable to this state for a civil penalty. Such civil
66 penalty shall be imposed, calculated and collected on a calendar year
67 basis, and the amount of such civil penalty for a calendar year shall be
68 equal to eighty per cent of the difference between:

69 (A) The revenue that the pharmaceutical manufacturer earned from
70 all sales of the identified prescription drug in this state during the
71 calendar year; and

72 (B) The revenue that the pharmaceutical manufacturer would have
73 earned from all sales of the identified prescription drug in this state
74 during the calendar year if the pharmaceutical manufacturer had sold
75 such identified prescription drug at a price that did not exceed the sum
76 calculated under subdivision (1) of subsection (a) of this section for such
77 identified prescription drug.

78 (2) No pharmaceutical manufacturer of an identified prescription
79 drug shall be liable to this state for the civil penalty imposed under
80 subdivision (1) of this subsection unless the pharmaceutical
81 manufacturer made at least two hundred fifty thousand dollars in total
82 annual sales in this state for the calendar year for which such civil
83 penalty would otherwise be imposed.

84 (c) (1) (A) Not later than March 1, 2024, and annually thereafter, each
85 pharmaceutical manufacturer that violated subsection (a) of this section
86 during the preceding calendar year shall:

87 (i) Pay to the commissioner the civil penalty imposed under
88 subsection (b) of this section for such calendar year; and

89 (ii) File with the commissioner a statement for such calendar year in
90 a form and manner, and containing all information, prescribed by the
91 commissioner.

92 (B) A pharmaceutical manufacturer that is required to file a statement
93 and pay a civil penalty pursuant to subparagraph (A) of this subdivision
94 shall electronically file such statement and make such payment by
95 electronic funds transfer in the manner provided by chapter 228g of the
96 general statutes, irrespective of whether the pharmaceutical
97 manufacturer would have otherwise been required to electronically file
98 such statement or make such payment by electronic funds transfer
99 under chapter 228g of the general statutes.

100 (2) If no statement is filed pursuant to subdivision (1) of this
101 subsection, the commissioner may make such statement at any time
102 thereafter, according to the best obtainable information and the
103 prescribed form.

104 (d) The commissioner may examine the records of any
105 pharmaceutical manufacturer that is subject to the civil penalty imposed
106 under subsection (b) of this section as the commissioner deems
107 necessary. If the commissioner determines from such examination that
108 the pharmaceutical manufacturer failed to pay the full amount of such

109 civil penalty, the commissioner shall bill such pharmaceutical
110 manufacturer for the full amount of such civil penalty.

111 (e) (1) The commissioner may require each pharmaceutical
112 manufacturer that is subject to a civil penalty imposed under this section
113 to keep such records as the commissioner may prescribe, and produce
114 books, papers, documents and other data, to provide or secure
115 information pertinent to the enforcement and collection of such civil
116 penalty.

117 (2) The commissioner, or any person authorized by the
118 commissioner, may examine the books, papers, records and equipment
119 of any person who is subject to the provisions of this section and may
120 investigate the character of the business of such person to verify the
121 accuracy of any statement made or, if no statement is made by such
122 person, to ascertain and determine the amount required to be paid.

123 (f) Any pharmaceutical manufacturer that is subject to a civil penalty
124 imposed under this section and aggrieved by any action of the
125 commissioner under subdivision (2) of subsection (c) of this section or
126 subsection (d) of this section may apply to the commissioner, in writing
127 and not later than sixty days after the notice of such action is delivered
128 or mailed to such pharmaceutical manufacturer, for a hearing, setting
129 forth the reasons why such hearing should be granted and the amount
130 by which the civil penalty should be reduced. The commissioner shall
131 promptly consider each such application and may grant or deny the
132 hearing requested. If the hearing request is denied, the commissioner
133 shall immediately notify the pharmaceutical manufacturer. If the
134 hearing request is granted, the commissioner shall notify the
135 pharmaceutical manufacturer of the date, time and place for such
136 hearing. After such hearing, the commissioner may make such order as
137 appears just and lawful to the commissioner and shall furnish a copy of
138 such order to the pharmaceutical manufacturer. The commissioner may,
139 by notice in writing, order a hearing on the commissioner's own
140 initiative and require a pharmaceutical manufacturer, or any other
141 person who the commissioner believes to be in possession of relevant

142 information concerning such pharmaceutical manufacturer, to appear
143 before the commissioner or the commissioner's authorized agent with
144 any specified books of account, papers or other documents for
145 examination under oath.

