



House of Representatives

General Assembly

File No. 243

February Session, 2014

Substitute House Bill No. 5262

House of Representatives, April 1, 2014

The Committee on General Law reported through REP. BARAM of the 15th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.

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

1 Section 1. Subsection (c) of section 20-619 of the 2014 supplement to
2 the general statutes is repealed and the following is substituted in lieu
3 thereof (*Effective July 1, 2014*):

4 (c) A prescribing practitioner may specify in writing or by a
5 telephonic or other electronic communication that there shall be no
6 substitution for the specified brand name drug product [in] appearing
7 on any prescription, provided (1) [in any prescription for a Medicaid
8 recipient, such practitioner specifies the basis on which the brand
9 name drug product and dosage form is medically necessary in
10 comparison to a chemically equivalent generic name drug product
11 substitution, and (2) the phrase "BRAND MEDICALLY NECESSARY",
12 shall be in the practitioner's handwriting on the prescription form or
13 on an electronically produced copy of the prescription form or, if the
14 prohibition was communicated by telephonic or other electronic

15 communication that did not reproduce the practitioner's handwriting,
16 a statement to that effect appears on the form. The phrase "BRAND
17 MEDICALLY NECESSARY" shall not be preprinted or stamped or
18 initialed on the form. If the practitioner specifies by telephonic or other
19 electronic communication that did not reproduce the practitioner's
20 handwriting that there shall be no substitution for the specified brand
21 name drug product in any prescription for a Medicaid recipient,
22 written certification in the practitioner's handwriting bearing the
23 phrase "BRAND MEDICALLY NECESSARY" shall be sent to the
24 dispensing pharmacy not later than ten days after the date of such
25 communication] for written prescriptions, the practitioner shall
26 indicate on the prescription form that the product is "brand medically
27 necessary" or "no substitution", (2) for prescriptions transmitted by
28 telephonic means, the pharmacist shall place the phrase "brand
29 medically necessary" or "no substitution" on the prescription in the
30 pharmacist's handwriting or in the electronic prescription record and
31 shall record on the prescription the time the telephonic authorization
32 was received and the name of the person who communicated the
33 telephonic authorization to the pharmacist, and (3) for prescriptions
34 transmitted by any other electronic communication, the practitioner
35 shall select the dispense as written code on the certified electronic
36 prescription to indicate that a substitution is not allowed by the
37 practitioner. No prescription form for written prescriptions, and no
38 prescription form for prescriptions transmitted pursuant to
39 subdivision (2) or (3) of this subsection, may default to "brand
40 medically necessary" or "no substitution".

41 Sec. 2. (NEW) (*Effective July 1, 2014*) (a) As used in this section:

42 (1) "Sterile compounding pharmacy" means a pharmacy, an
43 institutional pharmacy within a facility licensed pursuant to section
44 19a-490 of the general statutes, or a nonresident pharmacy as defined
45 in section 20-627 of the general statutes, as amended by this act, that
46 dispenses or compounds sterile pharmaceuticals; and

47 (2) "Sterile pharmaceutical" means any dosage form of a drug,

48 including, but not limited to, parenterals, injectables, surgical irrigants
49 and ophthalmics, devoid of viable microorganisms.

50 (b) Whenever a sterile compounding pharmacy intends to
51 compound sterile pharmaceuticals for use in this state for the first
52 time, the sterile compounding pharmacy shall file an addendum to its
53 pharmacy application to include sterile compounding. Such sterile
54 compounding pharmacy shall present the application change,
55 including changes to the pharmacy layout, to the Commissioner of
56 Consumer Protection for approval. Such pharmacy shall not
57 compound sterile pharmaceuticals until the proposed changes are
58 inspected by the Department of Consumer Protection or the
59 appropriate state agency for nonresident pharmacies, and until such
60 proposed changes are approved by such department and the
61 Commission of Pharmacy.

62 (c) A sterile compounding pharmacy shall comply with the most
63 recent United States Pharmacopeia, Chapter 797, Pharmaceutical
64 Compounding - Sterile Preparations, as amended from time to time. A
65 sterile compounding pharmacy shall also comply with all applicable
66 federal and state statutes and regulations.

67 (d) (1) A sterile compounding pharmacy may only provide patient-
68 specific sterile pharmaceuticals to patients, practitioners of medicine,
69 osteopathy, podiatry, dentistry or veterinary medicine, or to an acute
70 care or long-term care hospital or health care facility licensed by the
71 Department of Public Health.

72 (2) If a sterile compounding pharmacy provides compounded sterile
73 products without a patient-specific prescription or medical order, the
74 sterile compounding pharmacy shall also obtain a manufacturing
75 license from the Department of Consumer Protection and any required
76 federal license or registration. A sterile compounding pharmacy may
77 prepare and maintain on-site anticipatory inventory of sterile
78 pharmaceuticals no greater than a thirty-day supply, calculated from
79 the completion of compounding, including third-party analytical
80 testing performed in accordance with the most recent United States

81 Pharmacopeia, Chapter 797, Pharmaceutical Compounding-Sterile
82 Preparations, as amended from time to time.

83 (e) (1) If a sterile compounding pharmacy plans to conduct a
84 remodel of a pharmacy clean room, a relocation of a clean room within
85 the facility or an upgrade or nonemergency repair to the heating,
86 ventilation, air conditioning or primary engineering controls for a
87 clean room within the facility, the sterile compounding pharmacy shall
88 notify the Department of Consumer Protection not later than ten days
89 prior to any such action. If a sterile compounding pharmacy makes an
90 emergency repair, the sterile compounding pharmacy shall notify the
91 department of such repair, in writing, as soon as possible after such
92 repair is made.

93 (2) If a remodel, relocation, upgrade or repair requires sterile
94 recertification, the sterile compounding pharmacy shall provide a copy
95 of the sterile recertification to the Department of Consumer Protection.
96 The recertification shall only be performed by an independent licensed
97 environmental monitoring entity.

98 (f) A sterile compounding pharmacy shall report, in writing, to the
99 Department of Consumer Protection any known violation or
100 noncompliance with viable and nonviable environmental sampling
101 testing, as defined in the most recent United States Pharmacopeia,
102 Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as
103 amended from time to time, not later than the next business day after
104 discovering such violation or noncompliance. A sterile compounding
105 pharmacy within a facility licensed pursuant to section 19a-490 of the
106 general statutes shall also report any such violations or noncompliance
107 to the Department of Public Health.

