



General Assembly

February Session, 2014

Raised Bill No. 5262

LCO No. 1342



Referred to Committee on GENERAL LAW

Introduced by:
(GL)

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2 the general statutes is repealed and the following is substituted in lieu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." No prescription form shall default to
28 "brand medically necessary" or "no substitution", (2) for prescriptions
29 transmitted by telephonic means, the pharmacist shall place the phrase
30 "brand medically necessary" or "no substitution" on the prescription in
31 the pharmacist's handwriting or in the electronic prescription record
32 and shall record on the prescription the time the telephonic
33 authorization was received and the name of the person who
34 communicated the authorization to the pharmacist, and (3) for
35 electronic prescriptions, the practitioner shall select the dispense-as-
36 written code indicating on the certified electronic prescription that a
37 substitution is not allowed by the practitioner. Electronic prescriptions
38 shall not default to "brand medically necessary" or "no substitution".

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

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

45 (2) "Sterile pharmaceutical" means any dosage form of a drug,
46 including, but not limited to, parenterals, injectables, surgical irrigants
47 and ophthalmics, devoid of viable microorganisms.

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

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

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

69 (2) If a sterile compounding pharmacy provides compounded sterile
70 products without a patient-specific prescription or medical order, it
71 shall also obtain a manufacturing license from the Department of
72 Consumer Protection and any required federal license or registration.
73 A sterile compounding pharmacy may prepare and maintain on-site
74 anticipatory inventory of sterile pharmaceuticals no greater than a
75 two-week supply.

76 (e) (1) If a sterile compounding pharmacy plans to conduct a
77 remodel of a pharmacy clean room, a relocation of a clean room within
78 the facility or an upgrade or nonemergency repair to the heating,

79 ventilation, air conditioning or primary engineering controls for a
80 clean room, it shall notify the Department of Consumer Protection not
81 later than ten days prior to any such action. If a sterile compounding
82 pharmacy makes an emergency repair, it shall notify the department of
83 such repair, in writing, as soon as possible after such repair is made.

84 (2) If a remodel, relocation, upgrade or repair requires sterile
85 recertification, the sterile compounding pharmacy shall provide a copy
86 of the sterile recertification to the Department of Consumer Protection.
87 The recertification shall only be performed by an independent licensed
88 environmental monitoring entity. The sterile compounding pharmacy
89 shall not resume preparing or dispensing sterile pharmaceuticals until
90 it receives the approval of said department. A nonresident sterile
91 compounding pharmacy shall not resume preparing or dispensing
92 sterile pharmaceuticals into this state without the approval of said
93 department and the oversight agency for the home state of such sterile
94 compounding pharmacy.

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

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

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

117 (h) A sterile compounding pharmacy shall prepare and maintain a
118 policy and procedure manual. The policy and procedure manual shall
119 comply with the latest United States Pharmacopeia, Chapter 797,
120 Pharmaceutical Compounding - Sterile Preparations, as amended from
121 time to time.

122 (i) A sterile compounding pharmacy shall report to the Department
123 of Consumer Protection any administrative or legal action commenced
124 against it by any state or federal regulatory agency or accreditation
125 entity not later than five business days after becoming aware of the
126 commencement of such action.

127 (j) A sterile compounding pharmacy that is a nonresident pharmacy,
128 as defined in section 20-627 of the general statutes, as amended by this
129 act, shall provide the Department of Consumer Protection proof of
130 current inspection by the nonresident pharmacy's home state
131 regulatory oversight agency. Such inspection shall be based on the
132 latest United States Pharmacopeia, Chapter 797, Pharmaceutical
133 Compounding - Sterile Preparations compliance standards, as
134 amended from time to time. Such nonresident pharmacy shall submit
135 to said department a copy of the most recent inspection report with the
136 initial nonresident pharmacy application and with each renewal
137 application.

138 (k) A medical practitioner, hospital or health care facility that
139 receives sterile pharmaceuticals dispensed by a sterile compounding
140 pharmacy or sold by a manufacturer registered pursuant to section
141 21a-70 of the general statutes, as amended by this act, shall report any

142 errors related to such dispensing or any suspected adulterated sterile
143 pharmaceuticals to the Department of Consumer Protection.

144 (l) The Commissioner of Consumer Protection may adopt
145 regulations pursuant to the provisions of chapter 54 of the general
146 statutes to carry out the provisions of this section.

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

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

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

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

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

169 (3) Disclose whether the nonresident pharmacy is dispensing sterile
170 compounded products to this state. If such dispensed sterile

171 compounded products are not patient specific, the nonresident
172 pharmacy shall submit a copy of the manufacturing license or
173 registration issued by the regulatory or licensing agency of the state in
174 which it is licensed, and a copy of any registration issued by the
175 federal Food and Drug Administration;

176 [(3)] (4) Maintain at all times, a valid unexpired license, permit or
177 registration to conduct such pharmacy in compliance with the laws of
178 the state in which the nonresident pharmacy is located; [.]

