



General Assembly

January Session, 2023

**Substitute Bill No. 6669**



**AN ACT PROTECTING PATIENTS AND PROHIBITING  
UNNECESSARY HEALTH CARE COSTS.**

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

1 Section 1. (NEW) (*Effective October 1, 2023*) (a) The Comptroller shall  
2 establish the Drug Discount Card Program to be made available to all  
3 residents of this state. To further the purpose of such program, the  
4 Comptroller may cooperate with other states and territories of the  
5 United States, or regional consortia to pool prescription drug  
6 purchasing power to (1) lower prescription drug costs, (2) negotiate  
7 discounts with prescription drug manufacturers, (3) centralize the  
8 purchasing of prescription drugs, and (4) establish volume discount  
9 contracting. As used in this subsection, "volume discount contracting"  
10 means a negotiated purchase of a prescription drug in a large quantity  
11 for a decreased cost.

12 (b) The Comptroller shall adopt regulations, in accordance with the  
13 provisions of chapter 54 of the general statutes, to implement the  
14 provisions of this section, including, but not limited to, establishing  
15 criteria and procedures for the Drug Discount Card Program.  
16 Notwithstanding the requirements of sections 4-168 to 4-172, inclusive,  
17 of the general statutes, in order to effectuate this section, prior to  
18 adopting such regulations and not later than January 1, 2024, the  
19 Comptroller shall issue policies and procedures to implement the

20 provisions of this section concerning the Drug Discount Card Program  
21 that shall have the force and effect of law. The Comptroller shall post all  
22 policies and procedures on the Comptroller's Internet web site and  
23 submit such policies and procedures to the Secretary of the State for  
24 posting on the eRegulations System, not less than fifteen days prior to  
25 the effective date of any policy or procedure. Any such policy or  
26 procedure shall no longer be effective upon the earlier of either the  
27 adoption of the policy or procedure as a final regulation under section  
28 4-172 of the general statutes or forty-eight months from July 1, 2023, if  
29 such regulations have not been submitted to the standing legislative  
30 regulation review committee for consideration under section 4-170 of  
31 the general statutes.

32 Sec. 2. Section 21a-254 of the general statutes is repealed and the  
33 following is substituted in lieu thereof (*Effective October 1, 2023*):

34 (a) The Commissioner of Consumer Protection, after investigation  
35 and hearing, may by regulation designate certain substances as  
36 restricted drugs or substances by reason of their exceptional danger to  
37 health or exceptional potential for abuse so as to require written records  
38 of receipt, use and dispensation, and may, after investigation and  
39 hearing, remove the designation as restricted drugs or substances from  
40 any substance so previously designated.

41 (b) Each physician, dentist, veterinarian or other person who is  
42 authorized to administer or professionally use schedule I substances  
43 shall keep a record of such schedule I substances received by [him] such  
44 person and a record of all such schedule I substances administered,  
45 dispensed or professionally used by [him] such person. The record of  
46 schedule I substances received shall in each case show the date of  
47 receipt, the name and address of the person from whom received and  
48 the kind and quantity of schedule I substances received. The record of  
49 all schedule I substances administered, dispensed or otherwise disposed  
50 of shall show the date of administering or dispensing, the name and  
51 address of the person to whom, or for whose use, or the owner and  
52 species of animal for which, the substances were administered or

53 dispensed and the kind and quantity of substances.

54 (c) Practitioners obtaining and dispensing controlled substances shall  
55 keep a record of all such controlled substances, received and dispensed  
56 by them in accordance with the provisions of subsections (f) and (h) of  
57 this section.

58 (d) Manufacturers and wholesalers shall keep records of all  
59 controlled substances, compounded, mixed, cultivated or grown, or by  
60 any other process produced or prepared, and of all controlled  
61 substances received and disposed of by them in accordance with the  
62 provisions of subsections (f) and (h) of this section.

63 (e) Pharmacies, hospitals, chronic and convalescent nursing homes,  
64 rest homes with nursing supervision, clinics, infirmaries, freestanding  
65 ambulatory surgical centers and laboratories shall keep records of all  
66 controlled substances, received and disposed of by them in accordance  
67 with the provisions of subsections (f) and (h) of this section, except that  
68 hospitals and chronic and convalescent nursing homes using a unit dose  
69 drug distribution system may instead keep such records in accordance  
70 with the provisions of subsections (g) and (h) of this section, and except  
71 that hospitals and freestanding ambulatory surgical centers shall not be  
72 required to maintain separate disposition records for schedule V  
73 controlled substances or records of administering of individual doses  
74 for ultra-short-acting depressants, including, but not limited to,  
75 Methohexital, Thiamylal and Thiopental.

76 (f) The form of record to be kept under subsection (c), (d) or (e) of this  
77 section shall in each case show the date of receipt, the name and address  
78 of the person from whom received, and the kind and quantity of  
79 controlled substances received, or, when applicable, the kind and  
80 quantity of controlled substances produced or removed from process of  
81 manufacture and the date of such production or removal from process  
82 of manufacture; and the record shall in each case show the proportion  
83 of controlled substances. The record of all controlled substances sold,  
84 administered, dispensed or otherwise disposed of shall show the date

85 of selling, administering or dispensing, the name of the person to whom  
86 or for whose use, or the owner and species of animal for which, the  
87 substances were sold, administered or dispensed, the address of such  
88 person or owner in the instance of records of other than hospitals,  
89 chronic and convalescent nursing homes, rest homes with nursing  
90 supervision and infirmaries, and the kind and quantity of substances. In  
91 addition, hospital and infirmary records shall show the time of  
92 administering or dispensing, the prescribing physician and the nurse  
93 administering or dispensing the substance. Each such record of  
94 controlled substances shall be separately maintained apart from other  
95 drug records and kept for a period of three years from the date of the  
96 transaction recorded.

97 (g) Hospitals using a unit dose drug distribution system shall  
98 maintain a record noting all dispositions of controlled substances from  
99 any area of the hospital to other hospital locations. Such record shall  
100 include, but need not be limited to, the name, form, strength and  
101 quantity of the drug dispensed, the date dispensed and the location  
102 within the hospital to which the drug was dispensed. Such dispensing  
103 record shall be separately maintained, apart from other drug or business  
104 records, for a period of three years. Such hospital shall, in addition,  
105 maintain for each patient a record which includes, but need not be  
106 limited to, the full name of the patient and a complete description of  
107 each dose of medication administered, including the name, form,  
108 strength and quantity of the drug administered, the date and time  
109 administered and identification of the nurse or practitioner  
110 administering each drug dose. Entries for controlled substances shall be  
111 specially marked in a manner which allows for ready identification.  
112 Such records shall be filed in chronological order and kept for a period  
113 of three years.

114 (h) A complete and accurate record of all stocks of controlled  
115 substances on hand shall, on and after July 1, 1981, be prepared annually  
116 within four days of the first day of May of the calendar year, except that  
117 a registrant may change this date provided the general physical

118 inventory date of such registrant is not more than six months from the  
119 annual inventory date, and kept on file for three years; and shall be  
120 made available to the commissioner or his authorized agents. All  
121 records required by this chapter shall be kept on the premises of the  
122 registrant and maintained current and separate from other business  
123 records in such form as to be readily available for inspection by the  
124 authorized agent at reasonable times. The use of a foreign language,  
125 codes or symbols to designate controlled substances or persons in the  
126 keeping of any required record is not deemed to be a compliance with  
127 this chapter.

128 (i) Whenever any record is removed by a person authorized to  
129 enforce the provisions of this chapter or the provisions of the state food,  
130 drug and cosmetic laws for the purpose of investigation or as evidence,  
131 such person shall tender a receipt in lieu thereof and the receipt shall be  
132 kept for a period of three years.

133 (j) (1) The commissioner shall, within available appropriations,  
134 establish an electronic prescription drug monitoring program to collect,  
135 by electronic means, prescription information for schedules II, III, IV  
136 and V controlled substances and legend drugs, legend devices,  
137 nonlegend drugs and nonlegend devices, as such terms are defined in  
138 section 20-571, that are dispensed by pharmacies, nonresident  
139 pharmacies, as defined in section 20-627, outpatient pharmacies in  
140 hospitals or institutions or by any other dispenser, including, but not  
141 limited to, the federal Substance Abuse and Mental Health Services  
142 Administration certified substance use disorder clinics licensed under  
143 section 19a-495 in accordance with 42 CFR 2. The program shall be  
144 designed to provide information regarding the prescription of  
145 controlled substances, legend drugs, legend devices, nonlegend drugs  
146 and nonlegend devices in order to prevent the improper or illegal use of  
147 [the] controlled substances, [and] legend drugs, legend devices,  
148 nonlegend drugs and nonlegend devices and to improve the ability of  
149 prescribing practitioners to identify medications that should be  
150 discontinued, deprescribed or modified in the best interest of the

151 patient. The program shall not infringe on the legitimate prescribing of  
152 a controlled substance, legend drug, legend device, nonlegend drug or  
153 nonlegend device by a prescribing practitioner acting in good faith and  
154 in the course of professional practice.

155 (2) The commissioner may identify other products or substances to  
156 be included in the electronic prescription drug monitoring program  
157 established pursuant to subdivision (1) of this subsection.

158 (3) Prior to July 1, [2016] 2024, each pharmacy, nonresident  
159 pharmacy, as defined in section 20-627, outpatient pharmacy in a  
160 hospital or institution and dispenser shall report to the commissioner,  
161 [at least] not less than weekly, by electronic means or, if a pharmacy or  
162 outpatient pharmacy does not maintain records electronically, in a  
163 format approved by the commissioner, the following information for all  
164 controlled substance, legend drug, legend medical device, nonlegend  
165 drug and nonlegend medical device prescriptions dispensed by such  
166 pharmacy or outpatient pharmacy or prescribing practitioner: (A)  
167 Dispenser identification number; (B) the date the prescription for the  
168 controlled substance, legend drug, legend medical device, nonlegend  
169 drug or nonlegend medical device was filled; (C) the prescription  
170 number; (D) whether the prescription for the controlled substance,  
171 legend drug, legend medical device, nonlegend drug or nonlegend  
172 medical device is new or a refill; (E) the national drug code number for  
173 the drug or medical device dispensed; (F) the amount of the controlled  
174 substance, legend drug, legend medical device, nonlegend drug or  
175 nonlegend medical device dispensed and the number of days' supply of  
176 the controlled substance, legend drug, legend medical device,  
177 nonlegend drug or nonlegend medical device; (G) a patient  
178 identification number; (H) the patient's first name, last name and street  
179 address, including postal code; (I) the date of birth of the patient; (J) the  
180 date the prescription for the controlled substance, legend drug, legend  
181 medical device, nonlegend drug or nonlegend medical device was  
182 issued by the prescribing practitioner and the prescribing practitioner's  
183 Drug Enforcement Agency's identification number; (K) the prescribing

184 practitioner's national provider identification number; (L) the date the  
185 prescription was delivered to the patient; and [(K)] (M) the type of  
186 payment.

