



General Assembly

**Amendment**

January Session, 2019

LCO No. 10094



Offered by:

REP. SCANLON, 98<sup>th</sup> Dist.

SEN. LESSER, 9<sup>th</sup> 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 Section 19a-754a of the general statutes is repealed and  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 provider organizations in the state, (D) monitoring  
28 the development of accountable care organizations and patient-  
29 centered medical homes in the state, and (E) monitoring the adoption  
30 of 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 five thousand  
83 patients; or (B) represents providers who collectively receive less than  
84 ten million dollars in net patient service revenue from health carriers;
- 85 (6) "Health status adjusted total medical expenses" means: (A) The  
86 total cost of care for the patient population of a group of health care  
87 providers with at least thirty-six thousand member months for a given  
88 calendar year, which cost (i) is calculated for such year on the basis of  
89 the allowed claims for all categories of medical expenses and all  
90 nonclaims payments for such year, including, but not limited to, cost-  
91 sharing payments, adjusted by health status and expressed on a per  
92 member, per month basis for all members in this state who are  
93 required to select a primary care physician for such year, (ii) is  
94 reported separately for Medicaid, Medicare and nongovernment  
95 health plans for such year, and (iii) discloses the health adjustment risk  
96 score and the version of the risk adjustment tool used to calculate such  
97 score for such group for such year; and (B) the total aggregate medical  
98 expenses for all physicians and physician groups with fewer than  
99 thirty-six thousand member months for a given calendar year;
- 100 (7) "Office" means the Office of Health Strategy established under  
101 section 19a-754a of the general statutes, as amended by this act;
- 102 (8) "Other entity" means a device manufacturer, drug manufacturer  
103 or pharmacy benefits manager;
- 104 (9) "Payer" means a payer that, during a given calendar year, pays  
105 providers for health care services on behalf of, or pharmacies for  
106 prescription drugs dispensed to, more than ten thousand individuals

107 in this state;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

166 (e) The office may enter into such contractual agreements as may be  
167 necessary to carry out the purposes of this section, including, but not

168 limited to, contractual agreements with actuarial, economic and other  
169 experts and consultants to assist the office in establishing health care  
170 cost growth benchmarks.

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

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

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

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

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

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

194 (b) Not later than October 1, 2022, and annually thereafter, the office  
195 shall prepare and submit a report, in accordance with section 11-4a of  
196 the general statutes, to the joint standing committees of the General  
197 Assembly having cognizance of matters relating to insurance and

198 public health. Such report shall:

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

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

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

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

215 (1) Data concerning:

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

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

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

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

224 (2) If such provider is a hospital, the data described in subdivision  
225 (1) of this subsection and such additional data, information and



226 documents designated by the executive director, including, but not  
227 limited to, charge masters, cost data, audited financial statements and  
228 merged billing and discharge data, provided such provider shall not  
229 be required to submit any data contained in a report that is filed  
230 pursuant to chapters 368aa to 368ll, inclusive, of the general statutes  
231 and available to the executive director.

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

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

252 (A) Major service category;

253 (B) Payment methodology;

254 (C) Relative price;

255 (D) Direct hospital inpatient cost;

256 (E) Indirect hospital inpatient cost;

257 (F) Direct hospital outpatient cost; and

258 (G) Indirect hospital outpatient cost.

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

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

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

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

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

286 taken to reduce such health care entity's contribution to future state-  
287 wide health care costs.

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

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

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

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

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

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

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

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

313 (ii) A waiver from the requirement that such entity or payer file a  
314 proposed performance improvement plan pursuant to subdivision (1)

315 of subsection (e) of this section.

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

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

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

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

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

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

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

337 (d) Each health care entity or payer identified by the executive  
338 director pursuant to subsection (a) of this section may, not later than  
339 thirty days after the executive director sends a notice to such entity or  
340 payer pursuant to subsection (b) of this section or subparagraph (B) of  
341 subdivision (2) of subsection (c) of this section, as applicable, file with  
342 the office a request for a hearing. Each hearing conducted pursuant to  
343 this subsection shall be conducted in accordance with the procedures  
344 for hearings on contested cases established in chapter 54 of the general

345 statutes.