146 (g) Any pharmaceutical manufacturer that is aggrieved by any order,
147 decision, determination or disallowance of the commissioner made
148 under subsection (f) of this section may, not later than thirty days after
149 service of notice of such order, decision, determination or disallowance,
150 take an appeal therefrom to the superior court for the judicial district of
151 New Britain, which appeal shall be accompanied by a citation to the
152 commissioner to appear before said court. Such citation shall be signed
153 by the same authority and such appeal shall be returnable at the same
154 time and served and returned in the same manner as is required in case
155 of a summons in a civil action. The authority issuing the citation shall
156 take from the appellant a bond or recognizance to this state, with surety,
157 to prosecute the appeal to effect and to comply with the orders and
158 decrees of the court in the premises. Such appeals shall be preferred
159 cases, to be heard, unless cause appears to the contrary, at the first
160 session, by the court or by a committee appointed by the court. Said
161 court may grant such relief as may be equitable and, if the civil penalty
162 was paid prior to the granting of such relief, may order the Treasurer to
163 pay the amount of such relief. If the appeal was taken without probable
164 cause, the court may tax double or triple costs, as the case demands and,
165 upon all such appeals that are denied, costs may be taxed against such
166 pharmaceutical manufacturer at the discretion of the court but no costs
167 shall be taxed against this state.

168 (h) The commissioner, and any agent of the commissioner duly
169 authorized to conduct any inquiry, investigation or hearing pursuant to
170 this section, shall have power to administer oaths and take testimony
171 under oath relative to the matter of inquiry or investigation. At any
172 hearing ordered by the commissioner, the commissioner, or the
173 commissioner's agent authorized to conduct such hearing and having
174 authority by law to issue such process, may subpoena witnesses and

175 require the production of books, papers and documents pertinent to
176 such inquiry or investigation. No witness under any subpoena
177 authorized to be issued under the provisions of this section shall be
178 excused from testifying or from producing books, papers or
179 documentary evidence on the ground that such testimony or the
180 production of such books, papers or documentary evidence would tend
181 to incriminate such witness, but such books, papers or documentary
182 evidence so produced shall not be used in any criminal proceeding
183 against such witness. If any person disobeys such process or, having
184 appeared in obedience thereto, refuses to answer any pertinent question
185 put to such person by the commissioner, or the commissioner's
186 authorized agent, or to produce any books, papers or other
187 documentary evidence pursuant thereto, the commissioner, or such
188 agent, may apply to the superior court of the judicial district wherein
189 the pharmaceutical manufacturer resides or wherein the business was
190 conducted, or to any judge of such court if the same is not in session,
191 setting forth such disobedience to process or refusal to answer, and such
192 court or such judge shall cite such person to appear before such court or
193 such judge to answer such question or to produce such books, papers or
194 other documentary evidence and, upon such person's refusal so to do,
195 shall commit such person to a community correctional center until such
196 person testifies, but not for a period longer than sixty days.
197 Notwithstanding the serving of the term of such commitment by any
198 person, the commissioner may proceed in all respects with such inquiry
199 and examination as if the witness had not previously been called upon
200 to testify. Officers who serve subpoenas issued by the commissioner or
201 under the commissioner's authority and witnesses attending hearings
202 conducted by the commissioner pursuant to this section shall receive
203 fees and compensation at the same rates as officers and witnesses in the
204 courts of this state, to be paid on vouchers of the commissioner on order
205 of the Comptroller from the proper appropriation for the administration
206 of this section.