187 (4) (A) Except as provided in this subdivision, on and after July 1,  
188 [2016] 2024, each pharmacy, nonresident pharmacy, as defined in  
189 section 20-627, outpatient pharmacy in a hospital or institution, and  
190 dispenser shall report to the commissioner by electronic means, in a  
191 format approved by the commissioner, the following information for all  
192 controlled substance, legend drug, legend medical device, nonlegend  
193 drug and nonlegend medical device prescriptions dispensed by such  
194 pharmacy or outpatient pharmacy immediately upon, but in no event  
195 later than the next business day after, dispensing such prescriptions: (i)  
196 Dispenser identification number; (ii) the date the prescription for the  
197 controlled substance, legend drug, legend medical device, nonlegend  
198 drug or nonlegend medical device was filled; (iii) the prescription  
199 number; (iv) whether the prescription for the controlled substance,  
200 legend drug, legend medical device, nonlegend drug or nonlegend  
201 medical device is new or a refill; (v) the national drug code number for  
202 the drug or medical device dispensed; (vi) the amount of the controlled  
203 substance, legend drug, legend medical device, nonlegend drug or  
204 nonlegend medical device dispensed and the number of days' supply of  
205 the controlled substance, legend drug, legend medical device,  
206 nonlegend drug or nonlegend medical device; (vii) a patient  
207 identification number; (viii) the patient's first name, last name and street  
208 address, including postal code; (ix) the date of birth of the patient; (x)  
209 the date the prescription for the controlled substance, legend drug,  
210 legend medical device, nonlegend drug or nonlegend medical device  
211 was issued by the prescribing practitioner and the prescribing  
212 practitioner's Drug Enforcement Agency's identification number; (xi)  
213 the prescribing practitioner's national provider identification number;  
214 (xii) the date the drug or medical device was delivered to the patient;  
215 and [(xi)] (xiii) the type of payment.

216 (B) If the electronic prescription drug monitoring program is not

217 operational, such pharmacy or dispenser shall report the information  
218 described in this subdivision not later than the next business day after  
219 regaining access to such program. For purposes of this subdivision,  
220 "business day" means any day during which the pharmacy is open to  
221 the public.

222 (C) Each veterinarian, licensed pursuant to chapter 384, who  
223 dispenses a controlled substance, legend drug, legend medical device,  
224 nonlegend drug or nonlegend medical device prescription shall report  
225 to the commissioner the information described in subparagraph (A) of  
226 this subdivision, [at least] not less than weekly, by electronic means or,  
227 if the veterinarian does not maintain records electronically, in a format  
228 approved by the commissioner.

229 (5) The commissioner may contract with a vendor for purposes of  
230 electronically collecting such controlled substance, legend drug, legend  
231 medical device, nonlegend drug or nonlegend medical device  
232 prescription information. The commissioner and any such vendor shall  
233 maintain the information in accordance with the provisions of chapter  
234 400j.

235 (6) The commissioner and any such vendor shall not disclose  
236 controlled substance, legend drug, legend medical device, nonlegend  
237 drug and nonlegend medical device prescription information reported  
238 pursuant to subdivisions (3) and (4) of this subsection, except as  
239 authorized pursuant to the provisions of sections 21a-240 to 21a-283,  
240 inclusive. Any person who knowingly violates any provision of this  
241 subdivision or subdivision (5) of this subsection shall be guilty of a class  
242 D felony.

243 (7) The commissioner shall provide, upon request, controlled  
244 substance, legend drug, legend medical device, nonlegend drug and  
245 nonlegend medical device prescription information obtained in  
246 accordance with subdivisions (3) and (4) of this subsection to the  
247 following: (A) The prescribing practitioner or such practitioner's  
248 authorized agent, who is treating or has treated a specific patient,



249 provided the information is obtained for purposes related to the  
250 treatment of the patient, including the monitoring of controlled  
251 substances, legend drugs, legend medical devices, nonlegend drugs or  
252 nonlegend medical devices obtained by the patient; (B) the prescribing  
253 practitioner with whom a patient has made contact for the purpose of  
254 seeking medical treatment or such practitioner's authorized agent,  
255 provided the request is accompanied by a written consent, signed by the  
256 prospective patient, for the release of controlled substance, legend drug,  
257 legend medical device, nonlegend drug and nonlegend medical device  
258 prescription information; or (C) the pharmacist who is dispensing  
259 controlled substances, legend drugs, legend medical devices, nonlegend  
260 drugs or nonlegend medical devices for a patient, or such pharmacist's  
261 authorized pharmacy technician, provided the information is obtained  
262 for purposes related to the scope of the pharmacist's practice and  
263 management of the patient's drug therapy, including the monitoring of  
264 controlled substances, legend drugs, legend medical devices, nonlegend  
265 drugs or nonlegend medical devices obtained by the patient. The  
266 prescribing practitioner, such practitioner's authorized agent, the  
267 pharmacist or such pharmacist's authorized pharmacy technician shall  
268 submit a written and signed request to the commissioner for controlled  
269 substance prescription information. Such prescribing practitioner,  
270 pharmacist or pharmacist's authorized pharmacy technician shall not  
271 disclose any such request except as authorized pursuant to sections 20-  
272 570 to 20-630, inclusive, or sections 21a-240 to 21a-283, inclusive.

273 (8) No person or employer shall prohibit, discourage or impede a  
274 prescribing practitioner, pharmacist or pharmacist's authorized  
275 pharmacy technician from requesting controlled substance, legend  
276 drug, legend medical device, nonlegend drug or nonlegend medical  
277 device prescription information pursuant to this subsection.

278 (9) Prior to prescribing greater than a seventy-two-hour supply of any  
279 controlled substance to any patient, the prescribing practitioner or such  
280 practitioner's authorized agent shall review the patient's records in the  
281 electronic prescription drug monitoring program established pursuant

282 to this subsection. Whenever a prescribing practitioner prescribes a  
283 controlled substance, other than a schedule V nonnarcotic controlled  
284 substance, for the continuous or prolonged treatment of any patient,  
285 such prescriber, or such prescriber's authorized agent, shall review, not  
286 less than once every ninety days, the patient's records in such  
287 prescription drug monitoring program. Whenever a prescribing  
288 practitioner prescribes a schedule V nonnarcotic controlled substance,  
289 for the continuous or prolonged treatment of any patient, such  
290 prescribing practitioner, or such prescribing practitioner's authorized  
291 agent, shall review, not less than annually, the patient's records in such  
292 prescription drug monitoring program. If such electronic prescription  
293 drug monitoring program is not operational, such prescribing  
294 practitioner may prescribe greater than a seventy-two-hour supply of a  
295 controlled substance to a patient during the time of such program's  
296 inoperability, provided such prescribing practitioner or such authorized  
297 agent reviews the records of such patient in such program not more than  
298 twenty-four hours after regaining access to such program.

299 (10) (A) A prescribing practitioner may designate an authorized  
300 agent to review the electronic prescription drug monitoring program  
301 and patient controlled substance, legend drug, legend medical device,  
302 nonlegend drug or nonlegend medical device prescription information  
303 on behalf of the prescribing practitioner. The prescribing practitioner  
304 shall ensure that any authorized agent's access to such program and  
305 patient controlled substance, legend drug, legend medical device,  
306 nonlegend drug or nonlegend medical device prescription information  
307 is limited to the purposes described in this section and occurs in a  
308 manner that protects the confidentiality of information that is accessed  
309 through such program. The prescribing practitioner and any authorized  
310 agent shall be subject to the provisions of 45 CFR 164.308, as amended  
311 from time to time, concerning administrative safeguards for the  
312 protection of electronic protected health information. A prescribing  
313 practitioner may be subject to disciplinary action for acts of the  
314 authorized agent as provided in section 21a-322.

315 (B) Notwithstanding the provisions of subparagraph (A) of this  
316 subdivision, a prescribing practitioner who is employed by or provides  
317 professional services to a hospital shall, prior to designating an  
318 authorized agent to review the electronic prescription drug monitoring  
319 program and patient controlled substance, legend drug or medical  
320 device and nonlegend drug or medical device prescription information  
321 on behalf of the prescribing practitioner, (i) submit a request to  
322 designate one or more authorized agents for such purposes and a  
323 written protocol for oversight of the authorized agent or agents to the  
324 commissioner, in the form and manner prescribed by the commissioner,  
325 and (ii) receive the commissioner's approval to designate such  
326 authorized agent or agents and of such written protocol. Such written  
327 protocol shall designate either the hospital's medical director, a hospital  
328 department head, who is a prescribing practitioner, or another  
329 prescribing practitioner as the person responsible for ensuring that the  
330 authorized agent's or agents' access to such program and patient  
331 controlled substance, legend drug, legend medical device, nonlegend  
332 drug or nonlegend medical device prescription information is limited to  
333 the purposes described in this section and occurs in a manner that  
334 protects the confidentiality of information that is accessed through such  
335 program. A hospital medical director, a hospital department head, who  
336 is a prescribing practitioner, or another prescribing practitioner  
337 designated as the person responsible for overseeing an authorized  
338 agent's or agents' access to such program and information in the written  
339 protocol approved by the commissioner may be subject to disciplinary  
340 action for acts of the authorized agent or agents as provided in section  
341 21a-322. The commissioner may inspect hospital records to determine  
342 compliance with written protocols approved in accordance with this  
343 section.

344 (C) A pharmacist may designate a pharmacy technician to access the  
345 electronic prescription drug monitoring program and patient controlled  
346 substance, legend drug, legend medical device, nonlegend drug and  
347 nonlegend medical device prescription information on behalf of the  
348 pharmacist only for the purposes of facilitating the pharmacist's review

349 of such patient information. The pharmacist shall ensure that any such  
350 pharmacy technician's access to such program and patient controlled  
351 substance, legend drug, legend medical device, nonlegend drug and  
352 nonlegend medical device prescription information is limited to the  
353 purposes described in this section and occurs in a manner that protects  
354 the confidentiality of information that is accessed through such  
355 program. The pharmacist and any authorized pharmacy technician shall  
356 be subject to the provisions of 45 CFR 164.308, as amended from time to  
357 time, concerning administrative safeguards for the protection of  
358 electronic protected health information. A pharmacist may be subject to  
359 disciplinary action for acts of the authorized pharmacy technician.