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

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

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

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

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

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

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

373 (B) After the executive director reviews a proposed performance  
374 improvement plan pursuant to subparagraph (A) of this subdivision,

375 the executive director shall:

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

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

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

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

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

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

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

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

398 (D) Each health care entity or payer that receives a notice from the  
399 executive director pursuant to subparagraph (C)(i) of this subdivision  
400 notifying such entity or payer that the executive director has denied  
401 such entity's or payer's proposed performance improvement plan shall  
402 file with the office, in a form and manner prescribed by the executive  
403 director and not later than thirty days after the date that the executive

404 director sends such notice to such entity or payer, such amendments as  
405 are necessary for such proposed plan to satisfy the criteria established  
406 in subparagraph (A) of this subdivision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

531 (ii) Include measures concerning health outcomes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

649 records.

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

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

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

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

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

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

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

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

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

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

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

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

701 (1) Determine the amount needed to fund the reinsurance program  
702 described in subsection (f) of this section; and

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

706 (d) (1) Each domestic insurer and domestic health care center doing  
707 health insurance business in this state, and each exempt insurer, shall  
708 annually pay to the Insurance Commissioner, for deposit in the  
709 Insurance Fund established under section 38a-52a of the general



710 statutes, a reinsurance fee assessed by the commissioner pursuant to  
711 this section.

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

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

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

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

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

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

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

776 (i) The amount of the overpayment exceeds five thousand dollars;  
777 and

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

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

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

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

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

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

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

798 (D) Nothing in this subdivision shall be construed to prohibit or  
799 limit the right of a domestic insurer, domestic health care center or  
800 exempt insurer to appeal pursuant to subparagraph (B) of subdivision  
801 (4) of this subsection.

802 (e) The annual assessment imposed under this section is not  
803 premium and shall not be considered premium for any purpose.

804 (f) The assessment imposed under this section shall be utilized to  
805 establish a reinsurance program for the individual health insurance  
806 market designed to lower premiums by between five and ten per cent  
807 annually on health benefit plans sold in such market, on and off the  
808 exchange, provided the United States Department of the Treasury or  
809 the United States Department of Health and Human Services, as  
810 applicable, approves a state innovation waiver under Section 1332 of  
811 the Affordable Care Act for such reinsurance program. Any such  
812 reinsurance program shall be administered by the Health Reinsurance  
813 Association created under section 38a-556 of the general statutes.

814 (g) The Insurance Commissioner may adopt regulations, in  
815 accordance with chapter 54 of the general statutes, to implement the  
816 provisions of this section.

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

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

823 (2) "Drug" means an article that is (A) recognized in the official  
824 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of  
825 the United States or official National Formulary, or any supplement  
826 thereto, (B) intended for use in the diagnosis, cure, mitigation,  
827 treatment or prevention of disease in humans, (C) not food and  
828 intended to affect the structure or any function of the human body,  
829 and (D) not a device and intended for use as a component of any  
830 article specified in subparagraphs (A) to (C), inclusive, of this  
831 subdivision;

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

834 (4) "Food, Drug and Cosmetic Act" means the federal Food, Drug

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

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

839 (6) "Laboratory testing" means a quantitative and qualitative  
840 analysis of a drug consistent with the official United States  
841 Pharmacopoeia;

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

846 (8) "Participating wholesaler" means a wholesaler that is (A)  
847 designated by the Department of Consumer Protection to distribute  
848 prescription drugs, in the manufacturer's original container, obtained  
849 from a participating Canadian supplier, and (B) participating in the  
850 program;

851 (9) "Program" means the Canadian prescription drug importation  
852 program established by the Commissioner of Consumer Protection, in  
853 conjunction with the Commissioner of Public Health, pursuant to  
854 section 13 of this act;

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

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

862 Sec. 13. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of  
863 Consumer Protection, in conjunction with the Commissioner of Public  
864 Health, shall establish a program to be known as the "Canadian

865 prescription drug importation program". Under such program, the  
866 Commissioner of Consumer Protection and the Commissioner of  
867 Public Health shall, notwithstanding any contrary provision of the  
868 general statutes, provide for the importation of safe and effective  
869 prescription drugs from Canada that have the highest potential for cost  
870 savings in this state.

