



General Assembly

January Session, 2021

Raised Bill No. 895

LCO No. 3421



Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING CHANGES TO VARIOUS PHARMACY STATUTES.

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

1 Section 1. Section 20-571 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective from passage*):

3 As used in sections 20-570 to 20-630, inclusive, unless the context
4 otherwise requires:

5 (1) "Administer" means the direct application of a drug or device to
6 the body of a patient or research subject by injection, inhalation,
7 ingestion or any other means;

8 (2) "Automated prescription dispensing machine" means a device
9 and associated software operated by a pharmacy licensed pursuant to
10 section 20-594 that is registered as a nonresident pharmacy pursuant to
11 section 20-627, in a nursing home or skilled nursing facility licensed
12 pursuant to section 19a-490, that packages and labels patient-specific
13 medication or multiple medications for the purposes of administration
14 by a registered nurse or a licensed practical nurse based on a

15 prescription that has completed final verification by a licensed
16 pharmacist;

17 [(2)] (3) "Care-giving institution" means an institution that provides
18 medical services and is licensed, operated, certified or approved by the
19 Commissioner of Public Health, the Commissioner of Developmental
20 Services or the Commissioner of Mental Health and Addiction Services;

21 [(3)] (4) "Commission" means the Commission of Pharmacy
22 appointed under the provisions of section 20-572;

23 [(4)] (5) "Commissioner" means the Commissioner of Consumer
24 Protection;

25 [(5)] (6) "Compound" means to combine, mix or put together two or
26 more ingredients pursuant to a prescription and includes the
27 preparation of drugs or devices in anticipation of prescriptions based on
28 routine, regularly-observed prescribing patterns;

29 [(6)] (7) "Correctional or juvenile training institution" means a facility
30 for the detention or incarceration of persons convicted or accused of
31 crimes or offenses or for training of delinquent juveniles, including
32 those state facilities under the jurisdiction of the Commissioner of
33 Correction, training schools for delinquent juveniles and any other
34 facilities operated by the state or municipalities for such detention,
35 incarceration or training;

36 [(7)] (8) "Device" means instruments, apparatuses and contrivances,
37 including their components, parts and accessories, intended (A) for use
38 in the diagnosis, cure, mitigation, treatment or prevention of disease in
39 humans or other animals, or (B) to affect the structure or any function of
40 the body of humans or other animals, but does not mean contact lenses;

41 [(8)] (9) "Department" means the Department of Consumer
42 Protection;

43 [(9)] (10) "Dispense" means those acts of processing a drug or device
44 for delivery or for administration for a patient pursuant to a prescription

45 consisting of: (A) Comparing the directions on the label with the
46 directions on the prescription to determine accuracy; (B) the selection of
47 the drug or device from stock to fill the prescription; (C) the counting,
48 measuring, compounding or preparation of the drug or device; (D) the
49 placing of the drug or device in the proper container; (E) the affixing of
50 the label to the container; and (F) the addition to a written prescription
51 of any required notations. "Dispense" does not include the acts of
52 delivering a drug or device to a patient or of administering the drug or
53 device to the patient;

54 [(10)] (11) "Dispensing outpatient facility" means a facility operated
55 by a corporation or municipality which provides medical services to
56 patients on an outpatient basis and which maintains stocks of drugs for
57 dispensing of drugs on a regular basis to patients for use off the
58 premises;

59 [(11)] (12) "Drug" means (A) an article recognized in the official
60 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of
61 the United States or official National Formulary, or any supplement to
62 any of them, (B) an article intended for use in the diagnosis, cure,
63 mitigation, treatment or prevention of disease in humans or other
64 animals, (C) an article, other than food, intended to affect the structure
65 or any function of the body of humans or any other animal, and (D) an
66 article intended for use as a component of any article specified in this
67 subdivision, but does not include a device;

68 [(12)] (13) "Institutional pharmacy" means that area within a care-
69 giving institution or within a correctional or juvenile training
70 institution, commonly known as the pharmacy, that is under the direct
71 charge of a pharmacist and in which drugs are stored and dispensed;

72 [(13)] (14) "Legend device" means a device that is required by
73 applicable federal or state law to be dispensed pursuant only to a
74 prescription or is restricted to use by prescribing practitioners only or
75 that, under federal law, is required to bear either of the following
76 legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES

77 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC
78 ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
79 FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

80 [(14)] (15) "Legend drug" means a drug that is required by any
81 applicable federal or state law to be dispensed pursuant only to a
82 prescription or is restricted to use by prescribing practitioners only, or
83 means a drug that, under federal law, is required to bear either of the
84 following legends: (A) "RX ONLY" IN ACCORDANCE WITH
85 GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND
86 COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS
87 DRUG FOR USE BY OR ON THE ORDER OF A LICENSED
88 VETERINARIAN.";