108 (g) (1) If a sterile compounding pharmacy conducts a recall of sterile
109 pharmaceuticals that were dispensed pursuant to a patient-specific
110 prescription or medical order, the sterile compounding pharmacy shall
111 notify each patient or patient care giver, the prescribing practitioner
112 and the Department of Consumer Protection of such recall not later
113 than the end of the next business day after such recall.

114 (2) If a sterile compounding pharmacy conducts a recall of sterile
115 pharmaceuticals that were not dispensed pursuant to a patient-specific
116 prescription or a medical order, the sterile compounding pharmacy
117 shall notify each purchaser of such pharmaceuticals, the Department of
118 Consumer Protection and the federal Food and Drug Administration
119 of such recall not later than the end of the next business day after such
120 recall.

121 (h) A sterile compounding pharmacy shall prepare and maintain a
122 policy and procedure manual. The policy and procedure manual shall
123 comply with the most recent United States Pharmacopeia, Chapter 797,
124 Pharmaceutical Compounding - Sterile Preparations, as amended from
125 time to time.

126 (i) A sterile compounding pharmacy shall report to the Department
127 of Consumer Protection any administrative or legal action commenced
128 against it by any state or federal regulatory agency or accreditation
129 entity not later than five business days after receiving notice of the
130 commencement of such action.

131 (j) A sterile compounding pharmacy that is a nonresident pharmacy,
132 as defined in section 20-627 of the general statutes, as amended by this
133 act, shall provide the Department of Consumer Protection proof that it
134 has passed an inspection in such nonresident pharmacy's home state,
135 based on the most recent United States Pharmacopeia, Chapter 797,
136 Pharmaceutical Compounding - Sterile Preparations compliance
137 standards, as amended from time to time. Such nonresident pharmacy
138 shall submit to said department a copy of the most recent inspection
139 report with the initial nonresident pharmacy application and every
140 two years thereafter.

141 (k) A medical practitioner, as specified in subdivision (1) of
142 subsection (d) of this section, a hospital or a health care facility that
143 receives sterile pharmaceuticals dispensed by a sterile compounding
144 pharmacy or sold by a manufacturer registered pursuant to section
145 21a-70 of the general statutes, as amended by this act, shall report any
146 errors related to such dispensing or any suspected adulterated sterile

147 pharmaceuticals to the Department of Consumer Protection.

148 (l) The Commissioner of Consumer Protection may adopt
149 regulations, in accordance with chapter 54 of the general statutes, to
150 implement the provisions of this section.

151 Sec. 3. Section 20-627 of the general statutes is repealed and the
152 following is substituted in lieu thereof (*Effective July 1, 2014*):

153 (a) As used in sections 20-627 to 20-630, inclusive, as amended by
154 this act, "nonresident pharmacy" means any pharmacy located outside
155 this state [which] that (1) ships, mails or delivers, in any manner,
156 legend devices or legend drugs into this state pursuant to a
157 prescription order, or (2) provides any aspect of the practice of
158 pharmacy to a resident of this state.

159 (b) A nonresident pharmacy shall be registered with the
160 department, upon approval of the commission, and shall:

161 (1) Disclose annually in a report to the commission the location,
162 names and titles of all principal corporate officers, if applicable, and all
163 pharmacists who are dispensing drugs or devices to residents of this
164 state or providing any aspect of the practice of pharmacy to a resident
165 of this state. A nonresident pharmacy shall file an additional report
166 within thirty days after any change of office, corporate officer or
167 pharmacist; [.]

168 (2) [Submit a statement that the nonresident pharmacy complies]
169 Comply with all lawful directions and requests for information from
170 the regulatory or licensing agency of the state in which it is licensed as
171 well as comply with all requests for information made by the
172 commission or department pursuant to this section; [.]

173 (3) Disclose whether the nonresident pharmacy is dispensing sterile
174 compounded products within this state. If any such dispensed sterile
175 compounded product is not patient-specific, the nonresident pharmacy
176 shall submit a copy of the manufacturing license or registration issued
177 by the regulatory or licensing agency of the state in which it is

178 licensed, and a copy of any registration issued by the federal Food and
179 Drug Administration;

180 [(3)] (4) Maintain at all times, a valid unexpired license, permit or
181 registration to conduct such pharmacy in compliance with the laws of
182 the state in which the nonresident pharmacy is located; [.]

183 [(4)] (5) Before receiving a certificate of registration from the
184 department, submit a copy of the most recent inspection report
185 resulting from an inspection conducted by the regulatory or licensing
186 agency of the state in which the nonresident pharmacy is located. Such
187 inspection report shall be based on standards required in the most
188 recent United States Pharmacopeia, Chapter 797, as amended from
189 time to time;

190 [(c) A nonresident pharmacy shall, during] (6) During its regular
191 hours of operation, but not less than six days per week, and for a
192 minimum of forty hours per week, provide a toll-free telephone
193 number to facilitate communication between patients in this state and
194 a pharmacist at such nonresident pharmacy who has access to the
195 patient's records. Such toll-free telephone number shall be disclosed on
196 a label affixed to each container of drugs dispensed to patients in this
197 state; [.]

198 (7) Notify the department if the nonresident pharmacy has had any
199 disciplinary action or written advisement or warning by any federal or
200 state regulatory agency or any accreditation body not later than ten
201 days after being notified of such action, advisement or warning; and

202 (8) Provide to the department the names and addresses of all
203 residents of this state to whom such legend devices or legend drugs
204 have been delivered, not later than twenty-four hours after the
205 initiation of such recall, if it conducts a recall of any legend devices or
206 legend drugs.

207 Sec. 4. Section 20-628 of the general statutes is repealed and the
208 following is substituted in lieu thereof (*Effective July 1, 2014*):

209 No nonresident pharmacy shall engage in the business of shipping,
210 mailing or delivering legend devices or legend drugs in this state, or
211 provide any aspect of the practice of pharmacy to residents of this
212 state, unless such nonresident pharmacy has been issued a certificate
213 of registration by the commission and has paid the fee for issuance or
214 renewal of such certificate of registration required in section 20-601.
215 Applications for a certificate of registration as a nonresident pharmacy
216 shall be made on a form furnished by the commission. The commission
217 may require such information as it deems reasonably necessary to
218 carry out the purpose of this section.