207 (i) The amount of any civil penalty unpaid under the provisions of
208 this section may be collected under the provisions of section 12-35 of the

209 general statutes. The warrant provided under section 12-35 of the
210 general statutes shall be signed by the commissioner or the
211 commissioner's authorized agent. The amount of any such civil penalty
212 shall be a lien on the real property of the pharmaceutical manufacturer
213 from the last day of the month next preceding the due date of such civil
214 penalty until such civil penalty is paid. The commissioner may record
215 such lien in the records of any town in which the real property of such
216 pharmaceutical manufacturer is situated, but no such lien shall be
217 enforceable against a bona fide purchaser or qualified encumbrancer of
218 such real property. When any civil penalty with respect to which a lien
219 was recorded under the provisions of this subsection is satisfied, the
220 commissioner shall, upon request of any interested party, issue a
221 certificate discharging such lien, which certificate shall be recorded in
222 the same office in which such lien was recorded. Any action for the
223 foreclosure of such lien shall be brought by the Attorney General in the
224 name of this state in the superior court for the judicial district in which
225 the real property subject to such lien is situated, or, if such property is
226 located in two or more judicial districts, in the superior court for any one
227 such judicial district, and the court may limit the time for redemption or
228 order the sale of such real property or make such other or further decree
229 as it judges equitable. The provisions of section 12-39g of the general
230 statutes shall apply to all civil penalties imposed under this section.

231 (j) (1) Any officer or employee of a pharmaceutical manufacturer who
232 owes a duty to the pharmaceutical manufacturer to pay a civil penalty
233 imposed under this section on behalf of such pharmaceutical
234 manufacturer, file a statement with the commissioner pursuant to
235 subsection (c) of this section on behalf of such pharmaceutical
236 manufacturer, keep records or supply information to the commissioner
237 on behalf of such pharmaceutical manufacturer pursuant to this section
238 and wilfully fails, at the time required under this section, to pay such
239 civil penalty, file such statement, keep such records or supply such
240 information on behalf of such pharmaceutical manufacturer shall, in
241 addition to any other penalty provided by law, be fined not more than
242 one thousand dollars or imprisoned not more than one year, or both.

243 Notwithstanding the provisions of section 54-193 of the general statutes,
244 no such officer or employee shall be prosecuted for a violation of the
245 provisions of this subdivision committed on or after July 1, 2022, except
246 within three years next after such violation is committed.

247 (2) Any officer or employee of a pharmaceutical manufacturer who
248 owes a duty to the pharmaceutical manufacturer to deliver or disclose
249 to the commissioner, or the commissioner's authorized agent, any list,
250 statement, return, account statement or other document on behalf of
251 such pharmaceutical manufacturer and wilfully delivers or discloses to
252 the commissioner, or the commissioner's authorized agent, any such list,
253 statement, return, account statement or other document that such officer
254 or employee knows to be fraudulent or false in any material matter shall,
255 in addition to any other penalty provided by law, be guilty of a class D
256 felony.

257 (3) No officer or employee of a pharmaceutical manufacturer shall be
258 charged with an offense under subdivisions (1) and (2) of this subsection
259 in relation to the same civil penalty, but such officer or employee may
260 be charged and prosecuted for both such offenses upon the same
261 information.

262 (k) The proceeds from all civil penalties imposed under this section
263 shall be deposited in the Covered Connecticut account. Each civil
264 penalty imposed under this section shall be deemed to constitute a civil
265 fine or penalty within the meaning of 42 USC 1396b(w), as amended
266 from time to time. No portion of any civil penalty imposed under this
267 section shall be waived under section 12-3a of the general statutes or any
268 other applicable law. No tax credit shall be allowable against any civil
269 penalty imposed under this section.

270 (l) Not later than July 1, 2024, and annually thereafter, the
271 commissioner shall prepare a list containing the name of each
272 pharmaceutical manufacturer that violated subsection (a) of this section
273 during the preceding calendar year. The commissioner shall make each
274 such list publicly available.

