Connecticut Comprehensive

Drug Laws

April 2014

3ß˘ø˚ß˘ ¸#¸ Ê#ª˘#

DEPARTMENT OF CONSUMER PROTECTION

Drug Control Division Commission of Pharmacy

Dannel Malloy, GOVERNOR

William Rubenstein, COMMISSIONER

CHAPTER 400j

PHARMACY

Table of Contents

Sec. 20-570. Short title: Pharmacy Practice Act.

Sec. 20-571. (Formerly Sec. 20-184a). Definitions.

Sec. 20-572. (Formerly Sec. 20-163). Commission of Pharmacy. Appointment and term of members.

Sec. 20-573. (Formerly Sec. 20-165). Meetings of commission. Records.

Sec. 20-574. (Formerly Sec. 20-164a). General supervision by Commissioner of Consumer Protection.

Sec. 20-575. Powers and responsibilities.

Sec. 20-576. (Formerly Sec. 20-164). Regulations.

Sec. 20-577. (Formerly Sec. 20-179). Employment of inspectors by Commissioner of Consumer Protection; duties. Inspection of correctional, juvenile training and care-giving institutions, dispensing outpatient facilities, institutional and retail pharmacies by commissioner.

Sec. 20-578. (Formerly Sec. 21a-306). Information not to be disclosed. Exception.

Sec. 20-579. (Formerly Sec. 20-175). Causes for suspension, revocation or refusal to issue or renew licenses, temporary permits and registrations and for assessment of civil penalty.

Sec. 20-580. (Formerly Sec. 20-167). Revocation or suspension of nonlegend drug permit.

Sec. 20-581. (Formerly Sec. 20-185). Penalty for violation of Pharmacy Practice Act. Exception.

Sec. 20-582. (Formerly Sec. 20-176). Appeals of decisions of Commission of Pharmacy.

Sec. 20-583. Where appeals returnable.

Secs. 20-584 to 20-589. **Reserved**

Sec. 20-590. (Formerly Sec. 20-170). Issuance of license or temporary permit to practice pharmacy; requirements.

Sec. 20-591. Graduates of foreign pharmacy schools. Regulations.

Sec. 20-592. Licensure of individual who is a licensed pharmacist in another state or jurisdiction.

Sec. 20-593. (Formerly Sec. 20-172). Pharmacist license certificate; expiration; renewal; fee; display document.

Sec. 20-594. (Formerly Sec. 20-168). Pharmacy license; application; information required; issuance or renewal of license; expiration. Transfer of pharmacy to new location.

Sec. 20-595. (Formerly Sec. 20-168a). Pharmacy licenses held by corporations. Notice of change in officers or directors.

Sec. 20-596. (Formerly Sec. 20-168b). Ownership of pharmacies by prescribing practitioners.

Sec. 20-597. (Formerly Sec. 20-169). Pharmacy to be supervised and managed by pharmacist. Regulations re prescription department. Change in management, ownership or name of pharmacy.

Sec. 20-598. (Formerly Sec. 20-177). Registration of pharmacy interns.

Sec. 20-598a. Registration and certification of pharmacy technicians.

Sec. 20-599. (Formerly Sec. 20-174a). Continuing education: Definitions.

Sec. 20-600. (Formerly Sec. 20-174b). Continuing education: Requirements; renewal of licenses; regulations.

Sec. 20-601. Fees.

Secs. 20-602 to 20-604. **Reserved**

Sec. 20-605. Practice of pharmacy without license or temporary permit prohibited.

Sec. 20-606. (Formerly Sec. 20-178). Use of the title "pharmacist".

Sec. 20-607. (Formerly Sec. 20-173). Certificate of license, temporary permit or registration to be available for inspection.

Sec. 20-608. (Formerly Sec. 20-174). Use of certificate of license, temporary permit or display document by unlicensed person prohibited.

Sec. 20-609. (Formerly Sec. 20-184). Pharmacy license to be posted. Business which is not a pharmacy prohibited from using words, displays or symbols indicating it is a pharmacy; exemption.

Sec. 20-609a. Use of electronic technology or telepharmacy by hospital. Quality assurance evaluations.

Sec. 20-610. (Formerly Sec. 20-166). Dispensing or retail sale of legend drugs, legend devices and certain other drugs by other than pharmacies and hospitals, prohibited.

Sec. 20-611. (Formerly Sec. 20-175b). Advertising legend drug prices.

Sec. 20-612. Only pharmacy may accept prescription for dispensing.

Sec. 20-612a. Confirmation of identification prior to release of controlled substance. Exceptions.

Sec. 20-613. (Formerly Sec. 21a-308). Dispensing of drug or legend device pursuant to prescription only; exceptions. Emergency dispensing of drug or device in care-giving, correctional or juvenile training institutions; regulations. Pharmacy technicians. Prescribing practitioner authorized to dispense own prescription, when.

Sec. 20-613a. Requests for controlled substance issued on results of answers to electronic questionnaire. Regulations.

Sec. 20-614. (Formerly Sec. 20-184b). Prescriptions: Form and content. Electronic data intermediaries.

Sec. 20-615. (Formerly Sec. 20-184c). Prescriptions: Pharmacy to assign serial number and maintain records. Transfer of records to another pharmacy.

Sec. 20-616. (Formerly Sec. 20-184d). Prescriptions: Refills; transfers.

Sec. 20-617. (Formerly Sec. 20-184e). Prescriptions: Notation of drug quantities and expiration dates required on labels.

Sec. 20-617a. Flavoring agent added to prescription product.

Sec. 20-618. (Formerly Sec. 21a-107). Repackaged drugs not considered misbranded, when.

Sec. 20-619. (Formerly Sec. 20-185a). Substitution of generic drugs. Regulations.

Sec. 20-620. (Formerly Sec. 20-185g). Pharmacist's duties towards

Medicaid recipients: To obtain, record and maintain pertinent patient information about the recipient; to undertake a review of the drugs previously dispensed to the recipient and to offer to discuss the drugs to be dispensed and to counsel the recipient on their correct usage. Exception.

Sec. 20-621. (Formerly Sec. 20-185h). Relabeling and dispensing of parenteral medication in hospital and nursing home pharmacies: When allowed.

Sec. 20-622. (Formerly Sec. 20-180a). Licensed practitioners may authorize medication to be dispensed from a hospital emergency room.

Sec. 20-623. Sale of nonlegend drugs. Labels, packaging and contents. Penalty.

Sec. 20-624. Permit to sell nonlegend drugs.

Sec. 20-625. Nonlegend veterinary drugs.

Sec. 20-626. Confidentiality of pharmacy records.

Sec. 20-627. Nonresident pharmacy. Definitions. Certificate of registration. Requirements.

Sec. 20-628. Shipping, mailing or delivering legend devices or drugs.

Sec. 20-629. Suspension or revocation of certificate.

Sec. 20-630. Advertising.

Sec. 20-631. Collaborative drug therapy management agreements between pharmacists and physicians. Scope. Pharmacist competency requirements. Regulations.

Sec. 20-631a. Collaborative drug management agreements between

pharmacists employed by community pharmacies and one or more physicians. Pilot program.

Sec. 20-631b. Collaborative drug therapy management agreements entered into prior to October 1, 2010.

Sec. 20-632. Regulatory action report re disciplinary action against persons with controlled substance registrations and sanctions against pharmacists or pharmacies.

Sec. 20-633. Administration of vaccines by licensed pharmacists. Regulations.

Sec. 20-634. **Reserved**

Sec. 20-635. Prescription error reporting. Definitions. Informational signs and statements. Regulations. Nondisclosure of records.

Secs. 20-636 to 20-639. **Reserved**

PART I

COMMISSION OF PHARMACY. POWERS AND DUTIES

Sec. 20-570. Short title: Pharmacy Practice Act. Sections 20-570 to 20-630, inclusive, may be cited as the "Pharmacy Practice Act".

Sec. 20-571. (Formerly Sec. 20-184a). Definitions. As used in sections 20-570 to 20-630, inclusive, unless the context otherwise requires:

(1) "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation,

ingestion or any other means;

(2) “Care-giving institution” means an institution that provides medical services and is licensed, operated, certified or approved by the Commissioner of Public Health, the Commissioner of Developmental Services or the Commissioner of Mental Health and Addiction Services;

(3) “Commission” means the Commission of Pharmacy appointed under the provisions of section 20-572;

(4) “Commissioner” means the Commissioner of Consumer Protection;

(5) “Compound” means to combine, mix or put together two or more ingredients pursuant to a prescription and includes the preparation of drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;

(6) “Correctional or juvenile training institution” means a facility for the detention or incarceration of persons convicted or accused of crimes or offenses or for training of delinquent juveniles, including those state facilities under the jurisdiction of the Commissioner of Correction, training schools for delinquent juveniles and any other facilities operated by the state or municipalities for such detention, incarceration or training;

(7) “Device” means instruments, apparatuses 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, but does not mean contact lenses;

(8) “Department” means the Department of Consumer Protection;

(9) “Dispense” means those acts of processing a drug or device for delivery or for administration for a patient pursuant to a prescription consisting of: (A) Comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug or device from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug or device; (D) the placing of the drug or device in the proper container; (E) the affixing of the label to the container; and (F) the addition to a written prescription of any required notations. “Dispense” does not include the acts of delivering a drug or device to a patient or of administering the drug or device to the patient;

(10) “Dispensing outpatient facility” means a facility operated by a corporation or municipality which provides medical services to patients on an outpatient basis and which maintains stocks of drugs for dispensing of drugs on a regular basis to patients for use off the premises;

(11) “Drug” means (A) an article 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) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals, (C) an article, other than food, intended to affect the structure or any function of the body of humans or any other animal, and (D) an article intended for use as a component of any article specified in this subdivision, but does not include a device;

(12) “Institutional pharmacy” means that area within a care-giving institution or within a correctional or juvenile training institution, commonly known as the pharmacy, that is under the direct charge of a pharmacist and in which drugs are stored and dispensed;

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

(14) “Legend drug” means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) “RX ONLY” IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) “CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.”;

(15) “Nonlegend drug” means a drug that is not a legend drug;

(16) “Person” means an individual, corporation, business trust, estate trust, partnership, association, joint venture or any other legal or commercial entity;

(17) “Pharmacist” means an individual who is licensed to practice pharmacy under the provisions of section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of Connecticut;

(18) “Pharmacy” means a place of business where drugs and devices may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594;

(19) “Pharmacy intern” means an individual registered under the provisions of section 20-598;

(20) “Pharmacy technician” means an individual who is registered with the department and qualified in accordance with section 20-598a;

(21) “Practice of pharmacy” or “to practice pharmacy” means the sum total of knowledge, understanding, judgments, procedures, securities, controls and ethics used by a pharmacist to assure optimal safety and accuracy in the distributing, dispensing and use of drugs and devices;

(22) “Prescribing practitioner” means an individual licensed by the state of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual’s practice;

(23) “Prescription” means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient;

(24) “Sale” includes barter, exchange or gift or offer and each such transaction made by a person whether as principal proprietor, agent, servant or employee; and

(25) “Substitute” means to dispense without the prescribing practitioner’s express authorization a different drug product than the drug product prescribed.

Sec. 20-572. (Formerly Sec. 20-163). Commission of Pharmacy. Appointment and term of members. There shall be in the department a Commission of Pharmacy which shall consist of seven persons appointed by the Governor, subject to the provisions of section 4-9a, five

of whom shall be pharmacists each actively engaged in the practice of pharmacy on a full-time basis during the term of such person's appointment in this state and two of whom shall be public members. At least two of the pharmacist members shall be community retail pharmacists, one from an independent retail setting and one from a chain retail setting, and at least one of the pharmacist members shall be a pharmacist employed on a full-time basis as a pharmacist in a hospital in the state during the term of such pharmacist member's appointment. Members of the commission may be selected from lists of individuals nominated by the Connecticut Pharmacists Association or by other professional associations of pharmacists or pharmacies. Any vacancy on the commission shall be filled by the Governor.

Sec. 20-573. (Formerly Sec. 20-165). Meetings of commission. Records. (a) Meetings of the commission for the purpose of conducting business of the commission shall be held at the office of the commission at least six times per calendar year and at such other times and places in each year as the chairperson or a majority of the commission deems necessary.

(b) The commission shall keep a record of its proceedings. Such record shall be made available to the public upon request and shall contain the name and license number of any pharmacist or pharmacy that the commission has recommended formal disciplinary action against. A copy of any such record, certified by the commissioner, shall be admitted as evidence in any civil or criminal action in lieu of the record.

Sec. 20-574. (Formerly Sec. 20-164a). General supervision by Commissioner of Consumer Protection. The commissioner shall exercise general supervision over the operations of the commission pursuant to sections 20-570 to 20-630, inclusive.

Sec. 20-575. Powers and responsibilities. (a) The commission shall administer and enforce the provisions of sections 20-570 to 20-630, inclusive. The commission has all powers specifically granted in the general statutes, including the powers set forth in sections 21a-7 and 21a-9, and all further powers that are reasonable and necessary to enable the commission to protect the public interest in accordance with the duties imposed by sections 20-570 to 20-630, inclusive.

(b) The commission may compel attendance of witnesses and the production of documents by subpoena and may administer oaths. If any person refuses or fails to appear, testify or produce any document when so ordered, a judge of the Superior Court may, upon application of the commission, make such order as may be appropriate to enforce this subsection.

(c) The commission may apply to the Superior Court for and the court may, upon hearing and for cause shown, grant a temporary or permanent injunction enjoining any person from violating any provision of sections 20-570 to 20-630, inclusive, or any regulation adopted in accordance with chapter 54 by the commissioner, with the advice and assistance of the commission, pursuant to sections 20-570 to 20-630, inclusive, irrespective of whether an adequate remedy at law exists. The commission also may apply to the Superior Court for, and the court shall have jurisdiction to grant, a temporary restraining order pending a hearing.

(d) An application to the Superior Court under subsection (b) or (c) of this section shall be brought by the Attorney General.

Sec. 20-576. (Formerly Sec. 20-164). Regulations. (a) The commissioner may, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, to govern the

performance of the commission's duties, the practice of pharmacy and the business of retailing drugs and devices. Such regulations may include, but are not limited to, provisions (1) concerning the licensing of any pharmacist or pharmacy, disciplinary action that may be taken against a licensee, the conduct of a pharmacist and the operation of a pharmacy, (2) specifying various classes of pharmacy licenses issued under section 20-594, including, but not limited to, licenses for infusion therapy pharmacies and nuclear pharmacies and specifying requirements for operation of pharmacies under the classes of pharmacy licenses permitted under the regulations, (3) concerning creation and maintenance of prescription records, and (4) concerning registration and activities of pharmacy interns, registered pharmacy technicians and certified pharmacy technicians.

(b) The commissioner shall, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, governing (1) the storage and retrieval of prescription information for noncontrolled substances, including refills, by pharmacists through the use of electronic data processing systems or other systems for the efficient storage and retrieval of information, (2) the operation of institutional pharmacies pursuant to chapters 368a and 418, and sections 17a-210 to 17a-273, inclusive, 19a-490 to 19a-520, inclusive, and 20-570 to 20-630, inclusive, and (3) the activities of pharmacy technicians in pharmacies and institutional pharmacies, including ratios of registered pharmacy technicians and certified pharmacy technicians to pharmacists in pharmacies and institutional pharmacies.

Sec. 20-577. (Formerly Sec. 20-179). Employment of inspectors by Commissioner of Consumer Protection; duties. Inspection of correctional, juvenile training and care-giving institutions, dispensing outpatient facilities, institutional and retail pharmacies

by commissioner. (a) The commissioner shall employ inspectors whose duty it shall be to inspect all pharmacies and other places in which drugs and devices are or may be dispensed or retailed, and to report any violations of sections 20-570 to 20-630, inclusive, or other laws relating to drugs and devices and violations of laws regarding pharmacy licenses, nonlegend drug permits, licenses of pharmacists and supervision of pharmacy interns and pharmacy technicians.

(b) The commissioner shall inspect correctional or juvenile training institutions and care-giving institutions throughout the state with respect to the handling of drugs, shall report violations of law and make recommendations for improvements in procedures to the authority responsible for the operation of the institution and shall take such other steps as may be necessary to ensure proper and adequate storage, handling and administration of drugs in such institutions. The commissioner may also inspect dispensing outpatient facilities and institutional pharmacies and take such steps as the commissioner considers appropriate to correct deficiencies found in such facilities or institutional pharmacies with respect to their operation.

(c) The commissioner shall inspect each retail pharmacy not less than once every four years and shall develop a methodology to sample prescriptions dispensed by retail pharmacies for compliance with state laws concerning the dispensing of prescriptions. Such methodology shall be based on the number of prescriptions received by such retail pharmacies.

Sec. 20-578. (Formerly Sec. 21a-306). Information not to be disclosed. Exception. (a) Information received by the department, the commission or the Department of Public Health, through filed reports or inspection or as otherwise authorized under chapters 418 and 420b and sections 20-570 to 20-630, inclusive, shall not be disclosed publicly in

such a manner as to identify individuals or institutions, except: (1) In a proceeding involving the question of licensure or the right to practice, and (2) in a proceeding where the commission has voted in favor of formal disciplinary action against a pharmacist or pharmacy licensed pursuant to this chapter, when such disciplinary action is related to an error in the dispensing of medication. Nothing in this section shall be construed to prohibit the commissioner from disclosing information gained through the inspection of pharmacies and outlets holding permits for the sale of nonlegend drugs if the commissioner considers such disclosure to be in the interest of public health.

(b) Notwithstanding the provisions of subsection (a) of this section, section 21a-265 and chapter 55, the Commissioners of Consumer Protection and Public Health and the authorized agents of said commissioners, in carrying out their duties under subsection (a) of this section, may: (1) Exchange information relating to a license or registration issued by their respective agencies, or (2) exchange investigative information relating to violations of this chapter with each other, with the Chief State's Attorney and with agencies charged with the enforcement of pharmacy or drug laws of the United States, this state and all other jurisdictions.

Sec. 20-579. (Formerly Sec. 20-175). Causes for suspension, revocation or refusal to issue or renew licenses, temporary permits and registrations and for assessment of civil penalty. (a) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a pharmacy intern or a

pharmacy technician, and may assess a civil penalty of up to one thousand dollars or take other action permitted in subdivision (7) of section 21a-7 if the applicant or holder of the license, temporary permit or registration: (1) Has violated a statute or regulation relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice of pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar to grounds on which Connecticut could refuse to issue or renew such a license or registration; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including alcohol; (7) has made false, misleading or deceptive representations to the public or the commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners,

nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619; (10) has accepted, for return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility; (12) has entered into an agreement with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other health care facility for the compounding or dispensing of secret formula or coded prescriptions; (13) has performed or been a party to a fraudulent or deceitful practice or transaction; (14) has presented to the commission a diploma, license or certificate illegally or fraudulently obtained, or obtained from a college or school of pharmacy not approved by the commission; (15) has performed incompetent or negligent work; (16) has falsified a continuing education document submitted to the commission or department or a certificate retained in accordance with the provisions of subsection (d) of section 20-600; (17) has permitted a person not licensed to practice pharmacy in this state to practice pharmacy in violation of section 20-605, to use a pharmacist license or pharmacy display document in violation of section 20-608, or to use words, displays or symbols in violation of section 20-609; or (18) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition.