219 Sec. 5. Section 20-629 of the general statutes is repealed and the
220 following is substituted in lieu thereof (*Effective July 1, 2014*):

221 (a) The commission may deny, revoke or suspend any certificate of
222 registration as a nonresident pharmacy for: [failure to comply with any
223 requirement of sections 20-627 to 20-630, inclusive.]

224 (1) Failure to comply with any requirement of chapter 400j or
225 chapter 420b;

226 (2) Failure to comply with any federal or state statute or regulation
227 concerning drugs or the practice of pharmacy;

228 (3) Delivering in any manner into this state legend drugs or legend
229 devices that are adulterated or misbranded in violation of chapter 418;
230 or

231 (4) Any disciplinary action taken against the nonresident pharmacy
232 by any state or federal agency.

233 (b) The commission may, [deny, revoke or suspend any certificate of
234 registration as a nonresident pharmacy for conduct which causes
235 serious bodily or serious psychological injury to a resident of this state
236 if the commission has referred] in addition to any action authorized
237 under subsection (a) of this section, refer the matter to the regulatory
238 or licensing agency in the state in which the nonresident pharmacy is
239 located, [and such regulatory or licensing agency fails to (1) initiate an

240 investigation within forty-five days of referral, (2) complete its
241 investigation within one hundred twenty days of referral, (3) resolve
242 the referral through formal agreement, settlement or decision within
243 one hundred eighty days, or (4) initiate disciplinary proceedings when
244 such proceedings are determined to be necessary in the judgment of
245 the regulatory or licensing agency in the state in which the nonresident
246 pharmacy is located.]

247 Sec. 6. Section 21a-70 of the 2014 supplement to the general statutes
248 is repealed and the following is substituted in lieu thereof (*Effective July*
249 *1, 2014*):

250 (a) As used in this section: (1) "Wholesaler" or "distributor" means a
251 person, whether within or without the boundaries of the state of
252 Connecticut, who supplies drugs, medical devices or cosmetics
253 prepared, produced or packaged by manufacturers, to other
254 wholesalers, manufacturers, distributors, hospitals, prescribing
255 practitioners, as defined in subdivision (22) of section 20-571,
256 pharmacies, federal, state or municipal agencies, clinics or any other
257 person as permitted under subsection (h) of this section, except that:
258 (A) A retail pharmacy or a pharmacy within a licensed hospital
259 [which] that supplies to another such pharmacy a quantity of a
260 noncontrolled drug or a schedule II, III, IV or V controlled substance
261 normally stocked by such pharmacies to provide for the immediate
262 needs of a patient pursuant to a prescription or medication order of an
263 authorized practitioner, (B) a pharmacy within a licensed hospital
264 [which] that supplies drugs to another hospital or an authorized
265 practitioner for research purposes, (C) a retail pharmacy [which] that
266 supplies a limited quantity of a noncontrolled drug or of a schedule II,
267 III, IV or V controlled substance for emergency stock to a practitioner
268 who is a medical director of a chronic and convalescent nursing home,
269 of a rest home with nursing supervision or of a state correctional
270 institution, and (D) a pharmacy within a licensed hospital that contains
271 another hospital wholly within its physical structure [which] that
272 supplies to such contained hospital a quantity of a noncontrolled drug
273 or a schedule II, III, IV, or V controlled substance normally stocked by

274 such hospitals to provide for the needs of a patient, pursuant to a
275 prescription or medication order of an authorized practitioner,
276 receiving inpatient care on a unit that is operated by the contained
277 hospital shall not be deemed a wholesaler under this section; (2)
278 "manufacturer" means (A) a person, whether within or without the
279 boundaries of the state of Connecticut, who produces, prepares,
280 cultivates, grows, propagates, compounds, converts or processes,
281 directly or indirectly, by extraction from substances of natural origin or
282 by means of chemical synthesis or by a combination of extraction and
283 chemical synthesis, or who packages, repackages, labels or relabels a
284 container under such manufacturer's own or any other trademark or
285 label any drug, device or cosmetic for the purpose of selling such
286 items, or (B) a compounding pharmacy that dispenses compounded
287 drugs without a prescription or an individual medical order. The
288 words "drugs", "devices" and "cosmetics" shall have the meaning
289 ascribed to them in section 21a-92, as amended by this act; and (3)
290 "commissioner" means the Commissioner of Consumer Protection.

291 (b) No wholesaler or manufacturer shall operate as such until he has
292 received a certificate of registration issued by the commissioner, which
293 certificate shall be renewed annually, provided no such certificate shall
294 be required of a manufacturer, except a sterile compounding
295 pharmacy, as defined in subsection (a) of section 2 of this act, whose
296 principal place of business is located outside the state, who is
297 registered with the federal Food and Drug Administration or any
298 successor agency and who files a copy of such registration with the
299 commissioner. A fee of one hundred ninety dollars shall be charged for
300 each wholesaler's certificate and renewal thereof. A separate certificate
301 and corresponding fee is required for each location existing in this
302 state and for each location existing outside of this state that distributes
303 products into this state. The fee for a manufacturer's certificate and
304 renewal thereof shall be two hundred eighty-five dollars for
305 manufacturers employing not more than five licensed pharmacists or
306 qualified chemists or both; three hundred seventy-five dollars for
307 manufacturers employing not more than ten licensed pharmacists or
308 qualified chemists or both; and nine hundred forty dollars for

309 manufacturers employing more than ten licensed pharmacists or
310 qualified chemists or both. No such certificate shall be issued to a
311 manufacturer unless such drugs, medical devices or cosmetics are
312 manufactured or compounded under the direct supervision of a
313 licensed pharmacist or a qualified chemist. No certificate of
314 registration shall be issued under this section until the applicant has
315 furnished proof satisfactory to the commissioner that the applicant is
316 equipped as to facilities and apparatus to properly carry on the
317 business described in his application and that the applicant conforms
318 to chapter 418 and regulations adopted thereunder.