89 [(15)] (16) "Medical device and oxygen provider" means a person who
90 distributes devices or oxygen pursuant to a medical order or
91 prescription, except if such person already maintains an active
92 pharmacy license;

93 [(16)] (17) "Nonlegend device" means a device that is not a legend
94 device;

95 [(17)] (18) "Nonlegend drug" means a drug that is not a legend drug;

96 [(18)] (19) "Person" means an individual, corporation, business trust,
97 estate trust, partnership, association, joint venture or any other legal or
98 commercial entity;

99 [(19)] (20) "Pharmacist" means an individual who is licensed to
100 practice pharmacy under the provisions of section 20-590, 20-591, 20-592
101 or 20-593, and who is thereby recognized as a health care provider by
102 the state of Connecticut;

103 [(20)] (21) "Pharmacy" means a place of business where drugs and
104 devices may be sold at retail and for which a pharmacy license has been
105 issued to an applicant under the provisions of section 20-594;

106 [(21)] (22) "Pharmacy intern" means an individual registered under

107 the provisions of section 20-598;

108 [(22)] (23) "Pharmacy technician" means an individual who is
109 registered with the department and qualified in accordance with section
110 20-598a;

111 [(23)] (24) "Practice of pharmacy" or "to practice pharmacy" means the
112 sum total of knowledge, understanding, judgments, procedures,
113 securities, controls and ethics used by a pharmacist to assure optimal
114 safety and accuracy in the distributing, dispensing and use of drugs and
115 devices;

116 [(24)] (25) "Prescribing practitioner" means an individual licensed by
117 the state of Connecticut, any other state of the United States, the District
118 of Columbia, the Commonwealth of Puerto Rico or any territory or
119 insular possession subject to the jurisdiction of the United States who is
120 authorized to issue a prescription within the scope of the individual's
121 practice;

122 [(25)] (26) "Prescription" means a lawful order of a prescribing
123 practitioner transmitted either orally, in writing or by electronic means
124 for a drug or device for a specific patient;

125 [(26)] (27) "Sale" includes barter, exchange or gift or offer and each
126 such transaction made by a person whether as principal proprietor,
127 agent, servant or employee;

128 [(27)] (28) "Substitute" means to dispense without the prescribing
129 practitioner's express authorization a different drug product than the
130 drug product prescribed;

131 [(28)] (29) "Third-party logistics provider" means a person who
132 distributes drugs, devices or cosmetics while taking possession of the
133 drugs, devices or cosmetics but who does not take title of the drugs,
134 devices or cosmetics;

135 [(29)] (30) "Virtual manufacturer" means a person who engages in the
136 manufacture of drugs, devices or cosmetics for which such person: (A)

137 Owns the new drug application or abbreviated new drug application
138 number, if a prescription drug; (B) owns the unique device identification
139 number, as available, for a prescription device; (C) contracts with a
140 contract manufacturing organization for the physical manufacture of
141 the drugs, devices or cosmetics; (D) is not involved in the physical
142 manufacture of the drugs, devices or cosmetics; and (E) at no time takes
143 physical possession of or stores the drugs, devices or cosmetics; and

144 [(30)] (31) "Virtual wholesale distributor" means a person who
145 facilitates or brokers the transfer of drugs, devices or cosmetics without
146 taking physical possession of the drugs, devices or cosmetics.

147 Sec. 2. (NEW) (*Effective from passage*) (a) A pharmacy licensed
148 pursuant to section 20-594 of the general statutes that has a long-term
149 care classification, as defined in section 20-576-54 of the regulations of
150 state agencies, may operate an automated prescription dispensing
151 machine, as defined in section 20-571 of the general statutes, as amended
152 by this act, in a nursing home, as defined in section 19a-490 of the
153 general statutes, by a protocol approved in writing by the Department
154 of Consumer Protection, until such time as regulations are adopted
155 pursuant to subsection (b) of this section. The fee to operate an
156 automated prescription dispensing machine shall be one hundred
157 dollars per machine.

158 (b) The Commissioner of Consumer Protection shall adopt
159 regulations, in accordance with the provisions of chapter 54 of the
160 general statutes, to implement the provisions of subsection (a) of this
161 section.

162 Sec. 3. Section 21a-65 of the general statutes is repealed and the
163 following is substituted in lieu thereof (*Effective from passage*):

164 (a) A licensed manufacturer or licensed wholesaler may sell
165 hypodermic needles and syringes only to the following: (1) To a licensed
166 manufacturer, licensed wholesaler or licensed pharmacy; (2) to a
167 physician, dentist, veterinarian, embalmer, podiatrist or scientific
168 investigator licensed to practice in this state; (3) to a person in charge of

169 a care-giving institution, as defined in subdivision (2) of section 20-571,
170 as amended by this act, incorporated college or scientific institution, but
171 only for use by or in such care-giving institution, college or institution
172 for medical or scientific purposes; (4) to a person in charge of a licensed
173 or registered laboratory, but only for use in that laboratory for scientific
174 and medical purposes; (5) to a farmer but only for use on the farmer's
175 own animals or poultry; (6) to a business authorized in accordance with
176 the regulations adopted under section 21a-66 to purchase hypodermic
177 needles and syringes but only for legitimate industrial or medical use
178 within that business; and (7) to a syringe services program established
179 pursuant to section 19a-124.