(b) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, or a registration of a

pharmacy intern or a pharmacy technician, or take other action permitted in subdivision (7) of section 21a-7 if the commission determines that the applicant or holder of the license, temporary permit or registration has a condition including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of pharmacy, operation of a pharmacy or activities as a pharmacy intern or pharmacy technician, provided the commission may not, in taking action against a license, temporary permit or registration holder on the basis of such a condition, violate the provisions of section 46a-73 or 42 USC Section 12132 of the federal Americans with Disabilities Act.

Sec. 20-580. (Formerly Sec. 20-167). Revocation or suspension of nonlegend drug permit. A permit to sell nonlegend drugs issued under section 20-624 may be revoked or suspended by the commission for any violation of the provisions of chapter 419 or of sections 20-570 to 20-630, inclusive, or for any violation of any federal law concerning the sale or offer for sale of any nonlegend drug, or for the violation of any regulation concerning the sale or offer for sale of any nonlegend drugs.

Sec. 20-581. (Formerly Sec. 20-185). Penalty for violation of Pharmacy Practice Act. Exception. Any person who violates any provision of sections 20-570 to 20-631, inclusive, and section 20-635 for the violation of which no other penalty has been provided shall be fined not more than five thousand dollars or imprisoned not more than five years or both. For purposes of this section, each instance of patient contact or consultation that is in violation of any provision of sections 20-570 to 20-631, inclusive, and section 20-635 shall be a separate offense. Failure to renew in a timely manner any license issued under said sections is not a violation for purposes of this section.

Sec. 20-582. (Formerly Sec. 20-176). Appeals of decisions of Commission of Pharmacy. Any person (1) holding a license, permit or registration under sections 20-570 to 20-630, inclusive, who has been disciplined by the commission, or (2) who has been refused a license, permit or registration under said sections or refused a renewal of a license or permit under said sections, may appeal as provided in section 4-183.

Sec. 20-583. Where appeals returnable. An appeal of a decision by the commission to discipline a person licensed to practice pharmacy or registered as a pharmacy intern or pharmacy technician, to refuse a person's application for a license to practice pharmacy or to refuse to register a person as a pharmacy intern or pharmacy technician shall be made returnable to the judicial district in which the person resides or, if the person does not reside in Connecticut, to the judicial district of New Britain. An appeal of a decision by the commission to discipline the holder of a pharmacy license or the holder of a permit to sell nonlegend drugs or to refuse a person's application for such a license or permit appeal shall be made returnable to the judicial district in which the building or store is located, for which the license or permit was sought or in which it was suspended or revoked. All appeals under the provisions of this section shall be treated as privileged and shall be assigned for trial and tried as soon as may be practicable.

Secs. 20-584 to 20-589. Reserved for future use.

PART II

LICENSING OF PHARMACISTS AND PHARMACIES. REGISTRATION OF PHARMACY INTERNS AND PHARMACY TECHNICIANS

Sec. 20-590. (Formerly Sec. 20-170). Issuance of license or temporary permit to practice pharmacy; requirements. (a) The department shall, upon authorization of the commission, issue a license to practice pharmacy as a pharmacist to any individual provided the individual:

(1) Has submitted a written application on a form approved by the department;

(2) Has graduated from a college or school of pharmacy approved by the commission with a degree that was, at the time of graduation, an entry level professional pharmacy degree;

(3) Has the professional experience as a pharmacy intern required by regulations adopted by the commissioner, with the advice and assistance of the commission, in accordance with chapter 54;

(4) Has successfully passed any examinations required by the commissioner; and

(5) Is eighteen years of age or older at the time of application.

(b) The Department of Consumer Protection shall, upon authorization

of the commission, issue a temporary permit to practice pharmacy to an individual who: (1) Practices under the direct supervision of a licensed pharmacist; (2) has an application for reciprocity on file with the commission; (3) is a licensed pharmacist in good standing in a state or jurisdiction from which such state's pharmacy board or commission of pharmacy grants similar reciprocal privileges to pharmacists licensed in this state; and (4) has no actions pending against such individual's license with any state's pharmacy board or commission of pharmacy.

(c) A temporary permit to practice pharmacy shall expire at the time the individual with the temporary permit is licensed as a pharmacist in this state, or not later than three months from the date of issuance of such temporary permit, whichever occurs first. The Department of Consumer Protection shall not issue more than one temporary permit to practice pharmacy to an individual, but the commission, at its discretion, may authorize one three-month extension of the temporary permit.

Sec. 20-591. Graduates of foreign pharmacy schools. Regulations. (a) An individual who has graduated from a foreign school of pharmacy not approved by the commission may apply for a license to practice pharmacy under this section.

(b) The individual shall comply with the requirements of subdivisions (1), (2), (4) and (5) of subsection (a) of section 20-590 and with regulations adopted as provided in subsection (c) of this section.

(c) The commissioner shall, with the advice and assistance of the commission, adopt regulations in accordance with chapter 54 concerning licensure as a pharmacist of an individual who has graduated from and received an entry-level professional pharmacy degree from a foreign school of pharmacy. The regulations shall include a requirement that

such a graduate pass a proficiency test for written and spoken English, a foreign pharmacy graduate equivalency examination and the examination described in subsection (b) of section 20-590.

Sec. 20-592. Licensure of individual who is a licensed pharmacist in another state or jurisdiction. Any individual who is a licensed pharmacist in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States, may be licensed to practice pharmacy in this state in accordance with regulations adopted under sections 20-570 to 20-630, inclusive, in accordance with chapter 54.

Sec. 20-593. (Formerly Sec. 20-172). Pharmacist license certificate; expiration; renewal; fee; display document. (a) A license to practice pharmacy issued under the provisions of section 20-590 or under the provisions of section 20-591 or 20-592 and a license to practice pharmacy renewed pursuant to subsections (b) and (c) of this section shall be evidenced by a certificate issued by the department upon authorization of the commission.

(b) A license to practice pharmacy shall expire biennially and may be renewed upon completion of an application on a form approved by the department, payment of one hundred twenty dollars and completion of continuing professional education, as required by sections 20-599 and 20-600.

(c) The commission shall not grant a renewal license to an applicant who has not held a license authorized by the commission within five

years of the date of application unless the applicant has passed an examination satisfactory to the commission and has paid the fee required in subsection (b) of this section.

(d) In addition to the certificate of license to practice pharmacy issued under subsection (a) of this section, the department may issue a document suitable for display indicating that the individual has been issued a certificate of license to practice pharmacy.

Sec. 20-594. (Formerly Sec. 20-168). Pharmacy license; application; information required; issuance or renewal of license; expiration. Transfer of pharmacy to new location. (a) Except as limited by section 20-596, a pharmacist or any other person may apply to the commission for a pharmacy license or for renewal of a pharmacy license.

(b) The applicant shall disclose on the application the name and address of the applicant and the owner of the pharmacy, the name and street and mailing address of the pharmacy and the name, address and license number of the pharmacist who manages the pharmacy. The commissioner may, by regulation adopted with the advice and assistance of the commission, in accordance with chapter 54, require such other information on the application as is necessary for the department to carry out its duties under sections 20-570 to 20-630, inclusive.

(c) The department shall, after receipt of an application under this section, (1) issue, on authorization of the commission, a pharmacy license to an applicant for a new pharmacy on payment of the fee required in section 20-601 and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and the regulations

adopted by the commissioner in accordance with chapter 54, and (2) issue a renewal of a pharmacy license to an applicant on payment of the fee required in section 20-601.

(d) Pharmacy licenses shall expire annually. Pharmacy licenses may be renewed on application and payment of the fee required in section 20-601 for a period not to exceed one year.

(e) When a pharmacy is transferred to a new location the pharmacy license for such pharmacy shall terminate. A pharmacy license that has been terminated under this subsection may be renewed under the provisions of subsection (d) of this section and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and the regulations adopted by the commissioner in accordance with chapter 54.

Sec. 20-595. (Formerly Sec. 20-168a). Pharmacy licenses held by corporations. Notice of change in officers or directors. Any corporation applying for a new or renewal pharmacy license under the provisions of section 20-594 shall state in the application the names of the officers and directors of the corporation. Notice of any change in such officers or directors shall be given by the corporation to the commission within ten days after the change. Such notice shall be accompanied by the filing fee set forth in section 20-601. Any such corporation that fails to give notice of a change in the officers or directors of the corporation within ten days of the change shall pay the late fee required in section 20-601.

Sec. 20-596. (Formerly Sec. 20-168b). Ownership of pharmacies by prescribing practitioners. (a) No prescribing practitioner, spouse of a prescribing practitioner, except a spouse who is a pharmacist, or dependent child of a prescribing practitioner shall have an ownership or investment interest in a pharmacy.

(b) The provisions of this section do not apply to a prescribing practitioner or spouse or dependent child of a prescribing practitioner (1) having an ownership or investment interest in a pharmacy prior to July 1, 1993, (2) who inherits an ownership or investment interest in a pharmacy, or (3) who is not required to maintain professional liability insurance pursuant to section 20-11b, provided (A) if the prescribing practitioner reinstates any such professional liability insurance, the prescribing practitioner shall, within thirty days of doing so, notify the Commissioner of Public Health of such reinstatement and divest any interest the prescribing practitioner may have in any pharmacy, or (B) if the interest is owned by the prescribing practitioner's spouse or dependent child, the spouse or child shall divest such interest in any pharmacy. Failure of the prescribing practitioner or the prescribing practitioner's spouse or dependent child to divest any such interest in a pharmacy within thirty days shall result in the prescribing practitioner's license being suspended until such time as the prescribing practitioner or the prescribing practitioner's spouse or dependent child divests such interest in the pharmacy.

(c) As used in this section, "ownership of investment interest" does not include ownership of investment securities by a prescribing practitioner, or the prescribing practitioner's spouse or dependent children, in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by the prescribing practitioner, the prescribing practitioner's spouse

and the prescribing practitioner's dependent children, in the aggregate, do not exceed one-half of one per cent of the total number of shares issued by the corporation.

Sec. 20-597. (Formerly Sec. 20-169). Pharmacy to be supervised and managed by pharmacist. Regulations re prescription department. Change in management, ownership or name of pharmacy. (a) No place of business may be operated as a pharmacy unless a pharmacy license has been issued for the place of business and unless it is under the direct supervision of a pharmacist on the premises, except that the commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, that specify when a pharmacy may remain open for business during hours when a pharmacist is not present and directly supervising such pharmacy. Such regulations shall include, but not be limited to: (1) A provision requiring that the prescription department be closed and properly secured during times when a pharmacist is not present; (2) the minimum number of hours of operation applicable to the prescription department; (3) requirements for the physical security of the prescription department; (4) requirements for the physical security of legend drugs, controlled substances and legend devices stored in all areas of the pharmacy; and (5) a definition of the term "prescription department".

(b) In addition to the on-premises supervision of a pharmacy required in subsection (a) of this section, a pharmacy shall be managed by a pharmacist practicing at the pharmacy on a full-time basis who is listed as manager in the application for a pharmacy license made under section 20-594 or enrolled with the commission under subsection (c) of this section. The managing pharmacist may also act as the supervising pharmacist. No pharmacist may manage more than one pharmacy at the

same time.

(c) The person to whom a pharmacy license has been issued shall immediately notify the commission whenever the pharmacist who manages the pharmacy ceases such management and shall immediately enroll with the commission the name, address and license number of the pharmacist who assumes management of the pharmacy. The notice of change in management of a pharmacy required to be filed with the commission under this section shall be accompanied by the filing fee required in section 20-601. The pharmacist who ceases management of the pharmacy shall also immediately notify the commission of that fact.

(d) The person to whom a pharmacy license has been issued shall immediately notify the commission of a change in ownership of the pharmacy and of a change in name of the pharmacy. The notice shall be accompanied by the filing fee required in section 20-601. Any such person who fails to give the notice of a change in ownership or name of the pharmacy within ten days of the change shall pay the late fee required in section 20-601.

Sec. 20-598. (Formerly Sec. 20-177). Registration of pharmacy interns. (a) Each individual who is employed by or is serving under the supervision of a pharmacist in a pharmacy or institutional pharmacy for the purpose of obtaining the professional experience required under the provisions of section 20-590 shall register as a pharmacy intern with the commission at the time of commencing employment or service under such supervision. The applicant may not be registered as a pharmacy intern unless the applicant has successfully completed two years of college and is enrolled in a professional program at a school or college of pharmacy, accredited by the American Council on Pharmaceutical

Education and approved by the commission, or has completed the requirements for graduation from such a school or college, or, if the applicant is a graduate from a foreign pharmacy school not approved by the commission, has passed a proficiency test for written and spoken English and a foreign pharmacy graduate equivalency examination. The application for registration shall be certified to, under oath, by the applicant.

(b) The fee required in section 20-601 shall accompany an application for registration and an identification number and card shall be issued by the commission to the applicant. The identification number and card shall become void and shall be returned to the commission if the pharmacy intern does not complete the requirements for graduation from, or terminates enrollment at, an accredited and approved school or college of pharmacy.

Sec. 20-598a. Registration and certification of pharmacy technicians. (a) No person shall act as a pharmacy technician unless registered with, or certified with, the department.

(b) The department shall, upon authorization of the commission, register as a pharmacy technician any person who presents evidence satisfactory to the department that such person is qualified to perform, under the direct supervision of a pharmacist, routine functions in the dispensing of drugs that do not require the use of professional judgment. The qualifications for registration as a pharmacy technician under this section shall be in accordance with (1) the standards of an institutional pharmacy, a care-giving institution or a correctional or juvenile training institution, in the case of employment in any such pharmacy or institution, or (2) the standards established by regulation adopted by the

commissioner in accordance with chapter 54, in the case of employment in a pharmacy. As used in this subsection, "direct supervision" means a supervising pharmacist (A) is physically present in the area or location where the pharmacy technician is performing routine drug dispensing functions, and (B) conducts in-process and final checks on the pharmacy technician's performance.

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

(d) The fee required by section 20-601 shall accompany an application for registration under this section. A registration as a pharmacy technician shall be valid for one year and may be renewed upon application and payment of the fee required by section 20-601.

Sec. 20-599. (Formerly Sec. 20-174a). Continuing education: Definitions. As used in this section and section 20-600:

(1) "Accredited continuing professional education" means any education of pharmacists which is designed to maintain professional competence in the practice of pharmacy and which is provided by an organization, institution or agency approved by the commission. Such education may include, but is not limited to, courses concerning: (A) The social, economic, behavioral, legal, administrative and managerial aspects of health care; (B) the properties and actions of drugs and dosage forms; (C) the etiology, characteristics, therapeutics and prevention of the disease states; (D) the pharmaceutical monitoring and management

of patients; and (E) other areas of information unique to specialized types of professional pharmacy practice;

(2) “Certificate of continuing education units” means a document issued to a pharmacist by an organization, institution or agency approved by the commission which offers accredited continuing professional education, which (A) certifies that the pharmacist has satisfactorily completed a specified number of continuing education units, and (B) bears the name of such organization, institution or agency, the title of the program, the dates during which the program was conducted, the number of continuing education units satisfactorily completed and the signature of the director of such organization, institution or agency or the director’s authorized agent;

(3) “Continuing education unit” means ten contact hours of participation in accredited continuing professional education;

(4) “Contact hours” means fifty to sixty minutes of participation in accredited continuing professional education;

(5) “Retired pharmacist” means a pharmacist who is at least sixty-two years of age and no longer actively engaged in the practice of pharmacy; and

(6) “Inactive license” means a license that is issued, in the same manner and for the same fee as specified in this chapter for a license to practice pharmacy, to a retired pharmacist which license does not authorize the retired pharmacist to practice pharmacy and on which the word “inactive” is printed or stamped.

Sec. 20-600. (Formerly Sec. 20-174b). Continuing education: Requirements; renewal of licenses; regulations. (a) Except as provided in subsections (b), (c), (f) and (g) of this section, the commission shall not authorize the department to renew a license to practice pharmacy as a pharmacist unless the pharmacist applying for the renewal submits a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed not less than fifteen contact hours of accredited continuing professional education in the previous calendar year immediately preceding expiration of the license. Not less than five contact hours of the annual continuing education requirement shall be earned by attendance at a live presentation of an accredited continuing professional education program. At least one of the fifteen contact hours shall be on the subject matter of pharmacy law or drug law.

(b) The provisions of this section shall not apply to a pharmacist who applies for the first renewal of a license to practice pharmacy.

(c) A pharmacist submitting an application for renewal of a license to practice pharmacy, whose license has lapsed and who has not held a license authorized by the commission and issued by the department for more than two years, shall submit a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed the requirements of this section in each of the years in the two-year period prior to the year of the application for renewal.

(d) A pharmacist who applies for renewal of a license to practice pharmacy shall retain all certificates of approved continuing education units for a period of not less than three years after the date on which such license is renewed. A pharmacist shall, upon the request of the department, and to satisfy the results of a random audit, make such certificates available to the department for purposes of verification.

(e) Continuing education units earned in one calendar year shall not be carried forward into the next calendar year for the purpose of fulfilling the subsequent year's accredited continuing professional education requirement for license renewal.

(f) A pharmacist who was unable to comply with the requirements of this section for reasons such as illness, incapacity or other extenuating circumstances may apply for a waiver of the requirements of this section or for an extension of time to fulfill the requirements of this section. A pharmacist who requests such a waiver or extension of time shall submit the request, in writing, to the department with the license renewal application. The department shall forward such a request to the commission for its consideration. If the commission waives the requirements of this section, the commission shall authorize the department to renew the license of such a pharmacist. If the commission extends the time for compliance with the requirements of this section, the commission shall authorize the department to renew the license, subject to the pharmacist's complying with the requirements of this section within the extended time period. If the pharmacist fails to comply with such requirements within the extended time period, the commission shall revoke or suspend the license.

(g) The commission may authorize the department to waive the requirements of this section and renew the license of a retired pharmacist provided the license is designated as an inactive license. A retired pharmacist holding an inactive license shall be required to obtain thirty hours of continuing education, not less than ten hours of which shall be earned by attendance at a live presentation, and apply for and receive a license to practice pharmacy issued pursuant to sections 20-570 to 20-630, inclusive, before the retired pharmacist reenters the active practice of pharmacy.