319 (c) The commissioner shall have the right to deny a certificate of
320 registration if he determines that the issuance of such registration is
321 inconsistent with the public interest. In determining the public interest,
322 the commissioner shall consider, at a minimum, the following factors:

323 (1) Any convictions or regulatory actions involving the applicant
324 under any federal, state or local law relating to drug samples,
325 wholesale or retail drug distribution, or distribution or possession of
326 drugs including controlled substances;

327 (2) Any felony convictions of the applicant under federal, state or
328 local laws;

329 (3) The applicant's past experience in the manufacture or
330 distribution of drugs;

331 (4) The furnishing by the applicant of false or fraudulent material in
332 any application made in connection with drug manufacturing or
333 distribution;

334 (5) Suspension, revocation or other sanction by federal, state or local
335 government of any license or registration currently or previously held
336 by the applicant for the manufacture or distribution of any drugs;

337 (6) Compliance with licensing or registration requirements under
338 previously granted licenses or registrations;

339 (7) Compliance with requirements to maintain or make available to
340 the commissioner or to federal, state or local law enforcement officials
341 those records required by any federal or state statute or regulation;

342 (8) Failure to provide adequate control against the diversion, theft
343 and loss of drugs;

344 (9) Provision of required security for legend drugs and, in the case
345 of controlled substances, compliance with security requirements for
346 wholesalers set forth in regulations adopted under chapter 420b; and

347 (10) Compliance with all regulations adopted to enforce the
348 provisions of this section.

349 (d) The commissioner may suspend, revoke or refuse to renew a
350 registration, or may issue a letter of reprimand or place a registrant on
351 probationary status, for sufficient cause. Any of the following shall be
352 sufficient cause for such action:

353 (1) The furnishing of false or fraudulent information in any
354 application or other document filed with the commissioner;

355 (2) Any criminal conviction of the registrant under any federal or
356 state statute concerning drugs;

357 (3) The suspension, revocation or other restriction or penalty issued
358 against a license or registration related to drugs;

359 (4) Failure to provide adequate control against the diversion, theft
360 and loss of drugs; or

361 (5) A violation of any provision of any federal or state statute or
362 regulation concerning drugs.

363 (e) Wholesalers and manufacturers shall operate in compliance with
364 applicable federal, state and local statutes, regulations and ordinances,
365 including any applicable laws concerning controlled substances, drug
366 product salvaging or reprocessing.

367 (f) Wholesalers and manufacturers shall permit the commissioner,
368 or his authorized representatives, to enter and inspect their premises
369 and delivery vehicles, and to audit their records and written operating
370 procedures, at reasonable times and in a reasonable manner.

371 (g) Before denying, suspending, revoking or refusing to renew a
372 registration, or before issuing a letter of reprimand or placing a
373 registrant on probationary status, the commissioner shall afford the
374 applicant or registrant an opportunity for a hearing in accordance with
375 the provisions of chapter 54. Notice of such hearing may be given by
376 certified mail. The commissioner may subpoena witnesses and require
377 the production of records, papers and documents pertinent to such
378 hearing.

379 (h) No manufacturer or wholesaler shall sell any drugs except to the
380 state or any political subdivision thereof, to another manufacturer or
381 wholesaler, to any hospital recognized by the state as a general or
382 specialty hospital, to any institution having a full-time pharmacist who
383 is actively engaged in the practice of pharmacy in such institution not
384 less than thirty-five hours a week, to a chronic and convalescent
385 nursing home having a pharmacist actively engaged in the practice of
386 pharmacy based upon the ratio of one-tenth of one hour per patient
387 per week but not less than twelve hours per week, to a practicing
388 physician, podiatrist, dentist, optometrist or veterinarian or to a
389 licensed pharmacy or a store to which a permit to sell nonlegend drugs
390 has been issued as provided in section 20-624. The commissioner may
391 adopt such regulations as are necessary to administer and enforce the
392 provisions of this section.

393 (i) Any person who violates any provision of this section shall be
394 fined not more than five hundred dollars or imprisoned not more than
395 six months, or both.

396 Sec. 7. Section 21a-92 of the 2014 supplement to the general statutes
397 is repealed and the following is substituted in lieu thereof (*Effective July*
398 *1, 2014*):

399 For the purposes of this chapter, [and] section 21a-65 and section 8
400 of this act, the following terms shall have the meanings hereinafter
401 specified:

402 (1) "Advertisement" means all representations disseminated in any
403 manner or by any means, other than by labeling, for the purpose of
404 inducing, or which are likely to induce, directly or indirectly, the
405 purchase of food, drugs, devices or cosmetics;

406 (2) (A) "Color additive" means a material [which] that (i) is a dye,
407 pigment or other substance made by a process of synthesis or similar
408 artifice, or extracted, isolated or otherwise derived, with or without
409 intermediate or final change of identity, from a vegetable, animal,
410 mineral or other source, and (ii) when added or applied to a food, drug
411 or cosmetic, or to the human body or any of its parts, is capable, alone
412 or through reaction with other substance, of imparting color thereto,
413 except that the term "color additive" does not include any material
414 exempted by regulation under the federal act, or [which] that the
415 commissioner, by regulation, determines is used, or intended to be
416 used, solely for a purpose or purposes other than coloring; (B) the term
417 "color" includes black, white and intermediate grays, as well as all
418 other colors; (C) nothing in subparagraph (A) of this subdivision shall
419 be construed to apply to any pesticide chemical, soil or plant nutrient,
420 or other agricultural chemical used, or intended to be used, solely
421 because of its effect in aiding, retarding or otherwise affecting, directly
422 or indirectly, the growth or other natural physiological processes of
423 produce of the soil [which] that thereby affects its color, whether
424 before or after harvest;

425 (3) "Commissioner" means the Commissioner of Consumer
426 Protection;

427 (4) "Contaminated with filth" applies to any food, drug, device or
428 cosmetic not securely protected from dust or dirt, and as far as may be
429 necessary, by all reasonable means, from all foreign or injurious
430 contaminations;

431 (5) "Cosmetic" means (A) articles intended to be rubbed, poured,
432 sprinkled or sprayed on, introduced into, or otherwise applied to the
433 human body or any of its parts for cleansing, beautifying, promoting
434 attractiveness or altering the appearance, and (B) articles intended for
435 use as a component of any such articles; except that such term shall not
436 include soap;

437 (6) "Device", except when used in subdivision (15) of this section
438 and in subsection (i) of section 21a-93, subdivision (6) of subsection (a)
439 of section 21a-102, subsection (c) of section 21a-106 and subsection (c)
440 of section 21a-112, means instruments, apparatus and contrivances,
441 including their components, parts and accessories, intended (A) for use
442 in the diagnosis, cure, mitigation, treatment or prevention of disease in
443 humans or other animals, or (B) to affect the structure or any function
444 of the body of humans or other animals;