275 (m) The commissioner may adopt regulations, in accordance with the
276 provisions of chapter 54 of the general statutes, to implement the
277 provisions of this section.

278 Sec. 4. (NEW) (*Effective July 1, 2022*) (a) No pharmaceutical
279 manufacturer of an identified prescription drug shall withdraw the
280 identified prescription drug from sale in this state for the purpose of
281 avoiding the civil penalty established in subsection (b) of section 3 of
282 this act.

283 (b) Any pharmaceutical manufacturer that intends to withdraw an
284 identified prescription drug from sale in this state shall, at least one
285 hundred eighty days before such withdrawal, send advance written
286 notice to the Office of Health Strategy disclosing such pharmaceutical
287 manufacturer's intention.

288 (c) Any pharmaceutical manufacturer that violates the provisions of
289 subsection (a) or (b) of this section shall be liable to this state for a civil
290 penalty in the amount of five hundred thousand dollars.

291 Sec. 5. (NEW) (*Effective July 1, 2022*) For the purposes of this section
292 and sections 6 to 10, inclusive, of this act unless the context otherwise
293 requires:

294 (1) "Drug" means an article that is (A) recognized in the official United
295 States Pharmacopoeia, official Homeopathic Pharmacopoeia of the
296 United States or official National Formulary, or any supplement thereto,
297 (B) intended for use in the diagnosis, cure, mitigation, treatment or
298 prevention of disease in humans, (C) not food and intended to affect the
299 structure or any function of the human body, and (D) not a device and
300 intended for use as a component of any other article specified in
301 subparagraphs (A) to (C), inclusive, of this subdivision;

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

304 (3) "Food, Drug and Cosmetic Act" means the Federal Food, Drug and

305 Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and
306 Security Act, as both may be amended from time to time;

307 (4) "Importation program" means the Canadian legend drug
308 importation program established by the Commissioner of Consumer
309 Protection pursuant to section 6 of this act;

310 (5) "Institutional pharmacy" has the same meaning as provided in
311 section 20-571 of the general statutes;

312 (6) "Laboratory testing" means a quantitative and qualitative analysis
313 of a prescription drug consistent with the official United States
314 Pharmacopoeia;

315 (7) "Legend drug" means a drug that (A) any applicable federal or
316 state law provides shall only be (i) dispensed pursuant to a prescription,
317 or (ii) used by a prescribing practitioner, or (B) applicable federal law
318 requires to bear the following legend: "RX ONLY" IN ACCORDANCE
319 WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG
320 AND COSMETIC ACT;

321 (8) "Participating Canadian supplier" means a manufacturer or
322 wholesale drug distributor that (A) is licensed or permitted under
323 applicable Canadian law to manufacture or distribute prescription
324 drugs, (B) exports legend drugs, in the manufacturer's original
325 container, to a participating wholesaler for distribution in this state
326 under the importation program, and (C) is properly registered, if such
327 Canadian supplier is required to be registered, with the United States
328 Food and Drug Administration, or any successor agency;

329 (9) "Participating wholesaler" means a qualified wholesaler that is
330 designated by the Commissioner of Consumer Protection to participate
331 in the importation program;

332 (10) "Pharmacy" has the same meaning as provided in section 20-571
333 of the general statutes;

334 (11) "Prescription" means a lawful oral, written or electronic order by
335 a prescribing practitioner for a drug for a specific patient;

336 (12) "Qualified laboratory" means a laboratory that is (A) adequately
337 equipped and staffed to properly perform qualitative and quantitative
338 laboratory testing on legend drugs, and (B) accredited to International
339 Organization for Standardization (ISO) 17025;

340 (13) "Qualified wholesaler" means a wholesaler, as defined in section
341 21a-70 of the general statutes, that has received a certificate of
342 registration from the Commissioner of Consumer Protection pursuant
343 to said section; and

344 (14) "Track-and-trace" means the product tracing process for the
345 components of the pharmaceutical distribution supply chain, as
346 described in Title II of the Drug Quality and Security Act.