360 (D) Prior to designating a pharmacy technician to access the  
361 electronic prescription drug monitoring program and patient controlled  
362 substance, legend drug, legend medical device, nonlegend drug and  
363 nonlegend medical device prescription information on behalf of the  
364 pharmacist, the supervising pharmacist shall provide training for the  
365 authorized pharmacy technicians. Such training shall designate a  
366 pharmacist as the person responsible for ensuring that the authorized  
367 pharmacy technician's access to such program and patient controlled  
368 substance, legend drug, legend medical device, nonlegend drug and  
369 nonlegend medical device prescription information is limited to the  
370 purposes described in this section and occurs in a manner that protects  
371 the confidentiality of information that is accessed through such  
372 program. A pharmacist designated as the person responsible for  
373 overseeing the pharmacy technician's access to such program may be  
374 subject to disciplinary action for acts of the authorized pharmacy  
375 technician. The commissioner may inspect records to document  
376 pharmacy technician training, that pharmacy technicians have access to  
377 the program and that patient controlled substance, legend drug, legend  
378 medical device, nonlegend drug and nonlegend medical device  
379 prescription information has been limited in accordance with the  
380 provisions of this section.

381 (11) The commissioner shall adopt regulations, in accordance with

382 chapter 54, concerning the reporting, evaluation, management and  
383 storage of electronic controlled substance, legend drug, legend medical  
384 device, nonlegend drug and nonlegend medical device prescription  
385 information.

386 (12) The provisions of this section shall not apply to (A) samples of  
387 controlled substances, legend drugs, legend medical devices, nonlegend  
388 drugs or nonlegend medical devices dispensed by a physician to a  
389 patient, or (B) any controlled substances, legend drugs, legend medical  
390 devices, nonlegend drugs or nonlegend medical devices dispensed to  
391 hospital inpatients.

392 (13) The provisions of this section shall not apply to any institutional  
393 pharmacy or pharmacist's drug room operated by a facility, licensed  
394 under section 19a-495 and regulations adopted pursuant to said section  
395 19a-495, that dispenses or administers directly to a patient an opioid  
396 agonist for treatment of a substance use disorder, unless the patient has  
397 signed a consent to disclose the patient's records to a prescription drug  
398 monitoring program that is compliant with 42 CFR 2 Subpart B. Each  
399 signed consent form shall be made available for review by the  
400 commissioner upon request. If consent is withdrawn by the patient, the  
401 institutional pharmacy or pharmacist's drug room operated by a facility  
402 shall immediately discontinue disclosing information about the specific  
403 patient who withdrew consent.

404 (14) The commissioner may provide controlled substance  
405 prescription information obtained in accordance with subdivisions (3)  
406 and (4) of this subsection to other state agencies, pursuant to an  
407 agreement between the commissioner and the head of such agency,  
408 provided the information is obtained for a study of disease prevention  
409 and control related to opioid abuse or the study of morbidity and  
410 mortality caused by overdoses of controlled substances. The provision  
411 of such information shall be in accordance with all applicable state and  
412 federal confidentiality requirements.

413 (15) Nothing in this section shall prohibit a prescribing practitioner

414 or such prescribing practitioner's authorized agent from disclosing  
415 controlled substance, legend drug, legend medical device, nonlegend  
416 drug and nonlegend medical device prescription information submitted  
417 pursuant to subdivisions (3) and (4) of this subsection to the Department  
418 of Social Services for the purposes of administering any of said  
419 department's medical assistance programs.

420 (16) Each pharmacy, nonresident pharmacy, as defined in section 20-  
421 627, outpatient pharmacy in a hospital or institution, and dispenser shall  
422 report to the commissioner, [at least] not less than daily, by electronic  
423 means or, if a pharmacy or outpatient pharmacy does not maintain  
424 records electronically, in a format approved by the commissioner  
425 information for all insulin drugs, glucagon drugs, diabetes devices and  
426 diabetic ketoacidosis devices prescribed and dispensed by such  
427 pharmacy or outpatient pharmacy, except such reporting requirement  
428 shall not apply to any veterinarian, licensed under chapter 384, who  
429 dispenses insulin drugs, glucagon drugs, diabetes devices and diabetic  
430 ketoacidosis devices for animal patients. Such pharmacy or outpatient  
431 pharmacy shall report such information to the commissioner in a  
432 manner that is consistent with the manner in which such pharmacy or  
433 outpatient pharmacy reports information for controlled substance,  
434 legend drug, legend medical device, nonlegend drug and nonlegend  
435 medical device prescriptions pursuant to subdivision (4) of this  
436 subsection. For the purposes of this subdivision, "insulin drug",  
437 "glucagon drug", "diabetes devices" and "diabetic ketoacidosis device"  
438 have the same meanings as provided in section 20-616.

439 (17) The electronic prescription drug monitoring program shall  
440 collect transaction information for controlled substances, legend drugs,  
441 legend medical devices, nonlegend drugs and nonlegend medical  
442 devices that have been electronically deprescribed and transmitted to  
443 licensed pharmacies and nonresident pharmacies. For purposes of this  
444 subdivision, "deprescribed" has the same meaning as provided in  
445 section 20-571, and "nonresident pharmacy" has the same meaning as  
446 provided in section 20-627.

447       Sec. 3. (*Effective from passage*) (a) For the purposes of this section,  
448 "academic detailing" means the process of identifying the best evidence-  
449 based practices for a particular medical condition and appropriate  
450 treatments for such medical condition, and providing such information  
451 to prescribing practitioners and qualified pharmacists participating in  
452 collaborative drug therapy management agreements to advance patient  
453 care.

454       (b) Not later than January 1, 2025, the Commissioner of Consumer  
455 Protection, in consultation with The University of Connecticut School of  
456 Pharmacy, shall submit a report, in accordance with the provisions of  
457 section 11-4a of the general statutes, to the joint standing committee of  
458 the General Assembly having cognizance of matters relating to public  
459 health. Such report may include, but need not be limited to, a framework  
460 for establishing an academic detailing program for physicians licensed  
461 pursuant to chapter 370 of the general statutes, advanced practice  
462 registered nurses licensed pursuant to chapter 378 of the general  
463 statutes and pharmacists licensed pursuant to chapter 400j of the general  
464 statutes, who participate in collaborative drug therapy management  
465 agreements, as defined in section 20-631 of the general statutes. Such  
466 report shall provide recommendations for ensuring that such  
467 physicians, advanced practice registered nurses and pharmacists  
468 participating in collaborative drug therapy management agreements are  
469 aware of cost-effective treatments for patients that are based on current  
470 practice and may include suggestions for cost-effective implementation  
471 and evaluation of an academic detailing program.

472       Sec. 4. (NEW) (*Effective October 1, 2023*) For the purposes of this  
473 section and sections 5 to 8, inclusive, of this act:

474       (1) "Commissioner" means the Commissioner of Consumer  
475 Protection;

476       (2) "Contact" means any communication transmitted in person or by  
477 telephone, electronic mail, text message or other electronic means  
478 between a pharmaceutical representative and a prescribing practitioner,

479 to promote or provide information relating to a legend drug;

480 (3) "Department" means the Department of Consumer Protection;

481 (4) "Legend drug" has the same meaning as provided in section 20-  
482 571 of the general statutes;

483 (5) "Pharmaceutical manufacturer" means any person, including, but  
484 not limited to, a virtual manufacturer, as defined in section 20-571 of the  
485 general statutes, who produces, prepares, cultivates, grows, propagates,  
486 compounds, converts or processes a controlled substance, either directly  
487 or indirectly, by extraction from substances of natural origin, or  
488 independently by means of chemical synthesis, or by a combination of  
489 extraction and chemical synthesis, or packages or repackages a  
490 controlled substance container under such person's own name or a  
491 trademark or label for the purpose of selling such controlled substance;

492 (6) "Pharmaceutical representative" means any person, including, but  
493 not limited to, a sales representative or medical science liaison, who  
494 markets, promotes or provides legend drug information to a prescribing  
495 practitioner and is employed or compensated by a pharmaceutical  
496 manufacturer;

497 (7) "Pharmacist" has the same meaning as provided in section 20-571  
498 of the general statutes; and

499 (8) "Prescribing practitioner" has the same meaning as provided in  
500 section 20-571 of the general statutes.

501 Sec. 5. (NEW) (*Effective October 1, 2023*) (a) No person shall engage in  
502 business as a pharmaceutical representative in this state unless such  
503 person has first obtained a license issued by the Commissioner of  
504 Consumer Protection.

505 (b) Any person seeking a license as a pharmaceutical representative  
506 shall (1) submit to the commissioner an application for such license in a  
507 form and manner prescribed by the commissioner, (2) pay a



508 nonrefundable application fee of five hundred fifty dollars, and (3)  
509 submit evidence that such applicant has completed the continuing  
510 professional education requirements set forth in subsection (f) of this  
511 section.

512 (c) The commissioner shall issue to each applicant who meets the  
513 requirements for licensure, as set forth in subsection (b) of this section,  
514 a pharmaceutical representative license.

515 (d) Each licensee holding a license as a pharmaceutical representative  
516 shall, annually, not later than June thirtieth, (1) renew such license with  
517 the commissioner, (2) submit a nonrefundable payment of five hundred  
518 fifty dollars, and (3) certify that such licensee has completed the  
519 continuing professional education requirements set forth in subsection  
520 (f) of this section.

521 (e) A licensee shall file a report with the commissioner not later than  
522 five business days after any change of name, address or other contact  
523 information for such licensee.

524 (f) Prior to submitting an application for (1) a license under  
525 subsection (b) of this section, or (2) a renewal of a license under  
526 subsection (d) of this section, such applicant or licensee shall furnish  
527 evidence satisfactory to the commissioner that such applicant or licensee  
528 has completed not less than five hours of continuing professional  
529 education. Continuing professional education shall include training in  
530 ethical standards, health equity, whistleblower protections, laws and  
531 regulations applicable to pharmaceutical marketing and any other  
532 training approved by the commissioner and published on the  
533 Department of Consumer Protection's Internet web site pursuant to  
534 subsection (g) of this section. Each applicant or licensee shall maintain  
535 continuing education certificate of completion records for not less than  
536 three years following the completion date for each continuing  
537 professional education training and, upon request by the commissioner,  
538 such applicant or licensee shall produce such records to the  
539 commissioner.

540 (g) The commissioner shall review submissions for continuing  
541 professional education programs and shall, upon approval by the  
542 commissioner, publish a list of approved continuing professional  
543 education programs on the department's Internet web site.

544 (h) Continuing professional education training programs shall (1) be  
545 approved by the commissioner, and (2) adhere to the following:

546 (A) An employer of a licensed pharmaceutical representative or an  
547 applicant for such license in this state shall not be a provider of  
548 continuing professional education;

549 (B) A provider of continuing professional education shall disclose  
550 any conflicts of interests, including, but not limited to, any personal  
551 conflict of interest that would interfere or prevent such provider from  
552 conducting continuing professional education training honestly,  
553 objectively and effectively; and

554 (C) Funding for continuing professional education shall not be  
555 provided by an entity in the pharmaceutical industry or by a third-party  
556 entity that is compensated by an entity in the pharmaceutical industry.

