General Assembly

Amendment

February Session, 2014

LCO No. **5519**

HB0526205519HD0

Offered by:
REP. BARAM, 15th Dist.

To: Subst. House Bill No. **5262** File No. 243 Cal. No. 150

"AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS."

Strike everything after the enacting clause and substitute the following in lieu thereof:

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 Subsection (c) of section 20-619 of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2014*):

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

prohibition was communicated by telephonic or other electronic communication that did not reproduce the practitioner's handwriting, a statement to that effect appears on the form. The phrase "BRAND MEDICALLY NECESSARY" shall not be preprinted or stamped or initialed on the form. If the practitioner specifies by telephonic or other electronic communication that did not reproduce the practitioner's handwriting that there shall be no substitution for the specified brand name drug product in any prescription for a Medicaid recipient, written certification in the practitioner's handwriting bearing the phrase "BRAND MEDICALLY NECESSARY" shall be sent to the dispensing pharmacy not later than ten days after the date of such communication**]** for written prescriptions, the practitioner shall specify on the prescription form that the drug product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

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

(1) "Medical order" means a written, oral or electronic order by a prescribing practitioner, as defined in section 20-14c of the general statutes, for a drug to be dispensed by a pharmacy for administration to a patient;

(2) "Sterile compounding pharmacy" means a pharmacy, as defined

in section 20-594 of the general statutes, or a nonresident pharmacy registered pursuant to section 20-627 of the general statutes, as amended by this act, that dispenses or compounds sterile pharmaceuticals; and

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

(b) (1) If an applicant for a new pharmacy license pursuant to section 20-594 of the general statutes intends to compound sterile pharmaceuticals, the applicant shall file an addendum to its pharmacy license application to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the proposed pharmacy premises of the applicant and the applicant shall not compound sterile pharmaceuticals until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(2) If an existing pharmacy licensed pursuant to section 20-594 of the general statutes intends to compound sterile pharmaceuticals for the first time on or after July 1, 2014, such pharmacy shall file an addendum application to its application on file with the department to include sterile pharmaceutical compounding. The Department of Consumer Protection shall inspect the pharmacy premises and the pharmacy shall not compound sterile pharmaceuticals until it receives notice that such addendum application has been approved by the department and the Commission of Pharmacy.

(3) If an applicant for a nonresident pharmacy registration intends to compound sterile pharmaceuticals for sale or delivery in this state, the applicant shall file an addendum to its application to include sterile pharmaceutical compounding. The applicant shall provide the department with written proof it has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such pharmacy shall not compound sterile

pharmaceuticals for sale or delivery in this state until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

(4) If a nonresident pharmacy registered pursuant to section 20-627 of the general statutes, as amended by this act, intends to compound sterile pharmaceuticals for sale or delivery in this state for the first time on or after July 1, 2014, the nonresident pharmacy shall file an addendum to its application to include sterile pharmaceutical compounding. The nonresident pharmacy shall provide the department with written proof it has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such pharmacy shall not compound sterile pharmaceuticals until it receives notice that the addendum application has been approved by the department and the Commission of Pharmacy.

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

(d) An institutional pharmacy within a facility licensed pursuant to section 19a-490 of the general statutes that compounds sterile pharmaceuticals shall comply with the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time, and shall also comply with all applicable federal and state statutes and regulations. Such institutional pharmacy may request from the Commissioner of Consumer Protection an extension of time, not to exceed six months, to comply, for state enforcement purposes, with any amendments to Chapter 797, for good cause shown. The commissioner may grant an extension for a length of time not to exceed six months. Nothing herein shall prevent such institutional pharmacy from requesting a subsequent extension of time or shall prevent the commissioner from

granting such extension.