445 (7) "Director" means the director of the agricultural experiment
446 station;

447 (8) "Drug" means (A) articles recognized in the official United States
448 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
449 States or official National Formulary, or any supplement to any of
450 them; (B) articles intended for use in the diagnosis, cure, mitigation,
451 treatment or prevention of disease in humans or other animals; (C)
452 articles, other than food, intended to affect the structure or any
453 function of the body of humans or any other animal; and (D) articles
454 intended for use as a component of any articles specified in this
455 subdivision; but shall not include devices or their components, parts or
456 accessories;

457 (9) "Federal act" means the federal Food, Drug and Cosmetic Act, as
458 amended, Title 21 USC 301 et seq.: 52 Stat. 1040 et seq.;

459 (10) "Food" means (A) articles used for food or drink for humans or
460 other animals, (B) chewing gum, (C) infant formula, and (D) articles
461 used for components of any such article;

462 (11) "Food additive" means any substance the intended use of which
463 results or reasonably may be expected to result, directly or indirectly,
464 in its becoming a component or otherwise affecting the characteristics
465 of any food, including any substance intended for use in producing,
466 manufacturing, packing, processing, preparing, treating, packaging,
467 transporting or holding food; and including any source of radiation
468 intended for any such use, if such substance is not generally
469 recognized, among experts qualified by scientific training and
470 experience to evaluate its safety, as having been adequately shown
471 through scientific procedures or, in the case of a substance used in
472 food prior to January 1, 1958, through either scientific procedures or
473 experience based on common use in food, to be safe under the
474 conditions of its intended use; except that such term does not include
475 (A) a pesticide chemical in or on a raw agricultural commodity; or (B) a
476 pesticide chemical to the extent that it is intended for use or is used in
477 the production, storage or transportation of any raw agricultural
478 commodity; or (C) a color additive; or (D) any substance used in
479 accordance with a sanction or approval granted prior to June 12, 1963,
480 or the federal Food, Drug and Cosmetic Act, the Poultry Products
481 Inspection Act (21 USC 451 et seq.) or the Meat Inspection Act of
482 March 4, 1907, as amended;

483 (12) "Immediate container" shall not include package liners;

484 (13) "Infant formula" means a milk-based or soy-based powder,
485 concentrated liquid or ready-to-feed substitute for human breast milk
486 that is intended for infant consumption and is commercially available;

487 (14) "Intrastate commerce" means any and all commerce within the
488 state of Connecticut and subject to its jurisdiction, and shall include the
489 operation of any business or service establishment;

490 (15) "Label" means a display of written, printed or graphic matter
491 upon the immediate container of any article, provided a requirement
492 made by or under authority of this chapter that any information or
493 other word or statement appear on the label shall not be considered to
494 be complied with unless such information or other word or statement

495 also appears on the outside container or wrapper, if any, of the retail
496 package of such article, or is easily legible through the outside
497 container or wrapper;

498 (16) "Labeling" means all labels and other written, printed or
499 graphic matter (A) upon any article or any of its containers or
500 wrappers, or (B) accompanying such article, [;] provided, if an article is
501 alleged to be misbranded because the labeling is misleading, or if an
502 advertisement is alleged to be false because it is misleading, then, in
503 determining whether the labeling or advertisement is misleading, there
504 shall be taken into account, among other things, not only
505 representations made or suggested by statement, word, design, device
506 or sound, or any combination thereof, but also the extent to which the
507 labeling or advertisement fails to reveal facts material in the light of
508 such representations or material with respect to consequences which
509 may result from the use of the article to which the labeling or
510 advertisement relates under the conditions of use prescribed in the
511 labeling or advertisement thereof or under such conditions of use as
512 are customary or usual, and provided the representation of a drug, in
513 its labeling or advertisement, as an antiseptic shall be considered to be
514 a representation that it is a germicide, except in the case of a drug
515 purporting to be, or represented as, an antiseptic for inhibitory use as a
516 wet dressing, ointment or dusting powder or for such other use as
517 involves prolonged contact with the body;

518 (17) "Natural food" means food (A) [which] that has not been treated
519 with preservatives, antibiotics, synthetic additives, artificial flavoring
520 or artificial coloring; (B) [which] that has not been processed in a
521 manner that makes such food significantly less nutritive; and (C)
522 [which] that has not been [genetically-engineered] genetically
523 engineered, as defined in section 21a-92b. Processing of food by
524 extracting, purifying, heating, fermenting, concentrating, dehydrating,
525 cooling or freezing shall not, of itself, prevent the designation of such
526 food as "natural food";

527 (18) "New drug" means (A) any drug the composition of which is

528 such that such drug is not generally recognized, among experts
529 qualified by scientific training and experience to evaluate the safety
530 and effectiveness of drugs, as safe and effective for use under the
531 conditions prescribed, recommended or suggested in its labeling, or
532 (B) any drug the composition of which is such that such drug, as a
533 result of investigation to determine its safety and effectiveness for use
534 under such conditions, has become so recognized, but which has not,
535 otherwise than in such investigations, been used to a material extent or
536 for a material time under such conditions, except that the provisions of
537 this subsection pertaining to "effectiveness" shall not apply to any drug
538 [which] that (i) was commercially sold or used in the United States on
539 October 9, 1962, (ii) was not a new drug as defined by this subsection
540 prior to the enactment of these provisions, and (iii) was not covered by
541 an effective application under section 21a-110 or under Section 355 of
542 the federal act, when such drug is intended solely for use under
543 conditions prescribed, recommended, or suggested in labeling with
544 respect to such drug on whichever of the above dates is applicable;

545 (19) "Official compendium" means the official United States
546 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
547 States, official National Formulary, or any supplement to any of them;

548 (20) "Organically grown" means produced through organic farming
549 methods, which involve a system of ecological soil management and
550 mechanical or biological methods to control insects, weeds, pathogens
551 and other pests and which rely on crop rotation, crop residues,
552 composted animal manures, legumes, green manures, composted
553 organic waste or mineral-bearing rocks;

554 (21) "Person" includes any individual, partnership, corporation,
555 limited liability company or association;

556 (22) "Pesticide chemical" means any substance [which] that, alone, in
557 chemical combination or in formulation with one or more other
558 substances is an "economic poison" within the meaning of the federal
559 Insecticide, Fungicide and Rodenticide Act, 7 USC 135-135k, and
560 [which] that is used in the production, storage or transportation of raw

561 agricultural commodities;

562 (23) "Raw agricultural commodity" means any food in its raw or
563 natural state, including all fruits that are washed, colored or otherwise
564 treated in their unpeeled natural form prior to marketing;

565 (24) The term "safe" has reference to the health of human or animal;

566 (25) "Sale" means any and every sale and includes (A) manufacture,
567 processing, packing, canning, bottling or any other production,
568 preparation or putting up; (B) exposure, offer or any other proffer; (C)
569 holding, storing or any other possessing; (D) dispensing, giving,
570 delivering, serving or any other supplying; and (E) applying,
571 administering or any other using.

