



General Assembly

Amendment

January Session, 2019

LCO No. 10219



Offered by:

REP. SCANLON, 98th Dist.

SEN. LESSER, 9th Dist.

To: Subst. House Bill No. 7267

File No. 353

Cal. No. 231

**"AN ACT CONCERNING PUBLIC OPTIONS FOR HEALTH CARE
IN CONNECTICUT."**

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

3 "Section 1. Section 19a-754a of the general statutes is repealed and
4 the following is substituted in lieu thereof (*Effective July 1, 2019*):

5 (a) There is established an Office of Health Strategy, which shall be
6 within the Department of Public Health for administrative purposes
7 only. The department head of said office shall be the executive director
8 of the Office of Health Strategy, who shall be appointed by the
9 Governor in accordance with the provisions of sections 4-5 to 4-8,
10 inclusive, with the powers and duties therein prescribed.

11 (b) The Office of Health Strategy shall be responsible for the
12 following:

13 (1) Developing and implementing a comprehensive and cohesive

14 health care vision for the state, including, but not limited to, a
15 coordinated state health care cost containment strategy;

16 (2) Promoting effective health planning and the provision of quality
17 health care in the state in a manner that ensures access for all state
18 residents to cost-effective health care services, avoids the duplication
19 of such services and improves the availability and financial stability of
20 such services throughout the state;

21 (3) (A) Directing and overseeing innovative health care delivery and
22 payment models in the state that reduce health care cost growth and
23 improve the quality of patient care, including, but not limited to, the
24 State Innovation Model Initiative and related successor initiatives, (B)
25 setting a health care cost growth benchmark, as defined in section 2 of
26 this act, for the state across all payers and populations, (C) enhancing
27 the transparency of health care entities in the state, (D) monitoring the
28 development of accountable care organizations and patient-centered
29 medical homes in the state, and (E) monitoring the adoption of
30 alternative payment methodologies in the state;

31 (4) (A) Coordinating the state's health information technology
32 initiatives, (B) seeking funding for and overseeing the planning,
33 implementation and development of policies and procedures for the
34 administration of the all-payer claims database program established
35 under section 19a-775a, (C) establishing and maintaining a consumer
36 health information Internet web site under 19a-755b, and (D)
37 designating an unclassified individual from the office to perform the
38 duties of a health information technology officer as set forth in sections
39 17b-59f and 17b-59g;

40 (5) Directing and overseeing the Health Systems Planning Unit
41 established under section 19a-612 and all of its duties and
42 responsibilities as set forth in chapter 368z; and

43 (6) Convening forums and meetings with state government and
44 external stakeholders, including, but not limited to, the Connecticut
45 Health Insurance Exchange, to discuss health care issues designed to

46 develop effective health care cost and quality strategies.

47 (c) The Office of Health Strategy shall constitute a successor, in
48 accordance with the provisions of sections 4-38d, 4-38e and 4-39, to the
49 functions, powers and duties of the following:

50 (1) The Connecticut Health Insurance Exchange, established
51 pursuant to section 38a-1081, relating to the administration of the all-
52 payer claims database pursuant to section 19a-755a; and

53 (2) The Office of the Lieutenant Governor, relating to the (A)
54 development of a chronic disease plan pursuant to section 19a-6q, (B)
55 housing, chairing and staffing of the Health Care Cabinet pursuant to
56 section 19a-725, and (C) (i) appointment of the health information
57 technology officer, and (ii) oversight of the duties of such health
58 information technology officer as set forth in sections 17b-59f and 17b-
59 59g.

60 (d) Any order or regulation of the entities listed in subdivisions (1)
61 and (2) of subsection (c) of this section that is in force on July 1, 2018,
62 shall continue in force and effect as an order or regulation until
63 amended, repealed or superseded pursuant to law.

64 Sec. 2. (NEW) (*Effective July 1, 2019*) For the purposes of this section
65 and sections 3 to 9, inclusive, of this act:

66 (1) "Device manufacturer" means a manufacturer that manufactures
67 a device for which annual sales attributable to residents of this state
68 exceed ten million dollars;

69 (2) "Drug manufacturer" means the manufacturer of a drug that is:
70 (A) Reported by a health carrier pursuant to section 38a-479qqq of the
71 general statutes; (B) studied or listed pursuant to subsection (c) or (d)
72 of section 19a-754b of the general statutes; or (C) in a therapeutic class
73 of drugs that the office determines, through public or private reports,
74 has had a substantial impact on prescription drug expenditures, net of
75 rebates, as a percentage of total health care expenditures;

- 76 (3) "Executive director" means the executive director of the office;
- 77 (4) "Health care cost growth benchmark" means the annual
78 benchmark established pursuant to section 3 of this act;
- 79 (5) "Health care entity" means an accountable care organization,
80 ambulatory surgical center, clinic, hospital or physician organization in
81 this state, other than a physician contracting unit that, for a given
82 calendar year: (A) Has a patient panel of not more than ten thousand
83 patients; or (B) represents providers who collectively receive less than
84 twenty million dollars in net patient service revenue from health
85 carriers;
- 86 (6) "Health status adjusted total medical expenses" means: (A) The
87 total cost of care for the patient population of a group of health care
88 providers with at least thirty-six thousand member months for a given
89 calendar year, which cost (i) is calculated for such year on the basis of
90 the allowed claims for all categories of medical expenses and all
91 nonclaims payments for such year, including, but not limited to, cost-
92 sharing payments, adjusted by health status and expressed on a per
93 member, per month basis for all members in this state who are
94 required to select a primary care physician for such year, (ii) is
95 reported separately for Medicaid, Medicare and nongovernment
96 health plans for such year, and (iii) discloses the health adjustment risk
97 score and the version of the risk adjustment tool used to calculate such
98 score for such group for such year; and (B) the total aggregate medical
99 expenses for all physicians and physician groups with fewer than
100 thirty-six thousand member months for a given calendar year;
- 101 (7) "Office" means the Office of Health Strategy established under
102 section 19a-754a of the general statutes, as amended by this act;
- 103 (8) "Other entity" means a device manufacturer, drug manufacturer
104 or pharmacy benefits manager;
- 105 (9) "Payer" means a payer that, during a given calendar year, pays
106 providers for health care services on behalf of, or pharmacies for

107 prescription drugs dispensed to, more than ten thousand individuals
108 in this state;

109 (10) "Pharmacy benefits manager" has the same meaning as
110 provided in section 38a-479o of the general statutes;

111 (11) "Total health care expenditures" means the per capita sum of all
112 health care expenditures in this state from public and private sources
113 for a given calendar year, including: (A) All categories of medical
114 expenses and all nonclaims-related payments to health care providers,
115 as included in the health status adjusted total medical expenses
116 reported by the office pursuant to subsection (c) of section 5 of this act;
117 (B) all patient cost-sharing amounts, including, but not limited to,
118 deductibles and copayments; (C) the net cost of nongovernment health
119 insurance; (D) prescription drug expenditures net of rebates and
120 discounts; (E) device manufacturer expenditures net of rebates and
121 discounts; and (F) any other expenditures specified by the executive
122 director;

123 (12) "Total medical expenses" means the sum, for a given calendar
124 year, of medical claims and total nonclaims payments for: (A) Each
125 physician and physician group with at least thirty-six thousand
126 member months, and serving members in this state required to select a
127 primary care physician, for such year; and (B) medical claims and total
128 nonclaims payments for all physicians or physician groups with fewer
129 than thirty-six thousand member months for such year; and

130 (13) "Total nonclaims payments" means the sum of all nonclaims
131 payments for a given calendar year, aggregated for the following
132 categories: (A) Incentive programs; (B) risk settlements; (C) care
133 management expenses; and (D) other.

