



# Senate

General Assembly

**File No. 89**

February Session, 2024

Substitute Senate Bill No. 133

*Senate, March 25, 2024*

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

## ***AN ACT CONCERNING REGULATION OF PRESCRIPTION DRUGS AND RELATED PROFESSIONS.***

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

1 Section 1. Section 20-571 of the 2024 supplement to the general  
2 statutes is repealed and the following is substituted in lieu thereof  
3 (*Effective October 1, 2024*):

4 As used in this chapter and sections 2 to 4, inclusive, of this act, unless  
5 the context otherwise requires:

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

9 (2) "Advanced pharmacy technician" means a pharmacy technician  
10 who receives an endorsement from the department and is qualified in  
11 accordance with section 2 of this act;

12 [(2)] (3) "Automated prescription dispensing machine" means a

13 device and associated software operated by a pharmacy or a pharmacy  
14 that is registered as a nonresident pharmacy pursuant to section 20-627,  
15 in a nursing home or skilled nursing facility licensed pursuant to  
16 sections 19a-490 and 19a-491, that packages and labels patient-specific  
17 medication or multiple medications for the purposes of administration  
18 by a registered nurse or a licensed practical nurse based on a  
19 prescription that has completed final verification by a licensed  
20 pharmacist;

21 [(3)] (4) "Care-giving institution" means an institution that provides  
22 medical services and is licensed, operated, certified or approved by the  
23 Commissioner of Public Health, the Commissioner of Developmental  
24 Services or the Commissioner of Mental Health and Addiction Services;

25 (5) "Clerk" means an individual who is: (A) Registered with the  
26 department to work in a pharmacy or institutional pharmacy in  
27 accordance with section 3 of this act; and (B) not involved in (i) order  
28 entry, (ii) the dispensing process, or (iii) preparing a prescription for  
29 final verification;

30 [(4)] (6) "Commission" means the Commission of Pharmacy  
31 appointed under the provisions of section 20-572;

32 [(5)] (7) "Commissioner" means the Commissioner of Consumer  
33 Protection;

34 (8) "Compatible drugs" means two or more drugs that are not  
35 contraindicated, or adversely impacted in constitution or quality, by  
36 each other;

37 (9) "Compliance packaging" means packaging that: (A) Bears an  
38 identification number; (B) is for dispensing drugs; (C) separates drugs  
39 into individual compartments by dose; and (D) is prepared at a  
40 pharmacy to assist a patient in administering doses of drugs that have  
41 been prescribed to the patient;

42 [(6)] (10) "Compound" means to combine, mix or put together two or  
43 more ingredients pursuant to a prescription and includes the

44 preparation of drugs or devices in anticipation of prescriptions based on  
45 routine, regularly-observed prescribing patterns;

46 [(7)] (11) "Correctional or juvenile training institution" means a  
47 facility for the detention or incarceration of persons convicted or  
48 accused of crimes or offenses or for training of delinquent juveniles,  
49 including those state facilities under the jurisdiction of the  
50 Commissioner of Correction, training schools for delinquent juveniles  
51 and any other facilities operated by the state or municipalities for such  
52 detention, incarceration or training;

53 [(8)] (12) "Device" means instruments, apparatuses and contrivances,  
54 including their components, parts and accessories, intended: (A) For use  
55 in the diagnosis, cure, mitigation, treatment or prevention of disease in  
56 humans or other animals; or (B) to affect the structure or any function of  
57 the body of humans or other animals, but does not mean contact lenses;

58 [(9)] (13) "Department" means the Department of Consumer  
59 Protection;

60 [(10)] (14) "Deprescribing" means the systematic process of  
61 identifying and discontinuing drugs in instances in which existing or  
62 potential harms outweigh existing or potential benefits within the  
63 context of an individual patient's care goals, current level of functioning,  
64 life expectancy, values and preferences;

65 (15) "Direct supervision" means supervision of another individual by  
66 a pharmacist who: (A) Is physically present in an area or at a location  
67 while routine drug dispensing functions are performed in such area or  
68 at such location; and (B) conducts in-process and final performance  
69 checks;

70 [(11)] (16) "Dispense" means those acts of processing a drug or device  
71 for delivery or for administration for a patient pursuant to a prescription  
72 consisting of: (A) Comparing the directions on the label with the  
73 directions on the prescription to determine accuracy; (B) the selection of  
74 the drug or device from stock to fill the prescription; (C) the counting,

75 measuring, compounding or preparation of the drug or device; (D) the  
76 placing of the drug or device in the proper container; (E) the affixing of  
77 the label to the container; and (F) the addition to a written prescription  
78 of any required notations. "Dispense" does not include the acts of  
79 delivering a drug or device to a patient or of administering the drug or  
80 device to the patient;

81 [(12)] (17) "Dispensing outpatient facility" means a facility operated  
82 by a corporation or municipality which provides medical services to  
83 patients on an outpatient basis and which maintains stocks of drugs for  
84 dispensing of drugs on a regular basis to patients for use off the  
85 premises;

86 [(13)] (18) "Drug" means: (A) An article recognized in the official  
87 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of  
88 the United States or official National Formulary, or any supplement to  
89 any of them; (B) an article intended for use in the diagnosis, cure,  
90 mitigation, treatment or prevention of disease in humans or other  
91 animals; (C) an article, other than food, intended to affect the structure  
92 or any function of the body of humans or any other animal; and (D) an  
93 article intended for use as a component of any article specified in this  
94 subdivision, but does not include a device;

95 (19) "Drug utilization review": (A) Means an authorized and  
96 structured review of a pharmacist's prescribing, dispensing and drug  
97 utilization activities, before, during and after the pharmacist dispenses  
98 a drug pursuant to a prescription, to ensure appropriate decision-  
99 making concerning the drug and a positive patient outcome; and (B)  
100 includes, but is not limited to, prospective and retrospective utilization  
101 reviews required under the Omnibus Budget Reconciliation Act of 1990,  
102 P.L. 101-508, as amended from time to time;

103 [(14)] (20) "Health care institution" means institution, as defined in  
104 section 19a-490;

105 [(15)] (21) "Health care institutional pharmacy" means an institutional  
106 pharmacy located within a health care institution;

107 [(16)] (22) "Institutional pharmacy" means that area within a care-  
108 giving institution or within a correctional or juvenile training  
109 institution, commonly known as the pharmacy, that is under the direct  
110 charge of a pharmacist and in which drugs are stored and dispensed;

111 [(17)] (23) "Legend device" means a device that is required by  
112 applicable federal or state law to be dispensed pursuant only to a  
113 prescription or is restricted to use by prescribing practitioners only or  
114 that, under federal law, is required to bear either of the following  
115 legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES  
116 ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC  
117 ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE  
118 FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

119 [(18)] (24) "Legend drug" means a drug that is required by any  
120 applicable federal or state law to be dispensed pursuant only to a  
121 prescription or is restricted to use by prescribing practitioners only, or  
122 means a drug that, under federal law, is required to bear either of the  
123 following legends: (A) "RX ONLY" IN ACCORDANCE WITH  
124 GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND  
125 COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS  
126 DRUG FOR USE BY OR ON THE ORDER OF A LICENSED  
127 VETERINARIAN.";