179 [(4)] (5) Before receiving a certificate of registration from the
180 department, submit a copy of the most recent inspection report
181 resulting from an inspection conducted by the regulatory or licensing
182 agency of the state in which the nonresident pharmacy is located. Such
183 inspection report shall be based on standards required in the latest
184 United States Pharmacopeia, Chapter 797, as amended from time to
185 time;

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

194 (7) Notify the department if the nonresident pharmacy has had any
195 disciplinary action or written advisement or warning by any federal or
196 state regulatory agency or any accreditation body not later than ten
197 days after becoming aware of such action, advisement or warning; and

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

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

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

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

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

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

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

223 (3) Delivering in any manner into this state legend drugs or legend
224 devices that are adulterated or misbranded in violation of chapter 418;
225 or

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

228 (b) The commission may, [deny, revoke or suspend any certificate of
229 registration as a nonresident pharmacy for conduct which causes
230 serious bodily or serious psychological injury to a resident of this state

231 if the commission has referred] in addition to any action authorized by
232 subsection (a) of this section, refer the matter to the regulatory or
233 licensing agency in the state in which the nonresident pharmacy is
234 located. [and such regulatory or licensing agency fails to (1) initiate an
235 investigation within forty-five days of referral, (2) complete its
236 investigation within one hundred twenty days of referral, (3) resolve
237 the referral through formal agreement, settlement or decision within
238 one hundred eighty days, or (4) initiate disciplinary proceedings when
239 such proceedings are determined to be necessary in the judgment of
240 the regulatory or licensing agency in the state in which the nonresident
241 pharmacy is located.]

242 Sec. 6. Section 21a-70 of the 2014 supplement to the general statutes
243 is repealed and the following is substituted in lieu thereof (*Effective July*
244 *1, 2014*):

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

264 of a rest home with nursing supervision or of a state correctional
265 institution, and (D) a pharmacy within a licensed hospital that contains
266 another hospital wholly within its physical structure [which] that
267 supplies to such contained hospital a quantity of a noncontrolled drug
268 or a schedule II, III, IV, or V controlled substance normally stocked by
269 such hospitals to provide for the needs of a patient, pursuant to a
270 prescription or medication order of an authorized practitioner,
271 receiving inpatient care on a unit that is operated by the contained
272 hospital shall not be deemed a wholesaler under this section; (2)
273 "manufacturer" means (A) a person, whether within or without the
274 boundaries of the state of Connecticut, who produces, prepares,
275 cultivates, grows, propagates, compounds, converts or processes,
276 directly or indirectly, by extraction from substances of natural origin or
277 by means of chemical synthesis or by a combination of extraction and
278 chemical synthesis, or who packages, repackages, labels or relabels a
279 container under such manufacturer's own or any other trademark or
280 label any drug, device or cosmetic for the purpose of selling such
281 items, or (B) a compounding pharmacy that dispenses compounded
282 drugs without a prescription or an individual medical order. The
283 words "drugs", "devices" and "cosmetics" shall have the meaning
284 ascribed to them in section 21a-92, as amended by this act; and (3)
285 "commissioner" means the Commissioner of Consumer Protection.

286 (b) No wholesaler or manufacturer shall operate as such until he has
287 received a certificate of registration issued by the commissioner, which
288 certificate shall be renewed annually, provided no such certificate shall
289 be required of a manufacturer, except a compounding pharmacy,
290 whose principal place of business is located outside the state, who is
291 registered with the federal Food and Drug Administration or any
292 successor agency and who files a copy of such registration with the
293 commissioner. A fee of one hundred ninety dollars shall be charged for
294 each wholesaler's certificate and renewal thereof. A separate certificate
295 and corresponding fee is required for each location existing in this
296 state and for each location existing outside of this state that distributes

297 products into this state. The fee for a manufacturer's certificate and
298 renewal thereof shall be two hundred eighty-five dollars for
299 manufacturers employing not more than five licensed pharmacists or
300 qualified chemists or both; three hundred seventy-five dollars for
301 manufacturers employing not more than ten licensed pharmacists or
302 qualified chemists or both; and nine hundred forty dollars for
303 manufacturers employing more than ten licensed pharmacists or
304 qualified chemists or both. No such certificate shall be issued to a
305 manufacturer unless such drugs, medical devices or cosmetics are
306 manufactured or compounded under the direct supervision of a
307 licensed pharmacist or a qualified chemist. No certificate of
308 registration shall be issued under this section until the applicant has
309 furnished proof satisfactory to the commissioner that the applicant is
310 equipped as to facilities and apparatus to properly carry on the
311 business described in his application and that the applicant conforms
312 to chapter 418 and regulations adopted thereunder.