871 (b) (1) Not later than January 1, 2021, the Commissioner of  
872 Consumer Protection shall, after consulting with the Commissioner of  
873 Public Health, submit a request to the federal Secretary of Health and  
874 Human Services seeking approval for the program under 21 USC  
875 384(l), as amended from time to time. Such request shall, at a  
876 minimum:

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

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

881 (i) Meet all applicable federal and state standards for safety and  
882 effectiveness; and

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

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

885 (2) (A) If the federal Secretary of Health and Human Services  
886 approves the Commissioner of Consumer Protection's request, the  
887 Commissioner of Consumer Protection shall:

888 (i) Submit to the Commissioner of Public Health a notice disclosing  
889 that the federal Secretary of Health and Human Services approved  
890 such request;

891 (ii) Submit to the joint standing committees of the General Assembly  
892 having cognizance of matters relating to appropriations, general law,  
893 human services and public health a notice disclosing that the federal

894 Secretary of Health and Human Services approved such request; and

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

898 (B) Except as otherwise provided in sections 12 to 19, inclusive, of  
899 this act, the Commissioner of Consumer Protection and the  
900 Commissioner of Public Health shall not operate the program unless  
901 the federal Secretary of Health and Human Services approves the  
902 Commissioner of Consumer Protection's request.

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

906 (1) Such drug meets the United States Food and Drug  
907 Administration's standards concerning drug safety, effectiveness,  
908 misbranding and adulteration;

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

910 (3) Such drug is not:

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

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

915 (C) An infused drug;

916 (D) An intravenously injected drug;

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

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

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

925 (1) A pharmacy or institutional pharmacy, as defined in section 20-  
926 571 of the general statutes; and

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

930 Sec. 16. (NEW) (*Effective July 1, 2019*) Each participating Canadian  
931 supplier and participating wholesaler shall comply with all applicable  
932 track-and-trace requirements, and shall not distribute, dispense or sell  
933 outside of this state any prescription drugs that are imported into this  
934 state under the program. Each participating wholesaler shall make  
935 available to the Commissioner of Consumer Protection all track-and-  
936 trace records not later than forty-eight hours after the Commissioner of  
937 Consumer Protection requests such records.

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

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

947 (2) For each shipment of a drug that is imported into this state by a  
948 participating wholesaler and has been sampled and tested pursuant to  
949 subdivision (1) of this subsection, ensure that a laboratory engaged by  
950 the participating wholesaler tests a statistically valid sample of such  
951 shipment for authenticity and degradation in a manner that is



952 consistent with the Food, Drug and Cosmetic Act;

953 (3) Certify that each drug imported into this state under the  
954 program:

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

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

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

963 (5) Maintain documentation demonstrating that the testing required  
964 by this section was conducted at a laboratory in accordance with the  
965 Food, Drug and Cosmetic Act and all other applicable federal and state  
966 laws and regulations concerning laboratory qualifications.

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

970 (c) Each participating wholesaler shall maintain all of the following  
971 information for each drug that such participating wholesaler imports  
972 and distributes in this state under the program, and submit such  
973 information to the Commissioner of Consumer Protection upon  
974 request by the Commissioner of Consumer Protection:

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

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

977 (3) The date on which such participating wholesaler received such  
978 drug;

979 (4) The quantity of such drug that such participating wholesaler

980 received;

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

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

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

984 (8) Such additional information and documentation that the  
985 Commissioner of Consumer Protection, in consultation with the  
986 Commissioner of Public Health, deems necessary to ensure the  
987 protection of the public health.