134 Sec. 3. (NEW) (*Effective July 1, 2019*) (a) Not later than October 1,
135 2020, and annually thereafter, the office shall establish a health care
136 cost growth benchmark for the calendar year next succeeding. Such
137 benchmark shall address the average growth in health care
138 expenditures across all payers and populations in this state for such

139 year.

140 (b) In establishing each health care cost growth benchmark pursuant
141 to subsection (a) of this section, the office shall, at a minimum:

142 (1) Consider any change in the consumer price index for all urban
143 consumers in the northeast region from the preceding calendar year,
144 and the most recent publicly available information concerning the
145 growth rate of the gross state product; and

146 (2) (A) Hold an informational public hearing concerning such
147 benchmark:

148 (i) At a time and place designated by the executive director in a
149 notice prominently posted on the office's Internet web site;

150 (ii) In a form and manner prescribed by the executive director; and

151 (iii) On the basis of the most recent report prepared by the office
152 pursuant to subsection (c) of section 5 of this act and any other
153 information that the executive director, in the executive director's
154 discretion, deems relevant for the purposes of such hearing.

155 (B) Notwithstanding subparagraph (A) of this subdivision, the office
156 shall not be required to hold an informational public hearing
157 concerning a health care cost growth benchmark for any calendar year
158 beginning on or after January 1, 2022, if such benchmark is the same as
159 the benchmark for the preceding calendar year.

160 (c) If the executive director determines, after any public hearing
161 held pursuant to subdivision (2) of subsection (b) of this section, that a
162 modification to the health care cost growth benchmark is, in such
163 executive director's discretion, reasonably warranted, the office may
164 modify such benchmark.

165 (d) The executive director shall cause each health care cost growth
166 benchmark to be posted on the office's Internet web site.

167 (e) The office may enter into such contractual agreements as may be
168 necessary to carry out the purposes of this section, including, but not
169 limited to, contractual agreements with actuarial, economic and other
170 experts and consultants to assist the office in establishing health care
171 cost growth benchmarks.

172 Sec. 4. (NEW) (*Effective July 1, 2019*) (a) (1) Not later than May 1,
173 2022, and annually thereafter, the office shall hold a public hearing to
174 compare the growth in total health care expenditures during the
175 preceding calendar year to the health care cost growth benchmark
176 established pursuant to section 3 of this act for such year. Each hearing
177 shall involve an examination of:

178 (A) The report most recently prepared by the office pursuant to
179 subsection (c) of section 5 of this act;

180 (B) The expenditures of health care entities, including, but not
181 limited to, health care cost trends and the factors contributing to such
182 costs;

183 (C) Whether one category of expenditures may be offset by savings
184 in another category; and

185 (D) Any other matters that the executive director, in the executive
186 director's discretion, deems relevant for the purposes of this section.

187 (2) The executive director may require that any health care entity
188 that is found to be a significant contributor to health care cost growth
189 in this state during the preceding calendar year participate in the
190 public hearing. Each such health care entity that is required to
191 participate in such public hearing shall provide testimony on issues
192 identified by the executive director, and provide additional
193 information on actions taken to reduce such health care entity's
194 contribution to future state-wide health care costs.

195 (b) Not later than October 1, 2022, and annually thereafter, the office
196 shall prepare and submit a report, in accordance with section 11-4a of

197 the general statutes, to the joint standing committees of the General
198 Assembly having cognizance of matters relating to insurance and
199 public health. Such report shall:

200 (1) Be based on the office's analysis of the information submitted
201 during the most recent public hearing conducted pursuant to
202 subsection (a) of this section and any other information that the
203 executive director, in the executive director's discretion, deems
204 relevant for the purposes of this section;

205 (2) Describe health care spending trends in this state and the factors
206 underlying such trends; and

207 (3) Disclose the office's recommendations, if any, concerning
208 strategies to increase the efficiency of this state's health care system,
209 including, but not limited to, any recommended legislation concerning
210 this state's health care system.

211 Sec. 5. (NEW) (*Effective July 1, 2019*) (a) Not later than March 1, 2021,
212 and annually thereafter, each institutional provider, on behalf of such
213 institutional provider and its parent organization and affiliated
214 entities, noninstitutional provider and provider organization in this
215 state shall submit to the office, for the preceding calendar year:

216 (1) Data concerning:

217 (A) The utilization of health care services provided by such provider
218 or organization;

219 (B) The charges, prices imposed and payments received by such
220 provider or organization for such services;

221 (C) The costs incurred, and revenues earned, by such provider or
222 organization in providing such services; and

223 (D) Any other matter that the executive director deems relevant for
224 the purposes of this section; and

225 (2) If such provider is a hospital, the data described in subdivision
226 (1) of this subsection and such additional data, information and
227 documents designated by the executive director, including, but not
228 limited to, charge masters, cost data, audited financial statements and
229 merged billing and discharge data, provided such provider shall not
230 be required to submit any data contained in a report that is filed
231 pursuant to chapters 368aa to 368ll, inclusive, of the general statutes
232 and available to the executive director.

233 (b) The executive director shall establish standards to ensure that
234 the data, information and documents submitted to the office pursuant
235 to subsection (a) of this section are submitted to the office in a uniform
236 manner. Such standards shall enable the executive director to identify,
237 on a patient-centered and provider-specific basis, state-wide and
238 regional trends in the availability, cost, price and utilization of medical,
239 surgical, diagnostic and ancillary services provided by acute care
240 hospitals, chronic disease hospitals, rehabilitation hospitals and other
241 specialty hospitals, clinics, including, but not limited to, psychiatric
242 clinics, and facilities providing ambulatory care. Such standards may
243 require hospitals to submit such data, information and documents to
244 the office in an electronic form, provided such standards shall provide
245 for a waiver of such requirement if such waiver is reasonable in the
246 judgment of the executive director.

247 (c) (1) Not later than December 1, 2021, and annually thereafter, the
248 office shall prepare, and the executive director shall cause to be posted
249 on the office's Internet web site, a report concerning health status
250 adjusted total medical expenses for the preceding calendar year,
251 including, but not limited to, a breakdown of such health status
252 adjusted total medical expenses by:

253 (A) Major service category;

254 (B) Payment methodology;

255 (C) Relative price;

- 256 (D) Direct hospital inpatient cost;
- 257 (E) Indirect hospital inpatient cost;
- 258 (F) Direct hospital outpatient cost; and
- 259 (G) Indirect hospital outpatient cost.

260 (2) Notwithstanding subdivision (1) of this subsection, the office
261 shall not disclose any provider specific data or information unless the
262 executive director provides at least ten days' advance written notice of
263 such disclosure to each provider that would be affected by such
264 disclosure.

265 (d) The executive director shall, at least annually, submit a request
266 to the federal Centers for Medicare and Medicaid Services for the
267 health status adjusted total medical expenses of provider groups that
268 served Medicare patients during the calendar year next preceding.

269 (e) The office may enter into such contractual agreements as may be
270 necessary to carry out the purposes of this section, including, but not
271 limited to, contractual agreements with actuarial, economic and other
272 experts and consultants.

273 Sec. 6. (NEW) (*Effective July 1, 2019*) (a) (1) For each calendar year
274 beginning on or after January 1, 2022, if the executive director
275 determines that the average annual percentage change in total health
276 care expenditures for the preceding calendar year exceeded the health
277 care cost growth benchmark for such year, the executive director shall
278 identify, not later than April first of such calendar year, each health
279 care entity or payer that exceeded such benchmark for such year.

280 (2) The executive director may require that any health care entity
281 that is found to be a significant contributor to health care cost growth
282 in this state during the preceding calendar year participate in the
283 public hearing held pursuant to subsection (a) of section 4 of this act.
284 Each such health care entity that is required to participate in such
285 public hearing shall provide testimony on issues identified by the

286 executive director, and provide additional information on actions
287 taken to reduce such health care entity's contribution to future state-
288 wide health care costs.

