



General Assembly

**Substitute Bill No. 5262**

February Session, 2014



**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2 the general statutes is repealed and the following is substituted in lieu  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.*