(h) The commissioner, with the advice and assistance of the commission, may adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 20-601. Fees. The department shall collect the following nonrefundable fees:

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

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

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

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

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

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

(7) The fee for filing notice of a change in name, ownership or

management of a pharmacy is ninety dollars. A late fee for failing to give such notice within ten days of the change is fifty dollars in addition to the fee for notice.

(8) The fee for application for registration as a pharmacy intern is sixty dollars.

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

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

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

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

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

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

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

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

Secs. 20-602 to 20-604. Reserved for future use.

PART III*

PRACTICE OF PHARMACY

Sec. 20-605. Practice of pharmacy without license or temporary permit prohibited. No individual may engage in the practice of pharmacy unless the individual holds a current license or temporary permit to practice pharmacy issued by the department.

Sec. 20-606. (Formerly Sec. 20-178). Use of the title "pharmacist". A pharmacist who conforms to the regulations of the commissioner, adopted with the advice and assistance of the commission in accordance with chapter 54, may have, use and exhibit the title "pharmacist" in the practice of pharmacy.

Sec. 20-607. (Formerly Sec. 20-173). Certificate of license, temporary permit or registration to be available for inspection. Each person practicing as a pharmacist, pharmacy intern or pharmacy technician shall at all times have available for inspection by an inspector of the department a current certificate of license or temporary permit to practice pharmacy or a current registration to act as a pharmacy intern or pharmacy technician.

Sec. 20-608. (Formerly Sec. 20-174). Use of certificate of license, temporary permit or display document by unlicensed person prohibited. A pharmacist who permits such pharmacist's certificate of license, temporary permit or display document to be used by an unlicensed person for unlawful use shall be fined one hundred dollars

and shall be subject to other disciplinary proceedings within the authority of the commission.

Sec. 20-609. (Formerly Sec. 20-184). Pharmacy license to be posted. Business which is not a pharmacy prohibited from using words, displays or symbols indicating it is a pharmacy; exemption. (a) A pharmacy license shall be conspicuously posted within the pharmacy.

(b) Any person owning, managing or conducting any store, shop or place of business not being a pharmacy who exhibits within or upon the outside of such store, shop or place of business, or includes in any advertisement the words “drug store”, “pharmacy”, “apothecary”, “drug”, “drugs” or “medicine shop” or any combination of such terms or any other words, displays or symbols indicating that such store, shop or place of business is a pharmacy shall be guilty of a class D misdemeanor. The provisions of this subsection shall not apply to any person that provides pharmacy-related services directly to pharmacies or practitioners and does not offer such services and drugs or medical services directly to the public.

Sec. 20-609a. Use of electronic technology or telepharmacy by hospital. Quality assurance evaluations. (a) As used in this section:

(1) “Electronic technology” or “telepharmacy” means the process: (A) By which each step involved in the dispensing of a sterile product is verified through use of a bar code tracking system and documented by means of digital photographs which are electronically recorded and preserved; and (B) which is monitored and verified through video and

audio communication between a licensed supervising pharmacist and a pharmacy technician;

(2) “Sterile product” means any drug, as that term is defined in section 20-571, that is compounded, manipulated or otherwise prepared under sterile conditions during the dispensing process, is not intended for self-administration by a patient and is intended to be used in a hospital, or its satellite, remote or affiliated office-based locations;

(3) “Pharmacist” means an individual who is licensed to practice pharmacy under the provisions of section 20-590, 20-591, 20-592 or 20-593 and who is thereby recognized as a health care provider by the state of Connecticut; and

(4) “Pharmacy technician” means an individual who is registered with the department and qualified in accordance with section 20-598a.

(b) A hospital, licensed in accordance with the provisions of chapter 368v, which operates a hospital pharmacy, may use electronic technology or telepharmacy at the hospital and at the hospital’s satellite or remote locations for purposes of allowing a pharmacist to supervise pharmacy technicians in the dispensing of sterile products. Notwithstanding the provisions of this chapter or regulations adopted pursuant to this chapter, a pharmacist shall be permitted to supervise a pharmacy technician through use of electronic technology, and under such supervision the pharmacist shall monitor and verify the activities of a pharmacy technician through audio and video communication. The pharmacist-to-technician ratio pursuant to section 20-576-33 of the regulations of Connecticut state agencies shall apply. In the event of a malfunction of the electronic technology, no sterile product prepared by a pharmacy technician during the time period of the malfunction may be distributed to patients, unless a licensed pharmacist is able to: (1)

Personally review and verify the accuracy of all processes utilized in the dispensing of the sterile product; or (2) upon the restoration of the electronic technology, utilize the mechanisms of the electronic technology which recorded the actions of the pharmacy technician to confirm that all proper steps were followed in the dispensing of the sterile product. All orders for sterile products to be dispensed using telepharmacy shall be verified by a pharmacist prior to being delegated to a pharmacy technician for such dispensing. A hospital shall ensure that appropriately licensed personnel administer medications dispensed using telepharmacy. All of the processes involved in a hospital's use of telepharmacy shall be under the purview of the hospital's director of pharmacy.

(c) A hospital using telepharmacy shall undertake periodic quality assurance evaluations, not less than once per calendar quarter, which shall include, upon discovery, prompt review of any error in medication administration which occurs where telepharmacy is used to dispense such medication. A hospital shall make such quality assurance evaluations available for review and inspection by the Departments of Consumer Protection and Public Health.

Sec. 20-610. (Formerly Sec. 20-166). Dispensing or retail sale of legend drugs, legend devices and certain other drugs by other than pharmacies and hospitals, prohibited. (a) No legend drug, legend device or drugs listed in subsection (b) of this section may be dispensed or sold at retail except (1) in a pharmacy, (2) by a hospital licensed under sections 19a-490 to 19a-503, inclusive, to an employee of the hospital when prescribed by a prescribing practitioner for the employee or the employee's spouse or dependent children, or (3) by such hospital to a retiree of such hospital or the retiree's spouse in accordance with the

retiree's retirement or pension plan.

(b) The following drugs may not be sold at retail except as permitted in subsection (a) of this section: (1) Injectable or ingestible antibiotics; (2) injectable biologicals; (3) sulfonamides and their compounds which are designed to be taken into the stomach for systemic action; (4) injectable or ingestible corticosteroids; or (5) camphorated tincture of opium.

(c) Any person who violates any provision of this section shall be fined not less than one hundred dollars nor more than five hundred dollars.

Sec. 20-611. (Formerly Sec. 20-175b). Advertising legend drug prices. A pharmacist or any person holding a pharmacy license (1) may advertise the price of any legend drug sold at retail based on the prescription of a prescribing practitioner, provided, each such advertisement shall clearly state the period during which the advertised price or prices shall remain in effect and shall not contain any statement indicating that the advertised price or prices are subject to change without notice; and (2) shall disclose, upon request, the price of any such legend drug to any prospective purchaser.

Sec. 20-612. Only pharmacy may accept prescription for dispensing. Subject to the provisions of subsection (d) of section 20-614, only a pharmacy shall accept a prescription for dispensing. No employee, personnel or owner of a place of business or establishment not licensed as a pharmacy may accept a prescription for transfer to or for collection for a pharmacy.

Sec. 20-612a. Confirmation of identification prior to release of controlled substance. Exceptions. A pharmacist licensed pursuant to this chapter or his or her agent shall require the presentation of valid photographic identification prior to releasing a controlled substance to any person not known to such pharmacist. The provisions of this section shall not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital.

Sec. 20-613. (Formerly Sec. 21a-308). Dispensing of drug or legend device pursuant to prescription only; exceptions. Emergency dispensing of drug or device in care-giving, correctional or juvenile training institutions; regulations. Pharmacy technicians. Prescribing practitioner authorized to dispense own prescription, when. (a) Except as provided in subsections (b) and (d) of this section, a drug or a legend device may be dispensed pursuant to a prescription only in a pharmacy or institutional pharmacy by a pharmacist or by a pharmacy intern when acting under the direct supervision of a pharmacist, or by an individual holding a temporary permit.

(b) In care-giving institutions and correctional or juvenile training institutions in emergency situations when the pharmacist is not available for the dispensing of drugs or devices from the institutional pharmacy, the prescription shall be reviewed by the nursing supervisor or a physician before administration of the drug or device and recorded with the pharmacist in its original form or a copy thereof. After the required review in such emergency situations, the person authorized by the institution may dispense drugs and devices from the institutional pharmacy pursuant to regulations adopted by the commissioner, with the advice and assistance of the commission, in accordance with chapter 54.

(c) A pharmacy technician in a pharmacy or an institutional pharmacy may assist, under the direct supervision of a pharmacist, in the dispensing of drugs and devices. A person whose license to practice pharmacy is under suspension or revocation shall not act as a pharmacy technician.

(d) Nothing in sections 20-570 to 20-630, inclusive, shall prevent a prescribing practitioner from dispensing the prescribing practitioner's own prescriptions to the prescribing practitioner's own patients when authorized within the scope of the prescribing practitioner's own practice and when done in compliance with sections 20-14c to 20-14g, inclusive.

Sec. 20-613a. Requests for controlled substance issued on results of answers to electronic questionnaire. Regulations. In the absence of a documented patient evaluation that includes a physical examination, any request for a controlled substance issued solely on the results of answers to an electronic questionnaire shall be considered to be issued outside the context of a valid practitioner-patient relationship and not be a valid prescription. The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, concerning such requests for controlled substances. For the purposes of this section, "electronic questionnaire" means any form in an electronic format that may require personal, financial or medical information from a consumer or patient.

Sec. 20-614. (Formerly Sec. 20-184b). Prescriptions: Form and content. Electronic data intermediaries. (a) A prescription shall be transmitted in either an oral, written or electronic manner to a pharmacy.

(b) Whenever a pharmacy, or an institutional pharmacy in a hospital dispensing a drug or device for outpatient use or dispensing a drug or device that is prescribed for an employee of the hospital or for the employee's spouse or dependent children, receives an oral or electronically-transmitted prescription, except for a controlled drug, as defined in section 21a-240, a record of such prescription shall be maintained in writing or electronically. The pharmacist or pharmacy intern shall, not later than the end of the business day when the prescription was received, record the prescription on a prescription form or in an electronic record including: (1) The name and address of the prescribing practitioner; (2) the date of the prescription; (3) the name, dosage form, strength, where applicable, and the amount of the drug prescribed; (4) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (5) the directions for use; (6) any required cautionary statements; and (7) the number of times the prescription may be refilled, including the use of refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills.

(c) A written prescription shall bear: (1) The written signature of the prescribing practitioner or shall comply with the requirements of section 19a-509c; (2) the address of the practitioner; (3) the date of the prescription; (4) the name, dosage form, strength, where applicable, and amount of the drug prescribed; (5) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (6) the directions for use; (7) any required cautionary statements; and (8) the number of times the prescription may be refilled, including the use of refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills. No written prescription form for a schedule II substance may contain an order for any other legend drug or device.

(d) (1) As used in this subsection, “electronic data intermediary” means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by prescribing practitioners with those used by pharmacies in order to facilitate the secure transmission of electronic prescription orders, refill authorization requests, communications and other patient care information between such entities.

(2) An electronic data intermediary may transfer electronically transmitted data between a prescribing practitioner licensed and authorized to prescribe and a pharmacy of the patient’s choice, licensed pursuant to this chapter or licensed under the laws of any other state or territory of the United States. Electronic data intermediaries shall not alter the transmitted data except as necessary for technical processing purposes. Electronic data intermediaries may archive copies of only that electronic data related to such transmissions necessary to provide for proper auditing and security of such transmissions. Such data shall only be maintained for the period necessary for auditing purposes. Electronic data intermediaries shall maintain patient privacy and confidentiality of all archived information as required by state and federal law.

(3) No electronic data intermediary shall operate without the approval of the Commissioner of Consumer Protection. An electronic data intermediary seeking approval shall apply to the Commission of Pharmacy in the manner prescribed by the commissioner. The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with the provisions of chapter 54, to establish criteria for the approval of electronic data intermediaries, to ensure that (A) procedures to be used for the transmission and retention of prescription data by an intermediary, and (B) mechanisms to be used by an intermediary to safeguard the confidentiality of such data, are

consistent with the provisions and purposes of this section.

Sec. 20-615. (Formerly Sec. 20-184c). Prescriptions: Pharmacy to assign serial number and maintain records. Transfer of records to another pharmacy. (a) An institutional pharmacy dispensing a drug in circumstances described in subsection (g) of this section and a pharmacy shall assign and record a serial number to each prescription that it fills and shall keep all written prescriptions and the record of oral and electronically-transmitted prescriptions required in section 20-614 in numerical order in a suitable file, electronic file or ledger for a period of not less than three years. The records shall indicate the date of filling, the name and address of the prescribing practitioner, the name and address of the patient or the name and address of the owner of an animal for whom the prescription was written and the species of the animal and the name of the pharmacist who dispensed the drug.

(b) A refill of a prescription shall be recorded on the face or back of the original prescription or in an electronic system.

(c) Records maintained under this section shall be made available for inspection upon request of any authorized agent of the commissioner or other person authorized by law.

(d) When a pharmacy closes temporarily or permanently, the pharmacy shall, in the interest of public health, safety and convenience, make its complete prescription records immediately available to a nearby pharmacy and post a notice of this availability on the window or door of the closed pharmacy.

(e) Any violation of this section shall be punishable as provided in section 20-581.

(f) This section shall not apply to records maintained in accordance with regulations adopted pursuant to section 20-576, 21a-244 or 21a-244a.

(g) When an institutional pharmacy in a hospital dispenses a drug or device for outpatient use or dispenses a drug or device that is prescribed for an employee of the hospital or for the employee's spouse or dependent children, the provisions of subsections (a), (b), (c) and (e) of this section shall apply.

Sec. 20-616. (Formerly Sec. 20-184d). Prescriptions: Refills; transfers. (a) Except as provided in subsection (b) of this section, a prescription may be refilled only upon the written, oral or electronically-transmitted order of a prescribing practitioner.

(b) A pharmacist may exercise his professional judgment in refilling a prescription that is not for a controlled drug, as defined in section 21a-240, without the authorization of the prescribing practitioner, provided (1) the pharmacist is unable to contact such practitioner after reasonable effort, (2) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering, and (3) the pharmacist informs the patient or representative of the patient at the time of dispensing that the refill is being provided without such authorization and informs the practitioner at the earliest reasonable time that authorization of the practitioner is required for future refills. Prescriptions may be refilled once pursuant to this subsection for a quantity of drug not to exceed a seventy-two hour supply.

(c) Any prescription that is not for a controlled drug, as defined in section 21a-240, may be transferred orally or electronically between pharmacies, provided:

(1) The prescribing practitioner has authorized the original prescription to be refilled in accordance with subsection (a) of this section;

(2) The pharmacist transferring the prescription shall cancel the original prescription in such pharmacist's records and shall indicate in such records the name of the pharmacy to which the prescription is transferred and the date of the transfer, provided, such cancellation shall not be required in the case of any transfer between pharmacies which electronically access the same prescription records and utilize the same computer or other electronic prescription transfer system; and

(3) The pharmacist receiving the prescription shall indicate in such pharmacist's records, in addition to any other information required by law, (A) the fact that the prescription has been transferred and the names of the transferring pharmacy and pharmacist, (B) the date of issuance and the prescription number of the original prescription, (C) the date the original prescription was first dispensed, (D) the number of refills authorized by the original prescription and the complete refill record for the prescription as of the date of the transfer, and (E) the number of valid refills remaining as of the date of the transfer.

Sec. 20-617. (Formerly Sec. 20-184e). Prescriptions: Notation of drug quantities and expiration dates required on labels. Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed in such container, in addition to any other information required by law; and (2) a prominently printed expiration date based on the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. The expiration date required pursuant to subdivision (2) of

this section shall be no later than the expiration date determined by the manufacturer.

Sec. 20-617a. Flavoring agent added to prescription product. (a) For purposes of this section, "flavoring agent" means an additive used in food or drugs when such additive: (1) Is used in accordance with good manufacturing practice principles and in the minimum quantity required to produce its intended effect, (2) consists of one or more ingredients generally recognized as safe in food and drugs, has been previously sanctioned for use in food and drugs by the state or the federal government, meets United States Pharmacopeia standards or is an additive permitted for direct addition to food for human consumption pursuant to 21 CFR 172, (3) is inert and produces no effect other than the instillation or modification of flavor, and (4) is not greater than five per cent of the total weight of the product.

(b) A flavoring agent may be added to a prescription product by: (1) A pharmacist upon the request of the prescribing practitioner, patient for whom the prescription is ordered or such patient's agent, or (2) a pharmacist acting on behalf of a hospital, as defined in section 19a-490.

Sec. 20-618. (Formerly Sec. 21a-107). Repackaged drugs not considered misbranded, when. Notwithstanding the provisions of section 21a-106 concerning misbranding of drugs or devices, a drug shall not be considered misbranded when repackaged by a pharmacy or an institutional pharmacy into stock packages for use within the pharmacy or the institutional pharmacy, provided the stock packages contain a label indicating the drug's name, strength, lot number, manufacturer and expiration date, if any.

Sec. 20-619. (Formerly Sec. 20-185a). Substitution of generic drugs. Regulations. (a) For the purposes of section 20-579 and this section:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

(2) "Generic name" means the established name designated in the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(3) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

(4) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

(5) "Epilepsy" means a neurological condition characterized by recurrent seizures;

(6) "Seizures" means a disturbance in the electrical activity of the

brain; and

(7) “Antiepileptic drug” means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.

(b) Except as limited by subsections (c), (e) and (i) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist’s professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(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 any prescription, provided (1) in any prescription for a Medicaid or ConnPACE 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 or ConnPACE 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.

(d) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, “THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE.” The printing on the sign shall be in block letters not less than one inch in height.

(e) A pharmacist may substitute a drug product under subsection (b) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

(f) Except as provided in subsection (g) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label shall indicate the generic name of the drug product dispensed along with the name of the drug manufacturer or distributor.

(g) A prescription dispensed by a pharmacist shall bear upon the label

the name of the drug in the container unless the prescribing practitioner writes “DO NOT LABEL”, or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

(h) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection (d) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

(i) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug, unless the pharmacist (1) provides prior notice of the use of a different drug manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient’s prescribing practitioner. For purposes of obtaining the consent of the patient’s prescribing practitioner required by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug manufacturer or distributor or return the prescription to the patient or to the patient’s representative for filling at another pharmacy. If a pharmacist is unable to contact the patient’s prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of section 20-616. For purposes of this subsection, “pharmacy” means a place of business where drugs and

devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(j) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 20-620. (Formerly Sec. 20-185g). Pharmacist's duties towards Medicaid recipients: To obtain, record and maintain pertinent patient information about the recipient; to undertake a review of the drugs previously dispensed to the recipient and to offer to discuss the drugs to be dispensed and to counsel the recipient on their correct usage. Exception. (a) Prior to or simultaneously with dispensing a prescription in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist or the designee of the pharmacist shall make a reasonable effort to obtain, record and maintain, in a manner deemed appropriate by the pharmacist, the following information regarding the individual receiving such prescription: (1) Name, address, telephone number, date of birth or age and gender; (2) individual history where significant, including disease states, known allergies and drug reactions; (3) a comprehensive list of drugs and relevant devices dispensed by the pharmacy within the last one hundred eighty days; and (4) the pharmacist's comments relevant to the individual's drug therapy.