180 (b) Except as provided in subsection (a) of this section, no licensed
181 manufacturer, licensed wholesaler or licensed pharmacist shall sell and
182 no person shall buy a hypodermic needle or syringe except upon a
183 prescription of a prescribing practitioner, as defined in subdivision (24)
184 of section 20-571, as amended by this act, in a quantity greater than ten.
185 Any such prescription shall be retained on file by the seller for a period
186 of not less than three years and shall be accessible to any public officer
187 engaged in the enforcement of this section. Such a prescription shall be
188 valid for one year from the date thereof and purchases and sales may be
189 made thereunder during such period, provided the seller shall confirm
190 the continued need for such sales with such practitioner at least every
191 six months if sales continue to be made thereunder. Hypodermic
192 needles and syringes in a quantity of ten or less without a prescription
193 may be provided or sold at retail only by the following: (1) By a
194 pharmacy licensed in accordance with section 20-594 and in such
195 pharmacy only by a licensed pharmacist or under his direct supervision;
196 (2) by a syringe services program established pursuant to section 19a-
197 124; and (3) by a health care facility or a licensed health care practitioner
198 for use by their own patients.

199 (c) A registered syringe service program established pursuant to
200 section 19a-124, with the approval of the department, may provide
201 access to not more than ten hypodermic needles and syringes per
202 transaction to program participants authorized by the department,

203 through a secured machine with the use of a patient-specific access
204 number, personalized magnetic strip card or any technology that
205 identifies an individual for the purpose of providing access to needles
206 and syringes. The secured machine shall prevent unauthorized access
207 and be immobile. Products provided by the secured machine shall
208 provide information on access to treatment services to assist individuals
209 obtaining products from the secured machine. The machine shall only
210 be placed in an area where contents can be stored within the
211 manufacturer's recommendation, unless the secured machine can
212 provide adequate environmental controls independent of the external
213 environment. A mechanism to accept syringes that have already been
214 used shall be available as part of the secured machine or in the area
215 around the secured machine.

216 [(c)] (d) Except as provided in subsection (c) of this section, [At] at all
217 locations where hypodermic needles and syringes are kept they shall be
218 stored in a manner so as to be available only to authorized personnel
219 and not be openly available to customers or patients. All used,
220 disposable hypodermic needles and used, disposable syringes shall be
221 destroyed. Destruction shall be conducted in a manner which renders
222 such needles and syringes nonrecoverable. Used needles and syringes
223 which have been discarded and are awaiting destruction shall be
224 securely safeguarded or rendered nonreusable.

225 [(d)] (e) Any person who violates any provision of this section shall
226 be fined not more than five hundred dollars or imprisoned not more
227 than one year or both.

228 Sec. 4. Section 20-571 of the general statutes is repealed and the
229 following is substituted in lieu thereof (*Effective from passage*):

230 As used in sections 20-570 to 20-630, inclusive, unless the context
231 otherwise requires:

232 (1) "Administer" means the direct application of a drug or device to
233 the body of a patient or research subject by injection, inhalation,
234 ingestion or any other means;

235 (2) "Care-giving institution" means an institution that provides
236 medical services and is licensed, operated, certified or approved by the
237 Commissioner of Public Health, the Commissioner of Developmental
238 Services or the Commissioner of Mental Health and Addiction Services;

239 (3) "Commission" means the Commission of Pharmacy appointed
240 under the provisions of section 20-572;

241 (4) "Commissioner" means the Commissioner of Consumer
242 Protection;

243 (5) "Compound" means to combine, mix or put together two or more
244 ingredients pursuant to a prescription and includes the preparation of
245 drugs or devices in anticipation of prescriptions based on routine,
246 regularly-observed prescribing patterns;

247 (6) "Correctional or juvenile training institution" means a facility for
248 the detention or incarceration of persons convicted or accused of crimes
249 or offenses or for training of delinquent juveniles, including those state
250 facilities under the jurisdiction of the Commissioner of Correction,
251 training schools for delinquent juveniles and any other facilities
252 operated by the state or municipalities for such detention, incarceration
253 or training;

254 (7) "Device" means instruments, apparatuses and contrivances,
255 including their components, parts and accessories, intended (A) for use
256 in the diagnosis, cure, mitigation, treatment or prevention of disease in
257 humans or other animals, or (B) to affect the structure or any function of
258 the body of humans or other animals, but does not mean contact lenses;