557 (i) Upon renewal of a license under subsection (d) of this section, or  
558 not later than July thirty-first if such license is not renewed, such  
559 licensee shall provide the commissioner with the following information  
560 for the previous calendar year in a form and manner prescribed by the  
561 commissioner:

562 (1) The aggregate number of contacts such licensee had with  
563 prescribing practitioners;

564 (2) The names and specialties of the prescribing practitioners such  
565 licensee contacted;

566 (3) The location and length of each contact;

567 (4) The name and a description of each legend drug marketed to each

568 contact;

569 (5) A description of each gift, voucher, coupon or other compensation  
570 of any value that was provided to a prescribing practitioner or staff in a  
571 prescribing practitioner's office; and

572 (6) Any other information requested by the commissioner.

573 (j) The license of a pharmaceutical representative in this state may be  
574 revoked, suspended or annulled, after notice and hearing if the  
575 commissioner determines that (1) such licensee obtained the license by  
576 means of fraud or misrepresentation, or (2) such licensee violated any  
577 provisions of this section, or regulations adopted by the commissioner  
578 in accordance with the provisions of chapter 54 of the general statutes.

579 Sec. 6. (NEW) (*Effective October 1, 2023*) The commissioner may adopt  
580 regulations, in accordance with the provisions of chapter 54 of the  
581 general statutes, to implement the provisions of sections 4 and 5 of this  
582 act concerning the licensing of pharmaceutical representatives.  
583 Notwithstanding the requirements of sections 4-168 to 4-172, inclusive,  
584 of the general statutes in order to effectuate this section, prior to  
585 adopting such regulations, the commissioner may issue policies and  
586 procedures to implement the provisions concerning the licensing of  
587 pharmaceutical representatives that shall have the force and effect of  
588 law. The commissioner shall post all policies and procedures on the  
589 department's Internet web site and submit such policies and procedures  
590 to the Secretary of the State for posting on the eRegulations System not  
591 less than fifteen days prior to the effective date of any policy or  
592 procedure. Any such policy or procedure shall no longer be effective  
593 upon the earlier of either the adoption of the policy or procedure as a  
594 final regulation under section 4-172 of the general statutes or forty-eight  
595 months from October 1, 2023, if such regulations have not been  
596 submitted to the standing legislative regulation review committee for  
597 consideration under section 4-170 of the general statutes.

598 Sec. 7. (NEW) (*Effective October 1, 2023*) Each pharmaceutical

599 representative engaged in legend drug marketing in this state shall  
600 disclose, in writing, to a prescribing practitioner, at the time of each  
601 contact with such prescribing practitioner, the following information:

602 (1) The wholesale acquisition cost of a legend drug when such  
603 pharmaceutical representative provides information concerning such  
604 legend drug to the prescribing practitioner based on the dose and  
605 quantity of such legend drug as described in the medication package  
606 insert;

607 (2) The names of not less than three legend drugs from the same  
608 therapeutic class or a similar therapeutic class for the disease or  
609 condition that such legend drug being marketed has an indication  
610 approved by the federal Food and Drug Administration; and

611 (3) Information on the variation efficacy of the legend drug marketed  
612 to different racial and ethnic groups, if available.

613 Sec. 8. (NEW) (*Effective October 1, 2023*) (a) No pharmaceutical  
614 representative shall:

615 (1) Engage in any deceptive or misleading marketing practices of a  
616 legend drug, including, but not limited to, concealment, suppression,  
617 omission, misrepresentation or misstatement of any material fact;

618 (2) Use a title or designation of a legend drug that could reasonably  
619 mislead a prescribing practitioner or an employee or representative of a  
620 prescribing practitioner; or

621 (3) Transport or provide samples of a legend drug to a prescribing  
622 practitioner or an employee or representative of a prescribing  
623 practitioner.

624 (b) Each pharmaceutical representative licensed in this state shall  
625 present a copy of such license issued pursuant to section 5 of this act at  
626 the time of each visit with a prescribing practitioner or an employee or  
627 representative of a prescribing practitioner.

628 Sec. 9. (*Effective from passage*) Not later than December 24, 2024, the  
629 Office of Health Strategy, in consultation with the Insurance  
630 Department, shall prepare and submit a report, in accordance with  
631 section 11-4a of the general statutes, to the joint standing committee of  
632 the General Assembly having cognizance of matters relating to  
633 insurance. Such report shall include an analysis of pharmacy benefits  
634 managers' practices of prescription drug distribution, including, but not  
635 limited to, spread pricing arrangements, manufacturing rebates and  
636 transparency and an evaluation of prescription drug distribution  
637 practices conducted by pharmacy benefits managers in other states.  
638 Such report shall provide recommendations (1) to reduce prescription  
639 drug costs for consumers, and (2) for the regulation of pharmacy  
640 benefits managers in this state.

641 Sec. 10. Subsection (d) of section 19a-754b of the general statutes is  
642 repealed and the following is substituted in lieu thereof (*Effective October*  
643 *1, 2023*):

644 (d) (1) On or before March 1, 2020, and annually thereafter, the  
645 executive director of the Office of Health Strategy, in consultation with  
646 the Comptroller, Commissioner of Social Services and Commissioner of  
647 Public Health, shall prepare a list of not more than ten outpatient  
648 prescription drugs that the executive director, in the executive director's  
649 discretion, determines are (A) provided at substantial cost to the state,  
650 considering the net cost of such drugs, or (B) critical to public health.  
651 The list shall include outpatient prescription drugs from different  
652 therapeutic classes of outpatient prescription drugs and [at least] not  
653 less than one generic outpatient prescription drug.

654 [(2) The executive director shall not list any outpatient prescription  
655 drug under subdivision (1) of this subsection unless the wholesale  
656 acquisition cost of the drug, less all rebates paid to the state for such  
657 drug during the immediately preceding calendar year, (A) increased by  
658 at least (i) twenty per cent during the immediately preceding calendar  
659 year, or (ii) fifty per cent during the immediately preceding three

660 calendar years, and (B) was not less than sixty dollars for (i) a thirty-day  
661 supply of such drug, or (ii) a course of treatment of such drug lasting  
662 less than thirty days.]

663 (2) Prior to publishing the annual list, the executive director shall  
664 prepare a preliminary list that includes outpatient prescription drugs  
665 the executive director plans to include on such annual list. The executive  
666 director shall make such preliminary list available for public comment  
667 for not less than thirty days. During the public comment period, any  
668 manufacturer of an outpatient prescription drug included on the  
669 preliminary list may produce documentation to the executive director  
670 to establish that the wholesale acquisition cost of such drug, less all  
671 rebates paid to the state for such outpatient prescription drug during  
672 the immediately preceding calendar year, does not exceed the limits  
673 established in subdivision (3) of this subsection. If such documentation  
674 establishes, to the satisfaction of the executive director, that the  
675 wholesale acquisition cost of the drug, less all rebates paid to the state  
676 for such drug during the immediately preceding calendar year, does not  
677 exceed the limits established in subdivision (3) of this subsection, the  
678 executive director shall, not later than fifteen days after the closing of  
679 the public comment period, remove such drug from the preliminary list  
680 before publishing the annual list pursuant to subdivision (1) of this  
681 subsection.

682 (3) The executive director shall not list any outpatient prescription  
683 drugs under subdivision (1) or (2) of this subsection unless the  
684 wholesale acquisition cost of such outpatient prescription drug (A)  
685 increased by not less than sixteen per cent cumulatively during the  
686 immediately preceding two calendar years, and (B) was not less than  
687 forty dollars for a course of treatment.

688 [(3)] (4) (A) The pharmaceutical manufacturer of an outpatient  
689 prescription drug included on a list prepared by the executive director  
690 pursuant to subdivision (1) of this subsection shall provide to the office,  
691 in a form and manner specified by the executive director, (i) a written,  
692 narrative description, suitable for public release, of all factors that

693 caused the increase in the wholesale acquisition cost of the listed  
694 outpatient prescription drug, and (ii) aggregate, company-level research  
695 and development costs and such other capital expenditures that the  
696 executive director, in the executive director's discretion, deems relevant  
697 for the most recent year for which final audited data are available.

698 (B) The quality and types of information and data that a  
699 pharmaceutical manufacturer submits to the office under this  
700 subdivision shall be consistent with the quality and types of information  
701 and data that the pharmaceutical manufacturer includes in (i) such  
702 pharmaceutical manufacturer's annual consolidated report on Securities  
703 and Exchange Commission Form 10-K, or (ii) any other public  
704 disclosure.

705 [(4)] (5) The office shall establish a standardized form for reporting  
706 information and data pursuant to this subsection after consulting with  
707 pharmaceutical manufacturers. The form shall be designed to minimize  
708 the administrative burden and cost of reporting on the office and  
709 pharmaceutical manufacturers.

710 Sec. 11. Section 19a-508c of the general statutes is repealed and the  
711 following is substituted in lieu thereof (*Effective July 1, 2023*):

712 (a) As used in this section:

713 (1) "Affiliated provider" means a provider that is: (A) Employed by a  
714 hospital or health system, (B) under a professional services agreement  
715 with a hospital or health system that permits such hospital or health  
716 system to bill on behalf of such provider, or (C) a clinical faculty member  
717 of a medical school, as defined in section 33-182aa, that is affiliated with  
718 a hospital or health system in a manner that permits such hospital or  
719 health system to bill on behalf of such clinical faculty member;

720 (2) "Campus" means: (A) The physical area immediately adjacent to a  
721 hospital's main buildings and other areas and structures that are not  
722 strictly contiguous to the main buildings but are located within two  
723 hundred fifty yards of the main buildings, or (B) any other area that has

724 been determined on an individual case basis by the Centers for Medicare  
725 and Medicaid Services to be part of a hospital's campus;

726 (3) "Facility fee" means any fee charged or billed by a hospital or  
727 health system for outpatient services provided in a hospital-based  
728 facility, regardless of the treatment modality through which such  
729 services were provided, that is: (A) Intended to compensate the hospital  
730 or health system for the operational expenses of the hospital or health  
731 system, and (B) separate and distinct from a professional fee;

732 (4) "Freestanding emergency department" means a freestanding  
733 facility that (A) is structurally separate and distinct from a hospital, (B)  
734 provides emergency care, (C) is a department of a hospital licensed  
735 under chapter 368v, and (D) has been issued a certificate of need to  
736 operate as a freestanding emergency department pursuant to chapter  
737 368z. "Freestanding emergency department" does not include an urgent  
738 care center, as defined in section 19a-493d;

739 (5) "Health care provider" means an individual, entity, corporation,  
740 person or organization, whether for-profit or nonprofit, that furnishes,  
741 bills or is paid for health care service delivery in the normal course of  
742 business, including, but not limited to, a health system, a hospital, a  
743 hospital-based facility, a freestanding emergency department and an  
744 urgent care center;

745 [(4)] (6) "Health system" means: (A) A parent corporation of one or  
746 more hospitals and any entity affiliated with such parent corporation  
747 through ownership, governance, membership or other means, or (B) a  
748 hospital and any entity affiliated with such hospital through ownership,  
749 governance, membership or other means;

750 [(5)] (7) "Hospital" has the same meaning as provided in section 19a-  
751 490;

752 [(6)] (8) "Hospital-based facility" means a facility that is owned or  
753 operated, in whole or in part, by a hospital or health system where  
754 hospital or professional medical services are provided;



755 (9) "Medicaid" means the program operated by the Department of  
756 Social Services pursuant to section 17b-260 and authorized by Title XIX  
757 of the Social Security Act, as amended from time to time;

758 ~~[(7)]~~ (10) "Payer mix" means the proportion of different sources of  
759 payment received by a hospital or health system, including, but not  
760 limited to, Medicare, Medicaid, other government-provided insurance,  
761 private insurance and self-pay patients;

762 ~~[(8)]~~ (11) "Professional fee" means any fee charged or billed by a  
763 provider for professional medical services provided in a hospital-based  
764 facility;

765 ~~[(9)]~~ (12) "Provider" means an individual, entity, corporation or  
766 health care provider, whether for profit or nonprofit, whose primary  
767 purpose is to provide professional medical services; and

768 ~~[(10)]~~ (13) "Tagline" means a short statement written in a non-English  
769 language that indicates the availability of language assistance services  
770 free of charge.