(b) Prior to or simultaneously with dispensing a drug to an individual eligible for benefits in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist shall undertake a review of drugs dispensed to the individual by the pharmacy during the previous one hundred eighty days. The review shall include screening for potential drug therapy problems due to therapeutic duplication, a contraindication between a drug and a disease, the interaction of one drug with another, incorrect drug dosage or duration of drug treatment, the interaction of a drug and an allergy, clinical abuse or misuse and any other significant clinical issues relating to the appropriate use of drugs. Such review shall be based upon current standards and information consistent with that provided in the following resources: The American Hospital Formulary Service Drug Information, the United States Pharmacopoeia Drug Information, the American Medical Association Drug Evaluations and the peer-reviewed medical literature.

(c) Prior to or simultaneously with dispensing drugs to individuals eligible for benefits in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist shall, whenever practicable, offer in person to discuss the drugs to be dispensed and to counsel the client on their usage, except when the person obtaining the prescription is other than the person named on the prescription form or the pharmacist determines it is appropriate to make such offer in writing. Any such written offer shall include an offer to communicate with the client either in person at the pharmacy or by telephone.

(d) The discussion and counseling offered in accordance with subsection (c) of this section shall include information deemed significant by the pharmacist based upon the findings of the review

conducted in accordance with subsection (b) of this section, including (1) the name and description of the drug; (2) dosage form, dosage, route of administration and duration of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications or precautions which the pharmacist deems relevant; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose or adverse reaction.

(e) Nothing in this section shall be construed as requiring a pharmacist to provide counseling or gather information when an individual receiving benefits refuses such counseling or refuses or is unable to provide the information requested. The pharmacist shall document the provision of counseling, a refusal by or the inability of the patient to accept counseling or a refusal by the patient to give information. Records kept pursuant to this subsection shall be maintained for the same length of time as prescription records are maintained pursuant to section 20-615.

(f) The provisions of subsections (c) and (d) of this section shall not apply to a drug dispensed to a patient of a nursing home that is in compliance with the requirements of 42 CFR 483.60.

Sec. 20-621. (Formerly Sec. 20-185h). Relabeling and dispensing of parenteral medication in hospital and nursing home pharmacies: When allowed. A pharmacist practicing in a hospital pharmacy or nursing home pharmacy may relabel and dispense to a registered inpatient, parenteral medication, except controlled substances, dispensed for another registered patient by a licensed pharmacy if the following

requirements are met: (1) The original medication order for the drug is discontinued; (2) the medication is in an unopened tamper-evident package; (3) the medication is not expired; (4) the original patient is not charged for the medication; and (5) upon receipt of the medication by the facility from the licensed pharmacy, it is processed through the hospital's pharmacy or nursing home pharmacy.

Sec. 20-622. (Formerly Sec. 20-180a). Licensed practitioners may authorize medication to be dispensed from a hospital emergency room. When the therapeutic needs of a patient require that medication be initiated immediately and the services of a licensed pharmacy are not available within a five-mile radius of a hospital emergency room, a person associated with such hospital authorized to dispense medication may dispense up to a twenty-four-hour supply of medication, excluding controlled substances, to such patient. Such dispensing shall be authorized by a verbal order of a licensed practitioner. For purposes of this section, "licensed practitioner" means a physician on the staff of such hospital or other prescribing practitioner associated with such hospital who has examined such patient and determined the patient's therapeutic needs.

Sec. 20-623. Sale of nonlegend drugs. Labels, packaging and contents. Penalty. (a) No nonlegend drug may be sold at retail except at a pharmacy or at a store that has obtained from the commission a permit to sell nonlegend drugs. Nonlegend drugs shall be labeled and packaged in accordance with state and federal law.

(b) Any person who violates any provision of this section shall be fined not less than one hundred dollars nor more than five hundred

dollars.

Sec. 20-624. Permit to sell nonlegend drugs. (a) Any person may apply to the commission for a permit to sell nonlegend drugs.

(b) The commission may, in accordance with regulations adopted under sections 20-570 to 20-630, inclusive, in accordance with chapter 54, and on payment of the fee required in section 20-601, issue to an applicant a permit to sell nonlegend drugs for one year.

(c) A permit that has expired under this section may be renewed, on application and payment of the renewal fee and any late fee required in section 20-601.

(d) The holder of a permit to sell nonlegend drugs shall notify the commission of a change of ownership, name or location of the permit premises. Any holder who fails to notify the commission of such change within five days of the change shall pay the late fee required in section 20-601.

(e) Any nonlegend drug permit issued by the commission pursuant to this section is nontransferable.

Sec. 20-625. Nonlegend veterinary drugs. Nothing in sections 20-570 to 20-630, inclusive, shall be construed to prohibit the sale of veterinary drugs that are nonlegend drugs by any person who holds a permit to sell nonlegend drugs.

Sec. 20-626. Confidentiality of pharmacy records. (a) No pharmacist or pharmacy shall reveal any records or information

concerning the nature of pharmaceutical services rendered to a patient without the oral or written consent of the patient or the patient's agent. If a patient or a patient's agent gives oral consent to release records or information, the pharmacist shall promptly record, in writing or in electronic data base form, the oral consent by listing the patient's name, the name of the patient's agent, if applicable, the date and the nature of the records or information released.

(b) Notwithstanding subsection (a) of this section, a pharmacist or pharmacy may provide pharmacy records or information to the following: (1) The patient; (2) the prescribing practitioner or a pharmacist or another prescribing practitioner presently treating the patient when deemed medically appropriate; (3) a person registered or licensed pursuant to chapter 378 who is acting as an agent for a prescribing practitioner that is presently treating the patient or a person registered or licensed pursuant to chapter 378 providing care to the patient in a hospital; (4) third party payors who pay claims for pharmaceutical services rendered to a patient or who have a formal agreement or contract to audit any records or information in connection with such claims; (5) any governmental agency with statutory authority to review or obtain such information; (6) any individual, the state or federal government or any agency thereof or court pursuant to a subpoena; and (7) any individual, corporation, partnership or other legal entity which has a written agreement with a pharmacy to access the pharmacy's database provided the information accessed is limited to data which does not identify specific individuals.

Sec. 20-627. Nonresident pharmacy. Definitions. Certificate of registration. Requirements. (a) As used in sections 20-627 to 20-630, inclusive, "nonresident pharmacy" means any pharmacy located outside

this state which 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 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 pursuant to this section.

(3) 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) 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.

(c) 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. Such toll-free telephone number shall be disclosed on a label affixed to each

container of drugs dispensed to patients in this state.

Sec. 20-628. Shipping, mailing or delivering legend devices or drugs. No nonresident pharmacy shall engage in the business of shipping, mailing or delivering legend devices or legend drugs in this state unless such nonresident pharmacy has been issued a certificate of registration by the commission and has paid the fee for issuance or renewal of such certificate of registration required in section 20-601. Applications for a certificate of registration as a nonresident pharmacy shall be made on a form furnished by the commission. The commission may require such information as it deems reasonably necessary to carry

Sec. 20-629. Suspension or revocation of certificate. (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.

(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 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. 20-630. Advertising. It shall be unlawful for any nonresident pharmacy which has not been issued a certificate of registration pursuant to section 20-628 to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not received a certificate of registration from the commission, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to dispense prescription orders.

Sec. 20-631. Collaborative drug therapy management agreements between pharmacists and physicians. Scope. Pharmacist competency requirements. Regulations. (a) Except as provided in section 20-631b, one or more pharmacists licensed under this chapter who are determined competent in accordance with regulations adopted pursuant to subsection (d) of this section may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients. In order to enter into a written protocol-based collaborative drug therapy management agreement, such physician shall have established a physician-patient relationship with the patient who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. For purposes of this subsection, a "physician-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of such discontinuance no later than twenty-four hours from the time of such discontinuance. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection (d) of this section, the competence necessary for participation in each drug therapy management agreement into which such pharmacist enters.

(d) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall adopt regulations, in

accordance with chapter 54, concerning competency requirements for participation in a written protocol-based collaborative drug therapy management agreement described in subsection (a) of this section, the minimum content of the collaborative drug therapy management agreement and the written protocol and such other matters said commissioners deem necessary to carry out the purpose of this section.

Sec. 20-631a. Collaborative drug management agreements between pharmacists employed by community pharmacies and one or more physicians. Pilot program. (a) Not later than January 1, 2006, the Commissioner of Consumer Protection, in consultation with the Commission of Pharmacy, shall establish and operate a two-year pilot program to allow not more than ten pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a licensed community pharmacy, to enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370, to manage the drug therapy of individual patients receiving drug therapy for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the licensed community pharmacy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

(b) A collaborative drug therapy management agreement may

authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report to the physician through oral, written or electronic manner regarding the implementation, administration, modification or discontinuation of a drug therapy that has been prescribed for a patient not later than twenty-four hours after such implementation, administration, modification or discontinuation. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) In order to be selected for participation in the program, a pharmacist shall be responsible for demonstrating, in accordance with this subsection, the competence necessary for participation in each drug therapy management agreement into which such pharmacist may enter. The pharmacist's competency shall be determined by the Commission of Pharmacy using criteria based on the continuing education requirements of sections 20-599 and 20-600.

(d) The Commissioner of Consumer Protection and the Commission of Pharmacy shall evaluate the pilot program established under this section and shall submit a report of the commissioner's findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to public health, human services and general law, not later than December 31, 2008, in accordance with the provisions of section 11-4a. Such report shall include an evaluation of the data collected with respect to improved medication management and cost savings, based on patient outcomes.

(e) Records or information collected or maintained pursuant to this section shall not be disclosed pursuant to subsection (a) of section 1-210 for a period of six months from the date such records or information were created or collected and shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law.

(f) For purposes of this section, "community pharmacy" means a pharmacy licensed under section 20-594 that stores and dispenses legend drugs, as defined by section 20-571, and legend devices, as defined by said section 20-571, and from which related pharmaceutical care services are provided, primarily to noninstitutionalized patients living in a community setting.

Sec. 20-631b. Collaborative drug therapy management agreements entered into prior to October 1, 2010. The provisions of section 20-631 in effect on September 30, 2010, shall apply to any written protocol-based collaborative drug therapy management agreement entered into prior to October 1, 2010.

Sec. 20-632. Regulatory action report re disciplinary action against persons with controlled substance registrations and sanctions against pharmacists or pharmacies. Not less than once every three months, the Department of Consumer Protection shall compile a regulatory action report that contains information regarding: (1) Any disciplinary action taken by the department against any person with a controlled substance registration, and (2) any sanction by the Commission of Pharmacy against a pharmacy or pharmacist. Such report shall contain the reasons for any such action or sanction and shall be posted on the web site of the department.

Sec. 20-633. Administration of vaccines by licensed pharmacists. Regulations. (a) Any person licensed as a pharmacist under part II of this chapter may administer, to an adult, any vaccine, approved by the United States Food and Drug Administration that is listed on the National Centers for Disease Control and Prevention's Adult Immunization Schedule, provided the administration of any such vaccine is conducted pursuant to the order of a licensed health care provider and in accordance with the regulations established pursuant to subsection (b) of this section.

(b) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health and the Commission of Pharmacy, shall adopt regulations, in accordance with the provisions of chapter 54, to implement the provisions of this section. Such regulations shall (1) require any pharmacist who administers a vaccine to an adult pursuant to this section to successfully complete an immunization training program for pharmacists; (2) define the basic requirements of such training program, which shall include training and instruction in pre-administration education and screening, vaccine storage and handling,

subcutaneous and intramuscular injections, recordkeeping, vaccine safety, cardiopulmonary resuscitation, basic cardiac life support and adverse event reporting; (3) identify qualifying training programs, which are accredited by the National Centers for Disease Control Prevention, the Accreditation Council for Pharmacy Education or other appropriate national accrediting body; and (4) establish a system of control and reporting.

(c) For purposes of this section, "adult" means an individual who has attained the age of eighteen years.

Sec. 20-634. Reserved for future use.

PART IV

PRESCRIPTION ERROR REPORTING

Sec. 20-635. Prescription error reporting. Definitions. Informational signs and statements. Regulations. Nondisclosure of records. (a) As used in this section:

(1) "Dispensing" means those acts of processing a drug for delivery or for administration for a patient pursuant to a prescription consisting of: (A) Comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug; (D) the placing of the drug in the proper container; (E) the affixing of the label to the container; and (F) the

addition to a written prescription of any required notations;

(2) “Drug” means (A) an article 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) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) an article, other than food, intended to affect the structure or any function of the body of humans;

(3) “Pharmacy” means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594. For the purposes of this section, “pharmacy” shall include any areas of an institutional pharmacy where prescription drugs are dispensed to outpatients, employees and retirees;

(4) “Prescribing practitioner” means an individual licensed by the state of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual’s practice;

(5) “Prescription” means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug for a specific patient; and

(6) “Prescription error” means an act or omission of clinical significance relating to the dispensing of a drug that results in or may reasonably be expected to result in injury to or death of a patient.

(b) Each pharmacy shall display a sign concerning the reporting of prescription errors in a conspicuous location visible to consumers of

prescription drugs. The sign shall measure a minimum of eight inches in height and ten inches in length and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the pharmacy prescription department distribution counter. The sign shall bear the following statement: “If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)”.

(c) Each pharmacy that dispenses a prescription to a consumer shall include the following printed statement on the receipt or in the bag or other similar packaging in which the prescription is contained: “If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)”. The statement shall be printed in a size and style that allows such statement to be read without difficulty by consumers.

(d) The Commissioner of Consumer Protection shall adopt regulations, with the advice and assistance of the Commission of Pharmacy, in accordance with chapter 54, concerning the implementation of a quality assurance program designed to detect, identify and prevent prescription errors in pharmacies. Such regulations shall require that each pharmacy implement a quality assurance program that describes in writing policies and procedures to be maintained in such pharmacy. Such policies and procedures shall include directions for communicating the details of a prescription error to the prescribing practitioner and to the patient, the patient’s caregiver or appropriate family member if the patient is deceased or is unable to fully

comprehend the communication. Such communication shall describe methods of correcting the prescription error or reducing the negative impact of the error on the patient. Such regulations shall require that records of all reported prescription errors shall be maintained in a manner ready for inspection for a minimum period of three years and that such records shall be made available for inspection by the Commissioner of Consumer Protection within forty-eight hours in any case where the commissioner is investigating a report of a prescription error.

(e) Records collected or maintained pursuant to this section shall not be required to be disclosed pursuant to subsection (a) of section 1-210 for a period of six months from the date such records were created pursuant to subsections (c) and (d) of this section and shall not be subject to subpoena or discovery or introduced into evidence in any judicial proceeding except as otherwise specifically provided by law.

Secs. 20-636 to 20-639. Reserved for future use.

CHAPTER 416*

DEPARTMENT OF CONSUMER PROTECTION

Table of Contents

Sec. 21a-1c. Appointment of director.

Sec. 21a-2. (Formerly Sec. 19-170e). Toll-free telephone line for inquiries and complaints.

Sec. 21a-4. (Formerly Sec. 19-171b). Refund of fees for unused permits. Fine for payment by check returned as uncollectible. Fine for late renewal of license, certificate or registration.

Sec. 21a-5. (Formerly Sec. 19-171d). Federal funds, separate account authorized.

Sec. 21a-6. (Formerly Sec. 19-171e). Boards and commissions within Department of Consumer Protection.

Sec. 21a-7. (Formerly Sec. 19-171f). Powers and duties of boards and commissions within Department of Consumer Protection.

Sec. 21a-8. (Formerly Sec. 19-171g). Department's and commissioner's powers and duties re boards and commissions.

Sec. 21a-8a. Consumer protection enforcement account.

Sec. 21a-9. (Formerly Sec. 19-171h). Uniform rules of procedure. Regulations re subjects within jurisdiction of boards and commissions within Department of Consumer Protection. Prohibited acts by practitioners. Definitions.

Sec. 21a-10. (Formerly Sec. 19-171i). Commissioner of Consumer Protection authorized to establish, combine or abolish divisions, sections or other units, exception. Regulations re staggered schedule for renewal of licenses. Prorated amount for guaranty fund fees and newly issued licenses, certificates, registrations and permits, allowed.

Sec. 21a-10a. Retirement status license.

Sec. 21a-11. (Formerly Sec. 19-171). Powers and duties of commissioner.

Sec. 21a-1c. Appointment of director. The Commissioner of Consumer Protection may appoint a director to perform such functions as the commissioner shall delegate to implement and administer the provisions of sections 7-169 to 7-186, inclusive, and chapters 226, 226b and 229a. Such director shall be exempt from the classified service.

Sec. 21a-2. (Formerly Sec. 19-170e). Toll-free telephone line for inquiries and complaints. A toll-free telephone line, available to consumers throughout the state, shall be established in the Department of Consumer Protection for the handling of consumer inquiries and complaints concerning consumer goods or services in the state or any other matter within the jurisdiction of the department and its licensing and regulatory boards. The line shall be in operation from 8:30 a.m. to 4:30 p.m. Monday through Friday each week, exclusive of those legal holidays on which state offices are closed, and shall be restricted to incoming calls.

Sec. 21a-4. (Formerly Sec. 19-171b). Refund of fees for unused permits. Fine for payment by check returned as uncollectible. Fine for late renewal of license, certificate or registration. (a) The Commissioner of Consumer Protection may refund to any permittee the fee paid by him for any permit issued by said commissioner and returned to him prior to its use, provided application for such refund shall be made not later than sixty days after the effective date of such permit.

(b) The Commissioner of Consumer Protection may impose a fine of twenty dollars on any applicant for a permit or license issued by the Commissioner of Consumer Protection who issues to the commissioner a check drawn on the account of such applicant in payment of a permit or license fee and whose check is returned to the Department of Consumer Protection as uncollectible.

(c) The Commissioner of Consumer Protection may impose a fine on any applicant who fails to renew a license, permit, certificate or registration not later than the expiration date of such license, permit, certificate or registration. The amount of the fine shall be equal to ten per cent of the renewal fee but shall not be less than ten dollars or more than one hundred dollars.