988 (d) Each participating Canadian supplier shall maintain the  
989 following information and documentation and, upon request by the  
990 Commissioner of Consumer Protection, submit such information and  
991 documentation to the Commissioner of Consumer Protection for each  
992 drug that such participating Canadian supplier exports into this state  
993 under the program:

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

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

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

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

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

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

1000 (4) The quantity of each lot of such drug originally received and the  
1001 source of such lot;

1002 (5) The lot or control number and the batch number assigned to  
1003 such drug by the manufacturer; and

1004 (6) Such additional information and documentation that the  
1005 Commissioner of Consumer Protection, in consultation with the

1006 Commissioner of Public Health, deems necessary to ensure the  
1007 protection of the public health.

1008 Sec. 18. (NEW) (*Effective July 1, 2019*) (a) The Commissioner of  
1009 Consumer Protection shall issue a written order:

1010 (1) Suspending importation and distribution of a drug under the  
1011 program if the Commissioner of Consumer Protection discovers that  
1012 such distribution or importation violates any provision of sections 12  
1013 to 19, inclusive, of this act or any other applicable state or federal law  
1014 or regulation;

1015 (2) Suspending all importation and distribution of drugs by a  
1016 participating wholesaler under the program if the Commissioner of  
1017 Consumer Protection discovers that the participating wholesaler has  
1018 violated any provision of sections 12 to 19, inclusive, of this act or any  
1019 other applicable state or federal law or regulation;

1020 (3) Suspending all importation and distribution of drugs by a  
1021 participating Canadian supplier under the program if the  
1022 Commissioner of Consumer Protection discovers that the participating  
1023 Canadian supplier has violated any provision of sections 12 to 19,  
1024 inclusive, of this act or any other applicable state or federal law or  
1025 regulation; or

1026 (4) Requiring the recall or seizure of any drug that was imported  
1027 and distributed under the program and has been identified as  
1028 adulterated, within the meaning of section 21a-105 of the general  
1029 statutes, or misbranded.

1030 (b) The Commissioner of Consumer Protection shall send a notice to  
1031 each participating Canadian supplier and participating wholesaler  
1032 affected by an order issued pursuant to subsection (a) of this section  
1033 notifying such participating Canadian supplier or participating  
1034 wholesaler that:

1035 (1) The Commissioner of Consumer Protection has issued such

1036 order, and provide the legal and factual basis for such order; and

1037 (2) Such participating Canadian supplier or participating wholesaler  
1038 may request, in writing, a hearing before the Commissioner of  
1039 Consumer Protection, provided such request is received by the  
1040 Commissioner of Consumer Protection not later than thirty days after  
1041 the date of such notice.

1042 (c) If a hearing is timely requested pursuant to subsection (b) of this  
1043 section, the Commissioner of Consumer Protection shall, not later than  
1044 thirty days after the receipt of the request, convene the hearing as a  
1045 contested case in accordance with the provisions of chapter 54 of the  
1046 general statutes. Not later than sixty days after the receipt of such  
1047 request, the Commissioner of Consumer Protection shall issue a final  
1048 decision vacating, modifying or affirming the Commissioner of  
1049 Consumer Protection's order. The participating Canadian supplier or  
1050 participating wholesaler aggrieved by such final decision may appeal  
1051 such decision in accordance with the provisions of section 4-183 of the  
1052 general statutes.

1053 Sec. 19. (NEW) (*Effective July 1, 2019*) The Commissioner of  
1054 Consumer Protection may, in consultation with the Commissioner of  
1055 Public Health, adopt regulations in accordance with the provisions of  
1056 chapter 54 of the general statutes to implement the provisions of  
1057 sections 12 to 18, inclusive, of this act.

1058 Sec. 20. (NEW) (*Effective July 1, 2019*) Not later than July 1, 2020, and  
1059 annually thereafter, the executive director of the Office of Health  
1060 Strategy established under section 19a-754a of the general statutes  
1061 shall submit a report, in accordance with section 11-4a of the general  
1062 statutes, to the joint standing committees of the General Assembly  
1063 having cognizance of matters relating to appropriations, general law,  
1064 human services and public health. Such report shall describe the  
1065 operations of the program established pursuant to section 13 of this act  
1066 during the fiscal year next preceding, and include all information  
1067 prescribed in regulations adopted pursuant to section 19 of this act.