771 (b) If a hospital or health system charges a facility fee utilizing a  
772 current procedural terminology evaluation and management (CPT  
773 E/M) code or assessment and management (CPT A/M) code for  
774 outpatient services provided at a hospital-based facility where a  
775 professional fee is also expected to be charged, the hospital or health  
776 system shall provide the patient with a written notice that includes the  
777 following information:

778 (1) That the hospital-based facility is part of a hospital or health  
779 system and that the hospital or health system charges a facility fee that  
780 is in addition to and separate from the professional fee charged by the  
781 provider;

782 (2) (A) The amount of the patient's potential financial liability,  
783 including any facility fee likely to be charged, and, where professional  
784 medical services are provided by an affiliated provider, any professional

785 fee likely to be charged, or, if the exact type and extent of the  
786 professional medical services needed are not known or the terms of a  
787 patient's health insurance coverage are not known with reasonable  
788 certainty, an estimate of the patient's financial liability based on typical  
789 or average charges for visits to the hospital-based facility, including the  
790 facility fee, (B) a statement that the patient's actual financial liability will  
791 depend on the professional medical services actually provided to the  
792 patient, (C) an explanation that the patient may incur financial liability  
793 that is greater than the patient would incur if the professional medical  
794 services were not provided by a hospital-based facility, and (D) a  
795 telephone number the patient may call for additional information  
796 regarding such patient's potential financial liability, including an  
797 estimate of the facility fee likely to be charged based on the scheduled  
798 professional medical services; and

799 (3) That a patient covered by a health insurance policy should contact  
800 the health insurer for additional information regarding the hospital's or  
801 health system's charges and fees, including the patient's potential  
802 financial liability, if any, for such charges and fees.

803 (c) If a hospital or health system charges a facility fee without  
804 utilizing a current procedural terminology evaluation and management  
805 (CPT E/M) code for outpatient services provided at a hospital-based  
806 facility, located outside the hospital campus, the hospital or health  
807 system shall provide the patient with a written notice that includes the  
808 following information:

809 (1) That the hospital-based facility is part of a hospital or health  
810 system and that the hospital or health system charges a facility fee that  
811 may be in addition to and separate from the professional fee charged by  
812 a provider;

813 (2) (A) A statement that the patient's actual financial liability will  
814 depend on the professional medical services actually provided to the  
815 patient, (B) an explanation that the patient may incur financial liability  
816 that is greater than the patient would incur if the hospital-based facility

817 was not hospital-based, and (C) a telephone number the patient may call  
818 for additional information regarding such patient's potential financial  
819 liability, including an estimate of the facility fee likely to be charged  
820 based on the scheduled professional medical services; and

821 (3) That a patient covered by a health insurance policy should contact  
822 the health insurer for additional information regarding the hospital's or  
823 health system's charges and fees, including the patient's potential  
824 financial liability, if any, for such charges and fees.

825 (d) Each initial billing statement that includes a facility fee shall: (1)  
826 Clearly identify the fee as a facility fee that is billed in addition to, or  
827 separately from, any professional fee billed by the provider; (2) provide  
828 the corresponding Medicare facility fee reimbursement rate for the same  
829 service as a comparison or, if there is no corresponding Medicare facility  
830 fee for such service, (A) the approximate amount Medicare would have  
831 paid the hospital for the facility fee on the billing statement, or (B) the  
832 percentage of the hospital's charges that Medicare would have paid the  
833 hospital for the facility fee; (3) include a statement that the facility fee is  
834 intended to cover the hospital's or health system's operational expenses;  
835 (4) inform the patient that the patient's financial liability may have been  
836 less if the services had been provided at a facility not owned or operated  
837 by the hospital or health system; and (5) include written notice of the  
838 patient's right to request a reduction in the facility fee or any other  
839 portion of the bill and a telephone number that the patient may use to  
840 request such a reduction without regard to whether such patient  
841 qualifies for, or is likely to be granted, any reduction. Not later than  
842 October 15, 2022, and annually thereafter, each hospital, health system  
843 and hospital-based facility shall submit to the Health Systems Planning  
844 Unit of the Office of Health Strategy a sample of a billing statement  
845 issued by such hospital, health system or hospital-based facility that  
846 complies with the provisions of this subsection and which represents  
847 the format of billing statements received by patients. Such billing  
848 statement shall not contain patient identifying information.

849 (e) The written notice described in subsections (b) to (d), inclusive,

850 and (h) to (j), inclusive, of this section shall be in plain language and in  
851 a form that may be reasonably understood by a patient who does not  
852 possess special knowledge regarding hospital or health system facility  
853 fee charges. On and after October 1, 2022, such notices shall include tag  
854 lines in at least the top fifteen languages spoken in the state indicating  
855 that the notice is available in each of those top fifteen languages. The  
856 fifteen languages shall be either the languages in the list published by  
857 the Department of Health and Human Services in connection with  
858 section 1557 of the Patient Protection and Affordable Care Act, P.L. 111-  
859 148, or, as determined by the hospital or health system, the top fifteen  
860 languages in the geographic area of the hospital-based facility.

861 (f) (1) For nonemergency care, if a patient's appointment is scheduled  
862 to occur ten or more days after the appointment is made, such written  
863 notice shall be sent to the patient by first class mail, encrypted electronic  
864 mail or a secure patient Internet portal not less than three days after the  
865 appointment is made. If an appointment is scheduled to occur less than  
866 ten days after the appointment is made or if the patient arrives without  
867 an appointment, such notice shall be hand-delivered to the patient when  
868 the patient arrives at the hospital-based facility.

869 (2) For emergency care, such written notice shall be provided to the  
870 patient as soon as practicable after the patient is stabilized in accordance  
871 with the federal Emergency Medical Treatment and Active Labor Act,  
872 42 USC 1395dd, as amended from time to time, or is determined not to  
873 have an emergency medical condition and before the patient leaves the  
874 hospital-based facility. If the patient is unconscious, under great duress  
875 or for any other reason unable to read the notice and understand and  
876 act on his or her rights, the notice shall be provided to the patient's  
877 representative as soon as practicable.

878 (g) Subsections (b) to (f), inclusive, and (l) of this section shall not  
879 apply if a patient is insured by Medicare or Medicaid or is receiving  
880 services under a workers' compensation plan established to provide  
881 medical services pursuant to chapter 568.

882 (h) A hospital-based facility shall prominently display written notice  
883 in locations that are readily accessible to and visible by patients,  
884 including patient waiting or appointment check-in areas, stating: (1)  
885 That the hospital-based facility is part of a hospital or health system, (2)  
886 the name of the hospital or health system, and (3) that if the hospital-  
887 based facility charges a facility fee, the patient may incur a financial  
888 liability greater than the patient would incur if the hospital-based  
889 facility was not hospital-based. On and after October 1, 2022, such  
890 notices shall include tag lines in at least the top fifteen languages spoken  
891 in the state indicating that the notice is available in each of those top  
892 fifteen languages. The fifteen languages shall be either the languages in  
893 the list published by the Department of Health and Human Services in  
894 connection with section 1557 of the Patient Protection and Affordable  
895 Care Act, P.L. 111-148, or, as determined by the hospital or health  
896 system, the top fifteen languages in the geographic area of the hospital-  
897 based facility. Not later than October 1, 2022, and annually thereafter,  
898 each hospital-based facility shall submit a copy of the written notice  
899 required by this subsection to the Health Systems Planning Unit of the  
900 Office of Health Strategy.

901 (i) A hospital-based facility shall clearly hold itself out to the public  
902 and payers as being hospital-based, including, at a minimum, by stating  
903 the name of the hospital or health system in its signage, marketing  
904 materials, Internet web sites and stationery.

905 (j) A hospital-based facility shall, when scheduling services for which  
906 a facility fee may be charged, inform the patient (1) that the hospital-  
907 based facility is part of a hospital or health system, (2) of the name of the  
908 hospital or health system, (3) that the hospital or health system may  
909 charge a facility fee in addition to and separate from the professional fee  
910 charged by the provider, and (4) of the telephone number the patient  
911 may call for additional information regarding such patient's potential  
912 financial liability.

913 (k) (1) If any transaction described in subsection (c) of section 19a-  
914 486i, results in the establishment of a hospital-based facility at which

915 facility fees may be billed, the hospital or health system, that is the  
916 purchaser in such transaction shall, not later than thirty days after such  
917 transaction, provide written notice, by first class mail, of the transaction  
918 to each patient served within the three years preceding the date of the  
919 transaction by the health care facility that has been purchased as part of  
920 such transaction.

921 (2) Such notice shall include the following information:

922 (A) A statement that the health care facility is now a hospital-based  
923 facility and is part of a hospital or health system, the health care facility's  
924 full legal and business name and the date of such facility's acquisition  
925 by a hospital or health system;

926 (B) The name, business address and phone number of the hospital or  
927 health system that is the purchaser of the health care facility;

928 (C) A statement that the hospital-based facility bills, or is likely to bill,  
929 patients a facility fee that may be in addition to, and separate from, any  
930 professional fee billed by a health care provider at the hospital-based  
931 facility;

932 (D) (i) A statement that the patient's actual financial liability will  
933 depend on the professional medical services actually provided to the  
934 patient, and (ii) an explanation that the patient may incur financial  
935 liability that is greater than the patient would incur if the hospital-based  
936 facility were not a hospital-based facility;

937 (E) The estimated amount or range of amounts the hospital-based  
938 facility may bill for a facility fee or an example of the average facility fee  
939 billed at such hospital-based facility for the most common services  
940 provided at such hospital-based facility; and

941 (F) A statement that, prior to seeking services at such hospital-based  
942 facility, a patient covered by a health insurance policy should contact  
943 the patient's health insurer for additional information regarding the  
944 hospital-based facility fees, including the patient's potential financial

945 liability, if any, for such fees.