Sec. 21a-5. (Formerly Sec. 19-171d). Federal funds, separate account authorized. The Commissioner of Consumer Protection is authorized to do all things necessary to apply for, qualify for and accept any federal funds made available or allotted under any federal act for any projects, programs or activities which may be established by federal law, for any of the purposes, or activities related thereto, of any provisions of the general statutes administered by said commissioner, and said commissioner shall administer any such funds allotted to the

department in accordance with federal law. The commissioner may enter into contracts with the federal government concerning the use and repayment of such funds under any such federal act, the prosecution of the work under any such contract and the establishment of, and disbursement from, a separate account in which federal and state funds estimated to be required for plan preparation or other eligible activities under such federal act shall be kept. Said account shall not be a part of the General Fund of the state or any subdivision of the state.

Sec. 21a-6. (Formerly Sec. 19-171e). Boards and commissions within Department of Consumer Protection. The following boards shall be within the Department of Consumer Protection:

(1) The Architectural Licensing Board established under chapter 390;

(2) Repealed by P.A. 93-151, S. 3, 4;

(3) The examining boards for electrical work; plumbing and piping work; heating, piping, cooling and sheet metal work; elevator installation, repair and maintenance work; fire protection sprinkler systems work and automotive glasswork and flat glass work established under chapter 393;

(4) The State Board of Television and Radio Service Examiners established under chapter 394;

(5) The Commission of Pharmacy established under chapter 400j;

(6) The State Board of Landscape Architects established under chapter 396;

(7) Deleted by P.A. 98-229;

(8) The State Board of Examiners for Professional Engineers and

Land Surveyors established under chapter 391;

(9) Repealed by P.A. 80-484, S. 175, 176;

(10) The Connecticut Real Estate Commission established under chapter 392;

(11) The Connecticut Real Estate Appraisal Commission established under chapter 400g;

(12) The State Board of Examiners of Shorthand Reporters established under chapter 400*l*;

(13) The Liquor Control Commission established under chapter 545;

(14) Repealed by P.A. 06-187, S. 99, effective October 1, 2006;

(15) The Home Inspection Licensing Board established under section 20-490a.

Sec. 21a-7. (Formerly Sec. 19-171f). Powers and duties of boards and commissions within Department of Consumer Protection. Each board or commission transferred to the Department of Consumer Protection under section 21a-6 shall have the following powers and duties:

(1) Each board or commission shall exercise its statutory functions, including licensing, certification, registration, accreditation of schools and the rendering of findings, orders and adjudications, independently of the Commissioner of Consumer Protection. The final decision of a board or commission shall be subject to judicial review as provided in section 4-183.

(2) Each board or commission may, in its discretion, issue (A) an

appropriate order to any person found to be violating an applicable statute or regulation providing for the immediate discontinuance of the violation, (B) an order requiring the violator to make restitution for any damage caused by the violation, or (C) both. Each board or commission may, through the Attorney General, petition the superior court for the judicial district wherein the violation occurred, or wherein the person committing the violation resides or transacts business, for the enforcement of any order issued by it and for appropriate temporary relief or a restraining order and shall certify and file in the court a transcript of the entire record of the hearing or hearings, including all testimony upon which such order was made and the findings and orders made by the board or commission. The court may grant such relief by injunction or otherwise, including temporary relief, as it deems equitable and may make and enter a decree enforcing, modifying and enforcing as so modified, or setting aside, in whole or in part, any order of a board or commission.

(3) Each board or commission may conduct hearings on any matter within its statutory jurisdiction. Such hearings shall be conducted in accordance with chapter 54 and the regulations established pursuant to subsection (a) of section 21a-9. In connection with any such hearing, the board or commission 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.

(4) Each board or commission may request the Commissioner of Consumer Protection to conduct an investigation and to make findings and recommendations regarding any matter within the statutory

jurisdiction of the board or commission.

(5) Each board or commission may recommend rules and regulations for adoption by the Commissioner of Consumer Protection and may review and comment upon proposed rules and regulations prior to their adoption by said commissioner.

(6) Each board or commission shall meet at least once in each quarter of a calendar year and at such other times as the chairperson deems necessary or at the request of a majority of the board or commission members. A majority of the members shall constitute a quorum except that for any examining board forty per cent of the members shall constitute a quorum. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings during any calendar year shall be deemed to have resigned from office. Members of boards or commissions shall not serve for more than two consecutive full terms which commence on or after July 1, 1982, except that if no successor has been appointed or approved, such member shall continue to serve until a successor is appointed or approved. Members shall not be compensated for their services but shall be reimbursed for necessary expenses incurred in the performance of their duties.

(7) In addition to any other action permitted under the general statutes, each board or commission may upon a finding of any cause specified in subsection (c) of section 21a-9: (A) Revoke or suspend a license, registration or certificate; (B) issue a letter of reprimand to a practitioner and send a copy of such letter to a complainant or to a state or local official; (C) place a practitioner on probationary status and require the practitioner to (i) report regularly to the board or commission on the matter which is the basis for probation, (ii) limit the practitioner's practice to areas prescribed by the board or commission, or (iii) continue or renew the practitioner's education until the practitioner has attained a

satisfactory level of competence in any area which is the basis for probation. Each board or commission may discontinue, suspend or rescind any action taken under this subsection.

(8) Each examining board within the Department of Consumer Protection shall conduct any hearing or other action required for an application submitted pursuant to section 20-333 and any completed renewal application submitted pursuant to section 20-335 not later than thirty days after the date of submission for such application or completed renewal application, as applicable.

Sec. 21a-8. (Formerly Sec. 19-171g). Department's and commissioner's powers and duties re boards and commissions. (a) The Department of Consumer Protection shall have the following powers and duties with regard to each board or commission transferred to the Department of Consumer Protection under section 21a-6:

(1) The department shall control the allocation, disbursement and budgeting of funds appropriated to the department for the operation of each board or commission transferred to said department.

(2) The department shall employ and assign such personnel as the commissioner deems necessary for the performance of each board's or commission's functions.

(3) The department shall perform all management functions, including purchasing, bookkeeping, accounting, payroll, secretarial, clerical, record-keeping and routine housekeeping functions.

(4) The department shall conduct any necessary review, inspection or

investigation regarding qualifications of applicants for licenses or certificates, possible violations of statutes or regulations, accreditation of schools, disciplinary matters and the establishment of regulatory policy, and make recommendations to the appropriate board or commission. In connection with any such investigation, the Commissioner of Consumer Protection, 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.

(5) The department shall administer any examinations necessary to ascertain the qualifications of applicants for licenses or certificates and shall issue licenses or certificates to qualified applicants. The department shall maintain rosters of licensees or registrants and update such rosters annually, and may provide copies of such rosters to the public for an appropriate fee.

(6) The department shall conduct any necessary investigation and follow-up in connection with complaints regarding persons subject to regulation or licensing by the board or commission.

(7) The department shall perform any other function necessary to the effective operation of the board or commission and not specifically vested by statute in the board or commission.

(8) The department shall receive complaints concerning the work and practices of persons licensed, registered or certified by such boards or commissions and shall receive complaints concerning unauthorized work and practice by persons not licensed, registered or certified by such boards or commissions. The department shall distribute monthly a list of

all complaints received within the previous month to the chairperson of the appropriate board or commission. The department shall screen all complaints and dismiss any in which the allegation, if substantiated, would not constitute a violation of any statute or regulation. The department shall distribute notice of all such dismissals monthly to the chairperson of the appropriate board or commission. The department shall investigate any complaint in which the allegation, if substantiated, would constitute a violation of a statute or regulation under its jurisdiction. In conducting the investigation, the commissioner may seek the assistance of a member of the appropriate board, an employee of any state agency with expertise in the area, or if no such member or employee is available, a person from outside state service licensed to perform the work involved in the complaint. Board or commission members involved in an investigation shall not participate in disciplinary proceedings resulting from such investigation. The Commissioner of Consumer Protection may dismiss a complaint following an investigation if the commissioner determines that such complaint lacks probable cause. Notice of such dismissal shall be given only after approval by the chairperson of the appropriate board or commission. The commissioner may authorize a settlement if the settlement is approved by the complainant, the practitioner, and the board or commission. The commissioner may bring a complaint before the appropriate board or commission for a formal hearing if the commissioner determines that there is probable cause to believe that the offense alleged in the complaint has been committed and that the practitioner named in the complaint was responsible. The commissioner, or the commissioner's authorized agent, shall have the power to issue subpoenas to require the attendance of witnesses or the production of records, correspondence, documents or other evidence in connection with any hearing of a board or commission. All dispositions and final decisions by the Department of

Consumer Protection after an investigation into a complaint has begun shall be forwarded to the chairperson of the appropriate board or commission on a monthly basis.

(9) The department may contract with a third party, if the commissioner deems it necessary and if the appropriate board or commission consents, to administer licensing examinations and perform all attendant administrative functions in connection with such examination and to monitor continuing professional education requirements, and may require the payment of a fee to such third party.

(b) The Commissioner of Consumer Protection shall have the following powers and duties with regard to each board or commission transferred to the Department of Consumer Protection under section 21a-6:

(1) The commissioner may, in the commissioner's discretion, issue an appropriate order to any person found to be violating any statute or regulation within the jurisdiction of such board or commission providing for the immediate discontinuance of the violation or requiring the violator to make restitution for any damage caused by the violation, or both. The commissioner may, through the Attorney General, petition the superior court for the judicial district in which the violation occurred, or in which the person committing the violation resides or transacts business, for the enforcement of any order issued by the commissioner under this subdivision and for appropriate temporary relief or a restraining order. The commissioner shall certify and file in the court a transcript of the entire record of the hearing or hearings, including all testimony upon which such order was made and the findings and orders made by the commissioner. The court may grant such relief by injunction or otherwise, including temporary relief, as the court deems equitable and may make and enter a decree enforcing, modifying and

enforcing as so modified, or setting aside, in whole or in part, any order of the commissioner issued under this subdivision.

(2) The commissioner may conduct hearings on any matter within the statutory jurisdiction of such board or commission. Such hearings shall be conducted in accordance with chapter 54 and the regulations established pursuant to subsection (a) of section 21a-9. 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 subdivision.

(3) In addition to any other action permitted under the general statutes, the commissioner may, upon a finding of any cause specified in subsection (c) of section 21a-9: (A) Revoke or suspend a license, registration or certificate; (B) issue a letter of reprimand to a practitioner and send a copy of such letter to a complainant or to a state or local official; (C) place a practitioner on probationary status and require the practitioner to (i) report regularly to the commissioner on the matter which is the basis for probation, (ii) limit the practitioner's practice to areas prescribed by the commissioner, or (iii) continue or renew the practitioner's education until the practitioner has attained a satisfactory level of competence in any area which is the basis for probation. The commissioner may discontinue, suspend or rescind any action taken under this subdivision.

Sec. 21a-8a. Consumer protection enforcement account. (a) There is established an account to be known as the "consumer protection

enforcement account". The account may contain any moneys required by law to be deposited in the account. Any balance remaining in the account at the end of any fiscal year shall be carried forward in the account for the fiscal year next succeeding. The account shall be used by the Department of Consumer Protection to fund positions and other related expenses for the enforcement of Department of Consumer Protection licensing and registration laws.

(b) Notwithstanding any provision of the general statutes to the contrary, the amount of any civil penalty imposed or assessed by the Commissioner of Consumer Protection, his legally authorized representative or agent or a licensing board in the department, pursuant to sections 20-341, 21a-75, 21a-79, 21a-86g, 21a-96, 21a-236 and 21a-340 and any other provisions of titles 20, 21 and 21a, shall, upon deposit in the General Fund, be credited to the account established by subsection (a) of this section.

Sec. 21a-9. (Formerly Sec. 19-171h). Uniform rules of procedure. Regulations re subjects within jurisdiction of boards and commissions within Department of Consumer Protection. Prohibited acts by practitioners. Definitions. (a) With regard to the boards and commissions within the Department of Consumer Protection, the Commissioner of Consumer Protection (1) shall adopt uniform rules of procedure, consistent with chapter 54, for hearings and other proceedings to be conducted by the boards or commissions or by the commissioner and for the giving of notice to persons affected by such proceedings, and (2) may, where authorized by statute, adopt regulations regarding any subject within the jurisdiction of a board or commission.

(b) Any rules of procedure and regulations adopted pursuant to this

section shall be adopted in accordance with chapter 54. No regulation shall be adopted pursuant to this section until the appropriate board or commission has had reasonable opportunity to review the proposed regulation and to offer comments thereon.

(c) Each such board or commission may act in accordance with the provisions of subdivision (7) of section 21a-7, and the commissioner may act in accordance with the provisions of subdivision (3) of subsection (b) of section 21a-8, in the case of a practitioner who: (1) Engages in fraud or material deception in order to obtain a license, registration or certificate issued by the board or commission or to aid another in obtaining a license, registration or certificate issued by the board or commission; (2) performs work beyond the scope of the license, registration or certificate issued by the board or commission; (3) illegally uses or transfers a license, registration or certificate issued by the board or commission; (4) performs incompetent or negligent work; (5) makes false, misleading or deceptive representations to the public; (6) has been subject to disciplinary action similar to that specified in subdivision (7) of section 21a-7 or subdivision (3) of subsection (b) of section 21a-8 by a duly authorized professional agency of the United States, any state within the United States, the District of Columbia, a United States possession or territory or a foreign jurisdiction; or (7) violates any provision of the general statutes or any regulation established thereunder, relating to the practitioner's profession or occupation.

(d) As used in chapters 390, 391, 392, 393, 394, 396, 400g, 400j, 482 and 400*l*:

(1) "Certificate" includes the whole or part of any Department of Consumer Protection permit which the department issues under authority of the general statutes and which (A) authorizes practice of the

profession by certified persons but does not prohibit the practice of the profession by others, not certified, (B) prohibits a person from falsely representing that such person is certified to practice the profession unless the person holds a certificate issued by the department, and (C) requires as a condition of certification that a person submit specified credentials to the department which attest to qualifications to practice the profession.

(2) "License" includes the whole or part of any Department of Consumer Protection permit, approval, or similar form of permission which the department issues under authority of the general statutes and which requires (A) practice of the profession by licensed persons only, (B) demonstration of competence to practice by examination or other means and meeting of certain minimum standards, and (C) enforcement of standards by the department or regulatory board or commission.

(3) "Registration" includes the whole or part of any Department of Consumer Protection permit which the department issues under authority of the general statutes and which (A) requires persons to place their names on a list maintained by the department before they can engage in the practice of a specified profession or occupation, (B) does not require a person to demonstrate competence by examination or other means, and (C) may be revoked or suspended by the commissioner for cause.

Sec. 21a-10. (Formerly Sec. 19-171i). Commissioner of Consumer Protection authorized to establish, combine or abolish divisions, sections or other units, exception. Regulations re staggered schedule for renewal of licenses. Prorated amount for guaranty fund fees and newly issued licenses, certificates, registrations and permits,

allowed. (a) The Commissioner of Consumer Protection may establish, combine or abolish divisions, sections or other units within the Department of Consumer Protection and allocate powers, duties and functions among such units, but no function vested by statute in any officer, division, board, agency or other unit within the department shall be removed from the jurisdiction of such officer, division, board, agency or other unit under the provisions of this section.

(b) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to designate a staggered schedule for the renewal of all licenses, certificates, registrations and permits issued by said department. If such designation of a staggered schedule results in the expiration of any license, certificate, registration or permit for a period of less than or more than one year, said commissioner may charge a prorated amount for such license, certificate, registration or permit. For any new license, certificate, registration or permit that is issued and for any guaranty fund fee that is imposed on or after January 1, 1995, the commissioner may charge a one-time prorated amount for such newly issued license, certificate, registration, permit or guaranty fund fee.

Sec. 21a-10a. Retirement status license. (a) Any person currently holding a license issued by the Department of Consumer Protection pursuant to title 20 who has attained the age of sixty-five may renew his or her license as a retirement status license pursuant to subsections (b) to (d), inclusive, of this section.

(b) An applicant for a retirement status license shall submit his or her original license to the Department of Consumer Protection, along with a letter of request for such classification. The letter shall contain a

statement expressing the licensee's current retirement status and the acceptance of a restriction on the retirement status license prohibiting the applicant from actively engaging in the practice of the occupation or trade for which a license was originally issued.

(c) A licensee issued a retirement status license shall not practice or offer to practice the occupation or trade for which a license was originally issued.

(d) If the Department of Consumer Protection issues a retirement status license pursuant to this section, it shall return the original license submitted pursuant to subsection (b) of this section to the applicant. Such original license shall bear a designation or be stamped "Retired".

(e) The fee for a retirement status license shall be twenty dollars.

(f) A licensee issued a retirement status license may restore such licensee's original license by submitting a form, to be provided by the Department of Consumer Protection, requesting reinstatement and by paying the current annual fee for such license.

(g) The Commissioner of Consumer Protection may, for good cause shown, grant a retirement status license to a person who does not meet the requirements of subsection (a) of this section.

Sec. 21a-11. (Formerly Sec. 19-171). Powers and duties of commissioner. The Commissioner of Consumer Protection may, subject to the provisions of chapter 67, employ such agents and assistants as are necessary to enforce the provisions of the general statutes wherein said commissioner is empowered to carry out the duties and responsibilities assigned to him or his department. For the purpose of inquiring into any suspected violation of such provisions, the commissioner and his deputy

and assistants shall have free access, at all reasonable hours, to all places and premises, homes and apartments of private families keeping no boarders excepted. On the tender of the market price, the commissioner or his deputy may take from any person, firm or corporation samples of any article which he suspects is sold, offered for sale, kept with intent to sell, made or manufactured contrary to any provision of this chapter or related chapters under the jurisdiction of said commissioner. He may analyze such samples or have them analyzed by a state chemist or by an experiment station or by the laboratories of the Department of Public Health, and a sworn or affirmed certificate by such analyst shall be prima facie evidence of the ingredients and constituents of the samples analyzed. If such analysis shows that any such sample does not conform to the requirements of law, and gives the commissioner or his deputy reasonable grounds for believing that any provision of this chapter or related chapters under his jurisdiction has been violated, he shall cause such violator to be prosecuted. Any person who refuses the access provided for herein to the commissioner, his deputy or assistants, or who refuses to sell the samples provided for herein, shall be guilty of a class D misdemeanor. Evidence of violation of any provision of this section shall be prima facie evidence of wilful violation.

CHAPTER 417*

GENERAL PROVISIONS. PURE FOOD AND DRUGS

Table of Contents

Sec. 21a-39. (Formerly Sec. 19-193f). Adulteration or misbranding.

Sec. 21a-40. (Formerly Sec. 19-193g). Inspections.

Sec. 21a-41. (Formerly Sec. 19-193h). Sanitary provisions.

Sec. 21a-63. (Formerly Sec. 19-210h). State clinical thermometer standard.

Sec. 21a-64. (Formerly Sec. 19-209). Distribution of drugs and poisons.

Sec. 21a-65. (Formerly Sec. 19-209a). Sale of hypodermic needles and syringes restricted.