259 (8) "Department" means the Department of Consumer Protection;

260 (9) "Deprescribing" is the process of tapering, stopping,
261 discontinuing, or withdrawing medications, with the goal of managing
262 polypharmacy and improving outcomes for the patient;

263 [(9)] (10) "Dispense" means those acts of processing a drug or device
264 for delivery or for administration for a patient pursuant to a prescription

265 consisting of: (A) Comparing the directions on the label with the
266 directions on the prescription to determine accuracy; (B) the selection of
267 the drug or device from stock to fill the prescription; (C) the counting,
268 measuring, compounding or preparation of the drug or device; (D) the
269 placing of the drug or device in the proper container; (E) the affixing of
270 the label to the container; and (F) the addition to a written prescription
271 of any required notations. "Dispense" does not include the acts of
272 delivering a drug or device to a patient or of administering the drug or
273 device to the patient;

274 [(10)] (11) "Dispensing outpatient facility" means a facility operated
275 by a corporation or municipality which provides medical services to
276 patients on an outpatient basis and which maintains stocks of drugs for
277 dispensing of drugs on a regular basis to patients for use off the
278 premises;

279 [(11)] (12) "Drug" means (A) an article recognized in the official
280 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of
281 the United States or official National Formulary, or any supplement to
282 any of them, (B) an article intended for use in the diagnosis, cure,
283 mitigation, treatment or prevention of disease in humans or other
284 animals, (C) an article, other than food, intended to affect the structure
285 or any function of the body of humans or any other animal, and (D) an
286 article intended for use as a component of any article specified in this
287 subdivision, but does not include a device;

288 [(12)] (13) "Institutional pharmacy" means that area within a care-
289 giving institution or within a correctional or juvenile training
290 institution, commonly known as the pharmacy, that is under the direct
291 charge of a pharmacist and in which drugs are stored and dispensed;

292 [(13)] (14) "Legend device" means a device that is required by
293 applicable federal or state law to be dispensed pursuant only to a
294 prescription or is restricted to use by prescribing practitioners only or
295 that, under federal law, is required to bear either of the following
296 legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES

297 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC
298 ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
299 FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

300 [(14)] (15) "Legend drug" means a drug that is required by any
301 applicable federal or state law to be dispensed pursuant only to a
302 prescription or is restricted to use by prescribing practitioners only, or
303 means a drug that, under federal law, is required to bear either of the
304 following legends: (A) "RX ONLY" IN ACCORDANCE WITH
305 GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND
306 COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS
307 DRUG FOR USE BY OR ON THE ORDER OF A LICENSED
308 VETERINARIAN.";

309 [(15)] (16) "Medical device and oxygen provider" means a person who
310 distributes devices or oxygen pursuant to a medical order or
311 prescription, except if such person already maintains an active
312 pharmacy license;

313 (17) "Medication reconciliation" means a process of comparing the
314 medications a patient is taking and should be taking with newly ordered
315 medications. The comparison addresses duplications, omissions, and
316 interactions, and the need to continue current medications. The type of
317 information that clinicians use to reconcile medications include, but are
318 not limited to, medication name, dose, frequency, route of
319 administration and purpose;

320 [(16)] (18) "Nonlegend device" means a device that is not a legend
321 device;

322 [(17)] (19) "Nonlegend drug" means a drug that is not a legend drug;

323 [(18)] (20) "Person" means an individual, corporation, business trust,
324 estate trust, partnership, association, joint venture or any other legal or
325 commercial entity;

326 [(19)] (21) "Pharmacist" means an individual who is licensed to

327 practice pharmacy under the provisions of section 20-590, 20-591, 20-592
328 or 20-593, and who is thereby recognized as a health care provider by
329 the state of Connecticut;

330 [(20)] (22) "Pharmacy" means a place of business where drugs and
331 devices may be sold at retail and for which a pharmacy license has been
332 issued to an applicant under the provisions of section 20-594;

333 [(21)] (23) "Pharmacy intern" means an individual registered under
334 the provisions of section 20-598;

335 [(22)] (24) "Pharmacy technician" means an individual who is
336 registered with the department and qualified in accordance with section
337 20-598a;

338 (25) "Polypharmacy" means the simultaneous use of multiple drugs
339 by a patient to treat one or more ailments or conditions;

340 [(23)] (26) "Practice of pharmacy" or "to practice pharmacy" means the
341 sum total of knowledge, understanding, judgments, procedures,
342 securities, controls and ethics used by a pharmacist to assure optimal
343 safety and accuracy in the distributing, dispensing and use of drugs and
344 devices;

345 [(24)] (27) "Prescribing practitioner" means an individual licensed by
346 the state of Connecticut, any other state of the United States, the District
347 of Columbia, the Commonwealth of Puerto Rico or any territory or
348 insular possession subject to the jurisdiction of the United States who is
349 authorized to issue a prescription within the scope of the individual's
350 practice;