289 (b) Not later than thirty days after the executive director identifies
290 each health care entity or payer pursuant to subsection (a) of this
291 section, the executive director shall send a notice to each such entity or
292 payer. Such notice shall be in a form and manner prescribed by the
293 executive director, and disclose to each such entity or payer, at a
294 minimum:

295 (1) That the executive director has identified such entity or payer
296 pursuant to subsection (a) of this section;

297 (2) The factual basis for the executive director's identification of
298 such entity or payer pursuant to subsection (a) of this section; and

299 (3) That such entity or payer shall file a proposed performance
300 improvement plan pursuant to subdivision (1) of subsection (e) of this
301 section, provided such entity or payer may:

302 (A) File a request for an extension of time, or a waiver, pursuant to
303 subdivision (1) of subsection (c) of this section; and

304 (B) Request a hearing pursuant to subsection (d) of this section.

305 (c) (1) (A) Each health care entity or payer identified by the
306 executive director pursuant to subsection (a) of this section may, not
307 later than thirty days after the executive director sends a notice to such
308 entity or payer pursuant to subsection (b) of this section, file with the
309 office, in a form and manner prescribed by the executive director, a
310 request seeking:

311 (i) An extension of time to file a proposed performance
312 improvement plan pursuant to subdivision (1) of subsection (e) of this
313 section; or

314 (ii) A waiver from the requirement that such entity or payer file a

315 proposed performance improvement plan pursuant to subdivision (1)
316 of subsection (e) of this section.

317 (B) Each health care entity or payer that files a request pursuant to
318 subparagraph (A) of this subdivision shall set forth the reasons for
319 such request in such request.

320 (2) Not later than thirty days after a health care entity, payer or
321 other entity files a request pursuant to subdivision (1) of this
322 subsection, the executive director shall:

323 (A) Examine the reasons set forth in the request and decide, on the
324 basis of such reasons, whether to approve or deny such request; and

325 (B) Send a notice, in a form and manner prescribed by the executive
326 director, to the entity or payer that filed such request disclosing, at a
327 minimum:

328 (i) The executive director's decision concerning such request and the
329 reasons therefor;

330 (ii) If the executive director denies such entity's or payer's request,
331 that such entity or payer may file a request for a hearing pursuant to
332 subsection (d) of this section; and

333 (iii) If such entity's or payer's request is a request for an extension of
334 time to file a proposed performance improvement plan pursuant to
335 subdivision (1) of subsection (e) of this section and the executive
336 director approves such request, the date by which such entity or payer
337 shall file such proposed plan.

338 (d) Each health care entity or payer identified by the executive
339 director pursuant to subsection (a) of this section may, not later than
340 thirty days after the executive director sends a notice to such entity or
341 payer pursuant to subsection (b) of this section or subparagraph (B) of
342 subdivision (2) of subsection (c) of this section, as applicable, file with
343 the office a request for a hearing. Each hearing conducted pursuant to
344 this subsection shall be conducted in accordance with the procedures

345 for hearings on contested cases established in chapter 54 of the general
346 statutes.

347 (e) (1) Each health care entity or payer identified by the executive
348 director pursuant to subsection (a) of this section, or required by the
349 executive director pursuant to subparagraph (C)(ii)(III) of subdivision
350 (4) of subsection (f) of this section, shall, subject to the provisions of
351 subsections (b) to (d), inclusive, of this section, file with the office a
352 proposed performance improvement plan. Such entity or payer shall
353 file such proposed plan, which shall include an implementation
354 timetable, with the office, in a form and manner prescribed by the
355 executive director, not later than whichever of the following dates first
356 occurs:

357 (A) The date that is thirty days after the date on which the executive
358 director sent a notice to such entity or payer pursuant to subsection (b)
359 of this section;

360 (B) The date that the executive director disclosed to such entity or
361 payer pursuant to subparagraph (B)(iii) of subdivision (2) of subsection
362 (c) of this section; or

363 (C) The date that is thirty days after the date on which the notice of
364 a final decision is issued following a public hearing conducted
365 pursuant to subsection (d) of this section.

366 (2) (A) The executive director shall review each health care entity's
367 and payer's proposed performance improvement plan filed pursuant
368 to subdivision (1) of this subsection to determine whether, in the
369 executive director's judgment, it is reasonably likely that:

370 (i) Such proposed plan will address the cause of such entity's or
371 payer's excessive cost growth; and

372 (ii) Such entity or payer will successfully implement such proposed
373 plan.

374 (B) After the executive director reviews a proposed performance

375 improvement plan pursuant to subparagraph (A) of this subdivision,
376 the executive director shall:

377 (i) Approve such proposed plan if the executive director determines,
378 in the executive director's judgment, that such proposed plan satisfies
379 the criteria established in subparagraph (A) of this subdivision; or

380 (ii) Deny such proposed plan if the executive director determines, in
381 the executive director's judgment, that such proposed plan does not
382 satisfy the criteria established in subparagraph (A) of this subdivision.

383 (C) (i) Not later than thirty days after the executive director
384 approves or denies a proposed performance improvement plan
385 pursuant to subparagraph (B) of this subdivision, the executive
386 director shall send a notice to the health care entity, payer or other
387 entity that filed such proposed plan disclosing, at a minimum, that:

388 (I) The executive director approved such proposed plan; or

389 (II) The executive director denied such proposed plan, the reasons
390 for such denial and that such entity or payer shall file with the office
391 such amendments as are necessary for such proposed plan to satisfy
392 the criteria established in subparagraph (A) of this subdivision.

393 (ii) The executive director shall cause a notice to be posted on the
394 office's Internet web site disclosing:

395 (I) The name of each health care entity or payer that files, and
396 receives approval for, a proposed performance improvement plan; and

397 (II) That such health care entity, payer or other entity is
398 implementing such plan.

399 (D) Each health care entity or payer that receives a notice from the
400 executive director pursuant to subparagraph (C)(i) of this subdivision
401 notifying such entity or payer that the executive director has denied
402 such entity's or payer's proposed performance improvement plan shall
403 file with the office, in a form and manner prescribed by the executive

404 director and not later than thirty days after the date that the executive
405 director sends such notice to such entity or payer, such amendments as
406 are necessary for such proposed plan to satisfy the criteria established
407 in subparagraph (A) of this subdivision.

408 (f) (1) Each health care entity or payer that receives a notice from the
409 executive director pursuant to subparagraph (C)(i) of subdivision (2) of
410 subsection (e) of this section notifying such entity or payer that the
411 executive director has approved such entity's or payer's proposed
412 performance improvement plan:

413 (A) Shall immediately make good faith efforts to implement such
414 plan; and

415 (B) May amend such plan at any time during the implementation
416 timetable included in such plan, provided the executive director
417 approves such amendment.

418 (2) The office shall provide such assistance to each health care entity
419 or payer that the executive director, in the executive director's
420 discretion, deems necessary and appropriate to ensure that such entity
421 or payer successfully implements such entity's or payer's performance
422 improvement plan.

423 (3) Each health care entity or payer shall be subject to such
424 additional reporting requirements that the executive director, in the
425 executive director's discretion, deems necessary to ensure that such
426 entity or payer successfully implements such entity's or payer's
427 performance improvement plan.

428 (4) (A) Each health care entity or payer that files, and receives
429 approval for, a performance improvement plan pursuant to this
430 section shall, not later than thirty days after the last date specified in
431 the implementation timetable included in such plan, submit to the
432 office, in a form and manner prescribed by the executive director, a
433 report regarding the outcome of such entity's or payer's
434 implementation of such plan.