128 [(19)] (25) "Medical device and oxygen provider" means a person who  
129 distributes devices or oxygen pursuant to a medical order or  
130 prescription, except if such person already maintains an active  
131 pharmacy license;

132 [(20)] (26) "Medication reconciliation" means a process of comparing  
133 the medications a patient is taking and should be taking with newly  
134 ordered medications: (A) For the purpose of addressing duplications,  
135 omissions and interactions and the need to continue current  
136 medications; and (B) by looking at information such as the medication  
137 name, dose, frequency, route of administration and purpose;

138 [(21)] (27) "Nonlegend device" means a device that is not a legend

139 device;

140 [(22)] (28) "Nonlegend drug" means a drug that is not a legend drug;

141 [(23)] (29) "Nonresident pharmacy" has the same meaning as  
142 provided in section 20-627;

143 (30) "Order entry" means the process by which pharmacy personnel  
144 enter into a pharmacy software system prescription data, including, but  
145 not limited to: (A) Patient demographic data; (B) drug name and  
146 strength; (C) drug quantity; (D) directions for use; (E) the number of  
147 authorized refills, including, but not limited to, any use of "PRN" or "ad  
148 lib" in lieu of a specific number of authorized refills; and (F) any required  
149 cautionary statement;

150 (31) "Patient" means a human or other animal who receives any  
151 health care service from a health care provider for treatment of a current  
152 or future medical condition;

153 [(24)] (32) "Person" means an individual, corporation, business trust,  
154 estate trust, partnership, association, joint venture or any other legal or  
155 commercial entity;

156 [(25)] (33) "Pharmacist" means an individual who is licensed to  
157 practice pharmacy under the provisions of section 20-590, 20-591, 20-592  
158 or 20-593, and who is thereby recognized as a health care provider by  
159 the state of Connecticut;

160 [(26)] (34) "Pharmacy" means a place of business where drugs and  
161 devices may be sold at retail and for which a pharmacy license has been  
162 issued to an applicant under the provisions of section 20-594;

163 [(27)] (35) "Pharmacy intern" means an individual registered under  
164 the provisions of section 20-598;

165 (36) "Pharmacy software system" means the computer software and  
166 programming that a pharmacy uses to log and verify prescription  
167 information, including, but not limited to, any data required to be

168 collected and maintained under any applicable law or regulation;

169 [(28)] (37) "Pharmacy technician" means an individual who is  
170 registered with the department and qualified in accordance with section  
171 20-598a, as amended by this act;

172 [(29)] (38) "Polypharmacy" means the use of multiple drugs by a  
173 patient, including any medication that is inappropriate or not medically  
174 necessary, such as those not indicated, not effective or constituting a  
175 therapeutic duplication;

176 [(30)] (39) "Practice of pharmacy" or "to practice pharmacy" means the  
177 sum total of knowledge, understanding, judgments, procedures,  
178 securities, controls and ethics used by a pharmacist to assure optimal  
179 safety and accuracy in the distributing, dispensing and use of drugs and  
180 devices;

181 [(31)] (40) "Prescribing practitioner" means an individual licensed by  
182 the state of Connecticut, any other state of the United States, the District  
183 of Columbia, the Commonwealth of Puerto Rico or any territory or  
184 insular possession subject to the jurisdiction of the United States who is  
185 authorized to issue a prescription within the scope of the individual's  
186 practice;

187 [(32)] (41) "Prescription" means a lawful order of a prescribing  
188 practitioner transmitted either orally, in writing or by electronic means  
189 for a drug or device for a specific patient;

190 [(33)] (42) "Sale" includes barter, exchange or gift or offer and each  
191 such transaction made by a person whether as principal proprietor,  
192 agent, servant or employee;

193 [(34)] (43) "Substitute" means to dispense without the prescribing  
194 practitioner's express authorization a different drug product than the  
195 drug product prescribed;

196 [(35)] (44) "Third-party logistics provider" means a person who  
197 distributes drugs, devices or cosmetics while taking possession of the

198 drugs, devices or cosmetics but who does not take title of the drugs,  
199 devices or cosmetics;

200 [(36)] (45) "Virtual manufacturer" means a person who engages in the  
201 manufacture of drugs, devices or cosmetics for which such person: (A)  
202 Owns the new drug application or abbreviated new drug application  
203 number, if a prescription drug; (B) owns the unique device identification  
204 number, as available, for a prescription device; (C) contracts with a  
205 contract manufacturing organization for the physical manufacture of  
206 the drugs, devices or cosmetics; (D) is not involved in the physical  
207 manufacture of the drugs, devices or cosmetics; and (E) at no time takes  
208 physical possession of or stores the drugs, devices or cosmetics; and

209 [(37)] (46) "Virtual wholesale distributor" means a person who  
210 facilitates or brokers the transfer of drugs, devices or cosmetics without  
211 taking physical possession of the drugs, devices or cosmetics.

212 Sec. 2. (NEW) (*Effective October 1, 2024*) (a) (1) No individual may  
213 perform the duties of an advanced pharmacy technician, including, but  
214 not limited to, dispensing to patients compatible drugs in compliance  
215 packaging under section 4 of this act, unless such individual is a  
216 pharmacy technician who applies for and receives an advanced  
217 pharmacy technician endorsement in accordance with the provisions of  
218 this section.

219 (2) Each advanced pharmacy technician endorsement issued under  
220 this section shall be in a form and manner prescribed by the department,  
221 shall be valid for one year and may be renewed for successive one-year  
222 periods upon application in the manner set forth in this section.

223 (b) The department shall issue an advanced pharmacy technician  
224 endorsement to a pharmacy technician who:

225 (1) Submits to the department, in a form and manner prescribed by  
226 the department, an application for an endorsement as an advanced  
227 pharmacy technician under this section;

228 (2) Is actively registered and qualified as a pharmacy technician in



229 accordance with section 20-598a of the general statutes, as amended by  
230 this act;

231 (3) Was continuously registered as a pharmacy technician in  
232 accordance with section 20-598a of the general statutes, as amended by  
233 this act, for the three-year period immediately preceding the date on  
234 which such pharmacy technician applies for an advanced pharmacy  
235 technician endorsement under this section;

236 (4) Continuously held a certification from the Pharmacy Technician  
237 Certification Board, or any other equivalent pharmacy technician  
238 certification program approved by the department, for the three-year  
239 period immediately preceding the date on which such pharmacy  
240 technician applies for an advanced pharmacy technician endorsement  
241 under this section, and maintains such certification in good standing;

242 (5) Successfully completed (A) an educational course, during the one-  
243 year period immediately preceding the date on which such pharmacy  
244 technician applies for an advanced pharmacy technician endorsement  
245 under this section, that is accredited by the Accreditation Council for  
246 Pharmacy Education or another appropriate national accrediting body,  
247 and (B) a competency assessment performed by a pharmacist in  
248 accordance with requirements established by the commissioner in  
249 regulations adopted pursuant to subsection (e) of this section;

250 (6) Works under the direct supervision of a pharmacist who satisfies  
251 the requirements established in subsection (c) of this section; and

252 (7) Is employed by a pharmacy or institutional pharmacy that  
253 satisfies the requirements established in subsection (d) of this section.