946 (3) A copy of the written notice provided to patients in accordance  
947 with this subsection shall be filed with the Health Systems Planning  
948 Unit of the Office of Health Strategy, established under section 19a-612.  
949 Said unit shall post a link to such notice on its Internet web site.

950 (4) A hospital, health system or hospital-based facility shall not collect  
951 a facility fee for services provided at a hospital-based facility that is  
952 subject to the provisions of this subsection from the date of the  
953 transaction until at least thirty days after the written notice required  
954 pursuant to this subsection is mailed to the patient or a copy of such  
955 notice is filed with the Health Systems Planning Unit of the Office of  
956 Health Strategy, whichever is later. A violation of this subsection shall  
957 be considered an unfair trade practice pursuant to section 42-110b.

958 (5) Not later than July 1, 2023, and annually thereafter, each hospital-  
959 based facility that was the subject of a transaction, as described in  
960 subsection (c) of section 19a-486i, during the preceding calendar year  
961 shall report to the Health Systems Planning Unit of the Office of Health  
962 Strategy the number of patients served by such hospital-based facility  
963 in the preceding three years.

964 (1) (1) A health care provider may only charge, bill for or collect a  
965 facility fee for services provided (A) on a hospital's campus, (B) at a  
966 facility that includes a hospital emergency department, or (C) at a  
967 freestanding emergency department.

968 [(1)] (2) Notwithstanding the provisions of [this section, no hospital,  
969 health system or hospital-based facility shall] subdivision (1) of this  
970 subsection, no health care provider shall charge, bill for or collect a  
971 facility fee for [(1)] (A) outpatient [health care services that use a current  
972 procedural terminology] evaluation and management [(CPT E/M)  
973 code] or assessment and management [(CPT A/M) code and are  
974 provided at a hospital-based facility located off-site from a hospital  
975 campus, or (2) outpatient health care services provided at a hospital-

976 based facility located off-site from a hospital campus, received by a  
977 patient who is uninsured of more than the Medicare rate] services, or  
978 (B) any other outpatient diagnostic or imaging service identified by the  
979 Office of Health Strategy pursuant to subdivision (3) of this subsection.

980 (3) The Office of Health Strategy may annually identify outpatient  
981 diagnostic and imaging services that may reliably be provided safely  
982 and effectively in a setting other than a hospital.

983 (4) Notwithstanding the provisions of subdivisions (1) to (3),  
984 inclusive, of this subsection, in circumstances when an insurance  
985 contract that is in effect on July 1, [2016] 2023, provides reimbursement  
986 for facility fees prohibited under the provisions of this section, a hospital  
987 or health system may continue to collect reimbursement from the health  
988 insurer for such facility fees until the date of expiration, renewal or  
989 amendment of such contract, whichever such date is the earliest.

990 (5) Notwithstanding the provisions of subdivisions (1) to (3),  
991 inclusive, of this subsection, to the extent that the Department of Social  
992 Services provides reimbursement under Medicaid for facility fees  
993 prohibited under the provisions of this section, the John Dempsey  
994 Hospital of The University of Connecticut Health Center and any  
995 hospital that is a party to the settlement agreement with the state  
996 approved pursuant to special act 19-1 of the December special session  
997 may continue to collect reimbursement from said department for such  
998 facility fees for dates of service beginning July 1, 2023, and ending June  
999 30, 2026.

1000 (6) A violation of this subsection shall be considered an unfair trade  
1001 practice pursuant to chapter 735a. [The provisions of this subsection  
1002 shall not apply to a freestanding emergency department. As used in this  
1003 subsection, "freestanding emergency department" means a freestanding  
1004 facility that (A) is structurally separate and distinct from a hospital, (B)  
1005 provides emergency care, (C) is a department of a hospital licensed  
1006 under chapter 368v, and (D) has been issued a certificate of need to  
1007 operate as a freestanding emergency department pursuant to chapter



1008 368z.]

1009 (m) (1) Each hospital and health system shall report not later than July  
1010 1, 2023, and annually thereafter to the executive director of the Office of  
1011 Health Strategy, on a form prescribed by the executive director,  
1012 concerning facility fees charged or billed during the preceding calendar  
1013 year. Such report shall include (A) the name and address of each facility  
1014 owned or operated by the hospital or health system that provides  
1015 services for which a facility fee is charged or billed, (B) the number of  
1016 patient visits at each such facility for which a facility fee was charged or  
1017 billed, (C) the number, total amount and range of allowable facility fees  
1018 paid at each such facility disaggregated by payer mix, (D) for each  
1019 facility, the total amount of facility fees charged and the total amount of  
1020 revenue received by the hospital or health system derived from facility  
1021 fees, (E) the total amount of facility fees charged and the total amount of  
1022 revenue received by the hospital or health system from all facilities  
1023 derived from facility fees, (F) a description of the ten procedures or  
1024 services that generated the greatest amount of facility fee gross revenue,  
1025 disaggregated by current procedural terminology category (CPT) code  
1026 for each such procedure or service and, for each such procedure or  
1027 service, patient volume and the total amount of gross and net revenue  
1028 received by the hospital or health system derived from facility fees, and  
1029 (G) the top ten procedures or services for which facility fees are charged  
1030 based on patient volume and the gross and net revenue received by the  
1031 hospital or health system for each such procedure or service. For  
1032 purposes of this subsection, "facility" means a hospital-based facility  
1033 that is located outside a hospital campus.

1034 (2) The executive director shall publish the information reported  
1035 pursuant to subdivision (1) of this subsection, or post a link to such  
1036 information, on the Internet web site of the Office of Health Strategy.

1037 Sec. 12. Section 19a-653 of the general statutes is repealed and the  
1038 following is substituted in lieu thereof (*Effective October 1, 2023*):

1039 (a) Any person or health care facility or institution that is required to

1040 file a certificate of need for any of the activities described in section 19a-  
1041 638, and any person or health care facility or institution that is required  
1042 to file data or information under any public or special act or under this  
1043 chapter or sections 19a-486 to 19a-486h, inclusive, or any regulation  
1044 adopted or order issued under this chapter or said sections, which  
1045 [wilfully] fails to seek certificate of need approval for any of the  
1046 activities described in section 19a-638 or to so file within prescribed time  
1047 periods, and any person or health care facility or institution that has  
1048 agreed to fully resolve a certificate of need application through  
1049 settlement and fails to comply with any term or condition enumerated  
1050 in the settlement agreement, shall be subject to a civil penalty of up to  
1051 one thousand dollars a day for each day such person or health care  
1052 facility or institution conducts any of the described activities without  
1053 certificate of need approval as required by section 19a-638, [or] for each  
1054 day such information is missing, incomplete or inaccurate or for each  
1055 day any condition of a settlement agreement is not met. Any civil  
1056 penalty authorized by this section shall be imposed by the Office of  
1057 Health Strategy in accordance with subsections (b) to (e), inclusive, of  
1058 this section.

1059 (b) If the Office of Health Strategy has reason to believe that a  
1060 violation has occurred for which a civil penalty is authorized by  
1061 subsection (a) of this section or subsection (e) of section 19a-632, it shall  
1062 notify the person or health care facility or institution by first-class mail  
1063 or personal service. The notice shall include: (1) A reference to the  
1064 sections of the statute, [or] regulation or settlement agreement involved;  
1065 (2) a short and plain statement of the matters asserted or charged; (3) a  
1066 statement of the amount of the civil penalty or penalties to be imposed;  
1067 (4) the initial date of the imposition of the penalty; and (5) a statement  
1068 of the party's right to a hearing.

1069 (c) The person or health care facility or institution to whom the notice  
1070 is addressed shall have fifteen business days from the date of mailing of  
1071 the notice to make written application to the unit to (1) request [(1)] a  
1072 hearing to contest the imposition of the penalty, [or] (2) request an

1073 extension of time to file the required data, or (3) comply with  
1074 enumerated conditions of an agreed settlement. A failure to make a  
1075 timely request for a hearing or an extension of time to file the required  
1076 data or a denial of a request for an extension of time shall result in a final  
1077 order for the imposition of the penalty. All hearings under this section  
1078 shall be conducted pursuant to sections 4-176e to 4-184, inclusive. The  
1079 Office of Health Strategy may grant an extension of time for filing the  
1080 required data or mitigate or waive the penalty upon such terms and  
1081 conditions as, in its discretion, it deems proper or necessary upon  
1082 consideration of any extenuating factors or circumstances.

1083 (d) A final order of the Office of Health Strategy assessing a civil  
1084 penalty shall be subject to appeal as set forth in section 4-183 after a  
1085 hearing before the unit pursuant to subsection (c) of this section, except  
1086 that any such appeal shall be taken to the superior court for the judicial  
1087 district of New Britain. Such final order shall not be subject to appeal  
1088 under any other provision of the general statutes. No challenge to any  
1089 such final order shall be allowed as to any issue which could have been  
1090 raised by an appeal of an earlier order, denial or other final decision by  
1091 the office.

1092 (e) If any person or health care facility or institution fails to pay any  
1093 civil penalty under this section, after the assessment of such penalty has  
1094 become final the amount of such penalty may be deducted from  
1095 payments to such person or health care facility or institution from the  
1096 Medicaid account.

1097 Sec. 13. Section 19a-639a of the general statutes is repealed and the  
1098 following is substituted in lieu thereof (*Effective October 1, 2023*):

1099 (a) An application for a certificate of need shall be filed with the unit  
1100 in accordance with the provisions of this section and any regulations  
1101 adopted by the Office of Health Strategy. The application shall address  
1102 the guidelines and principles set forth in (1) subsection (a) of section 19a-  
1103 639, and (2) regulations adopted by the department. The applicant shall  
1104 include with the application a nonrefundable application fee based on

1105 the cost of the project. The amount of the fee shall be as follows: (A) One  
1106 thousand dollars for a project that will cost not greater than fifty  
1107 thousand dollars; (B) two thousand dollars for a project that will cost  
1108 greater than fifty thousand dollars but not greater than one hundred  
1109 thousand dollars; (C) three thousand dollars for a project that will cost  
1110 greater than one hundred thousand dollars but not greater than five  
1111 hundred thousand dollars; (D) four thousand dollars for a project that  
1112 will cost greater than five hundred thousand dollars but not greater than  
1113 one million dollars; (E) five thousand dollars for a project that will cost  
1114 greater than one million dollars but not greater than five million dollars;  
1115 (F) eight thousand dollars for a project that will cost greater than five  
1116 million dollars but not greater than ten million dollars; and (G) ten  
1117 thousand dollars for a project that will cost greater than ten million  
1118 dollars.