347 Sec. 6. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of
348 Consumer Protection shall establish a program to be known as the
349 "Canadian legend drug importation program". Under such importation
350 program, the commissioner shall, notwithstanding any provision of the
351 general statutes:

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

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

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

361 (b) (1) Not later than July 1, 2023, the Commissioner of Consumer
362 Protection shall submit a request to the federal Secretary of Health and

363 Human Services seeking approval for the importation program under
364 21 USC 384, as amended from time to time. Such request shall, at a
365 minimum:

366 (A) Describe the commissioner's plans for operating the importation
367 program;

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

370 (i) Meet all applicable federal and state standards for safety and
371 effectiveness; and

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

373 (C) Disclose the costs of implementing the importation program.

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

376 (i) Submit to (I) the Commissioner of Public Health a notice disclosing
377 that the federal Secretary of Health and Human Services has approved
378 such request, and (II) the joint standing committees of the General
379 Assembly having cognizance of matters relating to appropriations,
380 general law, human services and public health a notice disclosing that
381 the federal Secretary of Health and Human Services has approved such
382 request; and

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

385 (B) Except as otherwise provided in this subsection, the
386 Commissioner of Consumer Protection shall not operate the
387 importation program unless the federal Secretary of Health and Human
388 Services approves the commissioner's request.

389 Sec. 7. (NEW) (*Effective July 1, 2022*) (a) Each participating wholesaler
390 may, subject to the provisions of this section and sections 6 and 9 of this

391 act, import into this state a legend drug from a participating Canadian
392 supplier, and distribute such legend drug to a licensed pharmacy or
393 institutional pharmacy, or a qualified laboratory in this state, under the
394 importation program if:

395 (1) Such participating wholesaler:

396 (A) Is registered with the federal Secretary of Health and Human
397 Services pursuant to Section 510(b) of the Food, Drug and Cosmetic Act,
398 21 USC 360(b), as amended from time to time; and

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

402 (2) Such legend drug:

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

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

408 (C) Is not:

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

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

413 (iii) An infused drug;

414 (iv) An intravenously, intradermally, intrathecally, intramuscularly
415 or subcutaneously injected drug;

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

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

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

421 (b) Each participating wholesaler shall:

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

426 (2) Not import into, or distribute, dispense or sell, in this state any
427 legend drugs under the importation program except in accordance with
428 the provisions of this section and sections 6 and 9 of this act;

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

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

433 (5) For each initial shipment of any legend drug that is imported into
434 this state by such participating wholesaler, ensure that a qualified
435 laboratory engaged by such participating wholesaler tests a statistically
436 valid sample size for each batch of such legend drug in such shipment
437 for authenticity and degradation in a manner that is consistent with the
438 Food, Drug and Cosmetic Act;

439 (6) For each subsequent shipment of a legend drug that is imported
440 into this state by such participating wholesaler, and sampled and tested
441 pursuant to subdivision (5) of this subsection, ensure that a qualified
442 laboratory engaged by such participating wholesaler tests a statistically
443 valid sample of such legend drug in such shipment for authenticity and
444 degradation in a manner that is consistent with the Food, Drug and
445 Cosmetic Act, and quarantine such shipment until the results of such

446 test conducted pursuant to this subdivision indicate that such legend
447 drug is consistent with its labeling;

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

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

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

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

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

463 (10) Maintain the following information for each legend drug that
464 such participating wholesaler imports and distributes in this state under
465 the importation program, and submit such information to the
466 Commissioner of Consumer Protection upon request by the
467 commissioner:

468 (A) The name and quantity of the active ingredient of such legend
469 drug;

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

471 (C) The date on which such participating wholesaler received such
472 legend drug;

473 (D) The quantity of such legend drug that such participating

474 wholesaler received;

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

476 (F) The price paid by such participating wholesaler for such legend
477 drug;

478 (G) A report for each legend drug that fails laboratory testing under
479 subdivision (5) or (6) of this subsection; and

480 (H) Such additional information and documentation that the
481 commissioner deems necessary to ensure the protection of the public
482 health;

483 (11) Ensure that any legend drug that fails laboratory testing under
484 subdivision (5) or (6) of this subsection is appropriately quarantined and
485 destroyed; and

486 (12) Maintain all information and documentation that is submitted to
487 the Commissioner of Consumer Protection pursuant to this subsection
488 for a period of not less than three years.