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

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

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

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

325 (4) The furnishing by the applicant of false or fraudulent material in
326 any application made in connection with drug manufacturing or
327 distribution;

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

331 (6) Compliance with licensing or registration requirements under
332 previously granted licenses or registrations;

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

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

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

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

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

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

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

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

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

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

357 (e) Wholesalers and manufacturers shall operate in compliance with
358 applicable federal, state and local statutes, regulations and ordinances,
359 including any applicable laws concerning controlled substances, drug
360 product salvaging or reprocessing.

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

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

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

386 provisions of this section.

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

390 Sec. 7. Section 21a-92 of the 2014 supplement to the general statutes
391 is repealed and the following is substituted in lieu thereof (*Effective July*
392 *1, 2014*):

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

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

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

417 produce of the soil [which] that thereby affects its color, whether
418 before or after harvest;

419 (3) "Commissioner" means the Commissioner of Consumer
420 Protection;

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

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

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

439 (7) "Director" means the director of the agricultural experiment
440 station;

441 (8) "Drug" means (A) articles recognized in the official United States
442 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
443 States or official National Formulary, or any supplement to any of
444 them; (B) articles intended for use in the diagnosis, cure, mitigation,
445 treatment or prevention of disease in humans or other animals; (C)
446 articles, other than food, intended to affect the structure or any

447 function of the body of humans or any other animal; and (D) articles
448 intended for use as a component of any articles specified in this
449 subdivision; but shall not include devices or their components, parts or
450 accessories;

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

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

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

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

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

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

484 (15) "Label" means a display of written, printed or graphic matter
485 upon the immediate container of any article, provided a requirement
486 made by or under authority of this chapter that any information or
487 other word or statement appear on the label shall not be considered to
488 be complied with unless such information or other word or statement
489 also appears on the outside container or wrapper, if any, of the retail
490 package of such article, or is easily legible through the outside
491 container or wrapper;

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

510 wet dressing, ointment or dusting powder or for such other use as
511 involves prolonged contact with the body;

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

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

539 (19) "Official compendium" means the official United States
540 Pharmacopoeia, official Homeopathic Pharmacopoeia of the United
541 States, official National Formulary, or any supplement to any of them;

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

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

550 (22) "Pesticide chemical" means any substance [which] that, alone, in
551 chemical combination or in formulation with one or more other
552 substances is an "economic poison" within the meaning of the federal
553 Insecticide, Fungicide and Rodenticide Act, 7 USC 135-135k, and
554 [which] that is used in the production, storage or transportation of raw
555 agricultural commodities;

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

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

560 (25) "Sale" means any and every sale and includes (A) manufacture,
561 processing, packing, canning, bottling or any other production,
562 preparation or putting up; (B) exposure, offer or any other proffer; (C)
563 holding, storing or any other possessing; (D) dispensing, giving,
564 delivering, serving or any other supplying; and (E) applying,
565 administering or any other using.

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

567 (1) "Counterfeit substance" means a drug or substance that, or the
568 container or labeling that, without authorization, bears the trademark,
569 trade name or other identifying mark, imprint, number or device, or
570 any likeness thereof, of a manufacturer, distributor or dispenser other

571 than the person or persons who in fact manufactured, distributed or
572 dispensed such drug or substance and that thereby falsely purports or
573 is represented to be the drug or substance of, or to have been
574 distributed by, such other manufacturer, distributor or dispenser; and

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

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

578 (c) The department shall conduct any necessary investigation
579 regarding possible violations of this section. In connection with any
580 such investigation, the commissioner, or the commissioner's
581 authorized agent, may administer oaths, issue subpoenas, compel
582 testimony and order the production of books, records and documents.
583 If any person refuses to appear, to testify or to produce any book,
584 record or document when so ordered, a judge of the Superior Court
585 may make such order as may be appropriate to aid in the enforcement
586 of this section.

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

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

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

599 (2) Assess a civil penalty of not more than one thousand dollars per

600 violation;

601 (3) Issue an appropriate order to any person found to be violating
602 this section providing for the immediate discontinuance of the
603 violation; and

604 (4) Issue an appropriate order to any person found to be violating
605 this section, requiring the violator to make restitution for any damage
606 caused by the violation.

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

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

613 Sec. 9. Section 21a-432 of the general statutes is repealed. (*Effective*
614 *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

Statement of Purpose:

To amend the Pharmacy Practice Act and Department of Consumer Protection statutes regarding programs under the jurisdiction of the Department of Social Services, sterile compounding pharmacies,

nonresident pharmacies, compounding pharmacies and counterfeit substances.

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