1119 (b) Prior to the filing of a certificate of need application, the applicant  
1120 shall publish notice that an application is to be submitted to the unit [in  
1121 a newspaper having a substantial circulation in the area where the  
1122 project is to be located] on the applicant's Internet web site in a clear and  
1123 conspicuous location that is easily accessible by members of the public.  
1124 Such notice shall (1) be published (A) not later than twenty days prior  
1125 to the date of filing of the certificate of need application, and (B) for not  
1126 less than three consecutive days, and (2) contain a brief description of  
1127 the nature of the project and the street address where the project is to be  
1128 located. An applicant shall file the certificate of need application with  
1129 the unit not later than ninety days after publishing notice of the  
1130 application in accordance with the provisions of this subsection. The  
1131 unit shall not accept the applicant's certificate of need application for  
1132 filing unless the application is accompanied by the application fee  
1133 prescribed in subsection (a) of this section and proof of compliance with  
1134 the publication requirements prescribed in this subsection.

1135 (c) (1) Not later than five business days after receipt of a properly filed  
1136 certificate of need application, the unit shall publish notice of the  
1137 application on its Internet web site. Not later than thirty days after the

1138 date of filing of the application, the unit may request such additional  
1139 information as the unit determines necessary to complete the  
1140 application. In addition to any information requested by the unit, if the  
1141 application involves the transfer of ownership of a hospital, as defined  
1142 in section 19a-639, the applicant shall submit to the unit (A) a plan  
1143 demonstrating how health care services will be provided by the new  
1144 hospital for the first three years following the transfer of ownership of  
1145 the hospital, including any consolidation, reduction, elimination or  
1146 expansion of existing services or introduction of new services, and (B)  
1147 the names of persons currently holding a position with the hospital to  
1148 be purchased or the purchaser, as defined in section 19a-639, as an  
1149 officer, director, board member or senior manager, whether or not such  
1150 person is expected to hold a position with the hospital after completion  
1151 of the transfer of ownership of the hospital and any salary, severance,  
1152 stock offering or any financial gain, current or deferred, such person is  
1153 expected to receive as a result of, or in relation to, the transfer of  
1154 ownership of the hospital.

1155 (2) The applicant shall, not later than sixty days after the date of the  
1156 unit's request, submit any requested information and any information  
1157 required under this subsection to the unit. If an applicant fails to submit  
1158 such information to the unit within the sixty-day period, the unit shall  
1159 consider the application to have been withdrawn.

1160 (d) Upon determining that an application is complete, the unit shall  
1161 provide notice of this determination to the applicant and to the public  
1162 in accordance with regulations adopted by the department. In addition,  
1163 the unit shall post such notice on its Internet web site. The date on which  
1164 the unit posts such notice on its Internet web site shall begin the review  
1165 period. Except as provided in this subsection, (1) the review period for  
1166 a completed application shall be ninety days from the date on which the  
1167 unit posts such notice on its Internet web site; and (2) the unit shall issue  
1168 a decision on a completed application prior to the expiration of the  
1169 ninety-day review period. The review period for a completed  
1170 application that involves a transfer of a large group practice, as

1171 described in subdivision (3) of subsection (a) of section 19a-638, when  
1172 the offer was made in response to a request for proposal or similar  
1173 voluntary offer for sale, shall be sixty days from the date on which the  
1174 unit posts notice on its Internet web site. Upon request or for good cause  
1175 shown, the unit may extend the review period for a period of time not  
1176 to exceed sixty days. If the review period is extended, the unit shall issue  
1177 a decision on the completed application prior to the expiration of the  
1178 extended review period. If the unit holds a public hearing concerning a  
1179 completed application in accordance with subsection (e) or (f) of this  
1180 section, the unit shall issue a decision on the completed application not  
1181 later than sixty days after the date the unit closes the public hearing  
1182 record.

1183 (e) Except as provided in this subsection, the unit shall hold a public  
1184 hearing on a properly filed and completed certificate of need application  
1185 if three or more individuals or an individual representing an entity with  
1186 five or more people submits a request, in writing, that a public hearing  
1187 be held on the application. For a properly filed and completed certificate  
1188 of need application involving a transfer of ownership of a large group  
1189 practice, as described in subdivision (3) of subsection (a) of section 19a-  
1190 638, when an offer was made in response to a request for proposal or  
1191 similar voluntary offer for sale, a public hearing shall be held if twenty-  
1192 five or more individuals or an individual representing twenty-five or  
1193 more people submits a request, in writing, that a public hearing be held  
1194 on the application. Any request for a public hearing shall be made to the  
1195 unit not later than thirty days after the date the unit determines the  
1196 application to be complete.

1197 (f) (1) The unit shall hold a public hearing with respect to each  
1198 certificate of need application filed pursuant to section 19a-638 after  
1199 December 1, 2015, that concerns any transfer of ownership involving a  
1200 hospital. Such hearing shall be held in the municipality in which the  
1201 hospital that is the subject of the application is located.

1202 (2) The unit may hold a public hearing with respect to any certificate  
1203 of need application submitted under this chapter. The unit shall provide

1204 not less than [two] three weeks' advance notice to the applicant, in  
1205 writing, and the applicant shall provide not less than two weeks'  
1206 advance notice to the public by publication [in a newspaper having a  
1207 substantial circulation in the area served by the health care facility or  
1208 provider] on the applicant's Internet web site in a clear and conspicuous  
1209 location that is easily accessible by members of the public. In conducting  
1210 its activities under this chapter, the unit may hold hearings with respect  
1211 to applications of a similar nature at the same time.

1212 (g) The unit may retain an independent consultant with expertise in  
1213 the specific area of health care that is the subject of a pending application  
1214 filed by an applicant if the review and analysis of an application cannot  
1215 reasonably be conducted by the unit without the expertise of an industry  
1216 analyst or other actuarial consultant. The unit shall submit bills for  
1217 independent consultant services to the applicant. Such applicant shall  
1218 pay such bills not later than thirty days after receipt of such bills. Such  
1219 bills shall be a reasonable amount per application. The provisions of  
1220 chapter 57, sections 4-212 to 4-219, inclusive, and section 4e-19 shall not  
1221 apply to any retainer agreement executed pursuant to this subsection.

1222 [(g)] (h) The executive director of the Office of Health Strategy may  
1223 implement policies and procedures necessary to administer the  
1224 provisions of this section while in the process of adopting such policies  
1225 and procedures as regulation, provided the executive director holds a  
1226 public hearing prior to implementing the policies and procedures and  
1227 posts notice of intent to adopt regulations on the office's Internet web  
1228 site and the eRegulations System not later than twenty days after the  
1229 date of implementation. Policies and procedures implemented pursuant  
1230 to this section shall be valid until the time final regulations are adopted.

1231 Sec. 14. Section 19a-633 of the general statutes is repealed and the  
1232 following is substituted in lieu thereof (*Effective October 1, 2023*):

1233 (a) The executive director, or any agent authorized by such executive  
1234 director to conduct any inquiry, investigation or hearing under the  
1235 provisions of this chapter, shall have power to administer oaths and take

1236 testimony under oath relative to the matter of inquiry or investigation.  
1237 At any hearing ordered by the unit, the executive director or such agent  
1238 having authority by law to issue such process may subpoena witnesses  
1239 and require the production of records, papers and documents pertinent  
1240 to such inquiry. If any person disobeys such process or, having  
1241 appeared in obedience thereto, refuses to answer any pertinent question  
1242 put to such person by the executive director or such executive director's  
1243 authorized agent or to produce any records and papers pursuant  
1244 thereto, the executive director or such executive director's agent may  
1245 apply to the superior court for the judicial district of Hartford or for the  
1246 judicial district wherein the person resides or wherein the business has  
1247 been conducted, or to any judge of said court if the same is not in  
1248 session, setting forth such disobedience to process or refusal to answer,  
1249 and said court or such judge shall cite such person to appear before said  
1250 court or such judge to answer such question or to produce such records  
1251 and papers.

1252 (b) If the executive director or such agent has received information or  
1253 has a reasonable belief that any person, health care facility or institution  
1254 has violated or is violating any provision of this chapter, or any  
1255 regulation or order of the unit, the executive director or such agent may  
1256 issue a notice pursuant to this section. Such executive director or agent  
1257 shall notify the person, health care facility or institution against whom  
1258 such order is issued by first-class mail or personal service. The notice  
1259 shall include: (1) A reference to the sections of the general statutes,  
1260 regulations of Connecticut state agencies or orders alleged or believed  
1261 to have been violated; (2) a short and plain language statement of the  
1262 matters asserted or charged; (3) a description of the activity alleged to  
1263 have violated a statute or regulation identified pursuant to subdivision  
1264 (1) of this subsection; (4) a statement concerning the right to a hearing  
1265 of such person, health care facility or institution; and (5) a statement that  
1266 such person, health care facility or institution may, not later than ten  
1267 business days after receipt of such notice, make a request for a hearing  
1268 on the matters asserted, to be sent to the executive director or such  
1269 agent.



1270 (c) The person, health care facility or institution to whom such notice  
1271 is provided pursuant to subsection (b) of this section may, not later than  
1272 ten business days after receipt of the notice, make written application to  
1273 the Office of Health Strategy to request a hearing to demonstrate that  
1274 such violation has not occurred, a certificate of need was not required,  
1275 or each required certificate of need was obtained. A failure to make a  
1276 timely request for a hearing shall result in the office issuing a cease and  
1277 desist order. Each hearing held under this subsection shall be conducted  
1278 as a contested case pursuant to chapter 54.

1279 (d) If the office finds, by a preponderance of the evidence, following  
1280 a hearing held under subsection (c) of this section that such person,  
1281 health care facility or institution has violated or is violating any  
1282 provision of this chapter, or any regulation or order of the unit, the office  
1283 shall issue a final cease and desist order to such person, health care  
1284 facility or institution. Such order shall be considered a final decision  
1285 subject to appeal to the Superior Court in accordance with section 4-183.

1286 (e) Any cease and desist order issued under this section may be  
1287 enforced by the Attorney General pursuant to section 19a-642.

1288 Sec. 15. Subsection (a) of section 19a-639f of the general statutes is  
1289 repealed and the following is substituted in lieu thereof (*Effective October*  
1290 *1, 2023*):

1291 (a) The Health Systems Planning Unit of the Office of Health Strategy  
1292 shall conduct a cost and market impact review in each case where (1) an  
1293 application for a certificate of need filed pursuant to section 19a-638  
1294 involves the transfer of ownership of a hospital, as defined in section  
1295 19a-639, and (2) the purchaser is a hospital, as defined in section 19a-  
1296 490, whether located within or outside the state [, that had net patient  
1297 revenue for fiscal year 2013 in an amount greater than one billion five  
1298 hundred million dollars,] or a hospital system, as defined in section 19a-  
1299 486i, whether located within or outside the state, [that had net patient  
1300 revenue for fiscal year 2013 in an amount greater than one billion five  
1301 hundred million dollars] or any person that is organized or operated for

1302 profit.

1303 Sec. 16. (NEW) (*Effective October 1, 2023*) (a) For the purposes of this  
1304 section and sections 17 and 18 of this act:

1305 (1) "Covered drug" means a drug purchased by a 340B covered entity  
1306 that is subject to the federal pricing requirements set forth in 42 USC  
1307 256b, as amended from time to time, or a drug that would be purchased  
1308 by such covered entity but for the requirements, conditions and  
1309 exclusions set forth in subsections (b) and (c) of this section or subsection  
1310 (b) of section 17 of this act.