435 (B) If the executive director determines, on the basis of the report
436 submitted by a health care entity or payer pursuant to subparagraph
437 (A) of this subdivision, that such entity or payer successfully
438 implemented such entity's or payer's performance improvement plan,
439 the executive director shall:

440 (i) Send a notice to such entity or payer, in a form and manner
441 prescribed by the executive director, disclosing such determination;
442 and

443 (ii) Cause the notice posted on the office's Internet web site pursuant
444 to subparagraph (C)(ii) of subdivision (2) of subsection (e) of this
445 section concerning such entity or payer to be removed from such
446 Internet web site.

447 (C) If the executive director determines, on the basis of the report
448 submitted by a health care entity or payer pursuant to subparagraph
449 (A) of this subdivision, that such entity or payer failed to successfully
450 implement such entity's or payer's performance improvement plan, the
451 executive director shall:

452 (i) Send a notice to such entity or payer, in a form and manner
453 prescribed by the executive director, disclosing such determination
454 and any action taken by the executive director pursuant to clause (ii) of
455 this subparagraph; and

456 (ii) In the executive director's discretion:

457 (I) Extend the implementation timetable included in such plan;

458 (II) Require such entity or payer to file with the office, in a form and
459 manner prescribed by the executive director, such amendments to such
460 plan as are, in the executive director's judgment, necessary to ensure
461 that such entity or payer successfully implements such plan;

462 (III) Require such entity or payer to file a new proposed
463 performance improvement plan pursuant to subdivision (1) of
464 subsection (e) of this section; or

465 (IV) Waive or delay the requirement that such entity or payer file
466 any future proposed performance improvement plan until the
467 executive director determines, in the executive director's discretion,
468 that such entity or payer has successfully implemented such plan.

469 (g) The office shall keep confidential all nonpublic clinical, financial,
470 operational or strategic documents and information filed with, or
471 submitted to, the office pursuant to this section. The office shall not
472 disclose any such document or information to any person without the
473 consent of the health care entity or payer that filed such document or
474 information with, or submitted such document or information to, the
475 office pursuant to this section, except in summary form as part of an
476 evaluative report if the executive director determines that such
477 disclosure should be made in the public interest after taking into
478 account any privacy, trade secret or anti-competitive considerations.
479 Notwithstanding any provision of the general statutes, no document or
480 information filed with, or submitted to, the office pursuant to this
481 section shall be deemed to be a public record or subject to disclosure
482 under the Freedom of Information Act, as defined in section 1-200 of
483 the general statutes.

484 Sec. 7. (NEW) (*Effective July 1, 2019*) (a) (1) For each calendar year
485 beginning on or after January 1, 2022, if the executive director
486 determines that the average annual percentage change in total health
487 care expenditures for the preceding calendar year exceeded the health
488 care cost growth benchmark for such year, the executive director shall
489 identify each other entity that significantly contributed to exceeding
490 such benchmark. Each identification shall be based on:

491 (A) The report prepared pursuant to subsection (c) of section 5 of
492 this act;

493 (B) The reports filed and submitted pursuant to sections 38a-479ooo
494 and 38a-479ppp of the general statutes;

495 (C) The information and data reported to the office pursuant to
496 section 19a-754b of the general statutes;

497 (D) Information obtained from the all-payer claims database
498 established under section 19a-755a of the general statutes; and

499 (E) Any other information that the executive director, in the
500 executive director's discretion, deems relevant for the purposes of this
501 section.

502 (2) The executive director shall account for costs, net of rebates and
503 discounts, when identifying other entities pursuant to this section.

504 (b) The executive director may require that any other entity that is
505 found to be a significant contributor to health care cost growth in this
506 state during the preceding calendar year participate in the public
507 hearing held pursuant to subsection (a) of section 4 of this act. Each
508 such other entity that is required to participate in such public hearing
509 shall provide testimony on issues identified by the executive director,
510 and provide additional information on actions taken to reduce such
511 health care entity's contribution to future state-wide health care costs.
512 If such other entity is a drug manufacturer, and the executive director
513 requires that such drug manufacturer participate in such public
514 hearing with respect to a specific drug or class of drugs, such public
515 hearing may, to the extent possible, include representatives from at
516 least one brand name manufacturer, one generic manufacturer and one
517 innovator company that is less than ten years old.

518 Sec. 8. (NEW) (*Effective July 1, 2019*) (a) The executive director shall
519 appoint a quality council, and shall ensure that the membership of
520 such council includes individuals with experience providing health
521 care services, and coverage for such services, in this state.

522 (b) The quality council shall have the following duties:

523 (1) (A) To develop, in consultation with national and other state
524 organizations and residents of this state who are stakeholders in all
525 aspects of the health care system that monitor and develop health care
526 quality and safety measures, a proposed standard quality measure set,
527 which, if adopted by the office, would:

528 (i) Enable health care providers, facilities, medical groups and
529 health care provider groups in this state to report to the office a
530 standard set of information concerning health care quality and safety
531 measures; and

532 (ii) Include measures concerning health outcomes.

533 (B) Not later than November 1, 2020, submit the proposed standard
534 quality measure set developed pursuant to subparagraph (A) of this
535 subdivision to the office, and make recommendations to the executive
536 director regarding adoption of such proposed standard quality
537 measure set.

538 (2) (A) To develop, on an ongoing basis, proposed updates to any
539 standard quality measure set adopted by the office. Such updates may
540 include, but need not be limited to:

541 (i) Nationally recognized quality measures that are recommended
542 by medical groups and health care provider groups concerning
543 appropriate quality measures for such groups' specialties; and

544 (ii) Newly developed measures concerning health outcomes, which
545 measures shall meet standards of patient-centeredness and ensure
546 consideration of important differences in preferences and clinical
547 characteristics within patient subpopulations.

548 (B) The quality council shall provide an opportunity for stakeholder
549 engagement and transparency surrounding any measure development
550 and research, whether provided by a state agency or third party, relied
551 upon for decision-making that addresses access to health care
552 treatments and services.

553 (C) Not later than November 1, 2021, and annually thereafter, make
554 recommendations to the executive director regarding adoption of
555 proposed updates to any standard quality measure set adopted by the
556 office.

557 (3) Advise the office on such other matters that the executive

558 director, in the executive director's discretion, may deem appropriate
559 to assist the office in performing its duties.

560 Sec. 9. (NEW) (*Effective July 1, 2019*) The office may adopt
561 regulations, in accordance with chapter 54 of the general statutes, to
562 implement the provisions of sections 2 to 8, inclusive, of this act.

563 Sec. 10. (NEW) (*Effective January 1, 2020, and applicable to sales*
564 *occurring on or after January 1, 2020*) (a) For the purposes of this section:

565 (1) "Covered entity" means any individual, partnership, company,
566 firm, public or private corporation, society or association acting as a
567 prescription drug manufacturer, outsourcing facility or wholesaler;

568 (2) "Distribute" means to deliver a controlled substance, unless such
569 delivery is made to administer or dispense the controlled substance to
570 the ultimate user or is an intra-company transfer by a transferor to a
571 division, affiliate, subsidiary, parent or other entity that is under
572 complete common ownership and control with the transferor;

573 (3) "Opioid drug" has the same meaning as provided in 42 CFR 8.2,
574 as amended from time to time, but does not mean an (A) opioid
575 agonist treatment medication as defined in said section, or (B) opioid
576 drug sold directly to a health care facility, or a pharmacy located at a
577 health care facility, that is intended to be dispensed and administered
578 only by a health care practitioner;

579 (4) "Morphine milligram equivalent" means a unit multiplied by its
580 strength per unit multiplied by the morphine milligram equivalent
581 conversion factor;

582 (5) "Morphine milligram equivalent conversion factor" means a
583 reference standard for an opioid drug that compares the potency of the
584 opioid drug to morphine, as determined by the federal Centers for
585 Medicare and Medicaid Services;