351 [(25)] (28) "Prescription" means a lawful order of a prescribing
352 practitioner transmitted either orally, in writing or by electronic means
353 for a drug or device for a specific patient;

354 [(26)] (29) "Sale" includes barter, exchange or gift or offer and each
355 such transaction made by a person whether as principal proprietor,
356 agent, servant or employee;

357 [(27)] (30) "Substitute" means to dispense without the prescribing
358 practitioner's express authorization a different drug product than the
359 drug product prescribed;

360 [(28)] (31) "Third-party logistics provider" means a person who
361 distributes drugs, devices or cosmetics while taking possession of the
362 drugs, devices or cosmetics but who does not take title of the drugs,
363 devices or cosmetics;

364 [(29)] (32) "Virtual manufacturer" means a person who engages in the
365 manufacture of drugs, devices or cosmetics for which such person: (A)
366 Owns the new drug application or abbreviated new drug application
367 number, if a prescription drug; (B) owns the unique device identification
368 number, as available, for a prescription device; (C) contracts with a
369 contract manufacturing organization for the physical manufacture of
370 the drugs, devices or cosmetics; (D) is not involved in the physical
371 manufacture of the drugs, devices or cosmetics; and (E) at no time takes
372 physical possession of or stores the drugs, devices or cosmetics; and

373 [(30)] (33) "Virtual wholesale distributor" means a person who
374 facilitates or brokers the transfer of drugs, devices or cosmetics without
375 taking physical possession of the drugs, devices or cosmetics.

376 Sec. 5. Section 20-631 of the general statutes is repealed and the
377 following is substituted in lieu thereof (*Effective from passage*):

378 (a) Except as provided in section 20-631b, one or more pharmacists
379 licensed under this chapter who are determined competent in
380 accordance with regulations adopted pursuant to subsection (d) of this
381 section may enter into a written protocol-based collaborative drug
382 therapy management agreement with one or more physicians licensed
383 under chapter 370 or advanced practice registered nurses licensed
384 under chapter 378 to manage the drug therapy of individual patients. In
385 order to enter into a written protocol-based collaborative drug therapy
386 management agreement, such physician or advanced practice registered
387 nurse shall have established a provider-patient relationship with the
388 patient who will receive collaborative drug therapy. Each patient's

389 collaborative drug therapy management shall be governed by a written
390 protocol [specific to that patient] which may include guideline directed
391 management established by the treating physician or advanced practice
392 registered nurse in consultation with the pharmacist. For purposes of
393 this subsection, a "provider-patient relationship" is a relationship based
394 on (1) the patient making a medical complaint, (2) the patient providing
395 a medical history, (3) the patient receiving a physical examination, and
396 (4) a logical connection existing between the medical complaint, the
397 medical history, the physical examination and any drug prescribed for
398 the patient.

399 (b) A collaborative drug therapy management agreement may
400 authorize a pharmacist to implement, modify, continue or discontinue
401 a drug therapy that has been prescribed for a patient, order associated
402 laboratory tests and administer drugs, all in accordance with a patient-
403 specific written protocol. The agreement may specifically address issues
404 that may arise during a medication reconciliation and concerns related
405 to polypharmacy that enable an authorized pharmacist to implement,
406 modify, continue or discontinue drug therapy. In instances where drug
407 therapy is discontinued or deprescribed, the pharmacist shall notify the
408 treating physician or advanced practice registered nurse of such
409 discontinuance no later than twenty-four hours from the time of such
410 discontinuance. Each protocol developed, pursuant to the collaborative
411 drug therapy management agreement, shall contain detailed direction
412 concerning the actions that the pharmacist may perform for that patient.
413 The protocol shall include, but need not be limited to, (1) the specific
414 drug or drugs to be managed by the pharmacist, (2) the terms and
415 conditions under which drug therapy may be implemented, modified
416 or discontinued, (3) the conditions and events upon which the
417 pharmacist is required to notify the physician or advanced practice
418 registered nurse, and (4) the laboratory tests that may be ordered. All
419 activities performed by the pharmacist in conjunction with the protocol
420 shall be documented in the patient's medical record. The pharmacist
421 shall report [at least every] any encounters within the scope of the
422 collaborative drug therapy management agreement within thirty days

423 to the physician or advanced practice registered nurse regarding the
424 patient's drug therapy management or document such information
425 within a shared medical record. The collaborative drug therapy
426 management agreement and protocols shall be available for inspection
427 by the Departments of Public Health and Consumer Protection. A copy
428 of the protocol shall be filed in the patient's medical record.

429 (c) A pharmacist shall be responsible for demonstrating, in
430 accordance with regulations adopted pursuant to subsection (d) of this
431 section, the competence necessary for participation in each drug therapy
432 management agreement into which such pharmacist enters.