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

(2) If a sterile compounding pharmacy provides sterile pharmaceuticals without a patient-specific prescription or medical order, the sterile compounding pharmacy shall also obtain a certificate of registration from the Department of Consumer Protection pursuant to section 21a-70 of the general statutes, as amended by this act, and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site inventory of sterile pharmaceuticals no greater than a thirty-day supply, calculated from the completion of compounding, which thirty-day period shall include the period required for third-party analytical testing, to be performed in accordance with the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations, as amended from time to time.

(f) (1) If a sterile compounding pharmacy plans to remodel a pharmacy clean room within the sterile compounding facility, relocate a pharmacy clean room within the facility or upgrade or conduct a nonemergency repair to the heating, ventilation, air conditioning or primary engineering controls for a pharmacy clean room within the facility, the sterile compounding pharmacy shall notify the Department of Consumer Protection not later than ten days prior to commencing such remodel, relocation, upgrade or repair. If a sterile compounding pharmacy makes an emergency repair, the sterile compounding pharmacy shall notify the department of such repair, in writing, as soon as possible after such repair is commenced.

(2) If the United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time,

requires sterile recertification after such remodel, relocation, upgrade or repair, the sterile compounding pharmacy shall provide a copy of its sterile recertification to the Department of Consumer Protection not later than five days after the sterile recertification approval. The recertification shall only be performed by an independent licensed environmental monitoring entity.

(g) A sterile compounding pharmacy shall report, in writing, to the Department of Consumer Protection any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined in the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time, not later than the end of the next business day after discovering such violation or noncompliance.

(h) (1) If a sterile compounding pharmacy initiates a recall of sterile pharmaceuticals that were dispensed pursuant to a patient-specific prescription or medical order, the sterile compounding pharmacy shall notify each patient or patient care giver, the prescribing practitioner and the Department of Consumer Protection of such recall not later than twenty-four hours after such recall was initiated.

(2) If a sterile compounding pharmacy initiates a recall of sterile pharmaceuticals that were not dispensed pursuant to a patient-specific prescription or a medical order, the sterile compounding pharmacy shall notify: (A) Each purchaser of such sterile pharmaceuticals, to the extent such sterile compounding pharmacy possesses contact information for each such purchaser, (B) the Department of Consumer Protection, and (C) the federal Food and Drug Administration of such recall not later than the end of the next business day after such recall was initiated.

(i) Each sterile compounding pharmacy and each institutional pharmacy within a facility licensed pursuant to section 19a-490 of the general statutes shall prepare and maintain a policy and procedure manual. The policy and procedure manual shall comply with the most

recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time.

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

(k) Notwithstanding the provisions of subdivisions (3) and (4) of subsection (b) of this section, a sterile compounding pharmacy that is a nonresident pharmacy shall provide the Department of Consumer Protection proof that it has passed an inspection in such nonresident pharmacy's home state, based on the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations compliance standards, as amended from time to time. Such nonresident pharmacy shall submit to the Department of Consumer Protection a copy of the most recent inspection report with its initial nonresident pharmacy application and shall submit to the department a copy of its most recent inspection report every two years thereafter. If the state in which the nonresident pharmacy is located does not conduct inspections based on standards required in the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding, as amended from time to time, such nonresident pharmacy shall provide satisfactory proof to the department that it is in compliance with the standards required in the most recent United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding as amended from time to time.

(l) A practitioner, as specified in subdivision (1) of subsection (e) of this section, a hospital or a health care facility that receives sterile pharmaceuticals shall report any errors related to such dispensing or any suspected adulterated sterile pharmaceuticals to the Department of Consumer Protection.

(m) The Commissioner of Consumer Protection may adopt

regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section.

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

(a) As used in sections 20-627 to 20-630, inclusive, as amended by this act, "nonresident pharmacy" means any pharmacy located outside this state **[**which**]** that ships, mails or delivers, in any manner, legend devices or legend drugs into this state pursuant to a prescription order.