Sec. 21a-66. (Formerly Sec. 19-209b). Regulations re sale, purchase, handling and disposal of hypodermic needles and syringes.

Sec. 21a-67. (Formerly Sec. 19-209c). Apricot kernels. Labeling requirement.

Sec. 21a-68. (Formerly Sec. 19-209d). Packaging of veterinary drugs.

Sec. 21a-69. (Formerly Sec. 19-209e). “Companion animal” defined by regulation.

Sec. 21a-70. (Formerly Sec. 19-210). Registration of manufacturers and wholesalers of drugs. Sale of drugs limited.

Sec. 21a-70a. (Formerly Sec. 21a-250a). Distribution of noncontrolled

drugs used as emergency stock.

Sec. 21a-70b. Regulation of sales of drugs at flea markets.

Sec. 21a-70c. Prescription drug pedigree program. Working group convened.

Sec. 21a-70d. Definitions.

Sec. 21a-70e. Pharmaceutical or medical device manufacturing company. Adoption of code on interaction with health care professionals and comprehensive compliance program. Civil penalty.

Sec. 21a-71. (Formerly Sec. 19-210a). Sale of food, drug or cosmetic at auction.

.

Sec. 21a-75. (Formerly Sec. 19-210e). Regulations. Hearings. Civil penalties for noncompliance.

Sec. 21a-76. (Formerly Sec. 19-210f). Exceptions.

Sec. 21a-77. (Formerly Sec. 19-210g). Criminal penalty.

Sec. 21a-78b. Suspension of application. Monitoring by department.

Sec. 21a-84a. Connecticut Poison Control Center: Publication and distribution of list of poisonous plants.

Sec. 21a-85. (Formerly Sec. 19-65d). Penalty.

Sec. 21a-63. (Formerly Sec. 19-210h). State clinical thermometer standard. The term "clinical thermometer", as used in this section, means a maximum self-registering thermometer of the type commonly

used for measuring body temperatures and a “correct clinical thermometer” means a thermometer which conforms, within the tolerances hereinafter established, to the standards herein established and to the specifications to be promulgated as provided herein. A “state clinical thermometer reference standard”, for the purposes of this section, means a thermometer supplied by the state and certified by the National Institute of Standards and Technology for use by the state. “Official test standards” means such additional thermometers as may be supplied by the state in order to carry out the provisions of this section. Official test standards shall be verified by the Department of Consumer Protection upon their initial receipt and thereafter at the discretion of the department while in use for testing purposes. Verification thereof shall be made by comparison with a state clinical thermometer reference standard. In addition, the Department of Consumer Protection shall promulgate requirements, specifications and tolerances for clinical thermometers. Official test standards may be used in making comparisons of all clinical thermometers under tests. The manufacturer of a clinical thermometer shall submit representative samples of such thermometer to the Department of Consumer Protection prior to the time the thermometer is first offered for sale in this state and thereafter as required by said department. If, upon inspection by said department or its agents or other representatives, a clinical thermometer which is offered for sale is found to be correct, said department shall have the authority to certify such thermometer as correct. When a clinical thermometer is found, upon inspection by said department or its agents or other representatives, not to be a correct clinical thermometer, it may be seized by said department and condemned or destroyed or returned to the owner thereof upon satisfactory guarantee that it will not be offered for sale, sold or used again within this state. All clinical thermometers shall be marked with the name, initials or trademark of the manufacturer.

Any person who, by himself or his agents or representatives, offers for sale, keeps for the purpose of sale or sells any clinical thermometer not certified as correct as herein provided shall be fined not more than fifty dollars.

Sec. 21a-64. (Formerly Sec. 19-209). Distribution of drugs and poisons. Any person who, by himself, his servant or agent, distributes or gives away, in any street or highway or from house to house, any bottle, box, envelope or package containing any liquid medicine, or any pill, powder, tablet or other article, which contains any drug or poison, shall be fined not more than fifty dollars or imprisoned not more than one year or both.

Sec. 21a-65. (Formerly Sec. 19-209a). Sale of hypodermic needles and syringes restricted. (a) A licensed manufacturer or licensed wholesaler may sell hypodermic needles and syringes only to the following: (1) To a licensed manufacturer, licensed wholesaler or licensed pharmacy; (2) to a physician, dentist, veterinarian, embalmer, podiatrist or scientific investigator licensed to practice in this state; (3) to a person in charge of a care-giving institution, as defined in subdivision (2) of section 20-571, incorporated college or scientific institution, but only for use by or in such care-giving institution, college or institution for medical or scientific purposes; (4) to a person in charge of a licensed or registered laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to a farmer but only for use on the farmer's own animals or poultry; (6) to a business authorized in accordance with the regulations adopted under section 21a-66 to purchase hypodermic needles and syringes but only for legitimate industrial or medical use

within that business; and (7) to a needle and syringe exchange program established pursuant to section 19a-124.

(b) Except as provided in subsection (a) of this section, no licensed manufacturer, licensed wholesaler or licensed pharmacist shall sell and no person shall buy a hypodermic needle or syringe except upon a prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571, in a quantity greater than ten. Any such prescription shall be retained on file by the seller for a period of not less than three years and shall be accessible to any public officer engaged in the enforcement of this section. Such a prescription shall be valid for one year from the date thereof and purchases and sales may be made thereunder during such period, provided the seller shall confirm the continued need for such sales with such practitioner at least every six months if sales continue to be made thereunder. Hypodermic needles and syringes in a quantity of ten or less without a prescription may be provided or sold at retail only by the following: (1) By a pharmacy licensed in accordance with section 20-594 and in such pharmacy only by a licensed pharmacist or under his direct supervision; (2) by a needle exchange program established pursuant to section 19a-124; and (3) by a health care facility or a licensed health care practitioner for use by their own patients.

(c) At all locations where hypodermic needles and syringes are kept they shall be stored in a manner so as to be available only to authorized personnel and not be openly available to customers or patients. All used, disposable hypodermic needles and used, disposable syringes shall be destroyed. Destruction shall be conducted in a manner which renders such needles and syringes nonrecoverable. Used needles and syringes which have been discarded and are awaiting destruction shall be securely safeguarded or rendered nonreusable.

(d) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than one year or both.

Sec. 21a-66. (Formerly Sec. 19-209b). Regulations re sale, purchase, handling and disposal of hypodermic needles and syringes. The Commissioner of Consumer Protection shall adopt regulations in accordance with the provisions of chapter 54 to control the sale, purchase, handling and disposal of hypodermic needles and syringes pursuant to section 21a-65.

Sec. 21a-67. (Formerly Sec. 19-209c). Apricot kernels. Labeling requirement. No person shall sell or offer for sale any apricot kernels unless such kernels are packaged and each package is labeled with a warning that such kernels contain cyanide and that ingestion of such kernels may be fatal.

Sec. 21a-68. (Formerly Sec. 19-209d). Packaging of veterinary drugs. Any substance containing aspirin, or a controlled substance as defined in section 21a-240, or a legend drug as defined in section 20-l84a, sold or offered for sale in this state and intended to be administered to companion animals in the home shall be packaged in accordance with the requirements established by regulation under the federal Poison Prevention Packaging Act of 1970, 84 Stat. 1670, 15 USC 1471, as amended.

Sec. 21a-69. (Formerly Sec. 19-209e). "Companion animal" defined by regulation. The Commissioner of Consumer Protection, with the advice and assistance of the State Board of Veterinary Registration and Examination, shall by regulation adopted in accordance with chapter 54 define the term "companion animals" for the purposes of section 21a-68.

Sec. 21a-70. (Formerly Sec. 19-210). Registration of manufacturers and wholesalers of drugs. Sale of drugs limited. (a) **Definitions.** 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 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 supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy which 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 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 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. The words "drugs", "devices" and "cosmetics" shall have the meaning ascribed to them in section 21a-92; and (3) "commissioner" means the Commissioner of Consumer Protection.

(b) **Registration of wholesalers and manufacturers of drugs required. Exception. Fees. Expenses.** 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 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 and 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) **Commissioner's right to deny certificate.** 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) **Suspension, revocation or refusal to renew registration.** 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) **Compliance with applicable laws.** Wholesalers 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) **Inspections and audits.** 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) **Hearings.** 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) **Sale of drugs limited. Regulations.** No manufacturer or wholesaler 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) **Penalty.** 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. 21a-70a. (Formerly Sec. 21a-250a). Distribution of noncontrolled drugs used as emergency stock. Noncontrolled drugs distributed as emergency stock to a medical director of a chronic and convalescent nursing home or a rest home with nursing supervision shall be supplied in containers which bear labels specifying the name of the drug and its strength, expiration date, lot number and manufacturer. Such noncontrolled drugs distributed as emergency stock shall be limited in type and quantity to those specifically documented and authorized by such medical director for use as emergency stock in such facility.

Sec. 21a-70b. Regulation of sales of drugs at flea markets. (a) As used in this section:

(1) “Flea market” means any location other than a permanent retail

store at which space is rented or otherwise made available to others for the conduct of business as transient or itinerant vendors, but does not include the location of (A) any sale by sample, catalog or brochure for future delivery, or (B) any sale or sales presentation pursuant to a prior invitation issued by the owner or legal occupant of the premises; and

(2) "Manufacturer's or distributor's representative" means any person authorized by a manufacturer or distributor of any drug, as defined in section 21a-92, to offer or sell any such product to the public at retail.

(b) No person, except a manufacturer's or distributor's representative, shall sell, offer for sale or knowingly permit the sale of any drug, as defined in section 21a-92, at any flea market.

(c) Any manufacturer's or distributor's representative, when selling or offering for sale any drug, as defined in section 21a-92, at any flea market shall carry on such representative's person written credentials indicating that such manufacturer's or distributor's representative is authorized by the manufacturer or distributor of such drug to engage in the retail sale of such drug to the public. Such credentials shall be made available for inspection by any interested person upon the request of such person. Such credentials shall include the name of the manufacturer's or distributor's representative and may include the date, if any, on which such credentials expire.

(d) No person shall present credentials required under subsection (c) of this section that are false, misleading or fraudulently obtained.

(e) The Commissioner of Consumer Protection may adopt regulations, in accordance with the provisions of chapter 54, to carry out the provisions of this section.

(f) Any person who violates any provision of this section, or any

regulation adopted under this section, shall be fined not more than one hundred dollars.

Sec. 21a-70c. Prescription drug pedigree program. Working group convened. (a) The Commissioner of Consumer Protection shall convene a working group comprised of the Commissioners of Consumer Protection and Emergency Services and Public Protection, or their designees, a member of the Commission of Pharmacy, the chairpersons of the joint standing committee of the General Assembly having cognizance of matters relating to public health, or their designees, and representatives of retail drug establishments, independent pharmacies and pharmaceutical manufacturers. The working group shall be responsible for submitting recommendations to the Governor and to the joint standing committee of the General Assembly having cognizance of matters relating to public health concerning the development and implementation of a program to authenticate the pedigree of prescription drugs distributed in this state.

(b) For purposes of this section, (1) "authenticate" means to affirmatively verify, before any distribution of a prescription drug occurs, that each transaction listed on the pedigree has occurred; (2) "pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug; and (3) "prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices required by federal law or regulations, to be dispensed only by a prescription, including finished

dosage forms and bulk drug substances subject to Section 503(b) of the federal Food, Drug and Cosmetic Act.

Sec. 21a-70d. Definitions. As used in this section and section 21a-70e:

(1) "Biologic" means a biological product, as defined in 42 USC 262(i), as amended from time to time, that is regulated as a drug under the federal Food, Drug and Cosmetic Act, 21 USC 301 et seq.;

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

(3) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is: (A) Recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (B) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (C) intended to affect the structure or function of the body of a person or animal, and that does not achieve its primary intended purposes through chemical action within or on such body and that is not dependent upon being metabolized for the achievement of its primary intended purposes; and

(4) "Pharmaceutical or medical device manufacturing company" means any entity that: (A) Is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics or medical devices, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical

synthesis; or (B) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices. "Pharmaceutical or medical device manufacturing company" does not include a health care provider, physician practice, home health agency, hospital licensed in this state, wholesale drug distributor licensed in this state or a retail pharmacy licensed in this state.

Sec. 21a-70e. Pharmaceutical or medical device manufacturing company. Adoption of code on interaction with health care professionals and comprehensive compliance program. Civil penalty. (a) On or before January 1, 2011, each pharmaceutical or medical device manufacturing company shall adopt and implement a code that is consistent with, and minimally contains all of the requirements prescribed in, the Pharmaceutical Research and Manufacturers of America's "Code on Interaction with Healthcare Professionals" or AdvaMed's "Code of Ethics on Interactions with Health Care Professionals" as such codes were in effect on January 1, 2010.

(b) Each pharmaceutical or medical device manufacturing company shall adopt a comprehensive compliance program in accordance with the guidelines provided in the "Compliance Program Guidance for Pharmaceutical Manufacturers" dated April, 2003 and issued by the United States Department of Health and Human Services Office of Inspector General.

(c) Upon complaint, the department may investigate an alleged (1) violation of subsection (a) of this section, or (2) failure to conduct any training program or regular audit for compliance with the code adopted

pursuant to subsection (a) of this section by a pharmaceutical or medical device manufacturing company. The Commissioner of Consumer Protection may impose a civil penalty of not more than five thousand dollars for any violation of the provisions of this section.

Sec. 21a-71. (Formerly Sec. 19-210a). Sale of food, drug or cosmetic at auction. No person shall sell any food, drug or cosmetic, as defined by section 21a-92, at an auction, unless such person has notified the Commissioner of Consumer Protection, in writing, of such sale; provided this section shall not apply to the sale of food by any church, parent teacher association, charitable organization as defined by subdivision (1) of section 21a-190a, or any organization of any political party. Such notice shall be given at least seven days prior to such sale and said commissioner may inspect such food, drug or cosmetic and prohibit the sale of the same if it is found to be unfit for human use. This section shall apply to the sale of unclaimed freight.

Sec. 21a-84a. Connecticut Poison Control Center: Publication and distribution of list of poisonous plants. (a) The Connecticut Poison Control Center shall annually furnish a list of poisonous plants to trade associations that represent retailers of flowers and plants for publication to their members.

(b) For the purposes of this section, “poisonous” means having the capacity to produce injury or illness to a human being or domestic animal through ingestion of the plant.

(c) The trade associations referred to in subsection (a) of this section shall annually distribute the list to their member companies that sell

flowers and plants at the retail level and shall encourage such companies to make the list available to persons who are customers in their retail establishments.

Sec. 21a-105. (Formerly Sec. 19-225). Adulterated drugs and devices. A drug or device shall be deemed to be adulterated: (a) (1) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or (2) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for the purposes of coloring only, a color additive which is unsafe within the meaning of section 21a-104; or (5) if it is a drug which has been stored, kept or held under conditions contrary to the cautionary label statements on the package or contrary to the recommendations as stated within the official compendium; or (6) if it has not been manufactured in accordance with good manufacturing practices as defined in the federal Food and Drug Act Parts 211 and 820; (b) if it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium; such determination as to strength, quality or purity to be made in accordance with the tests or methods of assay set forth in such compendium or prescribed by regulations promulgated under Section 351(b) of the federal act, provided no drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label and provided, whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the

United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia; (c) if it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; (d) if it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

Sec. 21a-106. (Formerly Sec. 19-226). Misbranded drugs and devices. A drug or device shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular. Any statement on the label or labeling either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government shall be considered misleading, unless the agency concerned has approved the statement prior to its use, or unless such statement is authorized by Section 357(c) of the federal act;

(b) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor, except that the label of a prescription drug packaged after October 1, 1976, shall contain the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, provided reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations promulgated by the commissioner and director, acting jointly, or by regulations issued under the federal act;

(c) If any information or other word or statement, required by or under authority of this chapter to appear on the label or labeling, is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote or sulphonmethane, or any chemical derivative of any such substance, which derivative has been designated as habit-forming by regulations promulgated under Section 352(d) of the federal act; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning–may be habit-forming";

(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula, (i) the established name, as defined in subdivision (2) of this subsection, of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided the requirement for stating the quantity of the active ingredients, other than those specifically named in this paragraph, shall apply only to prescription drugs packaged prior to July 1, 1980, and provided further, the requirement for stating the quantity or proportion of the active ingredients, other than those specifically named in this paragraph, shall apply to all drugs packaged on or after July 1, 1980, except

nonprescription drugs which are also cosmetics; and (B) if it is a prescription drug, unless the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient. To the extent that compliance with the requirements of clause (A) (ii) or clause (B) is impracticable, exemptions shall be established by regulations promulgated by the commissioner and director, acting jointly, or by regulations issued under the federal act. (2) As used in this subsection (e), the term, "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to Section 358 of the federal act, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) applies, then the common or usual name, if any, of such ingredient. Where clause (B) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply;

(f) Unless its labeling bears (1) adequate directions for use and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; provided, when any requirement of subdivision (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the commissioner and director, acting jointly, shall promulgate regulations exempting such drug or device from such requirement; provided further, articles exempted under regulations issued under Section 352(f) of the federal act shall also be exempt from the requirements of this subsection;

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided the method of packing may be modified with the consent of the commissioner and director, acting jointly, and provided whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia; provided further, in the event of inconsistency between the requirements of this subsection and those of subsection (e) as to the name by which the drug or its ingredients shall be designated, the requirements of subsection (e) shall prevail;

(h) If it has been found by the commissioner to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the commissioner and director, acting jointly, by regulations, require as necessary for the protection of public health; provided no such regulations shall be established for any drug recognized in an official compendium until the commissioner has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body has failed within a reasonable time to prescribe such requirements;

(i) (1) If it is a drug and its container is so made, formed or filled as to be misleading or (2) if it is an imitation of another drug or (3) if it is offered for sale under the name of another drug;

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended or suggested in the labeling thereof;

(k) If it is a legend drug, as defined in subdivision (14) of section 20-571, that is not administered, dispensed, prescribed or otherwise

possessed or distributed in accordance with federal and state laws and regulations;

(l) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements contained in regulations issued under the federal act;

(m) In the case of any prescription drug distributed or offered for sale in any state, unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that drug a true statement of (1) the established name, as defined in subsection (e) (2) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under subsection (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications and effectiveness as required in regulations issued under the federal act unless it is a drug which has been exempted from the labeling provisions of the federal act, as effective on April 26, 1974, or is permitted to be sold without a prescription under the federal act, as effective on said date;

(n) If it is a drug and was manufactured, prepared, propagated, compounded or processed in an establishment in this state not duly registered under section 21a-70;

(o) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to Section 357 of the federal act, and (2) such certificate or release is in effect with respect to such drug; provided that this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under

Section 357 (c) or (d) of the federal act. For the purpose of this subsection, “antibiotic drug” means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution, and the chemically synthesized equivalent of any such substance.