586 (6) "Sale" means any transfer of title to an opioid drug for
587 consideration where actual or constructive possession of the opioid

588 drug is transferred from a covered entity to a purchaser or a
589 purchaser's designee located in this state, but does not mean
590 dispensing an opioid drug to an ultimate consumer pursuant to a
591 prescription or transferring title to an opioid unit from a manufacturer
592 in this state to a purchaser outside this state when such opioid unit will
593 be used or consumed outside this state;

594 (7) "Strength per unit" means the amount of opioid drug in a unit as
595 measured by concentration, volume, weight or any other metric;

596 (8) "Unit" means a single finished dosage form of an opioid drug,
597 including, but not limited to, a buccal film, capsule, milligram of
598 topical preparation, milliliter of liquid, pill, suppository, tablet or
599 transdermal patch; and

600 (9) "Wholesale acquisition cost" means the manufacturer's list price
601 for an opioid drug unit to wholesalers or direct purchasers in the
602 United States, excluding prompt pay or other discounts, rebates or
603 reductions in price, for the most recent month for which the
604 information is available, as reported in wholesale price guides or other
605 publications of drug or biological pricing data.

606 (b) An excise tax is hereby imposed on the first sale of any opioid
607 drug in this state on or after January 1, 2020, at the following rate:

608 (1) One-quarter of one cent per morphine milligram equivalent
609 when the wholesale acquisition cost per unit is less than fifty cents; or

610 (2) One and one-half cents per morphine milligram equivalent when
611 the wholesale acquisition cost per unit is not less than fifty cents.

612 (c) The excise tax imposed under subsection (b) of this section shall
613 be charged against, and paid by, the covered entity making such first
614 sale and accrue at the time of such first sale, and at least a portion of
615 the remittances for such tax shall be used for substance abuse
616 treatment. The economic incidence of such tax may be passed to a
617 purchaser. For the purpose of the proper administration of this section

618 and to prevent evasion of such tax, it shall be presumed that any sale
619 of an opioid drug in this state by a covered entity is the first sale of
620 such opioid drug in this state until the contrary is established, and the
621 burden of proving that any sale is not the first sale in this state shall be
622 upon the covered entity.

623 (d) Every covered entity liable for the tax imposed under subsection
624 (b) of this section shall file with the Commissioner of Revenue Services
625 a return, on a form prescribed by the commissioner, showing the total
626 morphine milligram equivalent and wholesale acquisition costs of the
627 opioid drugs that are subject to such tax, the amount of tax due
628 thereon, and such further information that the commissioner may
629 require. Such return shall be filed for quarterly periods ending on the
630 last day of March, June, September and December of each year. Each
631 quarterly tax return shall be filed on or before the last day of the month
632 next succeeding the end of each quarterly period and the payment of
633 the taxes due with such return shall be made by the same date. Each
634 covered entity shall file such return electronically with the Department
635 of Revenue Services and make such payment by electronic funds
636 transfer in the manner provided by chapter 228g of the general
637 statutes. If a return is not filed when due, the tax shall be due the day
638 on which the return is required to be filed.

639 (e) (1) Each covered entity liable for the tax imposed under
640 subsection (b) of this section shall maintain records containing:

641 (A) The address from which the units are shipped or delivered
642 along with the address to which such units are shipped or delivered;
643 or

644 (B) The place at which actual physical possession of the units is
645 transferred.

646 (2) Each covered entity that is required to maintain records pursuant
647 to subdivision (1) of this subsection shall retain such records for a
648 minimum of six years and produce such records to the Commissioner
649 of Revenue Services upon a demand by the commissioner for such

650 records.

651 (f) No officer or employee, including, but not limited to, any former
652 officer or former employee, of the state or of any other person who has
653 or had access to a return filed pursuant to subsection (d) of this section
654 or the information contained in such return shall disclose or inspect
655 such return or information except as provided in section 12-15 of the
656 general statutes.

657 (g) Any tax due and unpaid under this section shall be subject to the
658 penalties and interest established in section 12-547 of the general
659 statutes and the amount of such tax, penalty or interest, due and
660 unpaid, may be collected under the provisions of section 12-35 of the
661 general statutes.

662 (h) The provisions of sections 12-548, 12-550 to 12-554, inclusive, and
663 12-555b of the general statutes shall apply to the provisions of this
664 section in the same manner and with the same force and effect as if the
665 language of said sections had been incorporated in full into this section
666 and had expressly referred to the tax imposed under this section,
667 except to the extent that any such provision is inconsistent with a
668 provision of this section.

669 (i) For the fiscal year ending June 30, 2020, and each fiscal year
670 thereafter, the Comptroller is authorized to record as revenue for each
671 fiscal year the amount of tax imposed under the provisions of this
672 section prior to the end of each fiscal year and which tax is received by
673 the Commissioner of Revenue Services not later than five business
674 days after the last day of July immediately following the end of each
675 fiscal year.

676 (j) The Commissioner of Revenue Services may adopt regulations, in
677 accordance with the provisions of chapter 54 of the general statutes, to
678 carry out the provisions of this section.

679 Sec. 11. (NEW) (*Effective July 1, 2019*) (a) For the purposes of this
680 section:

681 (1) "Affordable Care Act" means the Patient Protection and
682 Affordable Care Act, P.L. 111-148, as amended by the Health Care and
683 Education Reconciliation Act, P.L. 111-152, as both may be amended
684 from time to time, and regulations adopted thereunder;

685 (2) "Exchange" means the Connecticut Health Insurance Exchange
686 established under section 38a-1081 of the general statutes;

687 (3) "Exempt insurer" means an insurer that administers self-insured
688 health benefit plans and is exempt from third-party administrator
689 licensure under subparagraph (C) of subdivision (11) of section 38a-
690 720 of the general statutes and section 38a-720a of the general statutes;
691 and

692 (4) "Office" means the Office of Health Strategy established under
693 section 19a-754a of the general statutes.

694 (b) The office shall seek a state innovation waiver from the United
695 States Department of the Treasury or the United States Department of
696 Health and Human Services, as applicable, pursuant to Section 1332 of
697 the Affordable Care Act to establish a reinsurance program pursuant
698 to subsection (e) of this section.

699 (c) Subject to the approval of a waiver described in subsection (b) of
700 this section, the office, not later than September 1, 2020, for plan year
701 2021 and annually thereafter for the subsequent plan year, shall:

702 (1) Determine the amount needed, not to exceed thirty million
703 dollars, annually, to fund the reinsurance program described in
704 subsection (e) of this section; and

705 (2) Inform the Office of Policy and Management of the amount
706 determined pursuant to subdivision (1) of this subsection, which office
707 shall then inform the Insurance Commissioner of such amount.

708 (d) (1) Each insurer and health care center doing health insurance
709 business in this state, and each exempt insurer, shall annually pay to
710 the Insurance Commissioner, for deposit in the Insurance Fund

711 established under section 38a-52a of the general statutes, a reinsurance
712 fee assessed by the commissioner pursuant to this section.

713 (2) Not later than September first, annually, each insurer, health care
714 center and exempt insurer described in subdivision (1) of this
715 subsection shall report to the commissioner, on a form designated by
716 said commissioner, the number of insured or enrolled lives in this state
717 as of the May first immediately preceding for which such insurer,
718 health care center or exempt insurer is providing health insurance
719 coverage, or administering a self-insured health benefit plan providing
720 coverage, of the types specified in subdivisions (1), (2), (4), (11) and
721 (12) of section 38a-469 of the general statutes. Such number shall not
722 include lives enrolled in Medicare, any medical assistance program
723 administered by the Department of Social Services, workers'
724 compensation insurance or Medicare Part C plans.