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

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

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

(3) Disclose to the department whether the nonresident pharmacy is dispensing sterile pharmaceuticals, as defined in section 2 of this act, within this state. If any such dispensed sterile pharmaceutical is not patient-specific, the nonresident pharmacy shall submit a copy of the manufacturing license or registration issued by the regulatory or licensing agency of the state in which it is licensed, and a copy of any registration issued by the federal Food and Drug Administration to the department;

[(3)**]** (4) Maintain at all times, a valid unexpired license, permit or

registration to conduct such pharmacy in compliance with the laws of the state in which the nonresident pharmacy is located; **[**.**]**

[(4)**]** (5) Before receiving a certificate of registration from the department, submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located. If the nonresident pharmacy is delivering sterile compounded products within this state such inspection report shall include a section based on standards required in the most recent United States Pharmacopeia, Chapter 797, as amended from time to time. If the state in which the nonresident pharmacy is located does not conduct inspections based on standards required in the most recent United States Pharmacopeia, Chapter 797, as amended from time to time, such nonresident pharmacy shall provide proof to the department that it is in compliance with such standards;

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

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

(8) Provide to the department the names and addresses of all residents of this state to whom legend devices or legend drugs have been delivered, not later than twenty-four hours after the nonresident pharmacy initiates a recall of any legend devices or legend drugs.

Sec. 4. Section 20-629 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2014*):

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

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

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

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

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

(b) The commission may, **[**deny, revoke or suspend any certificate of registration as a nonresident pharmacy for conduct which causes serious bodily or serious psychological injury to a resident of this state if the commission has referred**]** in addition to any action authorized under subsection (a) of this section, refer the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located. **[**and such regulatory or licensing agency fails to (1) initiate an investigation within forty-five days of referral, (2) complete its investigation within one hundred twenty days of referral, (3) resolve the referral through formal agreement, settlement or decision within one hundred eighty days, or (4) initiate disciplinary proceedings when such proceedings are determined to be necessary in the judgment of the regulatory or licensing agency in the state in which the nonresident pharmacy is located.**]**

Sec. 5. Section 21a-70 of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July*

1, 2014):

(a) As used in this section: (1) "Wholesaler" or "distributor" means a person, whether within or without the boundaries of the state of Connecticut, who supplies drugs, medical devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in subdivision (22) of section 20-571, pharmacies, federal, state or municipal agencies, clinics or any other person as permitted under subsection (h) of this section, except that: (A) A retail pharmacy or a pharmacy within a licensed hospital **[**which**]** that supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule II, III, IV or V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a licensed hospital **[**which**]** that supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy **[**which**]** that supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision or of a state correctional institution, and (D) a pharmacy within a licensed hospital that contains another hospital wholly within its physical structure **[**which**]** that supplies to such contained hospital a quantity of a noncontrolled drug or a schedule II, III, IV, or V controlled substance normally stocked by such hospitals to provide for the needs of a patient, pursuant to a prescription or medication order of an authorized practitioner, receiving inpatient care on a unit that is operated by the contained hospital shall not be deemed a wholesaler under this section; (2) "manufacturer" means (A) a person, whether within or without the boundaries of the state of Connecticut, who produces, prepares, cultivates, grows, propagates, compounds, converts or processes, directly or indirectly, by extraction from substances of natural origin or by means of chemical synthesis or by a combination of extraction and

chemical synthesis, or who packages, repackages, labels or relabels a container under such manufacturer's own or any other trademark or label any drug, device or cosmetic for the purpose of selling such items, or (B) a sterile compounding pharmacy, as defined in section 2 of this act, that dispenses sterile pharmaceuticals without a prescription or a patient-specific medical order. The words "drugs", "devices" and "cosmetics" shall have the meaning ascribed to them in section 21a-92, as amended by this act; and (3) "commissioner" means the Commissioner of Consumer Protection.