489 Sec. 8. (NEW) (*Effective July 1, 2022*) Each participating Canadian
490 supplier shall:

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

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

495 (3) Maintain the following information and documentation and,
496 upon request by the Commissioner of Consumer Protection, submit
497 such information and documentation to the commissioner for each
498 legend drug that such participating Canadian supplier exports into this
499 state under the importation program:

500 (A) The original source of such legend drug, including, but not

501 limited to:

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

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

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

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

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

509 (D) The quantity of each lot of such legend drug that such
510 participating Canadian supplier originally received and the source of
511 such lot;

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

514 (F) Such additional information and documentation that the
515 commissioner deems necessary to ensure the protection of the public
516 health.

517 Sec. 9. (NEW) (*Effective July 1, 2022*) (a) The Commissioner of
518 Consumer Protection shall issue a written order:

519 (1) Suspending importation and distribution of a legend drug under
520 the importation program if the commissioner discovers that such
521 importation or distribution violates any provision of sections 6 to 8,
522 inclusive, of this act or any other applicable state or federal law or
523 regulation;

524 (2) Suspending all importation and distribution of legend drugs by a
525 participating wholesaler under the importation program if the
526 commissioner discovers that the participating wholesaler has violated
527 any provision of section 6 or 7 of this act or any other applicable state or

528 federal law or regulation;

529 (3) Suspending all importation and distribution of legend drugs by a
530 participating Canadian supplier under the importation program if the
531 commissioner discovers that the participating Canadian supplier has
532 violated any provision of section 6 or 8 of this act or any other applicable
533 state or federal law or regulation;

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

538 (5) Requiring retesting, at the expense of the participating wholesaler
539 and by a laboratory approved by the commissioner, of any legend drug
540 distributed by the participating wholesaler if the commissioner deems
541 such retesting necessary.

542 (b) The Commissioner of Consumer Protection shall send a notice to
543 each participating Canadian supplier and participating wholesaler
544 affected by an order issued pursuant to subsection (a) of this section
545 notifying such participating Canadian supplier or participating
546 wholesaler that:

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

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

553 (c) If a participating Canadian supplier or participating wholesaler
554 timely requests a hearing pursuant to subsection (b) of this section, the
555 Commissioner of Consumer Protection shall, not later than thirty days
556 after the receipt of the request, convene the hearing as a contested case
557 in accordance with the provisions of chapter 54 of the general statutes.

558 Not later than sixty days after the receipt of such request, the
559 commissioner shall issue a final decision vacating, modifying or
560 affirming the commissioner's order. If the participating Canadian
561 supplier or participating wholesaler is aggrieved by such final decision,
562 such participating Canadian supplier or participating wholesaler may
563 appeal such decision in accordance with the provisions of section 4-183
564 of the general statutes.

565 Sec. 10. (NEW) (*Effective July 1, 2022*) The Commissioner of Consumer
566 Protection may, in consultation with the Commissioner of Public
567 Health, adopt regulations in accordance with the provisions of chapter
568 54 of the general statutes to implement the provisions of sections 5 to 9,
569 inclusive, of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>July 1, 2022</i>	New section
Sec. 2	<i>July 1, 2022</i>	New section
Sec. 3	<i>July 1, 2022</i>	New section
Sec. 4	<i>July 1, 2022</i>	New section
Sec. 5	<i>July 1, 2022</i>	New section
Sec. 6	<i>July 1, 2022</i>	New section
Sec. 7	<i>July 1, 2022</i>	New section
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

INS *Joint Favorable Subst.*