725 (3) Not later than November first, annually, the commissioner shall
726 determine the fee to be assessed for the next plan year against each
727 insurer, health care center and exempt insurer described in subdivision
728 (1) of this subsection. Such fee shall be calculated by multiplying the
729 number of lives reported to the commissioner pursuant to subdivision
730 (2) of this subsection by a factor, determined annually by the
731 commissioner, to fully fund the amount determined under subsection
732 (c) of this section, adjusted for a reinsurance fee by subtracting, if the
733 amount appropriated was more than the amount expended, or by
734 adding, if the amount expended was more than the amount
735 appropriated, the amount determined under subsection (c) of this
736 section, less the amount of federal pass-through savings available
737 pursuant to the waiver described in subsection (b) of this section. The
738 commissioner shall determine the factor by dividing the adjusted
739 amount by the total number of lives reported to the commissioner
740 pursuant to subdivision (2) of this subsection.

741 (4) (A) Not later than December first, annually, the commissioner
742 shall submit a statement to each insurer, health care center and exempt
743 insurer described in subdivision (1) of this subsection that includes the

744 proposed fee, identified on such statement as the "reinsurance fee", for
745 such insurer, health care center or exempt insurer calculated in
746 accordance with this subsection. Each such insurer, health care center
747 and exempt insurer shall pay such fee to the commissioner not later
748 than February first, annually.

749 (B) Any insurer, health care center or exempt insurer described in
750 subdivision (1) of this subsection that is aggrieved by an assessment
751 levied under this subsection may appeal therefrom in the same manner
752 as provided for appeals under section 38a-52 of the general statutes.

753 (5) Any insurer, health care center or exempt insurer that fails to file
754 the report required under subdivision (2) of this subsection shall pay a
755 late filing fee of one hundred dollars per day for each day from the
756 date such report was due. The commissioner may require an insurer,
757 health care center or exempt insurer subject to this subsection to
758 produce any records in its possession, and may require any other
759 person to produce any records in such other person's possession, that
760 were used to prepare such report for examination by the commissioner
761 or the commissioner's designee. If the commissioner determines there
762 exists anything other than a good faith discrepancy between the actual
763 number of insured or enrolled lives that should have been reported
764 pursuant to subdivision (2) of this subsection and the number actually
765 reported, such insurer, health care center or exempt insurer shall pay a
766 civil penalty of not more than fifteen thousand dollars for each report
767 filed for which the commissioner determines there is such a
768 discrepancy.

769 (6) (A) The commissioner shall apply an overpayment of the
770 reinsurance fee by an insurer, health care center or exempt insurer for
771 any fiscal year as a credit against the reinsurance fee due from such
772 insurer, health care center or exempt insurer for the succeeding fiscal
773 year, subject to an adjustment under subdivision (3) of this subsection,
774 if:

775 (i) The amount of the overpayment exceeds five thousand dollars;

776 and

777 (ii) On or before June first of the calendar year of the overpayment,
778 the insurer, health care center, or exempt insurer:

779 (I) Notifies the commissioner of the amount of the overpayment;
780 and

781 (II) Provides the commissioner with evidence sufficient to prove the
782 amount of the overpayment.

783 (B) Not later than ninety days following receipt of notice and
784 supporting evidence under subparagraph (A) of this subdivision, the
785 commissioner shall:

786 (i) Determine whether the insurer, health care center or exempt
787 insurer made an overpayment; and

788 (ii) Notify the insurer, health care center or exempt insurer of the
789 commissioner's determination under clause (i) of this subparagraph.

790 (C) Failure of an insurer, health care center or exempt insurer to
791 notify the commissioner of the amount of an overpayment within the
792 time prescribed in subparagraph (A) of this subdivision constitutes a
793 waiver of any demand of the insurer, health care center or exempt
794 insurer against this state on account of such overpayment.

795 (D) Nothing in this subdivision shall be construed to prohibit or
796 limit the right of an insurer, health care center or exempt insurer to
797 appeal pursuant to subparagraph (B) of subdivision (4) of this
798 subsection.

799 (e) The assessment imposed under this section shall be utilized to
800 establish a reinsurance program for the individual health insurance
801 market designed to lower premiums by between five and ten per cent
802 annually on health benefit plans sold in such market, on and off the
803 exchange, provided the United States Department of the Treasury or
804 the United States Department of Health and Human Services, as

805 applicable, approves a state innovation waiver under Section 1332 of
806 the Affordable Care Act for such reinsurance program. Any such
807 reinsurance program shall be administered by the Health Reinsurance
808 Association created under section 38a-556 of the general statutes.

809 (f) If another state, territory or district of the United States, or a
810 foreign country, imposes on a Connecticut domiciled insurer, fraternal
811 benefit society, hospital service corporation, medical service
812 corporation, health care center or other domestic entity a retaliatory
813 charge for the fee imposed under this section, such domestic entity
814 may, not later than sixty days after receipt of notice of the imposition
815 of the retaliatory charge for such fee, appeal to the Insurance
816 Commissioner for a verification that the fee imposed under this section
817 is subject to retaliation by another state, territory or district of the
818 United States, or a foreign country. If the Insurance Commissioner
819 verifies, upon appeal to and certification by the commissioner, that the
820 fee imposed under this section is the subject of a retaliatory tax, fee,
821 assessment or other obligation by another state, territory or district of
822 the United States, or a foreign country, such fee shall not be assessed
823 against nondomestic insurers and nondomestic exempt insurers
824 pursuant to this section. Any such domestic insurer, fraternal benefit
825 society, hospital service corporation, medical service corporation,
826 health care center or other entity aggrieved by the commissioner's
827 decision issued under this subsection may appeal therefrom in the
828 same manner as provided under section 38a-52 of the general statutes.

829 (g) If the waiver described in subsection (b) of this section
830 terminates and is not replaced, the fee imposed under this section shall
831 immediately terminate.

832 (h) The Insurance Commissioner may adopt regulations, in
833 accordance with chapter 54 of the general statutes, to implement the
834 provisions of this section.

835 Sec. 12. (NEW) (*Effective July 1, 2019*) For the purposes of this section
836 and sections 13 to 19, inclusive, of this act, unless the context otherwise

837 requires:

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

841 (2) "Drug" means an article that is (A) recognized in the official
842 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of
843 the United States or official National Formulary, or any supplement
844 thereto, (B) intended for use in the diagnosis, cure, mitigation,
845 treatment or prevention of disease in humans, (C) not food and
846 intended to affect the structure or any function of the human body,
847 and (D) not a device and intended for use as a component of any
848 article specified in subparagraphs (A) to (C), inclusive, of this
849 subdivision;

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

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

855 (5) "Laboratory" means an environmental laboratory as defined in
856 section 19a-29a of the general statutes and accredited by ISO 17025;

857 (6) "Laboratory testing" means a quantitative and qualitative
858 analysis of a drug consistent with the official United States
859 Pharmacopoeia;

860 (7) "Participating Canadian supplier" means a Canadian supplier
861 that is exporting prescription drugs, in the manufacturer's original
862 container, to a participating wholesaler for distribution in this state
863 under the program;

864 (8) "Participating wholesaler" means a wholesaler that is (A)
865 designated by the Department of Consumer Protection to distribute
866 prescription drugs, in the manufacturer's original container, obtained

867 from a participating Canadian supplier, and (B) participating in the
868 program;

869 (9) "Program" means the Canadian prescription drug importation
870 program established by the Commissioner of Consumer Protection, in
871 conjunction with the Commissioner of Public Health, pursuant to
872 section 13 of this act;

873 (10) "Track-and-trace" means the product tracing process for the
874 components of the pharmaceutical distribution supply chain as
875 described in Title II of the Drug Quality and Security Act; and

876 (11) "Wholesaler" means a wholesaler, as defined in section 21a-70
877 of the general statutes, that has received a certificate of registration
878 from the Commissioner of Consumer Protection pursuant to said
879 section.