254 (c) (1) Except as provided in subdivision (2) of this subsection, the  
255 pharmacist who directly supervises an advanced pharmacy technician  
256 as required under subdivision (6) of subsection (b) of this section shall  
257 (A) perform all drug utilization reviews, and (B) verify that (i) all  
258 prescription data entered into the pharmacy software system are  
259 correct, and (ii) the original prescription and the contents of the

260 prescription label and prescription container are correct.

261 (2) The pharmacist who directly supervises an advanced pharmacy  
262 technician may allow the advanced pharmacy technician to verify that  
263 the original prescription and the contents of the prescription label and  
264 prescription container are correct.

265 (d) (1) The pharmacy or institutional pharmacy that employs an  
266 advanced pharmacy technician shall:

267 (A) Use bar code technology, or another technology approved by the  
268 department, to assist in dispensing drugs; and

269 (B) Not permit the ratio of advanced pharmacy technicians to  
270 pharmacists physically present in the pharmacy premises or  
271 institutional pharmacy to exceed one advanced pharmacy technician to  
272 one pharmacist providing direct supervision. A pharmacy or  
273 institutional pharmacy may employ a ratio of three pharmacy  
274 technicians to one supervising pharmacist, as provided in section 20-  
275 576-33 of the regulations of Connecticut state agencies, and an advanced  
276 pharmacy technician shall not be counted in determining whether such  
277 pharmacy or institutional pharmacy satisfies such three-to-one ratio if  
278 the advanced pharmacy technician exclusively engages in the duties of  
279 an advanced pharmacy technician.

280 (2) If an advanced pharmacy technician is employed by a pharmacy,  
281 the pharmacy shall, in addition to satisfying the requirements  
282 established in subdivision (1) of this subsection, use a technology that  
283 includes images of the medication that is reviewed as part of a final  
284 verification.

285 (3) If an advanced pharmacy technician is employed by an  
286 institutional pharmacy, the institutional pharmacy shall, in addition to  
287 satisfying the requirements established in subdivision (1) of this  
288 subsection, use bar code scanning at the point of administration to  
289 confirm accuracy in dispensing.

290 (e) The commissioner shall adopt regulations, in accordance with

291 chapter 54 of the general statutes, to implement the provisions of this  
292 section. Such regulations shall, at a minimum, establish (1) requirements  
293 for performance of competency assessments required under  
294 subparagraph (B) of subdivision (5) of subsection (b) of this section, and  
295 (2) additional requirements concerning the duties of advanced  
296 pharmacy technicians.

297       Sec. 3. (NEW) (*Effective October 1, 2024*) (a) No individual may  
298 perform the duties of a clerk unless such individual is registered with  
299 the department in accordance with the provisions of this section.

300       (b) (1) The department shall register as a clerk any individual who  
301 (A) submits to the department, in a form and manner prescribed by the  
302 department, an application for registration as a clerk under this section,  
303 and (B) satisfies all requirements established in any regulations adopted  
304 pursuant to subsection (e) of this section.

305       (2) Each registration issued under this section shall be valid for one  
306 year and may be renewed for successive one-year periods upon  
307 application in the manner set forth in this section.

308       (c) A clerk may handle dispensed drugs and deliver such drugs to  
309 patients (1) under the direct supervision of a pharmacist, or (2) as  
310 otherwise authorized in regulations adopted by the commissioner  
311 pursuant to subsection (e) of this section.

312       (d) No clerk shall (1) perform any drug utilization review, (2) verify  
313 the accuracy of the prescription data entered into a pharmacy software  
314 system, an original prescription, the contents of a prescription label or  
315 the contents of a prescription container, (3) perform any task that  
316 requires any professional pharmaceutical judgment, or (4) participate in  
317 order entry.

318       (e) The commissioner may adopt regulations, in accordance with  
319 chapter 54 of the general statutes, to implement the provisions of this  
320 section, including, but not limited to, regulations establishing additional  
321 requirements (1) for registration as a clerk, and (2) concerning (A) the

322 scope of clerks' authority, and (B) the duties and performance of clerks.

323 Sec. 4. (NEW) (*Effective October 1, 2024*) (a) A pharmacist or advanced  
324 pharmacy technician may, at the request of a patient or the patient's  
325 prescribing practitioner, dispense to the patient compatible drugs in  
326 compliance packaging.

327 (b) Compliance packaging shall:

328 (1) Exclusively contain (A) individual compartments that are tamper-  
329 proof and tamper-evident, and (B) drugs that are (i) prescribed to a  
330 single patient by the patient's prescribing practitioner, and (ii)  
331 dispensed to a single patient by a pharmacist or an advanced pharmacy  
332 technician;

333 (2) Be labeled or relabeled by a pharmacist in accordance with the  
334 provisions of section 20-617 of the general statutes;

335 (3) Be child-resistant unless the pharmacy provides to the patient, and  
336 the patient returns to the pharmacy, a waiver explaining that the drugs  
337 contained in the compliance packaging are not in a child-resistant  
338 container;

339 (4) Identify, on each individual compartment, the name and strength  
340 of the drug contained in such compartment;

341 (5) Not contain more than a sixty-five-day supply of any drug, as  
342 prescribed; and

343 (6) Be compliant with all applicable provisions of the United States  
344 Pharmacopeia, as amended from time to time.

345 (c) Compliance packaging may contain reusable components and  
346 multiple drugs, prescribed to the same patient, that are contained within  
347 individual compartments comprising a single package. An individual  
348 compartment of compliance packaging may contain multiple prescribed  
349 drugs, provided:

350 (1) A pharmacist has determined that all drugs contained in such

351 compartment are compatible drugs;

352 (2) All drugs contained in such compartment are subject to the same  
353 instructions concerning time of administration or duration between  
354 doses; and

355 (3) No drug contained in such compartment (A) has instructions for  
356 use that permit such drug to be used on an as needed basis, or (B) is a  
357 controlled substance.

358 (d) (1) If a patient's prescribing practitioner modifies the patient's  
359 prescription for any previously dispensed drug by deprescribing or  
360 issuing a new prescription for such drug by way of any oral, written or  
361 electronic means, the pharmacy that first dispensed such drug in  
362 compliance packaging may, if such pharmacy documents such  
363 modification in writing, receive and remove any previously dispensed  
364 drugs from such compliance packaging and repackage such drugs, in  
365 the manner set forth in subdivision (2) of this subsection, for the purpose  
366 of ensuring that the patient's compliance packaging exclusively contains  
367 drugs that are currently prescribed to the patient.