433 (d) The Commissioner of Consumer Protection, in consultation with
434 the Commissioner of Public Health, shall adopt regulations, in
435 accordance with chapter 54, concerning competency requirements for
436 participation in a written protocol-based collaborative drug therapy
437 management agreement described in subsection (a) of this section, the
438 minimum content of the collaborative drug therapy management
439 agreement and the written protocol and such other matters said
440 commissioners deem necessary to carry out the purpose of this section.

441 Sec. 6. Subsection (j) of section 21a-254 of the general statutes is
442 repealed and the following is substituted in lieu thereof (*Effective from*
443 *passage*):

444 (j) (1) The commissioner shall, within available appropriations,
445 establish an electronic prescription drug monitoring program to collect,
446 by electronic means, prescription information for schedules II, III, IV
447 and V controlled substances that are dispensed by pharmacies,
448 nonresident pharmacies, as defined in section 20-627, outpatient
449 pharmacies in hospitals or institutions or by any other dispenser,
450 including, but not limited to, the federal Substance Abuse and Mental
451 Health Services Administration certified substance use disorder clinics.
452 The program shall be designed to provide information regarding the
453 prescription of controlled substances in order to prevent the improper
454 or illegal use of the controlled substances and shall not infringe on the

455 legitimate prescribing of a controlled substance by a prescribing
456 practitioner acting in good faith and in the course of professional
457 practice.

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

461 (3) Prior to July 1, 2016, each pharmacy, nonresident pharmacy, as
462 defined in section 20-627, outpatient pharmacy in a hospital or
463 institution and dispenser shall report to the commissioner, at least
464 weekly, by electronic means or, if a pharmacy or outpatient pharmacy
465 does not maintain records electronically, in a format approved by the
466 commissioner, the following information for all controlled substance
467 prescriptions dispensed by such pharmacy or outpatient pharmacy: (A)
468 Dispenser identification number; (B) the date the prescription for the
469 controlled substance was filled; (C) the prescription number; (D)
470 whether the prescription for the controlled substance is new or a refill;
471 (E) the national drug code number for the drug dispensed; (F) the
472 amount of the controlled substance dispensed and the number of days'
473 supply of the controlled substance; (G) a patient identification number;
474 (H) the patient's first name, last name and street address, including
475 postal code; (I) the date of birth of the patient; (J) the date the
476 prescription for the controlled substance was issued by the prescribing
477 practitioner and the prescribing practitioner's Drug Enforcement
478 Agency's identification number; and (K) the type of payment.

479 (4) (A) Except as provided in this subdivision, on and after July 1,
480 2016, each pharmacy, nonresident pharmacy, as defined in section 20-
481 627, outpatient pharmacy in a hospital or institution, and dispenser shall
482 report to the commissioner by electronic means, in a format approved
483 by the commissioner, the following information for all controlled
484 substance prescriptions dispensed by such pharmacy or outpatient
485 pharmacy immediately upon, but in no event later than the next
486 business day after, dispensing such prescriptions: (i) Dispenser
487 identification number; (ii) the date the prescription for the controlled

488 substance was filled; (iii) the prescription number; (iv) whether the
489 prescription for the controlled substance is new or a refill; (v) the
490 national drug code number for the drug dispensed; (vi) the amount of
491 the controlled substance dispensed and the number of days' supply of
492 the controlled substance; (vii) a patient identification number; (viii) the
493 patient's first name, last name and street address, including postal code;
494 (ix) the date of birth of the patient; (x) the date the prescription for the
495 controlled substance was issued by the prescribing practitioner and the
496 prescribing practitioner's Drug Enforcement Agency's identification
497 number; and (xi) the type of payment.

498 (B) If the electronic prescription drug monitoring program is not
499 operational, such pharmacy or dispenser shall report the information
500 described in this subdivision not later than the next business day after
501 regaining access to such program. For purposes of this subdivision,
502 "business day" means any day during which the pharmacy is open to
503 the public.

504 (C) Each veterinarian, licensed pursuant to chapter 384, who
505 dispenses a controlled substance prescription shall report to the
506 commissioner the information described in subparagraph (A) of this
507 subdivision, at least weekly, by electronic means or, if the veterinarian
508 does not maintain records electronically, in a format approved by the
509 commissioner.

510 (5) The commissioner may contract with a vendor for purposes of
511 electronically collecting such controlled substance prescription
512 information. The commissioner and any such vendor shall maintain the
513 information in accordance with the provisions of chapter 400j.

514 (6) The commissioner and any such vendor shall not disclose
515 controlled substance prescription information reported pursuant to
516 subdivisions (3) and (4) of this subsection, except as authorized
517 pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Any
518 person who knowingly violates any provision of this subdivision or
519 subdivision (5) of this subsection shall be guilty of a class D felony.