880 Sec. 13. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of
881 Consumer Protection, in conjunction with the Commissioner of Public
882 Health, shall establish a program to be known as the "Canadian
883 prescription drug importation program". Under such program, the
884 Commissioner of Consumer Protection and the Commissioner of
885 Public Health shall, notwithstanding any contrary provision of the
886 general statutes, provide for the importation of safe and effective
887 prescription drugs from Canada that have the highest potential for cost
888 savings in this state.

889 (b) (1) Not later than January 1, 2021, the Commissioner of
890 Consumer Protection shall, after consulting with the Commissioner of
891 Public Health, submit a request to the federal Secretary of Health and
892 Human Services seeking approval for the program under 21 USC
893 384(l), as amended from time to time. Such request shall, at a
894 minimum:

895 (A) Describe the Commissioner of Consumer Protection's and
896 Commissioner of Public Health's plans for operating the program;

897 (B) Demonstrate that the prescription drugs that will be imported
898 and distributed in this state under the program will:

899 (i) Meet all applicable federal and state standards for safety and
900 effectiveness; and

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

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

903 (2) (A) If the federal Secretary of Health and Human Services
904 approves the Commissioner of Consumer Protection's request, the
905 Commissioner of Consumer Protection shall:

906 (i) Submit to the Commissioner of Public Health a notice disclosing
907 that the federal Secretary of Health and Human Services approved
908 such request;

909 (ii) Submit to the joint standing committees of the General Assembly
910 having cognizance of matters relating to appropriations, general law,
911 human services and public health a notice disclosing that the federal
912 Secretary of Health and Human Services approved such request; and

913 (iii) Begin operating the program in conjunction with the
914 Commissioner of Public Health not later than one hundred eighty days
915 after the date of such approval.

916 (B) Except as otherwise provided in sections 12 to 19, inclusive, of
917 this act, the Commissioner of Consumer Protection and the
918 Commissioner of Public Health shall not operate the program unless
919 the federal Secretary of Health and Human Services approves the
920 Commissioner of Consumer Protection's request.

921 Sec. 14. (NEW) (*Effective July 1, 2019*) Each participating wholesaler
922 may import and distribute a prescription drug in this state from a
923 participating Canadian supplier under the program if:

924 (1) Such drug meets the United States Food and Drug

925 Administration's standards concerning drug safety, effectiveness,
926 misbranding and adulteration;

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

928 (3) Such drug is not:

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

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

933 (C) An infused drug;

934 (D) An intravenously injected drug;

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

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

939 Sec. 15. (NEW) (*Effective July 1, 2019*) Participating wholesalers may,
940 subject to the provisions of sections 12 to 19, inclusive, of this act,
941 import and distribute drugs in this state from a participating Canadian
942 supplier under the program to:

943 (1) A pharmacy or institutional pharmacy, as defined in section 20-
944 571 of the general statutes; and

945 (2) A laboratory registered with the Department of Public Health
946 under section 19a-29a of the general statutes to perform analytical
947 testing.

948 Sec. 16. (NEW) (*Effective July 1, 2019*) Each participating Canadian
949 supplier and participating wholesaler shall comply with all applicable
950 track-and-trace requirements, and shall not distribute, dispense or sell
951 outside of this state any prescription drugs that are imported into this

952 state under the program. Each participating wholesaler shall make
953 available to the Commissioner of Consumer Protection all track-and-
954 trace records not later than forty-eight hours after the Commissioner of
955 Consumer Protection requests such records.

956 Sec. 17. (NEW) (*Effective July 1, 2019*) (a) The participating
957 wholesaler shall ensure the safety and quality of all drugs that are
958 imported and distributed in this state under the program. The
959 participating wholesaler shall:

960 (1) For each initial shipment of a drug that is imported into this state
961 by a participating wholesaler, ensure that a laboratory engaged by the
962 participating wholesaler tests a statistically valid sample size for each
963 batch of each drug in such shipment for authenticity and degradation
964 in a manner that is consistent with the Food, Drug and Cosmetic Act;

965 (2) For each shipment of a drug that is imported into this state by a
966 participating wholesaler and has been sampled and tested pursuant to
967 subdivision (1) of this subsection, ensure that a laboratory engaged by
968 the participating wholesaler tests a statistically valid sample of such
969 shipment for authenticity and degradation in a manner that is
970 consistent with the Food, Drug and Cosmetic Act;

971 (3) Certify that each drug imported into this state under the
972 program:

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

975 (B) Meets all of the labeling requirements under 21 USC 352, as
976 amended from time to time;

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

981 (5) Maintain documentation demonstrating that the testing required

982 by this section was conducted at a laboratory in accordance with the
983 Food, Drug and Cosmetic Act and all other applicable federal and state
984 laws and regulations concerning laboratory qualifications.

985 (b) The participating wholesaler shall maintain all information and
986 documentation that is submitted pursuant to this section for a period
987 of not less than three years.

988 (c) Each participating wholesaler shall maintain all of the following
989 information for each drug that such participating wholesaler imports
990 and distributes in this state under the program, and submit such
991 information to the Commissioner of Consumer Protection upon
992 request by the Commissioner of Consumer Protection:

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

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

995 (3) The date on which such participating wholesaler received such
996 drug;

997 (4) The quantity of such drug that such participating wholesaler
998 received;

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

1000 (6) The price paid by such participating wholesaler for such drug;

1001 (7) A report for any drug that fails laboratory testing; and

1002 (8) Such additional information and documentation that the
1003 Commissioner of Consumer Protection, in consultation with the
1004 Commissioner of Public Health, deems necessary to ensure the
1005 protection of the public health.

1006 (d) Each participating Canadian supplier shall maintain the
1007 following information and documentation and, upon request by the
1008 Commissioner of Consumer Protection, submit such information and
1009 documentation to the Commissioner of Consumer Protection for each

1010 drug that such participating Canadian supplier exports into this state
1011 under the program:

1012 (1) The original source of such drug, including, but not limited to:

1013 (A) The name of the manufacturer of such drug;

1014 (B) The date on which such drug was manufactured; and

1015 (C) The location where such drug was manufactured;

1016 (2) The date on which such drug was shipped;

1017 (3) The quantity of such drug that was shipped;

1018 (4) The quantity of each lot of such drug originally received and the
1019 source of such lot;

1020 (5) The lot or control number and the batch number assigned to
1021 such drug by the manufacturer; and

1022 (6) Such additional information and documentation that the
1023 Commissioner of Consumer Protection, in consultation with the
1024 Commissioner of Public Health, deems necessary to ensure the
1025 protection of the public health.

1026 Sec. 18. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of
1027 Consumer Protection shall issue a written order:

1028 (1) Suspending importation and distribution of a drug under the
1029 program if the Commissioner of Consumer Protection discovers that
1030 such distribution or importation violates any provision of sections 12
1031 to 19, inclusive, of this act or any other applicable state or federal law
1032 or regulation;

1033 (2) Suspending all importation and distribution of drugs by a
1034 participating wholesaler under the program if the Commissioner of
1035 Consumer Protection discovers that the participating wholesaler has
1036 violated any provision of sections 12 to 19, inclusive, of this act or any

1037 other applicable state or federal law or regulation;

1038 (3) Suspending all importation and distribution of drugs by a
1039 participating Canadian supplier under the program if the
1040 Commissioner of Consumer Protection discovers that the participating
1041 Canadian supplier has violated any provision of sections 12 to 19,
1042 inclusive, of this act or any other applicable state or federal law or
1043 regulation; or

1044 (4) Requiring the recall or seizure of any drug that was imported
1045 and distributed under the program and has been identified as
1046 adulterated, within the meaning of section 21a-105 of the general
1047 statutes, or misbranded.