368 (2) Once a pharmacy receives any compliance packaging containing  
369 previously dispensed drugs as set forth in subdivision (1) of this  
370 subsection, a pharmacist at such pharmacy shall:

371 (A) Remove from the compliance packaging any drug (i) that the  
372 patient's prescribing practitioner has deprescribed, or (ii) for which the  
373 patient's prescribing practitioner has issued a new prescription;

374 (B) Dispense in compliance packaging (i) any compatible drug that  
375 was not previously included in compliance packaging, but for which the  
376 patient's prescribing practitioner has since issued a prescription, and (ii)  
377 any previously dispensed and compatible drug (I) that the patient's  
378 prescribing practitioner has not deprescribed, or (II) for which the  
379 patient's prescribing practitioner has not issued a new prescription;

380 (C) Label or relabel the compliance packaging in accordance with the  
381 provisions of section 20-617 of the general statutes; and

382 (D) Not return any drug described in subparagraph (A) of this  
383 subdivision to the pharmacy's general inventory or regular stock.

384 (3) If a pharmacist removes from any compliance packaging any drug  
385 described in subparagraph (A) of subdivision (2) of this subsection, the  
386 pharmacist shall return such drug to the patient in a separate container  
387 with instructions for proper use or disposal, as applicable, which  
388 disposal instructions shall disclose (A) the procedures for any lawfully  
389 available means of destroying such drug at home, and (B) the nearest  
390 location where such drug may be deposited for destruction, including,  
391 but not limited to, the nearest retail location allowed to accept such drug  
392 under regulations adopted pursuant to section 20-576a of the general  
393 statutes.

394 (e) A pharmacy that provides compliance packaging services shall:

395 (1) Maintain an area dedicated to the preparation of drugs that are to  
396 be dispensed in compliance packaging, which area shall include all  
397 equipment necessary to (A) ensure that all compliance packaging is  
398 accurately prepared, and (B) prevent any contamination of such drugs;

399 (2) Maintain standard operating procedures (A) for the use of  
400 compliance packaging and associated equipment, which procedures  
401 shall include, at a minimum, provisions concerning (i) inspections of  
402 compliance packaging integrity, (ii) cleaning, (iii) labeling, (iv)  
403 dispensing, (v) proper hand hygiene, (vi) quarantine, and (vii) handling  
404 of dispensed drugs that are removed from compliance packaging and  
405 returned to patients in the manner set forth in subsection (d) of this  
406 section, and (B) that specify which drugs (i) are not compatible drugs,  
407 (ii) are suitable to be dispensed in compliance packaging, or (iii) require  
408 special consideration to be dispensed in compliance packaging;

409 (3) Maintain a log of all drugs that the pharmacy dispenses in  
410 compliance packaging, which log shall include, at a minimum, for each  
411 drug that the pharmacy dispenses in any compliance packaging, (A) the  
412 patient's name and address, (B) the identification number for the  
413 compliance packaging in which such pharmacy dispensed such drug,

414 the date such compliance packaging was prepared, the initials of the  
415 individual who prepared such compliance packaging and the initials of  
416 the individual who conducted a final performance check of such  
417 compliance packaging, (C) the name, strength, lot number and national  
418 drug code number for such drug, (D) the serial number of the  
419 prescription for such drug, and (E) a visual description of such drug;

420 (4) Maintain a log of all drugs, other than controlled substances, that  
421 are removed from compliance packaging and returned to patients in the  
422 manner set forth in subsection (d) of this section, which log shall  
423 include, at a minimum, for each removed and returned drug, (A) the  
424 patient's name, (B) the identification number for the compliance  
425 packaging that contained such drug, (C) the serial number of the  
426 prescription, (D) the date such drug was dispensed, (E) the name and  
427 strength of such drug, and (F) the quantity of such drug that was  
428 removed and returned;

429 (5) Maintain a log of all controlled substances that are removed from  
430 compliance packaging and returned to patients in the manner set forth  
431 in subsection (d) of this section, which log shall include, at a minimum,  
432 for each removed and returned controlled substance, the information  
433 required under subdivision (4) of this subsection for drugs that are  
434 removed and returned to patients in the manner set forth in subsection  
435 (d) of this section; and

436 (6) Not later than forty-eight hours after the department requests that  
437 the pharmacy disclose a copy of a log maintained pursuant to  
438 subdivision (4) or (5) of this subsection, disclose such copy to the  
439 department in electronic form or, if such pharmacy is unable to disclose  
440 such copy in electronic form, in paper form.

441 (f) The commissioner may adopt regulations, in accordance with  
442 chapter 54 of the general statutes, to implement the provisions of this  
443 section.

444 Sec. 5. Subsection (a) of section 20-579 of the general statutes is  
445 repealed and the following is substituted in lieu thereof (*Effective October*

446 1, 2024):

447 (a) The commission may refuse to authorize the issuance of a  
448 temporary permit to practice pharmacy, may refuse to authorize the  
449 issuance or renewal of a license to practice pharmacy, a license to  
450 operate a pharmacy or a registration of a pharmacy intern or pharmacy  
451 technician, and may revoke, suspend or place conditions on a license or  
452 temporary permit to practice pharmacy, a license to operate a pharmacy,  
453 or a registration of a pharmacy intern or a pharmacy technician, and  
454 may assess a civil penalty of up to one thousand dollars per violation of  
455 any provision of this chapter or take other action permitted in  
456 subdivision (7) of section 21a-7 if the applicant or holder of the license,  
457 temporary permit or registration: (1) Has violated a statute or regulation  
458 relating to drugs, devices or the practice of pharmacy of this state, any  
459 state of the United States, the United States, the District of Columbia, the  
460 Commonwealth of Puerto Rico, any territory or insular possession  
461 subject to the jurisdiction of the United States or a foreign jurisdiction;  
462 (2) has been convicted of violating any criminal statute relating to drugs,  
463 devices or the practice of pharmacy of this state, any state of the United  
464 States, the United States, the District of Columbia, the Commonwealth  
465 of Puerto Rico, any territory or insular possession subject to the  
466 jurisdiction of the United States or a foreign jurisdiction; (3) has been  
467 disciplined by, or is the subject of pending disciplinary action or an  
468 unresolved complaint before, the duly authorized pharmacy  
469 disciplinary agency of any state of the United States, the United States,  
470 the District of Columbia, the Commonwealth of Puerto Rico, any  
471 territory or insular possession subject to the jurisdiction of the United  
472 States or a foreign jurisdiction; (4) has been refused a license or  
473 registration or renewal of a license or registration by any state of the  
474 United States, the United States, the District of Columbia, the  
475 Commonwealth of Puerto Rico, any territory or insular possession  
476 subject to the jurisdiction of the United States or a foreign jurisdiction  
477 based on grounds that are similar to grounds on which Connecticut  
478 could refuse to issue or renew such a license or registration; (5) has  
479 illegally possessed, diverted, sold or dispensed drugs or devices; (6)  
480 abuses or excessively uses drugs, including alcohol; (7) has made false,