1068 Sec. 21. Subsection (a) of section 38a-510 of the general statutes is  
1069 repealed and the following is substituted in lieu thereof (*Effective July*  
1070 *1, 2019*):

1071 (a) No insurance company, hospital service corporation, medical  
1072 service corporation, health care center or other entity delivering,  
1073 issuing for delivery, renewing, amending or continuing an individual  
1074 health insurance policy or contract that provides coverage for  
1075 prescription drugs may:

1076 (1) Require any person covered under such policy or contract to  
1077 obtain prescription drugs, except for prescription drugs indicated as  
1078 maintenance drugs in such policy or contract, from a mail order  
1079 pharmacy as a condition of obtaining benefits for such drugs; or

1080 (2) Require, if such insurance company, hospital service corporation,  
1081 medical service corporation, health care center or other entity uses step  
1082 therapy for such drugs, the use of step therapy for (A) any prescribed  
1083 drug for longer than sixty days, or (B) a prescribed drug for cancer  
1084 treatment for an insured who has been diagnosed with stage IV  
1085 metastatic cancer provided such prescribed drug is in compliance with  
1086 approved federal Food and Drug Administration indications.

1087 (3) At the expiration of the time period specified in subparagraph  
1088 (A) of subdivision (2) of this subsection or for a prescribed drug  
1089 described in subparagraph (B) of subdivision (2) of this subsection, an  
1090 insured's treating health care provider may deem such step therapy  
1091 drug regimen clinically ineffective for the insured, at which time the  
1092 insurance company, hospital service corporation, medical service  
1093 corporation, health care center or other entity shall authorize  
1094 dispensation of and coverage for the drug prescribed by the insured's  
1095 treating health care provider, provided such drug is a covered drug  
1096 under such policy or contract. If such provider does not deem such  
1097 step therapy drug regimen clinically ineffective or has not requested  
1098 an override pursuant to subdivision (1) of subsection (b) of this section,  
1099 such drug regimen may be continued. For purposes of this section,

1100 "step therapy" means a protocol or program that establishes the  
1101 specific sequence in which prescription drugs for a specified medical  
1102 condition are to be prescribed.

1103 Sec. 22. Subsection (a) of section 38a-544 of the general statutes is  
1104 repealed and the following is substituted in lieu thereof (*Effective July*  
1105 *1, 2019*):

1106 (a) No insurance company, hospital service corporation, medical  
1107 service corporation, health care center or other entity delivering,  
1108 issuing for delivery, renewing, amending or continuing a group health  
1109 insurance policy or contract that provides coverage for prescription  
1110 drugs may:

1111 (1) Require any person covered under such policy or contract to  
1112 obtain prescription drugs, except for prescription drugs indicated as  
1113 maintenance drugs in such policy or contract, from a mail order  
1114 pharmacy as a condition of obtaining benefits for such drugs; or

1115 (2) Require, if such insurance company, hospital service corporation,  
1116 medical service corporation, health care center or other entity uses step  
1117 therapy for such drugs, the use of step therapy for (A) any prescribed  
1118 drug for longer than sixty days, or (B) a prescribed drug for cancer  
1119 treatment for an insured who has been diagnosed with stage IV  
1120 metastatic cancer provided such prescribed drug is in compliance with  
1121 approved federal Food and Drug Administration indications.

1122 (3) At the expiration of the time period specified in subparagraph  
1123 (A) of subdivision (2) of this subsection or for a prescribed drug  
1124 described in subparagraph (B) of subdivision (2) of this subsection, an  
1125 insured's treating health care provider may deem such step therapy  
1126 drug regimen clinically ineffective for the insured, at which time the  
1127 insurance company, hospital service corporation, medical service  
1128 corporation, health care center or other entity shall authorize  
1129 dispensation of and coverage for the drug prescribed by the insured's  
1130 treating health care provider, provided such drug is a covered drug  
1131 under such policy or contract. If such provider does not deem such

1132 step therapy drug regimen clinically ineffective or has not requested  
 1133 an override pursuant to subdivision (1) of subsection (b) of this section,  
 1134 such drug regimen may be continued. For purposes of this section,  
 1135 "step therapy" means a protocol or program that establishes the  
 1136 specific sequence in which prescription drugs for a specified medical  
 1137 condition are to be prescribed."

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