1311 (2) "340B covered entity" means a provider participating in the federal  
1312 340B drug pricing program authorized by 42 USC 256b, as amended  
1313 from time to time.

1314 (3) "Drug manufacturer" means the following:

1315 (A) An entity described in 42 USC 1396r-8(k)(5) that is subject to the  
1316 pricing limitations set forth in 42 USC 256b; and

1317 (B) A wholesaler described in 42 USC 1396r-8(k)(11) engaged in the  
1318 distribution of covered drugs for an entity described in 42 USC 1396r-  
1319 8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b.

1320 (4) "Payer" means a pharmacy benefits manager.

1321 (5) "Pharmacy benefits manager" has the same meaning as provided  
1322 in section 38a-479aaa of the general statutes and includes a wholly or  
1323 partially owned or controlled subsidiary of a pharmacy benefits  
1324 manager.

1325 (6) "Specified pharmacy" means a pharmacy owned by, or under  
1326 contract with, a 340B covered entity that is registered with the 340B  
1327 discount drug purchasing program set forth in 42 USC 256b to dispense  
1328 covered drugs on behalf of the 340B covered entity, whether in person  
1329 or by mail.

1330 (b) Any payer shall not impose any requirements, conditions or  
1331 exclusions that:

1332 (1) Discriminate against a 340B covered entity or a specified  
1333 pharmacy in connection with dispensing covered drugs; and

1334 (2) Prevent a 340B covered entity from retaining the benefit of  
1335 discounted pricing for the purchase of covered drugs.

1336 (c) Discrimination prohibited pursuant to subsection (b) of this  
1337 section includes:

1338 (1) Payment terms, reimbursement methodologies, or other terms  
1339 and conditions that distinguish between covered drugs and other drugs,  
1340 account for the availability of discounts under the 340B discount drug  
1341 purchasing program set forth in 42 USC 256b in determining  
1342 reimbursement or are less favorable than the payment or purchase  
1343 terms or reimbursement methodologies for similarly situated entities  
1344 that are not furnishing or dispensing covered drugs;

1345 (2) Terms or conditions applied to 340B covered entities or specified  
1346 pharmacies based on the furnishing or dispensing of covered drugs or  
1347 their status as a 340B covered entity or specified pharmacy, including  
1348 restrictions or requirements for participating in standard or preferred  
1349 pharmacy networks or requirements related to the frequency or scope  
1350 of audits;

1351 (3) Requiring a 340B covered entity or specified pharmacy to identify,  
1352 either directly or through a third party, covered drugs or covered drug  
1353 costs or other information not sought from other drug purchasers;

1354 (4) Refusing to contract with or terminating a contract with a 340B  
1355 covered entity or specified pharmacy, or otherwise excluding a 340B  
1356 covered entity or specified pharmacy from a standard or preferred  
1357 network, on the basis that such entity or pharmacy is a 340B covered  
1358 entity or a specified pharmacy or for reasons other than those that apply  
1359 equally to entities or pharmacies that are not 340B covered entities or

1360 specified pharmacies;

1361 (5) Refusing to sell covered drugs to a 340B covered entity or specified  
1362 pharmacy on the basis that such entity or pharmacy is a 340B covered  
1363 entity or specified pharmacy or for reasons other than those that apply  
1364 equally to entities or pharmacies that are not 340B covered entities or  
1365 specified pharmacies;

1366 (6) Retaliation against a 340B covered entity or specified pharmacy  
1367 based on its exercise of any right or remedy under this section; and

1368 (7) Interfering with an individual's choice to receive a covered drug  
1369 from a 340B covered entity or specified pharmacy, whether in person or  
1370 via direct delivery, mail or other form of shipment.

1371 (d) This section shall apply to self-insured employee welfare benefit  
1372 plans, as defined in the federal Employee Retirement Income Security  
1373 Act of 1974, as amended from time to time, administered through a  
1374 pharmacy benefits manager.

1375 (e) Notwithstanding any provision of title 38a of the general statutes  
1376 and chapter 54 of the general statutes, to the extent that any contract  
1377 provisions contained in a contract between a pharmacy benefits  
1378 manager and a 340B covered entity entered into, amended or renewed  
1379 after October 1, 2023, violates subsection (b) or (c) of this section, such  
1380 contract provisions shall be void and unenforceable.

1381 Sec. 17. (NEW) (*Effective October 1, 2023*) (a) A drug manufacturer  
1382 shall comply with federal pricing requirements set forth in 42 USC 256b  
1383 when selling covered drugs to 340B covered entities located in this state  
1384 and shall not impose any preconditions, limitations, delays or other  
1385 barriers to the purchase of covered drugs that are not required under 42  
1386 USC 256b.

1387 (b) Preconditions, limitations, delays or other barriers prohibited by  
1388 subsection (a) of this section include:

1389 (1) Implementation of policies or limitations that restrict the ability of  
1390 340B covered entities or specified pharmacies to dispense covered  
1391 drugs, including restrictions on the number or type of locations through  
1392 which covered drugs may be dispensed by or on behalf of a 340B  
1393 covered entity;

1394 (2) Conditioning the sale of covered drugs for 340B covered entities  
1395 on enrollment with third-party vendors or on the sharing of claims  
1396 information or other data;

1397 (3) Charging 340B covered entities for covered drugs at amounts  
1398 above the federal ceiling price, including policies that condition  
1399 discounts on rebate requests;

1400 (4) Interfering with an individual's choice to receive a covered drug  
1401 from a 340B covered entity or specified pharmacy, whether in person or  
1402 via direct delivery, mail or other form of shipment;

1403 (5) Delays in shipping covered drugs compared to drugs that are not  
1404 discounted; and

1405 (6) Retaliation against a 340B covered entity or specified pharmacy  
1406 based on such entity's or pharmacy's exercise of any right or remedy  
1407 under this section.

1408 Sec. 18. (NEW) (*Effective October 1, 2023*) (a) A covered entity or the  
1409 Attorney General may seek a temporary or permanent injunction and  
1410 such other relief as may be appropriate to enjoin a pharmacy benefits  
1411 manager or drug manufacturer from continuing to enforce contract  
1412 provisions that violate the requirements set forth in subsections (b) and  
1413 (c) of section 16 of this act or subsections (a) and (b) of section 17 of this  
1414 act. If the court determines that such violation or violations exist, the  
1415 court may grant such injunctive relief and such other relief as justice  
1416 may require and may set a time period within which such pharmacy  
1417 benefits manager or drug manufacturer shall comply with any such  
1418 order.

1419 (b) Any appeal taken from any permanent injunction granted under  
1420 subsection (a) of this section shall not stay the operation of such  
1421 injunction unless the court is of the opinion that great and irreparable  
1422 injury will be done by not staying the operation of such injunction.

1423 Sec. 19. Section 19a-649 of the general statutes is amended by adding  
1424 subsection (d) as follows (*Effective October 1, 2023*):

1425 (NEW) (d) (1) As used in this subsection:

1426 (A) "Ceiling price" means the maximum price a payer may be  
1427 required to pay as provided in Section 340B(a)(1) of the Public Health  
1428 Service Act, 42 USC 256b, as amended from time to time;

1429 (B) "Covered outpatient drug" has the same meaning as provided in  
1430 in Section 340B of the Public Health Service Act, 42 USC 256b, as  
1431 amended from time to time;

1432 (C) "Federal 340B drug pricing program" means the plan described in  
1433 Section 340B of the Public Health Service Act, 42 USC 256b, as amended  
1434 from time to time, that instructs the federal Secretary of Health and  
1435 Human Services to enter into agreements with any manufacturer of  
1436 covered outpatient drugs under which the amount paid to any  
1437 manufacturer by certain statutorily defined covered entities does not  
1438 exceed the 340B ceiling price;

1439 (D) "Manufacturer" has the same meaning as provided in 42 USC  
1440 1396r-8(k)(5), as amended from time to time; and

1441 (E) "Payer" means: (i) Any person, legal entity, governmental body or  
1442 organization that meets the definition of "eligible organization" as  
1443 provided in 42 USC 1395mm(b), as amended from time to time, except  
1444 for Medicare and Medicaid which purchases covered outpatient drugs  
1445 under the federal 340B drug pricing program, or (ii) any legal entity  
1446 whose membership includes not less than one payer or third-party  
1447 payer.

1448 (2) Not later than January 15, 2024, and annually thereafter, each  
 1449 hospital that participates in the federal 340B drug pricing program shall  
 1450 file the following information in such form and manner prescribed by  
 1451 the unit:

1452 (A) A list of manufacturers from whom the hospital purchased  
 1453 covered outpatient drugs in the immediately preceding year as part of  
 1454 the federal 340B drug pricing program;

1455 (B) A list of covered outpatient drugs, identified by the national drug  
 1456 code number, purchased from each manufacturer identified in  
 1457 subparagraph (A) of this subdivision, categorized by quantity, actual  
 1458 purchase price and ceiling price;

1459 (C) The reimbursement amount by each payer for covered outpatient  
 1460 drugs, categorized by manufacturer, quantity, actual purchase price and  
 1461 ceiling price;

1462 (D) The difference in cost for each covered outpatient drug, identified  
 1463 by such drug's national drug code number, due to the difference in the  
 1464 ceiling price or actual price paid, and the actual price paid by any patient  
 1465 or payer; and

1466 (E) A summary providing how the difference in cost identified in  
 1467 subparagraph (D) of this subdivision was applied for the benefit of the  
 1468 community.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2023</i>	New section
Sec. 2	<i>October 1, 2023</i>	21a-254
Sec. 3	<i>from passage</i>	New section
Sec. 4	<i>October 1, 2023</i>	New section
Sec. 5	<i>October 1, 2023</i>	New section
Sec. 6	<i>October 1, 2023</i>	New section
Sec. 7	<i>October 1, 2023</i>	New section
Sec. 8	<i>October 1, 2023</i>	New section

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Sec. 9	<i>from passage</i>	New section
Sec. 10	<i>October 1, 2023</i>	19a-754b(d)
Sec. 11	<i>July 1, 2023</i>	19a-508c
Sec. 12	<i>October 1, 2023</i>	19a-653
Sec. 13	<i>October 1, 2023</i>	19a-639a
Sec. 14	<i>October 1, 2023</i>	19a-633
Sec. 15	<i>October 1, 2023</i>	19a-639f(a)
Sec. 16	<i>October 1, 2023</i>	New section
Sec. 17	<i>October 1, 2023</i>	New section
Sec. 18	<i>October 1, 2023</i>	New section
Sec. 19	<i>October 1, 2023</i>	19a-649(d)

- PH**      *Joint Favorable Subst. -LCO*
- APP**    *Joint Favorable*
- GL**      *Joint Favorable*