481 misleading or deceptive representations to the public or the  
482 commission; (8) has maintained exclusive telephone lines to, has  
483 maintained exclusive electronic communication with, or has exclusive  
484 access to computers located in offices of prescribing practitioners,  
485 nursing homes, clinics, hospitals or other health care facilities; (9) has  
486 substituted drugs or devices except as permitted in section 20-619; (10)  
487 has accepted, for return to regular stock, any drug already dispensed in  
488 good faith or delivered from a pharmacy, and exposed to possible and  
489 uncontrolled contamination or substitution; (11) has accepted, for return  
490 to general inventory or regular stock, any drug sold or delivered to a  
491 patient; (12) has split fees for professional services, including a discount  
492 or rebate, with a prescribing practitioner or an administrator or owner  
493 of a nursing home, hospital or other health care facility; [(12)] (13) has  
494 entered into an agreement with a prescribing practitioner or an  
495 administrator or owner of a nursing home, hospital or other health care  
496 facility for the compounding or dispensing of secret formula or coded  
497 prescriptions; [(13)] (14) has performed or been a party to a fraudulent  
498 or deceitful practice or transaction; [(14)] (15) has presented to the  
499 commission a diploma, license or certificate illegally or fraudulently  
500 obtained, or obtained from a college or school of pharmacy not  
501 approved by the commission; [(15)] (16) has performed incompetent or  
502 negligent work; [(16)] (17) has falsified a continuing education  
503 document submitted to the commission or department or a certificate  
504 retained in accordance with the provisions of subsection (d) of section  
505 20-600; [(17)] (18) has permitted a person not licensed to practice  
506 pharmacy in this state to practice pharmacy in violation of section 20-  
507 605, to use a pharmacist license or pharmacy display document in  
508 violation of section 20-608, or to use words, displays or symbols in  
509 violation of section 20-609; [(18)] (19) has failed to maintain the entire  
510 pharmacy premises, its components and contents in a clean, orderly and  
511 sanitary condition; [(19)] (20) has failed to demonstrate adherence to  
512 applicable provisions of United States Pharmacopeia, Chapter 797,  
513 Pharmaceutical Compounding - Sterile Preparations, as amended from  
514 time to time; or [(20)] (21) has failed to demonstrate adherence to  
515 applicable provisions of United States Pharmacopeia, Chapter 795,

516 Pharmaceutical Compounding - Nonsterile Preparations, as amended  
517 from time to time.

518 Sec. 6. Subsections (a) to (c), inclusive, of section 20-598a of the  
519 general statutes are repealed and the following is substituted in lieu  
520 thereof (*Effective October 1, 2024*):

521 (a) No person shall act as a pharmacy technician unless registered  
522 with, or certified with, the department, except an individual who is  
523 enrolled in an accredited pharmacy technician education program may  
524 engage in the duties of a pharmacy technician, as part of the curriculum  
525 of such program, under the direct supervision of a pharmacist who is an  
526 instructor for such program.

527 (b) The department shall [, upon authorization of the commission,]  
528 register as a pharmacy technician any person who presents evidence  
529 satisfactory to the department that such person is qualified to perform,  
530 under the direct supervision of a pharmacist, routine functions in the  
531 dispensing of drugs that do not require the use of professional  
532 judgment. The qualifications for registration as a pharmacy technician  
533 under this section shall be in accordance with (1) the standards of an  
534 institutional pharmacy, a care-giving institution or a correctional or  
535 juvenile training institution, in the case of employment in any such  
536 pharmacy or institution, or (2) the standards established by regulation  
537 adopted by the commissioner in accordance with chapter 54, in the case  
538 of employment in a pharmacy. [As used in this subsection, "direct  
539 supervision" means a supervising pharmacist (A) is physically present  
540 in the area or location where the pharmacy technician is performing  
541 routine drug dispensing functions, and (B) conducts in-process and final  
542 checks on the pharmacy technician's performance.]

543 (c) The department shall [, upon authorization of the commission,]  
544 certify as a pharmacy technician any person who meets the  
545 requirements for registration as a pharmacy technician, pursuant to  
546 subsection (b) of this section, and who holds a certification from the  
547 Pharmacy Technician Certification Board or any other equivalent  
548 pharmacy technician certification program approved by the

549 department.

550 Sec. 7. Section 20-601 of the 2024 supplement to the general statutes  
551 is repealed and the following is substituted in lieu thereof (*Effective*  
552 *October 1, 2024*):

553 The department shall collect the following nonrefundable fees:

554 (1) The fee for issuance of a pharmacist license is two hundred  
555 dollars, payable at the date of application for the license.

556 (2) The fee for renewal of a pharmacist license is the professional  
557 services fee for class A, as defined in section 33-182l. Before the  
558 commission or commissioner grants a license to an applicant who has  
559 not held a license authorized by the commission or commissioner within  
560 five years of the date of application, the applicant shall pay the fee  
561 required in subdivision (1) of this section.

562 (3) The fee for issuance of a pharmacy license is seven hundred fifty  
563 dollars.

564 (4) The fee for renewal of a pharmacy license is one hundred ninety  
565 dollars.

566 (5) The late fee for an application for renewal of a license to practice  
567 pharmacy, a pharmacy license or a permit to sell nonlegend drugs is the  
568 amount set forth in section 21a-4.

569 (6) The fee for notice of a change in officers or directors of a  
570 corporation holding a pharmacy license is sixty dollars for each  
571 pharmacy license held. A late fee for failing to give such notice within  
572 ten days of the change is fifty dollars in addition to the fee for notice.

573 (7) The fee for filing notice of a change in name, ownership or  
574 management of a pharmacy is ninety dollars. A late fee for failing to give  
575 such notice within ten days of the change is fifty dollars in addition to  
576 the fee for notice.

577 (8) The fee for application for registration as a pharmacy intern is

578 sixty dollars.

579 (9) The fee for application for a permit to sell nonlegend drugs is one  
580 hundred forty dollars.

581 (10) The fee for renewal of a permit to sell nonlegend drugs is one  
582 hundred dollars.

583 (11) The late fee for failing to notify the [commission] department of  
584 a change of ownership, name or location of the premises of a permit to  
585 sell nonlegend drugs within five days of the change is twenty dollars.

586 (12) The fee for issuance of a nonresident pharmacy certificate of  
587 registration is seven hundred fifty dollars.

588 (13) The fee for renewal of a nonresident pharmacy certificate of  
589 registration is one hundred ninety dollars.

590 (14) The fee for notice of a change in officers or directors of a  
591 corporation holding a nonresident pharmacy certificate of registration  
592 is sixty dollars for each pharmacy license held. A late fee for failing to  
593 give such notice within ten days of the change is fifty dollars, in addition  
594 to the fee for notice.

595 (15) The fee for filing notice of a change in name, ownership or  
596 management of a nonresident pharmacy is ninety dollars. A late fee for  
597 failing to give such notice within ten days of the change is fifty dollars,  
598 in addition to the fee for notice.

599 (16) The fee for application for registration as a pharmacy technician  
600 is one hundred dollars.

601 (17) The fee for renewal of a registration as a pharmacy technician is  
602 fifty dollars.

603 (18) The fee for issuance of a temporary permit to practice pharmacy  
604 is two hundred dollars.

605 Sec. 8. Section 20-601 of the 2024 supplement to the general statutes,

606 as amended by section 259 of public act 23-204, is repealed and the  
607 following is substituted in lieu thereof (*Effective July 1, 2025*):

608 The department shall collect the following nonrefundable fees:

609 (1) The fee for issuance of a pharmacist license is two hundred  
610 dollars, payable at the date of application for the license.