Sec. 21a-107. Transferred to Chapter 400j, Part III, Sec. 20-618.

Sec. 21a-108. (Formerly Sec. 19-227). Illegal obtaining or supplying of drugs. Forged labels. (1) No person shall obtain or attempt to obtain a drug covered by subsection (k) of section 21a-106 or procure or attempt to procure the administration of such drug: (a) By fraud, deceit, misrepresentation or subterfuge; or (b) by the forgery or alteration of a prescription or of any written order; or (c) by the concealment of a material fact; or (d) by the use of a false statement in any prescription, order or report required by this chapter.

(2) No person shall manufacture, possess, have under his control, sell, prescribe, administer, dispense or compound any drug covered by said subsection, except as authorized in this chapter.

(3) No person shall, for the purpose of obtaining a drug covered by said subsection, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, apothecary, physician, dentist, veterinarian or other authorized person.

(4) No person shall make or utter any false or forged prescription or false or forged written order.

(5) No person shall affix any false or forged label to a package or receptacle containing any drug covered by said subsection.

Sec. 21a-109. (Formerly Sec. 19-228). Drugs dispensed on prescription. A drug dispensed on a written or oral prescription of a practitioner licensed by law to administer such drug, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, shall, if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of filling or refilling of such prescription, the name of such practitioner licensed by law to administer such drugs and the name of the patient, be exempt from the requirements of section 21a-106, except that no prescription for a legend drug or any derivative of any legend drug, shall be refilled except upon the order of the practitioner licensed by law to administer such drug.

Sec. 21a-110. (Formerly Sec. 19-229). New drugs. (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved under Section 355 of the federal act or (2), when not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the commissioner an application setting forth (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the commissioner may require; and (F) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subdivision (2) of subsection (a) shall become effective on the one hundred eightieth day after the filing thereof, except that, if the commissioner finds, after due notice to the

applicant and giving him an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply: (1) To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug shall be plainly labeled in compliance with regulations issued under Section 355 (i) or 357 (d) of the federal act; or (2) to a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) to any drug which is licensed under Title 42 USC 262; or (4) to any drug subject to subsection (o) of section 21a-106.

(d) An order refusing to permit an application under this section to become effective may be revoked by the commissioner.

Sec. 21a-111. (Formerly Sec. 19-230). Adulterated cosmetics. A cosmetic shall be deemed to be adulterated: (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual; provided this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution–This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing, and provided, for the purposes of this subsection and subsection (e), the term "hair-dye" shall not include eyelash dyes or eyebrow dyes; (b) if it consists in whole or in part of any filthy, putrid or decomposed

substance; (c) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health; (d) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (e) if it is not a hair-dye and it bears or contains a color additive which is unsafe within the meaning of section 21a-104.

Sec. 21a-112. (Formerly Sec. 19-231). Misbranded cosmetics. A cosmetic shall be deemed to be misbranded: (a) If its labeling is false or misleading in any particular. Any statement on the label or labeling of such cosmetic, either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government, shall be considered misleading, unless such agency has approved such statement prior to such use; (b) if in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, provided, under subdivision (2) of this subsection, reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the commissioner and director, acting jointly; (c) if any information or other word or statement, required by or under authority of this chapter to appear on the label or labeling, is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or (d) if its container is so made, formed or filled as to be misleading.

Sec. 21a-113. (Formerly Sec. 19-232). False advertisement of food, drugs, devices and cosmetics. An advertisement of a food, drug, device or cosmetic shall be deemed to be false, if it is false or misleading in any

particular. Any statement either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government shall be considered misleading, unless the agency concerned has approved the statement prior to its use.

Sec. 21a-114. (Formerly Sec. 19-233). When advertisement of drugs and devices deemed to be false. The advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia or venereal disease, shall also be deemed to be false; except that no advertisement not in violation of section 21a-113 shall be deemed to be false under this section if it is disseminated only to members of the medical, dental or veterinary profession, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided, whenever the commissioner and director, acting jointly, agree that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the commissioner and director, acting jointly, shall, by regulation, authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the commissioner and director, acting jointly, deem necessary in the interests of public health; and provided this section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Sec. 21a-115. (Formerly Sec. 19-234). Regulations and hearings. Exemption. (a) The authority to promulgate regulations for the efficient

enforcement of this chapter is vested in the commissioner and director, acting jointly. The provisions of such regulations shall not prohibit the sale of food at a noncommercial function such as an educational, religious, political or charitable organization's bake sale or potluck supper provided the seller maintains such food under the temperature, pH level and water activity level conditions which will inhibit the rapid and progressive growth of infectious or toxigenic microorganisms. For the purposes of this section, a "noncommercial function" means a function where food is sold by a person not regularly engaged in the business of selling such food.

(b) The purpose of this chapter being to promote uniformity of state legislation with the federal act, the commissioner and director, acting jointly, are authorized (1) to adopt, so far as applicable, the regulations from time to time promulgated under the federal act, (2) to make the regulations promulgated under this chapter conform, so far as practicable, with those promulgated under the federal act and (3) to adopt regulations banning the sale or introduction into intrastate commerce of any adulterated food, drug, device or cosmetic, which adversely affects the health or safety of the public.

(c) Hearings authorized or required by this chapter shall be conducted by the commissioner and director, acting jointly, or their authorized representative designated for the purpose.

(d) The commissioner and director, acting jointly, shall hold a public hearing upon a proposal to promulgate any new or amended regulation under this chapter, which requires or prohibits any practice in intrastate commerce; except in the case of a proposal to adopt an applicable regulation promulgated under the federal act. The commissioner shall give appropriate notice of such hearing. The notice shall state the time and place of the hearing to be held not fewer than ten days after the date of such notice, except in the case of an emergency found by the commissioner. No regulation promulgated under this chapter, by order issued after such hearing, shall take effect prior to the thirtieth day after

the date of such order, except in the case of an emergency found by the commissioner.

(e) In the promulgation of regulations under the provisions of this section applicable to prescribing practitioners, care-giving institutions, and correctional and juvenile training institutions, as defined in subdivision (6) of section 20-571, the Commissioner of Consumer Protection shall act in place of the director. Existing regulations shall continue in effect unless superseded by action of said commissioner pursuant to this subsection.

Sec. 21a-116. (Formerly Sec. 19-235). Examinations and investigations. (a) The commissioner shall cause the investigation and examination of food, drugs, devices and cosmetics subject to this chapter. The commissioner or his authorized representative shall have the right (1) to take a sample or specimen of any such article, for examination under this chapter, upon tendering the market price therefor to the person having such article in custody, and (2) to enter any place or establishment within this state, at reasonable times, for the purpose of taking a sample or specimen of such article, for such examination. Samples or specimens taken under the provisions of this subsection shall be submitted to the agricultural experiment station or to the laboratory services section of the Department of Public Health for examination.

(b) When a sample or specimen of any such article is taken for examination under this chapter, the commissioner shall, upon request, provide a part thereof for examination by any person named on the label of such article or the owner thereof, or his attorney or agent; except that the commissioner is authorized, by regulations, to make such reasonable exceptions from, and to impose such reasonable terms and conditions

relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) For the purpose of enforcing the provisions of this chapter, pertinent records of any administrative agency of the state government shall be open to inspection by the commissioner or his authorized representative.

Sec. 21a-117. (Formerly Sec. 19-236). Records of intrastate shipment. For the purpose of enforcing the provisions of this chapter, carriers engaged in intrastate commerce, and persons receiving food, drugs, devices or cosmetics in intrastate commerce or holding such articles so received, shall, upon the request of an authorized representative of the commissioner, permit such representative, at reasonable times, to have access to and to copy all records showing the movement in intrastate commerce of any food, drug, device or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof; and no such carrier or person shall fail to permit such access to, and the copying of, any such records so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device or cosmetic to which such request relates; provided evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained and provided carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.

Sec. 21a-118. (Formerly Sec. 19-237). Inspections. Right to hearing. Reinspection of food facilities; costs imposed. Suspension or revocation of license for violation of provisions of chapter 417. (a) For the purpose of enforcing the provisions of chapter 417 and this chapter, the commissioner, or his authorized representative, is authorized (1) to enter, at reasonable times, any factory, warehouse or establishment subject to this chapter, or to enter any vehicle being used to transport or

hold food, drugs, devices or cosmetics in intrastate commerce and (2) to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling and advertisements, records, files and papers therein.

(b) If an inspection reveals a violation of any provision of this chapter concerning a food factory, food warehouse or food establishment, the commissioner shall notify the owner of such factory, warehouse or establishment of any such violation and his right to a hearing under this section by certified mail within fifteen days of the date of such original inspection. Such owner may contest the violations cited in such notice by requesting a hearing in writing by certified mail within fifteen days of the date of receipt of such notice. The commissioner shall grant such a request and conduct a hearing in accordance with the provisions of chapter 54. The cost of all reinspections necessary to determine compliance with any such provision shall be forty dollars an hour and shall be charged to such owner, except that if the first reinspection following the original inspection indicates compliance with such provision no charge shall be made.

(c) If an inspection reveals a violation of any provision of chapter 417 or this chapter concerning any drug or device by any establishment licensed in accordance with the provisions of chapter 417, the commissioner may suspend or revoke the license of such establishment after notice and a hearing conducted in accordance with the provisions of chapter 54.

Sec. 21a-119. (Formerly Sec. 19-238). Publicity. (a) The commissioner may cause to be published, from time to time, reports summarizing all judgments, decrees and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) The commissioner may also cause to be disseminated such information regarding food, drugs, devices or cosmetics as the

commissioner deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the commissioner and director from collecting, reporting and illustrating the results of their examinations and investigations under this chapter.

Sec. 21a-120. (Formerly Sec. 19-239). Interpretation. This chapter and the regulations promulgated hereunder shall be so interpreted and construed as to effectuate its general purpose to enact state legislation uniform with the federal act.

Secs. 21a-121 to 21a-125. Reserved for future use.

CHAPTER 419

RETAIL DRUG CONTROL ACT

Table of Contents

Sec. 21a-126. (Formerly Sec. 19-240). Definitions.

Sec. 21a-127. (Formerly Sec. 19-241). Illegal advertising.

Sec. 21a-128. (Formerly Sec. 19-242). Unfair competition.

Secs. 21a-129 to 21a-134. **Reserved**

Sec. 21a-126. (Formerly Sec. 19-240). Definitions. The following terms shall have the following meanings, when used in this chapter, unless the context otherwise indicates:

(1) "Retail drug trade" means the selling to the consumer, not for the purpose of resale, of any form of drugs, medicines, cosmetics, toilet preparations, drug sundries or allied articles, but shall not include the dispensing of drugs, medicines and medical supplies by a physician, dentist, surgeon or veterinary in the legitimate practice of his profession;

(2) “Drug retailer” means any individual, firm or corporation engaged wholly or partially in the retail drug trade;

(3) “Retail drug establishment” means any store or department of a store engaged in the retail drug trade;

(4) “Drug” means any substance or preparation, except soaps, intended for external or internal use in the cure, mitigation, treatment, remedy or prevention of disease or ailment in man or any other animal, and any substance or preparation intended to affect the structure or function of the body of man or any other animal, not including food, but including medicinal or quasi-medicinal preparations;

(5) “Cosmetics” and “toilet preparations” mean toilet articles and perfumes, toilet waters, face powders, creams, lotions, rouges, shaving creams, dentifrices, bath salts and all other similar preparations and substances, except soaps, designed and intended for application to the person for the purpose of cleansing, improving or changing in any way the appearance of the person, or of refreshing or preserving the person;

(6) “Drug sundries” means such articles as are used in conjunction with, but not included in, drugs, cosmetics or toilet preparations;

(7) “Manufacturer’s wholesale list price” means the manufacturer’s published wholesale price or, if there is no such published or list price, the invoice price, exclusive of all discounts, of the wholesaler to the retailer.

Sec. 21a-127. (Formerly Sec. 19-241). Illegal advertising. (a) No drug retailer shall use advertising, whether printed, electronic, audiovisual or display or of any other nature, which is intentionally inaccurate in any material particular or misrepresents merchandise, in

respect to its use, trademark, grade, quality, quantity, size, origin, material, content or preparation; and no drug retailer shall use advertising or selling methods which tend to deceive or mislead the customer.

(b) No drug retailer shall use advertising which refers inaccurately in any material particular to any competitor or his merchandise, prices, values, credit terms, policies or services.

(c) No drug retailer shall use advertising which lays claim to a policy or a continuing practice of generally underselling competitors.

(d) No drug retailer shall secretly give anything of value to a customer or to the employee or agent of a customer for the purpose of influencing a sale or, in furtherance of a sale, render a bill or statement of account to the employee, agent or customer which is inaccurate in any material particular.

(e) No drug retailer shall sell or offer for sale any merchandise upon a condition which involves a lottery, gamble or other element of chance.

(f) No drug retailer shall permit any demonstrator or sales employee whose salary is wholly or partially paid by a manufacturer or distributor to work in his establishment unless such demonstrator or sales employee is clearly and openly identified as the agent of such manufacturer or distributor.

Sec. 21a-128. (Formerly Sec. 19-242). Unfair competition. No drug retailer shall sell any drugs, medicines, cosmetics, toilet preparations or drug sundries at a price below the manufacturer's wholesale list price per dozen; nor, in the case of biologicals or other of the above-mentioned products which are not customarily sold in dozens or greater

lots, sell such products at less than the manufacturer's wholesale list price per unit. Notwithstanding the provisions of the preceding sentence, any drug retailer may sell at less than the prices specified above, imperfect or actually damaged merchandise or bona fide discontinued lines of merchandise, if advertised, marked and sold as such; merchandise sold upon the complete final liquidation of any business; merchandise sold or donated for charitable purposes or to unemployment relief agencies and drugs or drug sundries sold to physicians, dentists, veterinarians or hospitals, but not for the purpose of resale by them.

Secs. 21a-129 to 21a-134. Reserved for future use.

CHAPTER 420b*

DEPENDENCY-PRODUCING DRUGS

Table of Contents

Sec. 21a-240. (Formerly Sec. 19-443). Definitions.

Sec. 21a-241. (Formerly Sec. 19-449). Prior regulations continued.

Sec. 21a-242. (Formerly Sec. 19-450a). Schedules of controlled substances. Exceptions.

Sec. 21a-243. (Formerly Sec. 19-451). Regulations. Schedules of controlled substances.

Sec. 21a-244. (Formerly Sec. 19-451a). Regulations re storage and retrieval of prescription information.

Sec. 21a-244a. Drug records maintained on electronic data processing systems or media systems. Electronic identifiers. Regulations.

Sec. 21a-245. (Formerly Sec. 19-452). Manufacture, sale, administering of restricted substances regulated.

Sec. 21a-246. (Formerly Sec. 19-453). License to manufacture, wholesale, supply, compound, etc. Exception. License fees. License to possess and supply marijuana.

Sec. 21a-247. (Formerly Sec. 19-454). Qualifications of applicant for license.

Sec. 21a-248. (Formerly Sec. 19-456). Sale or dispensing of controlled drugs by licensed manufacturer or wholesaler. Records; orders. Scope of uses limited.

Sec. 21a-249. (Formerly Sec. 19-457). Prescription requirements.

Sec. 21a-250. (Formerly Sec. 19-458). Rights and duties of pharmacist.

Sec. 21a-250a. **Transferred**

Sec. 21a-251. (Formerly Sec. 19-459). Dispensing of controlled substances by hospitals, infirmaries or clinics.

Sec. 21a-252. (Formerly Sec. 19-460). Prescription and dispensing of controlled substances by certain practitioners. Surrender of unused substances by patients.

Sec. 21a-253. Possession of marijuana pursuant to a prescription by a physician.

Sec. 21a-254. (Formerly Sec. 19-461). Designation of restricted drugs or substances by regulations. Records required by chapter. Establishment of electronic prescription drug monitoring program. Pharmacy and outpatient pharmacy controlled substance prescription reporting. Vendor collection of information. Confidentiality. Disclosure of information. Regulations.

Sec. 21a-254a. Appointment of prescription drug monitoring working group. Membership.

Sec. 21a-255. (Formerly Sec. 19-462). Penalty for failure to make, furnish or keep records, statements or information. General penalty.

Sec. 21a-256. (Formerly Sec. 19-463). Labeling of package or container of controlled substances.

Sec. 21a-257. (Formerly Sec. 19-464). Person receiving narcotic drug to keep it in original container.

Sec. 21a-258. (Formerly Sec. 19-465). Exceptions concerning possession and control.

Sec. 21a-259. (Formerly Sec. 19-466). Common nuisances. Receivership of rental housing property development.

Sec. 21a-260. (Formerly Sec. 19-467a). Narcotics control section in Department of Consumer Protection.

Sec. 21a-261. (Formerly Sec. 19-468). Inspection of records. Entry on premises. Warrants and arrests.

Sec. 21a-262. (Formerly Sec. 19-469). Commissioner's authority and duties re controlled substances. When seizing authority may destroy. Disposal by long-term care facilities and outpatient surgical facilities.

Sec. 21a-263. (Formerly Sec. 19-469a). Power of commissioner to receive and destroy drug paraphernalia. Records.

Sec. 21a-264. (Formerly Sec. 19-470). Notice to licensing boards of violations by licensees.

Sec. 21a-265. (Formerly Sec. 19-471). Inspection of prescriptions, orders, records and stocks restricted to government officers and third-party payors. Confidentiality.

Sec. 21a-266. (Formerly Sec. 19-472). Prohibited acts.

Sec. 21a-267. (Formerly Sec. 19-472a). Penalty for use, possession or delivery of drug paraphernalia. Immunity.

Sec. 21a-268. (Formerly Sec. 19-473). Misrepresentation of substance as controlled substance. Exemption.

Sec. 21a-269. (Formerly Sec. 19-474). Burden of proof of exception, excuse, proviso or exemption.

Sec. 21a-270. (Formerly Sec. 19-474a). Drug paraphernalia: Factors to be considered by court or other authority in determination.

Sec. 21a-271. (Formerly Sec. 19-474b). Severability of provisions concerning drug paraphernalia.

Sec. 21a-272. (Formerly Sec. 19-475). Preparations which may be sold and dispensed. Exceptions.

Sec. 21a-273. (Formerly Sec. 19-476). Substances exempt under federal law.

Sec. 21a-274. (Formerly Sec. 19-477). Cooperation in enforcement of law.

Sec. 21a-274a. Drug enforcement grant program. Safe neighborhoods grant program. Community mobilization antidrug grant program.

Sec. 21a-275. (Formerly Sec. 19-478). Revocation or suspension of licenses by commissioner.

Sec. 21a-276. (Formerly Sec. 19-479). Discretion of commissioner to issue warning.