520 (7) The commissioner shall provide, upon request, controlled
521 substance prescription information obtained in accordance with
522 subdivisions (3) and (4) of this subsection to the following: (A) The
523 prescribing practitioner or such practitioner's authorized agent, who is
524 treating or has treated a specific patient, provided the information is
525 obtained for purposes related to the treatment of the patient, including
526 the monitoring of controlled substances obtained by the patient; (B) the
527 prescribing practitioner with whom a patient has made contact for the
528 purpose of seeking medical treatment or such practitioner's authorized
529 agent, provided the request is accompanied by a written consent, signed
530 by the prospective patient, for the release of controlled substance
531 prescription information; or (C) the pharmacist who is dispensing
532 controlled substances for a patient, or such pharmacist's authorized
533 pharmacy technician, provided the information is obtained for purposes
534 related to the scope of the pharmacist's practice and management of the
535 patient's drug therapy, including the monitoring of controlled
536 substances obtained by the patient. The prescribing practitioner, such
537 practitioner's authorized agent, the pharmacist or such pharmacist's
538 authorized pharmacy technician shall submit a written and signed
539 request to the commissioner for controlled substance prescription
540 information. Such prescribing practitioner, pharmacist or pharmacist's
541 authorized pharmacy technician shall not disclose any such request
542 except as authorized pursuant to sections 20-570 to 20-630, inclusive, or
543 sections 21a-240 to 21a-283, inclusive.

544 (8) No person or employer shall prohibit, discourage or impede a
545 prescribing practitioner, pharmacist or pharmacist's authorized
546 pharmacy technician from requesting controlled substance prescription
547 information pursuant to this subsection.

548 (9) Prior to prescribing greater than a seventy-two-hour supply of any
549 controlled substance to any patient, the prescribing practitioner or such
550 practitioner's authorized agent shall review the patient's records in the
551 electronic prescription drug monitoring program established pursuant
552 to this subsection. Whenever a prescribing practitioner prescribes a
553 controlled substance, other than a schedule V nonnarcotic controlled

554 substance, for the continuous or prolonged treatment of any patient,
555 such prescriber, or such prescriber's authorized agent, shall review, not
556 less than once every ninety days, the patient's records in such
557 prescription drug monitoring program. Whenever a prescribing
558 practitioner prescribes a schedule V nonnarcotic controlled substance,
559 for the continuous or prolonged treatment of any patient, such
560 prescribing practitioner, or such prescribing practitioner's authorized
561 agent, shall review, not less than annually, the patient's records in such
562 prescription drug monitoring program. If such electronic prescription
563 drug monitoring program is not operational, such prescribing
564 practitioner may prescribe greater than a seventy-two-hour supply of a
565 controlled substance to a patient during the time of such program's
566 inoperability, provided such prescribing practitioner or such authorized
567 agent reviews the records of such patient in such program not more than
568 twenty-four hours after regaining access to such program.

569 (10) (A) A prescribing practitioner may designate an authorized
570 agent to review the electronic prescription drug monitoring program
571 and patient controlled substance prescription information on behalf of
572 the prescribing practitioner. The prescribing practitioner shall ensure
573 that any authorized agent's access to such program and patient
574 controlled substance prescription information is limited to the purposes
575 described in this section and occurs in a manner that protects the
576 confidentiality of information that is accessed through such program.
577 The prescribing practitioner and any authorized agent shall be subject
578 to the provisions of 45 CFR 164.308, as amended from time to time,
579 concerning administrative safeguards for the protection of electronic
580 protected health information. A prescribing practitioner may be subject
581 to disciplinary action for acts of the authorized agent as provided in
582 section 21a-322.

583 (B) Notwithstanding the provisions of subparagraph (A) of this
584 subdivision, a prescribing practitioner who is employed by or provides
585 professional services to a hospital shall, prior to designating an
586 authorized agent to review the electronic prescription drug monitoring
587 program and patient controlled substance prescription information on

588 behalf of the prescribing practitioner, (i) submit a request to designate
589 one or more authorized agents for such purposes and a written protocol
590 for oversight of the authorized agent or agents to the commissioner, in
591 the form and manner prescribed by the commissioner, and (ii) receive
592 the commissioner's approval to designate such authorized agent or
593 agents and of such written protocol. Such written protocol shall
594 designate either the hospital's medical director, a hospital department
595 head, who is a prescribing practitioner, or another prescribing
596 practitioner as the person responsible for ensuring that the authorized
597 agent's or agents' access to such program and patient controlled
598 substance prescription information is limited to the purposes described
599 in this section and occurs in a manner that protects the confidentiality
600 of information that is accessed through such program. A hospital
601 medical director, a hospital department head, who is a prescribing
602 practitioner, or another prescribing practitioner designated as the
603 person responsible for overseeing an authorized agent's or agents'
604 access to such program and information in the written protocol
605 approved by the commissioner may be subject to disciplinary action for
606 acts of the authorized agent or agents as provided in section 21a-322.
607 The commissioner may inspect hospital records to determine
608 compliance with written protocols approved in accordance with this
609 section.