(b) No wholesaler or manufacturer shall operate as such until he has received a certificate of registration issued by the commissioner, which certificate shall be renewed annually, provided no such certificate shall be required of a manufacturer, except a sterile compounding pharmacy, as defined in subsection (a) of section 2 of this act, whose principal place of business is located outside the state, who is registered with the federal Food and Drug Administration or any successor agency and who files a copy of such registration with the commissioner. A fee of one hundred ninety dollars shall be charged for each wholesaler's certificate and renewal thereof. A separate certificate and corresponding fee is required for each location existing in this state and for each location existing outside of this state that distributes products into this state. The fee for a manufacturer's certificate and renewal thereof shall be two hundred eighty-five dollars for manufacturers employing not more than five licensed pharmacists or qualified chemists or both; three hundred seventy-five dollars for manufacturers employing not more than ten licensed pharmacists or qualified chemists or both; and nine hundred forty dollars for manufacturers employing more than ten licensed pharmacists or qualified chemists or both. No such certificate shall be issued to a manufacturer unless such drugs, medical devices or cosmetics are manufactured or compounded under the direct supervision of a licensed pharmacist or a qualified chemist. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant is

equipped as to facilities and apparatus to properly carry on the business described in his application and that the applicant conforms to chapter 418 and regulations adopted thereunder.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) Before denying, suspending, revoking or refusing to renew a

registration, or before issuing a letter of reprimand or placing a registrant on probationary status, the commissioner shall afford the applicant or registrant an opportunity for a hearing in accordance with the provisions of chapter 54. Notice of such hearing may be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

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

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

Sec. 6. Section 21a-92 of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2014*):

For the purposes of this chapter, **[**and**]** section 21a-65 and section 7 of this act, the following terms shall have the meanings hereinafter specified:

(1) "Advertisement" means all representations disseminated in any

manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics;

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

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

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

(5) "Cosmetic" means (A) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any of its parts for cleansing, beautifying, promoting attractiveness or altering the appearance, and (B) articles intended for

use as a component of any such articles; except that such term shall not include soap;

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

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

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

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

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

(11) "Food additive" means any substance the intended use of which results or reasonably may be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing,

manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use; except that such term does not include (A) a pesticide chemical in or on a raw agricultural commodity; or (B) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or (C) a color additive; or (D) any substance used in accordance with a sanction or approval granted prior to June 12, 1963, or the federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act (21 USC 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended;

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

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

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

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

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

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

(18) "New drug" means (A) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the

conditions prescribed, recommended or suggested in its labeling, or (B) any drug the composition of which is such that such drug, as a result of investigation to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions, except that the provisions of this subsection pertaining to "effectiveness" shall not apply to any drug **[**which**]** that (i) was commercially sold or used in the United States on October 9, 1962, (ii) was not a new drug as defined by this subsection prior to the enactment of these provisions, and (iii) was not covered by an effective application under section 21a-110 or under Section 355 of the federal act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on whichever of the above dates is applicable;

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

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

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

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

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

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

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

Sec. 7. (NEW) (*Effective July 1, 2014*) (a) For the purposes of this section:

(1) "Counterfeit drug or device" means a drug, as defined in section 21a-92 of the general statutes, as amended by this act, or a "device", as defined in section 21a-92 of the general statutes, as amended by this act, or the container or labeling of which, that without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person or persons who in fact manufactured, distributed or dispensed such drug or device and that thereby falsely purports or is represented to be the drug or device of, or to have been distributed by, such other manufacturer, distributor or dispenser; and

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

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

(c) The department shall conduct any necessary investigation regarding possible violations of this section. In connection with any such investigation, the commissioner, or the commissioner's authorized agent, may administer oaths, issue subpoenas, compel

testimony and order the production of books, records and documents. If any person refuses to appear, to testify or to produce any book, record or document when so ordered, a judge of the Superior Court may make such order as may be appropriate to aid in the enforcement of this section.

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

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

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

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

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

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

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

(g) Any person who violates any provision of this section shall be

fined not more than ten thousand dollars or imprisoned not more than one year, or both, for each violation.

Sec. 8. Section 21a-432 of the general statutes is repealed. (*Effective July 1, 2014*)"

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