611 (2) The fee for renewal of a pharmacist license is one hundred five  
612 dollars. Before the commission or commissioner grants a license to an  
613 applicant who has not held a license authorized by the commission or  
614 commissioner within five years of the date of application, the applicant  
615 shall pay the fee required in subdivision (1) of this section. On or before  
616 the last day of January, April, July and October in each year, the  
617 commissioner shall transfer five dollars of each renewal fee collected  
618 pursuant to this subdivision to the pharmacy professional assistance  
619 program account established in section 20-638c.

620 (3) The fee for issuance of a pharmacy license is seven hundred fifty  
621 dollars.

622 (4) The fee for renewal of a pharmacy license is one hundred ninety  
623 dollars.

624 (5) The late fee for an application for renewal of a license to practice  
625 pharmacy, a pharmacy license or a permit to sell nonlegend drugs is the  
626 amount set forth in section 21a-4.

627 (6) The fee for notice of a change in officers or directors of a  
628 corporation holding a pharmacy license is sixty dollars for each  
629 pharmacy license held. A late fee for failing to give such notice within  
630 ten days of the change is fifty dollars in addition to the fee for notice.

631 (7) The fee for filing notice of a change in name, ownership or  
632 management of a pharmacy is ninety dollars. A late fee for failing to give  
633 such notice within ten days of the change is fifty dollars in addition to  
634 the fee for notice.

635 (8) The fee for application for registration as a pharmacy intern is  
636 sixty-five dollars. On or before the last day of January, April, July and  
637 October in each year, the commissioner shall transfer five dollars of each  
638 fee collected pursuant to this subdivision to the pharmacy professional  
639 assistance program account established in section 20-638c.

640 (9) The fee for application for a permit to sell nonlegend drugs is one  
641 hundred forty dollars.

642 (10) The fee for renewal of a permit to sell nonlegend drugs is one  
643 hundred dollars.

644 (11) The late fee for failing to notify the [commission] department of  
645 a change of ownership, name or location of the premises of a permit to  
646 sell nonlegend drugs within five days of the change is twenty dollars.

647 (12) The fee for issuance of a nonresident pharmacy certificate of  
648 registration is seven hundred fifty dollars.

649 (13) The fee for renewal of a nonresident pharmacy certificate of  
650 registration is one hundred ninety dollars.

651 (14) The fee for notice of a change in officers or directors of a  
652 corporation holding a nonresident pharmacy certificate of registration  
653 is sixty dollars for each pharmacy license held. A late fee for failing to  
654 give such notice within ten days of the change is fifty dollars, in addition  
655 to the fee for notice.

656 (15) The fee for filing notice of a change in name, ownership or  
657 management of a nonresident pharmacy is ninety dollars. A late fee for  
658 failing to give such notice within ten days of the change is fifty dollars,  
659 in addition to the fee for notice.

660 (16) The fee for application for registration as a pharmacy technician  
661 is one hundred dollars.

662 (17) The fee for renewal of a registration as a pharmacy technician is  
663 fifty dollars.

664 (18) The fee for issuance of a temporary permit to practice pharmacy  
665 is two hundred dollars.

666 Sec. 9. Subsection (a) of section 20-633 of the 2024 supplement to the  
667 general statutes is repealed and the following is substituted in lieu  
668 thereof (*Effective from passage*):

669 (a) (1) Any person licensed as a pharmacist under part II of this  
670 chapter may order and administer:

671 (A) Any vaccine, approved or authorized by the United States Food  
672 and Drug Administration that is listed on the National Centers for  
673 Disease Control and Prevention's [Adult Immunization Schedule] age-  
674 appropriate immunization schedule, to any patient who is: (i) Eighteen  
675 years of age or older; or (ii) at least twelve years of age but younger than  
676 eighteen years of age with (I) the consent of such patient's parent, legal  
677 guardian or other person having legal custody of such patient, or (II)  
678 proof that such patient is an emancipated minor; [.]

679 (B) Any vaccine not included on the National Centers for Disease  
680 Control and Prevention's Adult Immunization Schedule, provided the  
681 vaccine administration instructions for such vaccine are available on the  
682 National Centers for Disease Control and Prevention's Internet web site;  
683 and

684 (C) Any vaccine pursuant to a verbal or written prescription of a  
685 prescribing practitioner for a specific patient.

686 (2) A pharmacist shall make a reasonable effort to review a patient's  
687 vaccination history to prevent any inappropriate use of a requested  
688 vaccine.

689 (3) All vaccines administered pursuant to this section shall be  
690 administered in accordance with the: (A) Vaccine manufacturer's  
691 package insert or the orders of a prescribing practitioner; and (B)  
692 regulations adopted pursuant to subsection (d) of this section.

693 Sec. 10. (*Effective from passage*) (a) There is established a task force to

694 study the impact of unannounced retail pharmacy closures. Such study  
695 shall include, but need not be limited to, an examination of any available  
696 means of ensuring that patients are able to maintain access to their  
697 prescriptions in the event of an unannounced retail pharmacy closure.

698 (b) The task force shall consist of the following members:

699 (1) Two appointed by the speaker of the House of Representatives;

700 (2) Two appointed by the president pro tempore of the Senate;

701 (3) One appointed by the majority leader of the House of  
702 Representatives;

703 (4) One appointed by the majority leader of the Senate;

704 (5) One appointed by the minority leader of the House of  
705 Representatives;

706 (6) One appointed by the minority leader of the Senate;

707 (7) The Commissioner of Consumer Protection, or the commissioner's  
708 designee; and

709 (8) Two persons appointed by the Governor.

710 (c) Any member of the task force appointed under subdivision (1),  
711 (2), (3), (4), (5) or (6) of subsection (b) of this section may be a member  
712 of the General Assembly.

713 (d) All initial appointments to the task force shall be made not later  
714 than thirty days after the effective date of this section. Any vacancy shall  
715 be filled by the appointing authority.

716 (e) The speaker of the House of Representatives and the president pro  
717 tempore of the Senate shall select the chairpersons of the task force from  
718 among the members of the task force. Such chairpersons shall schedule  
719 the first meeting of the task force, which shall be held not later than sixty  
720 days after the effective date of this section.



721 (f) The administrative staff of the joint standing committee of the  
722 General Assembly having cognizance of matters relating to consumer  
723 protection shall serve as administrative staff of the task force.

724 (g) Not later than January 1, 2025, the task force shall submit a report  
725 on its findings and recommendations to the joint standing committee of  
726 the General Assembly having cognizance of matters relating to  
727 consumer protection, in accordance with the provisions of section 11-4a  
728 of the general statutes. The task force shall terminate on the date that it  
729 submits such report or January 1, 2025, whichever is later.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2024</i>	20-571
Sec. 2	<i>October 1, 2024</i>	New section
Sec. 3	<i>October 1, 2024</i>	New section
Sec. 4	<i>October 1, 2024</i>	New section
Sec. 5	<i>October 1, 2024</i>	20-579(a)
Sec. 6	<i>October 1, 2024</i>	20-598a(a) to (c)
Sec. 7	<i>October 1, 2024</i>	20-601
Sec. 8	<i>July 1, 2025</i>	20-601
Sec. 9	<i>from passage</i>	20-633(a)
Sec. 10	<i>from passage</i>	New section

**Statement of Legislative Commissioners:**

In Section 2(d)(1)(B), "physically" was added before "present" for internal consistency; in Section 4(d)(2), "containing previously dispensed drugs" was added after "compliance packaging" for clarity; in Section 4(e)(3)(B), "performed a final check" was changed to "conducted a final performance check" for internal consistency; and in Section 4(e)(5), "said subsection (d)" was changed to "subsection (d) of this section" for consistency with standard drafting conventions.