572 Sec. 8. (NEW) (*Effective July 1, 2014*) (a) For the purposes of this
573 section:

574 (1) "Counterfeit substance" means a drug or substance, or the
575 container or labeling of which, that without authorization, bears the
576 trademark, trade name or other identifying mark, imprint, number or
577 device, or any likeness thereof, of a manufacturer, distributor or
578 dispenser other than the person or persons who in fact manufactured,
579 distributed or dispensed such drug or substance and that thereby
580 falsely purports or is represented to be the drug or substance of, or to
581 have been distributed by, such other manufacturer, distributor or
582 dispenser; and

583 (2) "Department" means the Department of Consumer Protection.

584 (b) No person shall knowingly purchase for resale, sell, offer for sale
585 or deliver in any manner a counterfeit substance.

586 (c) The department shall conduct any necessary investigation
587 regarding possible violations of this section. In connection with any
588 such investigation, the commissioner, or the commissioner's
589 authorized agent, may administer oaths, issue subpoenas, compel
590 testimony and order the production of books, records and documents.

591 If any person refuses to appear, to testify or to produce any book,
592 record or document when so ordered, a judge of the Superior Court
593 may make such order as may be appropriate to aid in the enforcement
594 of this section.

595 (d) The commissioner may conduct hearings regarding violations of
596 this section. Such hearings shall be conducted in accordance with
597 chapter 54 of the general statutes. In connection with any such hearing,
598 the commissioner may administer oaths, issue subpoenas, compel
599 testimony and order the production of books, records and documents.
600 If any person refuses to appear, testify or produce any book, record or
601 document when so ordered, a judge of the Superior Court may make
602 such order as may be appropriate to aid in the enforcement of this
603 section.

604 (e) For any violation of this section, the commissioner may:

605 (1) Suspend, revoke, refuse to renew, or place on probationary
606 status a license or registration issued by the department;

607 (2) Assess a civil penalty of not more than one thousand dollars per
608 violation;

609 (3) Issue an appropriate order to any person found to be in violation
610 of this section to provide for the immediate discontinuance of the
611 violation; and

612 (4) Issue an appropriate order to any person found to be in violation
613 of this section, requiring the person to make restitution for any damage
614 caused by the violation.

615 (f) The commissioner may adopt regulations, in accordance with
616 chapter 54 of the general statutes, to enforce the provisions of this
617 section.

618 (g) Any person who violates any provision of this section shall be
619 fined not more than ten thousand dollars or imprisoned not more than
620 one year, or both, for each violation.

621 Sec. 9. Section 21a-432 of the general statutes is repealed. (*Effective*
622 *July 1, 2014*)

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>July 1, 2014</i>	20-619(c)
Sec. 2	<i>July 1, 2014</i>	New section
Sec. 3	<i>July 1, 2014</i>	20-627
Sec. 4	<i>July 1, 2014</i>	20-628
Sec. 5	<i>July 1, 2014</i>	20-629
Sec. 6	<i>July 1, 2014</i>	21a-70
Sec. 7	<i>July 1, 2014</i>	21a-92
Sec. 8	<i>July 1, 2014</i>	New section
Sec. 9	<i>July 1, 2014</i>	Repealer section

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 15 \$	FY 16 \$
Consumer Protection, Dept.	GF - Revenue Gain	less than \$5,000	less than \$5,000

Municipal Impact: None

Explanation

The bill results in a revenue gain of less than \$5,000 in FY 15 and FY 16 due to the expanded authority of the Department of Consumer Protection with regard to the sale of counterfeit substances and associated penalties.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to the number of penalties.

OLR Bill Analysis**sHB 5262*****AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.*****SUMMARY:**

This bill makes several changes to the pharmacy laws, including adding requirements for (1) sterile compounding, including making certain compounding pharmacies register as drug manufacturers; (2) counterfeit substances; (3) nonresident pharmacies; and (4) “dispense as written” prescriptions.

The bill gives the Department of Consumer Protection (DCP) more oversight over sterile compounding pharmacies by, among other things, requiring them to file more reports with the department and comply with the latest pharmacopeia standards on sterile pharmaceutical preparations. It also requires sterile compounding pharmacies that provide compounded sterile products without a patient-specific prescription or medical order to obtain a DCP manufacturing license.

The bill bans the sale and delivery of counterfeit substances and grants DCP additional investigatory and enforcement authority, including the authority to impose civil penalties. The bill’s definition of “counterfeit substances” mirrors the language recognized by the federal Food and Drug Administration. Existing law already prohibits selling counterfeit or misbranded drugs under the state Uniform Food, Drug, and Cosmetic Act (see BACKGROUND).

The bill broadens the categories of nonresident pharmacies that must (1) register in Connecticut, (2) comply with pharmacy reporting requirements, and (3) provide patient contact information.

Finally, the bill establishes new procedures for prescribing practitioners and pharmacists when dispensing drugs that cannot be substituted for a generic version.

EFFECTIVE DATE: July 1, 2014

§ 2 — STERILE COMPOUNDING

The bill requires sterile compounding pharmacies to comply with (1) the latest United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as amended from time to time (pharmacopeia standards) and (2) all applicable federal and state law and regulations. Such pharmacies must prepare and maintain a policy and procedure manual that complies with the pharmacopeia standards, including, among other things, information on sterilization methods and training.

Under the bill, a “sterile compounding pharmacy” is a pharmacy, including any located in healthcare institution, or a nonresident pharmacy that dispenses or compounds sterile pharmaceuticals. “Sterile pharmaceuticals” mean any drug dosage, including parenterals (medicine not administered orally), injectables, surgical irrigants and ophthalmics, devoid of viable microorganisms.