1048 (b) The Commissioner of Consumer Protection shall send a notice to
1049 each participating Canadian supplier and participating wholesaler
1050 affected by an order issued pursuant to subsection (a) of this section
1051 notifying such participating Canadian supplier or participating
1052 wholesaler that:

1053 (1) The Commissioner of Consumer Protection has issued such
1054 order, and provide the legal and factual basis for such order; and

1055 (2) Such participating Canadian supplier or participating wholesaler
1056 may request, in writing, a hearing before the Commissioner of
1057 Consumer Protection, provided such request is received by the
1058 Commissioner of Consumer Protection not later than thirty days after
1059 the date of such notice.

1060 (c) If a hearing is timely requested pursuant to subsection (b) of this
1061 section, the Commissioner of Consumer Protection shall, not later than
1062 thirty days after the receipt of the request, convene the hearing as a
1063 contested case in accordance with the provisions of chapter 54 of the
1064 general statutes. Not later than sixty days after the receipt of such
1065 request, the Commissioner of Consumer Protection shall issue a final
1066 decision vacating, modifying or affirming the Commissioner of
1067 Consumer Protection's order. The participating Canadian supplier or

1068 participating wholesaler aggrieved by such final decision may appeal
1069 such decision in accordance with the provisions of section 4-183 of the
1070 general statutes.

1071 Sec. 19. (NEW) (*Effective July 1, 2019*) The Commissioner of
1072 Consumer Protection may, in consultation with the Commissioner of
1073 Public Health, adopt regulations in accordance with the provisions of
1074 chapter 54 of the general statutes to implement the provisions of
1075 sections 12 to 18, inclusive, of this act.

1076 Sec. 20. (NEW) (*Effective July 1, 2019*) Not later than July 1, 2020, and
1077 annually thereafter, the executive director of the Office of Health
1078 Strategy established under section 19a-754a of the general statutes
1079 shall submit a report, in accordance with section 11-4a of the general
1080 statutes, to the joint standing committees of the General Assembly
1081 having cognizance of matters relating to appropriations, general law,
1082 human services and public health. Such report shall describe the
1083 operations of the program established pursuant to section 13 of this act
1084 during the fiscal year next preceding, and include all information
1085 prescribed in regulations adopted pursuant to section 19 of this act.

1086 Sec. 21. Subsection (a) of section 38a-510 of the general statutes is
1087 repealed and the following is substituted in lieu thereof (*Effective July*
1088 *1, 2019*):

1089 (a) No insurance company, hospital service corporation, medical
1090 service corporation, health care center or other entity delivering,
1091 issuing for delivery, renewing, amending or continuing an individual
1092 health insurance policy or contract that provides coverage for
1093 prescription drugs may:

1094 (1) Require any person covered under such policy or contract to
1095 obtain prescription drugs, except for prescription drugs indicated as
1096 maintenance drugs in such policy or contract, from a mail order
1097 pharmacy as a condition of obtaining benefits for such drugs; or

1098 (2) Require, if such insurance company, hospital service corporation,

1099 medical service corporation, health care center or other entity uses step
1100 therapy for such drugs, the use of step therapy for (A) any prescribed
1101 drug for longer than sixty days, or (B) a prescribed drug for cancer
1102 treatment for an insured who has been diagnosed with stage IV
1103 metastatic cancer provided such prescribed drug is in compliance with
1104 approved federal Food and Drug Administration indications.

1105 (3) At the expiration of the time period specified in subparagraph
1106 (A) of subdivision (2) of this subsection or for a prescribed drug
1107 described in subparagraph (B) of subdivision (2) of this subsection, an
1108 insured's treating health care provider may deem such step therapy
1109 drug regimen clinically ineffective for the insured, at which time the
1110 insurance company, hospital service corporation, medical service
1111 corporation, health care center or other entity shall authorize
1112 dispensation of and coverage for the drug prescribed by the insured's
1113 treating health care provider, provided such drug is a covered drug
1114 under such policy or contract. If such provider does not deem such
1115 step therapy drug regimen clinically ineffective or has not requested
1116 an override pursuant to subdivision (1) of subsection (b) of this section,
1117 such drug regimen may be continued. For purposes of this section,
1118 "step therapy" means a protocol or program that establishes the
1119 specific sequence in which prescription drugs for a specified medical
1120 condition are to be prescribed.

1121 Sec. 22. Subsection (a) of section 38a-544 of the general statutes is
1122 repealed and the following is substituted in lieu thereof (*Effective July*
1123 *1, 2019*):

1124 (a) No insurance company, hospital service corporation, medical
1125 service corporation, health care center or other entity delivering,
1126 issuing for delivery, renewing, amending or continuing a group health
1127 insurance policy or contract that provides coverage for prescription
1128 drugs may:

1129 (1) Require any person covered under such policy or contract to
1130 obtain prescription drugs, except for prescription drugs indicated as

1131 maintenance drugs in such policy or contract, from a mail order
 1132 pharmacy as a condition of obtaining benefits for such drugs; or

1133 (2) Require, if such insurance company, hospital service corporation,
 1134 medical service corporation, health care center or other entity uses step
 1135 therapy for such drugs, the use of step therapy for (A) any prescribed
 1136 drug for longer than sixty days, or (B) a prescribed drug for cancer
 1137 treatment for an insured who has been diagnosed with stage IV
 1138 metastatic cancer provided such prescribed drug is in compliance with
 1139 approved federal Food and Drug Administration indications.

1140 (3) At the expiration of the time period specified in subparagraph
 1141 (A) of subdivision (2) of this subsection or for a prescribed drug
 1142 described in subparagraph (B) of subdivision (2) of this subsection, an
 1143 insured's treating health care provider may deem such step therapy
 1144 drug regimen clinically ineffective for the insured, at which time the
 1145 insurance company, hospital service corporation, medical service
 1146 corporation, health care center or other entity shall authorize
 1147 dispensation of and coverage for the drug prescribed by the insured's
 1148 treating health care provider, provided such drug is a covered drug
 1149 under such policy or contract. If such provider does not deem such
 1150 step therapy drug regimen clinically ineffective or has not requested
 1151 an override pursuant to subdivision (1) of subsection (b) of this section,
 1152 such drug regimen may be continued. For purposes of this section,
 1153 "step therapy" means a protocol or program that establishes the
 1154 specific sequence in which prescription drugs for a specified medical
 1155 condition are to be prescribed."

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2019	19a-754a
Sec. 2	July 1, 2019	New section
Sec. 3	July 1, 2019	New section
Sec. 4	July 1, 2019	New section
Sec. 5	July 1, 2019	New section
Sec. 6	July 1, 2019	New section

Sec. 7	<i>July 1, 2019</i>	New section
Sec. 8	<i>July 1, 2019</i>	New section
Sec. 9	<i>July 1, 2019</i>	New section
Sec. 10	<i>January 1, 2020, and applicable to sales occurring on or after January 1, 2020</i>	New section
Sec. 11	<i>July 1, 2019</i>	New section
Sec. 12	<i>July 1, 2019</i>	New section
Sec. 13	<i>July 1, 2019</i>	New section
Sec. 14	<i>July 1, 2019</i>	New section
Sec. 15	<i>July 1, 2019</i>	New section
Sec. 16	<i>July 1, 2019</i>	New section
Sec. 17	<i>July 1, 2019</i>	New section
Sec. 18	<i>July 1, 2019</i>	New section
Sec. 19	<i>July 1, 2019</i>	New section
Sec. 20	<i>July 1, 2019</i>	New section
Sec. 21	<i>July 1, 2019</i>	38a-510(a)
Sec. 22	<i>July 1, 2019</i>	38a-544(a)