**GL**            *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

**OFA Fiscal Note**

**State Impact:**

Agency Affected	Fund-Effect	FY 25 \$	FY 26 \$
Resources of the General Fund	GF - Potential Revenue Gain	See Below	See Below

Note: GF=General Fund

**Municipal Impact:** None

**Explanation**

The bill adds to the reasons for which the state Pharmacy Commission may take disciplinary action (which includes issuing a civil penalty of up to \$1,000) resulting in a potential revenue gain to the state to the extent violations occur and civil penalties are issued.

The bill also establishes a task force to study the impact of unannounced retail pharmacy closures resulting in no fiscal impact because the task force has the expertise to meet the requirements of the bill.

**The Out Years**

The annualized ongoing fiscal impact identified above would continue into the future subject to the number of violations that result in civil penalties.

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**OLR Bill Analysis****sSB 133*****AN ACT CONCERNING REGULATION OF PRESCRIPTION DRUGS AND RELATED PROFESSIONS.*****SUMMARY**

This bill makes various changes to laws on pharmacies and pharmacists.

It establishes the advanced pharmacy technician and clerk occupational categories. Among other related provisions, it sets certain parameters of their allowable duties.

The bill authorizes pharmacists and advanced pharmacy technicians to dispense to patients their prescription drugs in compliance packaging (packaging that separates drugs into individual compartments by dose) if they follow certain criteria. Pharmacies that provide compliance packaging are required to keep logs with specific details of the drugs they dispense and who they dispense them to.

The bill also allows for the repackaging of pharmaceutical drug compliance packaging, subject to certain requirements. This includes the requirement to return any drugs removed from compliance packaging to the patient with directions on how to properly dispose of the drugs.

The bill makes it a punishable offense for pharmacists, pharmacy operators, pharmacy interns, and pharmacy technicians to return to the general inventory or regular drug stock of the pharmacy any drug that has been sold or delivered to a patient, in addition to existing law's prohibition on such returns of drugs exposed to possible contamination or substitution.

The bill allows individuals enrolled in pharmacy technician education programs to engage in duties of a pharmacy technician if they are under the direct supervision of a pharmacist who is an instructor in the program.

It allows pharmacists to order and administer, not just administer, vaccines for certain patients, and applies this authority to all federally approved vaccines on the Centers for Disease Control and Prevention's (CDC) age-appropriate immunization schedule.

The bill establishes a task force to study the impact of unannounced retail pharmacy closures.

For purposes of the state's pharmacy laws, the bill generally defines a "patient" as a human or other animal receiving health care services from a provider to treat a current or future medical condition (§ 1).

The bill also makes minor, technical, and conforming changes.

EFFECTIVE DATE: October 1, 2024, except (1) upon passage for provisions on pharmacists ordering vaccinations and the task force and (2) July 1, 2025, for a technical change.

## **§§ 1 & 2 — ADVANCED PHARMACY TECHNICIANS**

The bill establishes the advanced pharmacy technician occupational category. It prohibits anyone from performing the duties of this occupation without getting an advanced pharmacy technician endorsement from the Department of Consumer Protection (DCP). To get the endorsement, a person must:

1. be an actively registered and qualified pharmacy technician;
2. have been registered as a pharmacy technician for the three-year period immediately before applying for an advanced pharmacy technician endorsement;
3. have continuously held a certification from the Pharmacy Technician Certification Board, or equivalent certification

program approved by DCP, for the three-year period immediately before applying for an advanced pharmacy technician endorsement, and keep that certification in good standing;

4. have successfully completed an educational course accredited by a nationally recognized accreditation body within one year of the date of applying to be an advanced pharmacy technician;
5. have successfully completed a competency assessment proctored by a pharmacist in keeping with requirements to be set by the commissioner;
6. work under the direct supervision of a licensed pharmacist; and
7. be employed by a pharmacy (including institutional pharmacies).

An advanced pharmacy technician endorsement is valid for one year and may be renewed for successive one-year periods.

An advanced pharmacy technician's duties may include, among other things, dispensing to patients compatible drugs in compliance packaging (see § 4 below).

### ***Supervisory and Staffing Requirements***

Under the bill, a pharmacist that directly supervises an advanced pharmacy technician generally must perform all drug utilization reviews (generally, reviewing a pharmacist's prescribing, dispensing, and utilization activities to ensure appropriate decision-making), and verify that (1) prescription drug data entered in the pharmacy software systems is correct and (2) the original prescription and contents of the label and container are correct. However, a pharmacist may allow the advanced pharmacy technician himself or herself to verify the accuracy of the original prescription and the contents of the label and container.

A pharmacy that employs an advanced pharmacy technician must:

1. use bar codes or a similar technology approved by DCP to assist in the dispensing of drugs and
2. keep the on-site ratio of advanced pharmacy technicians to pharmacists providing direct supervision at no more than 1:1.

Advanced pharmacy technicians do not count towards the existing 3:1 ratio of pharmacy technicians to supervising pharmacists if the advanced pharmacy technician exclusively performs duties of an advanced technician.

Pharmacies that employ advanced pharmacy technicians are required to use technology that includes images of each type of medication as part of a final verification check of dispensed drugs. Institutional pharmacies employing advanced pharmacy technicians must use bar code scanning at the point of administration to the patient to confirm the correct drugs have been dispensed.

### ***Regulations***

The bill requires the DCP commissioner to adopt implementing regulations that, at minimum, set (1) performance requirements for the competency assessment required for endorsement as an advanced pharmacy technician, and (2) additional requirements for the duties of advanced pharmacy technicians.

### **§ 3 — PHARMACY CLERKS**

The bill establishes the clerk occupational category and prohibits anyone from performing a clerk's duties unless registered as such with DCP.

To become registered, an applicant must satisfy the registration requirements set by any DCP regulations on the matter (see below). A clerk's registration is valid for one year and may be renewed for successive one-year periods.

Clerks are authorized to handle dispensed drugs and deliver those drugs to patients under the direct supervision of a pharmacist or

otherwise as authorized in regulations.

Clerks may not:

1. perform drug utilization reviews;
2. verify the accuracy of prescription data entered into the pharmacy's software system, the prescription itself, and the contents of a prescription label or container;
3. perform any task that requires professional pharmaceutical judgment; or
4. participate in order entry (generally, the process of entering prescription data into the pharmacy's software system).

Clerks are also not involved in the dispensing process or preparing a prescription for final verification.

The commissioner is authorized to establish regulations that include, among other things, creating additional requirements for clerk registration, the scope of clerks' professional authority, and the professional duties of clerks.