610 (C) A pharmacist may designate a pharmacy technician to access the
611 electronic prescription drug monitoring program and patient controlled
612 substance prescription information on behalf of the pharmacist only for
613 the purposes of facilitating the pharmacist's review of such patient
614 information. The pharmacist shall ensure that any such pharmacy
615 technician's access to such program and patient controlled substance
616 prescription information is limited to the purposes described in this
617 section and occurs in a manner that protects the confidentiality of
618 information that is accessed through such program. The pharmacist and
619 any authorized pharmacy technician shall be subject to the provisions
620 of 45 CFR 164.308, as amended from time to time, concerning
621 administrative safeguards for the protection of electronic protected

622 health information. A pharmacist may be subject to disciplinary action
623 for acts of the authorized pharmacy technician.

624 (D) Prior to designating a pharmacy technician to access the
625 electronic prescription drug monitoring program and patient controlled
626 substance prescription information on behalf of the pharmacist, the
627 supervising pharmacist shall provide training for the authorized
628 pharmacy technicians. Such training shall designate a pharmacist as the
629 person responsible for ensuring that the authorized pharmacy
630 technician's access to such program and patient controlled substance
631 prescription information is limited to the purposes described in this
632 section and occurs in a manner that protects the confidentiality of
633 information that is accessed through such program. A pharmacist
634 designated as the person responsible for overseeing the pharmacy
635 technician's access to such program may be subject to disciplinary action
636 for acts of the authorized pharmacy technician. The commissioner may
637 inspect records to document pharmacy technician training, that
638 pharmacy technicians have access to the program and that patient
639 controlled substance prescription information has been limited in
640 accordance with the provisions of this section.

641 (11) The commissioner shall adopt regulations, in accordance with
642 chapter 54, concerning the reporting, evaluation, management and
643 storage of electronic controlled substance prescription information.

644 (12) The provisions of this section shall not apply to (A) samples of
645 controlled substances dispensed by a physician to a patient, or (B) any
646 controlled substances dispensed to hospital inpatients.

647 (13) The provisions of this section shall not apply to any institutional
648 pharmacy or pharmacist's drug room operated by a facility, licensed
649 under section 19a-495 and regulations adopted pursuant to said section
650 19a-495, that dispenses or administers directly to a patient an opioid
651 agonist for treatment of a substance use disorder.

652 (14) The commissioner may provide controlled substance
653 prescription information obtained in accordance with subdivisions (3)

654 and (4) of this subsection to other state agencies, pursuant to an
 655 agreement between the commissioner and the head of such agency,
 656 provided the information is obtained for a study of disease prevention
 657 and control related to opioid abuse or the study of morbidity and
 658 mortality caused by overdoses of controlled substances. The provision
 659 of such information shall be in accordance with all applicable state and
 660 federal confidentiality requirements.

661 (15) Nothing in this section shall prohibit a prescribing practitioner
 662 or such prescribing practitioner's authorized agent from disclosing
 663 controlled substance prescription information submitted pursuant to
 664 subdivisions (3) and (4) of this subsection to the Department of Social
 665 Services for the purposes of administering any of said department's
 666 medical assistance programs.

667 (16) Each pharmacy, nonresident pharmacy, as defined in section 20-
 668 627, outpatient pharmacy in a hospital or institution, and dispenser shall
 669 report to the commissioner, at least daily, by electronic means or, if a
 670 pharmacy or outpatient pharmacy does not maintain records
 671 electronically, in a format approved by the commissioner information
 672 for all insulin drugs, glucagon drugs, diabetes devices and diabetic
 673 ketoacidosis devices prescribed and dispensed by such pharmacy or
 674 outpatient pharmacy. Such pharmacy or outpatient pharmacy shall
 675 report such information to the commissioner in a manner that is
 676 consistent with the manner in which such pharmacy or outpatient
 677 pharmacy reports information for controlled substance prescriptions
 678 pursuant to subdivision (4) of this subsection. For the purposes of this
 679 subdivision, "insulin drug", "glucagon drug", "diabetes devices" and
 680 "diabetic ketoacidosis device" have the same meanings as provided in
 681 section 20-616.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	20-571
Sec. 2	<i>from passage</i>	New section
Sec. 3	<i>from passage</i>	21a-65

Sec. 4	<i>from passage</i>	20-571
Sec. 5	<i>from passage</i>	20-631
Sec. 6	<i>from passage</i>	21a-254(j)

Statement of Purpose:

To make changes to various pharmacy statutes.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]