Amending Pharmacy Application

The bill requires sterile compounding pharmacies to file an addendum to their pharmacy application with DCP before compounding sterile pharmaceuticals for use in the state. The addendum must include notice that they are engaged in sterile compounding and a description of changes to the pharmacy layout. DCP, or the appropriate state oversight agency for nonresident pharmacies, must inspect the changes and DCP and the Pharmacy Commission must approve them before a pharmacy can begin compounding sterile pharmaceuticals. (It is unclear how the Pharmacy Commission or the out-of-state oversight agency will receive notice of the changes.)

With its initial nonresident pharmacy application and then every

two years thereafter, the nonresident pharmacy must provide DCP with (1) proof of current inspection by its home state's regulatory oversight agency and (2) a copy of the most recent inspection report. The inspection must be based on the latest pharmacopeia compliance standard.

Patient-Specific Requirement

The bill allows a sterile compounding pharmacy to provide patient-specific sterile pharmaceuticals only to patients, physicians, osteopaths, podiatrists, dentists, veterinarians; an acute care or long-term care hospital; or a Department of Public Health (DPH) licensed health care facility.

Manufacturing License

The bill requires sterile compounding pharmacies that provide compounded sterile products without a prescription or medical order to get a DCP manufacturing license and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site up to a 30-day supply of sterile pharmaceuticals. The 30 days start from the day compounding is completed, including third party analytical testing performed according to pharmacopeia standards.

Remodeling

The bill requires sterile compounding pharmacies to notify DCP at least 10 days before remodeling or relocating a pharmacy clean room; or upgrading or starting nonemergency repairs to the heating, ventilation, air conditioning, or primary engineering controls for a clean room. They must notify DCP, in writing, as soon as possible after making any emergency repair.

If the remodel, relocation, upgrade, or repair requires sterile recertification, the pharmacy must provide DCP with a copy of the recertification. An independent licensed environmental monitoring entity must perform the recertification. (The bill does not specify when the recertification is required or when DCP must receive the copy.)

Reporting Requirements

The bill requires sterile compounding pharmacies, other than those in health care institutions, to give DCP a written report of any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined by pharmacopeia standards, within one business day after discovery. A sterile compounding pharmacy within a health care facility must report the violation or noncompliance to DPH. A sampling test measures the number of particles and microorganisms in the air around the compounding area.

Under the bill, sterile compounding pharmacies must also report to DCP any administrative or legal action commenced against them by any state or federal regulatory agency or accreditation entity within five business days after becoming aware of such an action.

A physician, hospital, or health care facility that receives sterile pharmaceuticals must report to DCP any (1) dispensing errors or (2) suspected adulterated sterile pharmaceuticals. (There are no such reporting requirements for the other health professionals that may receive sterile pharmaceuticals.)

Recalls

The bill requires sterile compounding pharmacies to notify certain people when they recall sterile pharmaceuticals. By the end of the business day following the recall, they must notify (1) each patient or patient caregiver, the prescribing practitioner, and DCP when the pharmaceutical was dispensed as a patient-specific prescription or medical order and (2) each purchaser of the pharmaceutical, DCP, and the federal Food and Drug Administration (FDA) for pharmaceuticals that were not dispensed as a patient-specific prescription or medical order.

By law, the Pharmacy Commission licenses pharmacies and pharmacists. The commission may, among other administrative sanctions, refuse to authorize or renew a license or assess a maximum civil penalty of \$1,000, if a pharmacy or pharmacist violates any state

statute or regulation related to drugs, devices, or the practice of pharmacy (CGS § 20-579). The Pharmacy Commission is located within DCP.

§§ 7-9 — COUNTERFEIT SUBSTANCES

The bill prohibits anyone from knowingly purchasing for resale, selling, offering for sale, or delivering a counterfeit substance in any manner. Existing law already prohibits several actions related to counterfeit or misbranded drugs (see BACKGROUND).

Under the bill, a counterfeit substance is a drug or substance which, or the container or labeling of which, (1) without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, likeness of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance and (2) falsely claims or represents the drug or substance to have been distributed by the other manufacturer, distributor, or dispenser. (It is unclear what would qualify as a “substance” or “having any likeness,” since both are undefined.)

Investigatory Authority

Under the bill, DCP must investigate possible counterfeit substance violations and may hold hearings. As part of any investigation or hearing, the commissioner may administer oaths; issue subpoenas; compel testimony; and order the production of books, records, and documents. If anyone refuses to appear; testify; or to produce any book, record, or document, a Superior Court judge may issue an order compelling compliance. The hearing must be conducted in accordance to the Uniform Administrative Procedures Act.

Penalties

The DCP commissioner may take the following actions against anyone who knowingly purchases for resale, sells, offers for sale, or delivers counterfeit substances in violation of the bill’s provisions:

1. suspend, revoke, refuse to renew, or place on probation a DCP

license or registration;

2. assess up to a \$1,000 civil penalty for each violation; and
3. issue a cease and desist order or order of restitution.

Violators may also be fined up to \$10,000, imprisoned for up to one year, or both for each violation.

Repealed Section

The bill repeals the current counterfeit substance ban, which has no penalties or enforcement procedures. The ban prohibits anyone from knowingly possessing, purchasing, trading, selling, or transferring a controlled substance that is illegally stamped or imprinted with the trademark, trade name, or other identifying mark, imprint, number, or device of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance. Under the law, controlled substances are drugs, substances, or immediate precursors in schedules I to V of the Connecticut controlled substance scheduling regulations. The term does not include alcohol, nicotine, or caffeine.

§§ 3 - 5 — NONRESIDENT PHARMACY

The bill broadens the categories of nonresident pharmacies that must (1) register in Connecticut, (2) comply with pharmacy reporting requirements, and (3) provide patient contract information. It also adds to the responsibilities of all nonresident pharmacies and to the grounds for denying, revoking, or suspending their registration.

Registration

The bill requires nonresident pharmacies that provide any aspect of the practice of pharmacy to Connecticut residents to be registered with DCP upon the Pharmacy Commission's approval. Under current law, only those that ship, mail, or deliver prescribed legend drugs or devices into the state need to register. By law, a nonresident pharmacy registration certificate fee is \$750. The renewal fee is \$190.