#### **§ 4 — COMPLIANCE PACKAGING**

The bill authorizes pharmacists and advanced pharmacy technicians to dispense to patients compatible drugs in compliance packaging, at the patient's or prescribing practitioner's request. Generally, compliance packaging is packaging prepared at a pharmacy that separates drugs into individual compartments by dose as prescribed to an individual patient.

Compliance packaging must:

1. only contain individual compartments that are tamper-proof and tamper-evident,
2. only contain drugs prescribed to a single patient by their prescribing practitioner and dispensed to that patient by a

- 
- pharmacist or an advanced pharmacy technician,
3. be labeled or relabeled by a pharmacist under existing requirements,
  4. be child-resistant unless the patient signs a waiver,
  5. identify on each individual compartment the name and strength of the drug it contains,
  6. not contain more than a 65-day supply of any drug, and
  7. be compliant with the United States Pharmacopeia.

***Reusable Components, Multiple Drugs, and Repackaging***

The bill allows compliance packaging to contain reusable components and multiple drugs (for one patient) within individual compartments in the same package. It also allows an individual compartment to contain multiple drugs if (1) a pharmacist determines that the drugs are compatible (i.e., not contraindicated or adversely impacted by each other); (2) the drugs have the same instructions for the time between doses and none are to be taken on an as-needed basis; and (3) none of the drugs are controlled substances.

The bill allows a pharmacy that dispensed drugs in compliance packaging to remove dispensed drugs from the packaging and repack them in keeping with a modified prescription from the patient's prescribing practitioner. To repack compliance packaging, a pharmacist must:

1. remove any drugs that the patient's prescribing practitioner has deprescribed or issued a new prescription for,
2. dispense the new prescribed compatible drugs in compliance packaging,
3. dispense the previously dispensed compatible drugs in compliance packaging,



4. label the new compliance packaging, and
5. never return any drug removed from compliance packaging into the pharmacy's general inventory.

The bill requires a pharmacist to return any drugs removed from compliance packaging to the patient in a separate container with instructions for proper use or disposal, as applicable (e.g., the location of the nearest pharmacy that accepts drugs for disposal).

### ***Standard Operating Procedures***

The bill requires pharmacies that provide compliance packaging services to maintain an area dedicated to that purpose and that contains the equipment necessary to ensure all compliance packaging is accurate and drug contaminant free.

The bill also requires these pharmacies to maintain a set of standard operating procedures for the use of compliance packaging and associated equipment that includes at least the following:

1. inspections of the integrity of compliance packaging,
2. cleaning,
3. labeling,
4. dispensing,
5. proper hand hygiene,
6. quarantine, and
7. handling of dispensed drugs that are removed from compliance packaging and returned to patients.

The standard operating procedures also must specify which drugs (1) are not compatible, (2) are suitable for compliance packaging, or (3) require special consideration to be dispensed in this way.

### ***Requirement to Maintain Records***

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The bill requires pharmacies that provide compliance packaging services to maintain a log (record) of drugs that the pharmacy dispenses in this packaging. That log must have:

1. the patient's name and address;
2. the compliance package's identification number;
3. the date the package was prepared;
4. the initials of the individuals who prepared the packaging and performed the final check of it;
5. the drug's name, strength, lot number, and national drug code number;
6. the serial number of the prescription; and
7. a visual description of the dispensed drug.

The bill also requires these pharmacies to maintain a log of controlled substances that are removed from compliance packaging and returned to patients, and a separate log for removed and returned drugs that are not controlled substances. Each log must contain the:

1. patient's name,
2. compliance package's identification number,
3. serial number of the prescription,
4. date the drug was dispensed,
5. name and strength of the drug, and
6. quantity of the drug that was removed and returned to the patient.

The bill requires pharmacies to give DCP a copy of any drug removal logs within 48 hours of a request. The logs must be given in electronic

form, or paper if electronic means is not available.

### **Regulations**

The bill allows the DCP commissioner to adopt regulations implementing its provisions on compliance packaging.

### **§ 5 — CAUSES OF DISCIPLINE FOR PHARMACY PROFESSIONALS**

The bill adds, to the reasons for which the state Pharmacy Commission may take disciplinary action against pharmacies or certain pharmacy personnel, that the person has accepted for return to the general inventory or regular stock any drug sold or delivered to a patient. Existing law already allows the commission to take these actions if the person has accepted for return to regular stock any drug already (1) dispensed in good faith or delivered and (2) exposed to possible contamination or substitution.

Under existing law, the possible disciplinary actions include, among other things, (1) refusing to issue or renew, revoking, suspending, or placing conditions on a license to practice pharmacy, a license to operate a pharmacy, a pharmacy intern registration, or a pharmacy technician registration or (2) imposing a civil penalty of up to \$1,000.

### **§ 6 — PHARMACY TECHNICIANS**

The bill authorizes individuals enrolled in accredited pharmacy technician education programs to engage in the duties of a pharmacy technician as part of the education program if they are under the direct supervision of a pharmacist who is an instructor in that program.

The bill also specifies that DCP, when issuing credentials for pharmacy technicians, does not need the Pharmacy Commission's specific authorization.

### **§ 9 — ORDERING AND ADMINISTRATION OF VACCINES**

Existing law allows pharmacists to administer certain vaccines to (1) adult patients or (2) patients ages 12 to 17 with the legal guardian's consent (or who are emancipated minors). The bill authorizes pharmacists to order and administer these vaccines for these patients.

It allows them to order and administer any vaccine approved or authorized by the U.S. Food and Drug Administration and listed on the CDC's age-appropriate immunization schedule, instead of on the Adult Immunization schedule as under current law. It also specifically allows them to order and administer other vaccines that they may administer under current law, including (1) vaccines not on the Adult Immunization Schedule, but with administration instructions available on the CDC website and (2) vaccines prescribed (verbally or written) by a practitioner for a specific patient.

Under existing law, pharmacists must complete specified training before administering vaccinations.

(Under temporary federal rules, pharmacists can also currently administer certain vaccines to children ages three and older.)

#### **§ 10 — TASK FORCE ON UNANNOUNCED RETAIL PHARMACY CLOSURES**

The bill establishes an 11-member task force to study the impact of unannounced retail pharmacy closures. The study must include an examination of available means to ensure patients are able to maintain access to their prescriptions.

The task force consists of eight members appointed by the legislative leaders (two each by the House Speaker and Senate president pro tempore, and one each by the House and Senate majority and minority leaders), the DCP commissioner or his designee, and two people appointed by the Governor. Legislative appointees may be legislators.

Appointing authorities must make their initial appointments by 30 days after the bill's passage and fill any vacancy.

The House speaker and Senate president pro tempore select the task force chairpersons from among its members. The chairpersons must schedule the first meeting, which must be held by 60 days after the bill's passage.

The General Law Committee's administrative staff serves in that

capacity for the task force.

The task force must issue a report on its findings and recommendations to the General Law Committee no later than January 1, 2025. The task force terminates when it submits the report or on January 1, 2025, whichever is later.

**COMMITTEE ACTION**

General Law Committee

Joint Favorable Substitute

Yea 22 Nay 0 (03/07/2024)