Annual Report

The bill requires registered nonresident pharmacies to:

1. Annually disclose to the Pharmacy Commission the names and titles of all pharmacists who provide any aspect of the practice of pharmacy to Connecticut residents. By law, nonresident pharmacies must also annually report the names and titles of the principal corporate officers and pharmacists who dispense drugs or devices to Connecticut residents.
2. Comply with all lawful directions and information requests from DCP. Under current law, such pharmacies are only required to comply with requests from the commission. The bill also eliminates the requirement that pharmacies submit a statement of compliance.
3. Disclose whether they are dispensing sterile compounded products in Connecticut and submit a copy of the manufacturing license or registration issued by the appropriate state oversight agency and a copy of any FDA registration if the products are not patient-specific. (The bill does not explicitly specify to whom the disclosure is made, but presumably it is to DCP.)
4. Submit a copy of their most recent inspection report, based on pharmacopeia standards, conducted by the appropriate state oversight agency before DCP can grant a registration certificate. (It is not clear whether all states inspect based on pharmacopeia standards. Presumably under the bill, DCP may refuse to grant a registration for those that do not comply.)
5. Notify DCP within 10 days, if they have been disciplined by, or received a written advisement or warning from any federal or state regulatory agency, or any accreditation body.
6. Provide DCP with the names and addresses of all state residents to whom they delivered legend (prescription) devices or drugs within 24 hours after initiating a recall of such devices or drugs.

Penalties

The bill expands the grounds for which the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy's registration certificate to include:

1. failing to comply with any pharmacy and dependency-producing drug law requirements;
2. failing to comply with any federal or state law or regulation concerning drugs or the practice of pharmacy;
3. delivering into the state, adulterated or misbranded legend drugs or devices in violation of the state Uniform Food, Drug, and Cosmetic Act; or
4. any disciplinary action taken by any state or federal agency.

Current law only allows the commission to take these disciplinary actions when a nonresident pharmacy fails to comply with laws governing registration; shipping, mailing, or delivering legend devices or drugs; or advertises without a certification of registration.

The bill eliminates the commission's authority to deny, revoke, or suspend a nonresident pharmacy's registration certificate for conduct that causes serious bodily or psychological injury to a Connecticut resident. The commissioner must first refer the matter to the appropriate oversight agency in the state where the pharmacy is located.

§ 6 — DRUG MANUFACTURERS

The bill requires pharmacies that dispense compounded drugs without a prescription or an individual medical order to register in Connecticut as drug manufacturers regardless of whether their principal place of business is located in the state. By law, out-of-state manufacturers that do not compound do not need to register. The registration fee is between \$285 and \$940 depending on the number of pharmacists or qualified chemists the pharmacies employ.

It also specifically requires manufacturers to comply with applicable federal, state, and local statutes, regulations, and ordinances, including applicable laws concerning controlled substances and drug product salvaging or reprocessing. Current law requires wholesalers to comply with these requirements.

By law, anyone who violates the manufacturing requirements may be subject to a fine of up to \$500, up to six months imprisonment, or both. In addition, the commissioner may suspend, revoke, or refuse to renew a registration, issue a reprimand letter, or place a registrant on probation, for:

1. furnishing false or fraudulent information filed with commissioner;
2. any federal or state criminal conviction concerning drugs;
3. any drug-related suspension, revocation, other restriction, or penalty issued against the registrant;
4. failing to provide adequate control against the diversion, theft, or loss of drugs; or
5. violating any federal or state drug law or regulation.

§1 — DISPENSE AS WRITTEN PRESCRIPTIONS

The bill creates new requirements for prescribing practitioners and pharmacists when dispensing drugs that cannot be substituted for a generic version.

Written Prescriptions

For written prescriptions, the bill requires the prescribing practitioner to indicate on the prescription form that the product is “brand medically necessary” or “no substitution.” The bill specifies that no prescription form may default to these terms.

Telephonic Prescriptions

For telephoned prescriptions, the bill requires the pharmacist to

write the phrase “brand medically necessary” or “no substitution” on the prescription or enter it in the electronic prescription record. The pharmacist must also record on the prescription (1) the time the telephone prescription was received and (2) name of the person who ordered the prescription.

Electronic Prescriptions

For electronic prescriptions, the bill requires the prescribing practitioner to select the “dispense-as-written” code. The bill specifies that no electronic prescriptions may default to “brand medically necessary” or “no substitution.”

Medicaid Prescriptions

The bill eliminates the specific “Medicaid dispense as written” prescription requirements and instead requires them to conform to the bill’s prescription requirements.

For Medicaid recipients, current law requires prescribing practitioners to specify the basis on which the brand name drug and dosage form is medically necessary compared to a chemically equivalent generic drug substitution. The practitioner must write, in his or her handwriting, the phrase “BRAND MEDICALLY NECESSARY,” on the prescription form or on an electronically produced copy of the form. If the prescription was ordered by telephone or electronically and the form did not reproduce the practitioner’s handwriting, then (1) a statement to that effect must still be on the form and (2) written certification in the practitioner’s handwriting with the phrase “BRAND MEDICALLY NECESSARY” must be sent to the dispensing pharmacy within 10 days after the communication date. The phrase “BRAND MEDICALLY NECESSARY” must not be preprinted, stamped, or initialed on the form.

BACKGROUND

Prohibitions Concerning Counterfeit or Misbranded Drugs

Among other things, the state Uniform Food, Drug, and Cosmetic

Act prohibits:

1. selling misbranded drugs in intrastate commerce;
2. forging or counterfeiting any mark, label, or other identification required by state or federal regulations to be on a drug;
3. placing any trademark, trade name, identifying mark, or any likeness thereof, on another drug or its container, with intent to defraud;
4. selling, dispensing, disposing of, or concealing or keeping any drug with intent to sell, dispense, or dispose, with knowledge that a trademark, trade name, other identifying mark, or any likeness of it, has been placed on the drug in a prohibited manner; or
5. making, selling, disposing of, or keeping or concealing any printing technology or tool designed to print a trademark, trade name, other identifying mark, or any likeness of it, on any drug, with intent to defraud (CGS § 21a-93).

A violation of any of these prohibitions is generally punishable by up to six months in prison, a fine of up to \$500, or both. A subsequent violation or a violation committed with intent to defraud or mislead is punishable by up to one year in prison, a fine of up to \$1,000, or both (CGS § 21a-95).

Related Bill

HB 5439, reported favorably by the Human Services Committee, transfers the “Medicaid dispense as written” provisions to the Human Services statutes and imposes substantially similar prescription requirements as this bill.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute

Yea 17 Nay 0 (03/13/2014)