Sec. 21a-277. (Formerly Sec. 19-480). Penalty for illegal manufacture, distribution, sale, prescription, dispensing.

Sec. 21a-278. (Formerly Sec. 19-480a). Penalty for illegal manufacture, distribution, sale, prescription or administration by non-drug-dependent person.

Sec. 21a-278a. Penalty for illegal manufacture, distribution, sale, prescription or administration.

Sec. 21a-279. (Formerly Sec. 19-481). Penalty for illegal possession. Alternative sentences. Immunity.

Sec. 21a-279a. Penalty for illegal possession of small amount of cannabis-type substance.

Sec. 21a-280. (Formerly Sec. 19-481a). Breathing of anesthesia not violation.

Sec. 21a-281. (Formerly Sec. 19-481b). Presumption of psychological dependence on volatile substances.

Sec. 21a-282. (Formerly Sec. 19-482). No prosecution where federal action has been taken.

Sec. 21a-283. (Formerly Sec. 19-483). Analytical tests for presence of controlled drugs or alcohol. Standards and procedures. Convictions constituting prior offense. Imposition of cost when analysis performed.

Sec. 21a-283a. Court authorized to depart from imposing mandatory minimum sentence.

Secs. 21a-284 and 21a-285. (Formerly Secs. 19-484 and 19-485). Suspension of prosecution for treatment for drug dependence; dismissal of charges. Order for treatment in addition to penalties on conviction; penalty for unauthorized departure from hospital.

Secs. 21a-286 to 21a-300. **Reserved**

Secs. 21a-301 to 21a-305. (Formerly Secs. 19-504a, 19-504c to 19-504e, 19-504g). Definitions. Regulations. Inspections of: Institutional pharmacies, pharmacist's drug rooms and dispensing outpatient facilities; correctional and juvenile training institutions and care-giving institutions. Reports by care-giving, correctional and juvenile training institutions.

Sec. 21a-306. **Transferred**

Sec. 21a-307. (Formerly Sec. 19-504i). Definitions re dispensing of drugs.

Sec. 21a-308. **Transferred**

Secs. 21a-309 to 21a-315. **Reserved**

PART I*

GENERAL PROVISIONS

Sec. 21a-240. (Formerly Sec. 19-443). Definitions. The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

(1) "Abuse of drugs" means the use of controlled substances solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent prescribed in the course of medical treatment or in a program of research operated under the direction of a physician or pharmacologist;

(2) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other

means, to the body of a patient or research subject by: (A) A practitioner, or, in his presence, by his authorized agent, or (B) the patient or research subject at the direction and in the presence of the practitioner, or (C) a nurse or intern under the direction and supervision of a practitioner;

(3) “Agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(4) “Amphetamine-type substances” include amphetamine, optical isomers thereof, salts of amphetamine and its isomers, and chemical compounds which are similar thereto in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(5) “Barbiturate-type drugs” include barbituric acid and its salts, derivatives thereof and chemical compounds which are similar thereto in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(6) “Bureau” means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice, or its successor agency;

(7) “Cannabis-type substances” include all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof whether growing or not; the seeds thereof; the resin extracted from any part of such a plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin; but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake

made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted therefrom, fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination. Included are cannabinon, cannabinol, cannabidiol and chemical compounds which are similar to cannabinon, cannabinol or cannabidiol in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(8) "Controlled drugs" are those drugs which contain any quantity of a substance which has been designated as subject to the federal Controlled Substances Act, or which has been designated as a depressant or stimulant drug pursuant to federal food and drug laws, or which has been designated by the Commissioner of Consumer Protection pursuant to section 21a-243, as having a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and as having a tendency to promote abuse or psychological or physiological dependence, or both. Such controlled drugs are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant drugs. Specifically excluded from controlled drugs and controlled substances are alcohol, nicotine and caffeine;

(9) "Controlled substance" means a drug, substance, or immediate precursor in schedules I to V, inclusive, of the Connecticut controlled substance scheduling regulations adopted pursuant to section 21a-243;

(10) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, 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 who in fact manufactured, distributed or dispensed the substance;

(11) “Deliver or delivery” means the actual, constructive or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship;

(12) “Dentist” means a person authorized by law to practice dentistry in this state;

(13) “Dispense” means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for the delivery;

(14) “Dispenser” means a practitioner who dispenses;

(15) “Distribute” means to deliver other than by administering or dispensing a controlled substance;

(16) “Distributor” means a person who distributes and includes a wholesaler who is a person supplying or distributing controlled drugs which he himself has not produced or prepared to hospitals, clinics, practitioners, pharmacies, other wholesalers, manufacturers and federal, state and municipal agencies;

(17) “Drug” means (A) substances recognized as drugs 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) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (C) substances, other than food, intended to affect the structure or any function of the body of man or animals; and (D) substances intended for

use as a component of any article specified in subparagraph (A), (B) or (C) of this subdivision. It does not include devices or their components, parts or accessories;

(18) “Drug dependence” means a psychoactive substance dependence on drugs as that condition is defined in the most recent edition of the “Diagnostic and Statistical Manual of Mental Disorders” of the American Psychiatric Association;

(19) “Drug-dependent person” means a person who has a psychoactive substance dependence on drugs as that condition is defined in the most recent edition of the “Diagnostic and Statistical Manual of Mental Disorders” of the American Psychiatric Association;

(20) (A) “Drug paraphernalia” refers to equipment, products and materials of any kind which are used, intended for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing or concealing, or ingesting, inhaling or otherwise introducing into the human body, any controlled substance contrary to the provisions of this chapter including, but not limited to: (i) Kits intended for use or designed for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived; (ii) kits used, intended for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances; (iii) isomerization devices used, intended for use in increasing the potency of any species of plant which is a controlled substance; (iv) testing equipment used, intended for use or designed for use in identifying or analyzing the strength, effectiveness or purity of controlled substances; (v) dilutents and adulterants, such as quinine

hydrochloride, mannitol, mannite, dextrose and lactose used, intended for use or designed for use in cutting controlled substances; (vi) separation gins and sifters used, intended for use or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana; (vii) capsules and other containers used, intended for use or designed for use in packaging small quantities of controlled substances; (viii) containers and other objects used, intended for use or designed for use in storing or concealing controlled substances; (ix) objects used, intended for use or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as: Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with screens, permanent screens, hashish heads or punctured metal bowls; water pipes; carburetion tubes and devices; smoking and carburetion masks; roach clips: Meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand; miniature cocaine spoons, and cocaine vials; chamber pipes; carburetor pipes; electric pipes; air-driven pipes; chillums; bongs or ice pipes or chillers;

(B) "Factory" means any place used for the manufacturing, mixing, compounding, refining, processing, packaging, distributing, storing, keeping, holding, administering or assembling illegal substances contrary to the provisions of this chapter, or any building, rooms or location which contains equipment or paraphernalia used for this purpose;

(21) "Federal Controlled Substances Act, 21 USC 801 et seq." means Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(22) "Federal food and drug laws" means the federal Food, Drug and Cosmetic Act, as amended, Title 21 USC 301 et seq.;

(23) “Hallucinogenic substances” are psychodysleptic substances which assert a confusional or disorganizing effect upon mental processes or behavior and mimic acute psychotic disturbances. Exemplary of such drugs are mescaline, peyote, psilocyn and d-lysergic acid diethylamide, which are controlled substances under this chapter unless modified;

(24) “Hospital”, as used in sections 21a-243 to 21a-283, inclusive, means an institution for the care and treatment of the sick and injured, approved by the Department of Public Health or the Department of Mental Health and Addiction Services as proper to be entrusted with the custody of controlled drugs and substances and professional use of controlled drugs and substances under the direction of a licensed practitioner;

(25) “Intern” means a person who holds a degree of doctor of medicine or doctor of dental surgery or medicine and whose period of service has been recorded with the Department of Public Health and who has been accepted and is participating in training by a hospital or institution in this state. Doctors meeting the foregoing requirements and commonly designated as “residents” and “fellows” shall be regarded as interns for purposes of this chapter;

(26) “Immediate precursor” means a substance which the Commissioner of Consumer Protection has found to be, and by regulation designates as being, the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture;

(27) “Laboratory” means a laboratory approved by the Department of Consumer Protection as proper to be entrusted with the custody of

controlled substances and the use of controlled substances for scientific and medical purposes and for purposes of instruction, research or analysis;

(28) “Manufacture” means the production, preparation, cultivation, growing, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging or labeling of a controlled substance: (A) By a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or (B) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale;

(29) “Marijuana” means all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. It does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted therefrom, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. Included are cannabinon, cannabinol or cannabidiol and chemical compounds which are similar to cannabinon, cannabinol or cannabidiol in chemical structure or which are similar

thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(30) “Narcotic substance” means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (A) Morphine-type: (i) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate which are similar thereto in chemical structure or which are similar thereto in physiological effect and which show a like potential for abuse, which are controlled substances under this chapter unless modified; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (B) cocaine-type, coca leaves and any salt, compound, derivative or preparation of coca leaves, and any salt, compound, isomer, derivatives or preparation thereof which is chemically equivalent or identical with any of these substances or which are similar thereto in physiological effect and which show a like potential for abuse, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine;

(31) “Nurse” means a person performing nursing as defined in section 20-87a;

(32) “Official written order” means an order for controlled substances written on a form provided by the bureau for that purpose under the federal Controlled Substances Act;

(33) “Opiate” means any substance having an addiction-forming or

addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability; it does not include, unless specifically designated as controlled under this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorthinan and its salts (dextro-methorphan) but shall include its racemic and levorotatory forms;

(34) “Opium poppy” means the plant of the species papaver somniferum l., except its seed;

(35) Repealed by P.A. 99-102, S. 51;

(36) “Other stimulant and depressant drugs” means controlled substances other than amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenics and morphine-type which are found to exert a stimulant and depressant effect upon the higher functions of the central nervous system and which are found to have a potential for abuse and are controlled substances under this chapter;

(37) “Person” includes any corporation, limited liability company, association or partnership, or one or more individuals, government or governmental subdivisions or agency, business trust, estate, trust, or any other legal entity. Words importing the plural number may include the singular; words importing the masculine gender may be applied to females;

(38) “Pharmacist” means a person authorized by law to practice pharmacy pursuant to section 20-590, 20-591, 20-592 or 20-593;

(39) “Pharmacy” means an establishment licensed pursuant to section 20-594;

(40) “Physician” means a person authorized by law to practice medicine in this state pursuant to section 20-9;

(41) “Podiatrist” means a person authorized by law to practice podiatry in this state;

(42) “Poppy straw” means all parts, except the seeds, of the opium poppy, after mowing;

(43) “Practitioner” means: (A) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (B) a pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state;

(44) “Prescribe” means order or designate a remedy or any preparation containing controlled substances;

(45) “Prescription” means a written, oral or electronic order for any controlled substance or preparation from a licensed practitioner to a pharmacist for a patient;

(46) “Production” includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance;

(47) “Registrant” means any person licensed by this state and assigned a current federal Bureau of Narcotics and Dangerous Drug Registry Number as provided under the federal Controlled Substances Act;

(48) “Registry number” means the alphabetical or numerical designation of identification assigned to a person by the federal Drug Enforcement Administration, or other federal agency, which is

commonly known as the federal registry number;

(49) “Restricted drugs or substances” are the following substances without limitation and for all purposes: Datura stramonium; hyoscyamus niger; atropa belladonna, or the alkaloids atropine; hyoscyamine; belladonnine; apatropine; or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids, except that any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled substance; amyl nitrite; the following volatile substances to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; benzene; butyl alcohol; butyl nitrate and its salts, isomers, esters, ethers or their salts; cyclohexanone; dichlorodifluoromethane; ether; ethyl acetate; formaldehyde; hexane; isopropanol; methanol; methyl cellosolve acetate; methyl ethyl ketone; methyl isobutyl ketone; nitrous oxide; pentochlorophenol; toluene; toluol; trichloroethane; trichloroethylene; 1,4 butanediol;

(50) “Sale” is any form of delivery which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant or employee;

(51) “State”, when applied to a part of the United States, includes any state, district, commonwealth, territory or insular possession thereof, and any area subject to the legal authority of the United States of America;

(52) “State food, drug and cosmetic laws” means the Uniform Food, Drug and Cosmetic Act, section 21a-91 et seq.;

(53) “Ultimate user” means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household;

(54) “Veterinarian” means a person authorized by law to practice veterinary medicine in this state;

(55) “Wholesaler” means a distributor or a person who supplies controlled substances that he himself has not produced or prepared to registrants as defined in subdivision (47) of this section;

(56) “Reasonable times” means the time or times any office, care-giving institution, pharmacy, clinic, wholesaler, manufacturer, laboratory, warehouse, establishment, store or place of business, vehicle or other place is open for the normal affairs or business or the practice activities usually conducted by the registrant;

(57) “Unit dose drug distribution system” means a drug distribution system used in a hospital or chronic and convalescent nursing home in which drugs are supplied in individually labeled unit of use packages, each patient’s supply of drugs is exchanged between the hospital pharmacy and the drug administration area or, in the case of a chronic and convalescent nursing home between a pharmacy and the drug administration area, at least once each twenty-four hours and each patient’s medication supply for this period is stored within a patient-specific container, all of which is conducted under the direction of a pharmacist licensed in Connecticut and, in the case of a hospital, directly involved in the provision and supervision of pharmaceutical services at such hospital at least thirty-five hours each week;

(58) “Cocaine in a free-base form” means any substance which contains cocaine, or any compound, isomer, derivative or preparation thereof, in a nonsalt form.

Sec. 21a-241. (Formerly Sec. 19-449). Prior regulations continued. Regulations promulgated under chapter 344 of the general statutes, revision of 1958, as amended, and chapters 344a and 344b of the 1965 supplement thereto, in effect on October 1, 1967, shall, unless clearly in conflict with the provisions of this chapter, continue in effect until superseded by regulations hereunder.

Sec. 21a-242. (Formerly Sec. 19-450a). Schedules of controlled substances. Exceptions. Section 21a-242 is repealed.

Sec. 21a-243. (Formerly Sec. 19-451). Regulations. Schedules of controlled substances. (a) The Commissioner of Consumer Protection shall adopt regulations for the efficient enforcement and operation of sections 21a-244 to 21a-282, inclusive.

(b) The Commissioner of Consumer Protection may, so far as may be consistent with sections 21a-244 to 21a-282, inclusive, adopt the regulations existing under the federal Controlled Substances Act and pertinent regulations existing under the federal food and drug laws and conform regulations adopted hereunder with those existing under the federal Controlled Substances Act and federal food and drug laws.

(c) The Commissioner of Consumer Protection, acting upon the advice of the Commission of Pharmacy, may by regulation designate, after investigation, as a controlled substance, a substance or chemical composition containing any quantity of a substance which has been found to have a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and having a tendency to promote abuse or physiological or psychological dependence or both. Such substances are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant substances, and specifically exclude alcohol, caffeine and nicotine. Substances which are designated as controlled substances shall be classified in schedules I to V by regulations adopted pursuant to subsection (a) of this section.

(d) The Commissioner of Consumer Protection may by regulation change the schedule in which a substance classified as a controlled substance in schedules I to V of the controlled substance scheduling regulations is placed. On or before December 15, 1986, and annually thereafter, the commissioner shall submit a list of all such schedule changes to the chairmen and ranking members of the joint standing committee of the General Assembly having cognizance of matters relating to public health.

(e) Notwithstanding the provisions of subsections (a) to (d), inclusive, of this section, not later than January 1, 2013, the Commissioner of Consumer Protection shall submit amendments to sections 21a-243-7 and 21a-243-8 of the regulations of Connecticut state agencies to the standing legislative regulation review committee to reclassify marijuana as a controlled substance in schedule II under the Connecticut controlled substance scheduling regulations.

(f) A new or amended regulation under this chapter shall be adopted

in accordance with the provisions of chapter 54.

(g) In the event of any inconsistency between the contents of schedules I, II, III, IV and V of the controlled substance scheduling regulations and schedules I, II, III, IV and V of the federal Controlled Substances Act, as amended, the provisions of the federal act shall prevail, except (1) when the provisions of the Connecticut controlled substance scheduling regulations place a controlled substance in a schedule with a higher numerical designation, schedule I being the highest designation, or (2) as provided in subsection (e) of this section.

(h) When a drug that is not a controlled substance in schedule I, II, III, IV or V, as designated in the Connecticut controlled substance scheduling regulations, is designated to be a controlled substance under the federal Controlled Substances Act, such drug shall be considered to be controlled at the state level in the same numerical schedule for a period of two hundred forty days from the effective date of the federal classification.

(i) The Commissioner of Consumer Protection shall, by regulation adopted pursuant to this section, designate the following substances, by whatever official, common, usual, chemical or trade name designation, as controlled substances and classify each such substance in the appropriate schedule:

(1) 1-pentyl-3-(1-naphthoyl)indole (JWH-018);

(2) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(3) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(4) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(5) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue);

(6) Salvia divinorum; and

(7) Salvinorum A.

(j) Notwithstanding the provisions of subsection (c) of this section, the Commissioner of Consumer Protection shall designate the following substances, by whatever official, common, usual, chemical or trade name designation, as controlled substances in schedule I of the controlled substances scheduling regulations:

(1) Mephedrone (4-methylmethcathinone); and

(2) MDPV (3,4-methyenedioxypyrovalerone).

Sec. 21a-244. (Formerly Sec. 19-451a). Regulations re storage and retrieval of prescription information. The Commissioner of Consumer Protection shall, on or before January 1, 1978, adopt regulations governing the storage and retrieval of prescription information for controlled substances, including refills, by pharmacists through the use of electronic data processing systems or other systems for the efficient storage and retrieval of information.

Sec. 21a-244a. Drug records maintained on electronic data processing systems or media systems. Electronic identifiers. Regulations. (a) The following terms shall have the following meanings when used in this section:

(1) “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 man or other animals; (C) articles, other than food, intended to affect the structure or any function of the body of man 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;

(2) "Licensed practitioner" means a person licensed by the state of Connecticut, any other state, the District of Columbia or the Commonwealth of Puerto Rico and authorized to prescribe medication within the scope of his practice; and

(3) "Drug record" means a record maintained pursuant to this chapter or chapter 400j, 417, 418 or 420c of drug ordering, drug distribution, receipt of drugs, storage of drugs, disposition of drugs, and orders of drugs issued by a licensed practitioner for a patient.

(b) In lieu of maintaining written drug records required by state or federal law to be kept in the state, such records may be created and maintained on electronic data processing systems or other electronic media systems. If a conflict exists between maintaining a written drug record and maintaining an electronic drug record, the written drug record shall be maintained.

(c) Electronic identifiers, including, but not limited to, electronic codes or signatures, voice prints, retinal prints or handprints may be substituted in lieu of required written signatures or initials.

(d) The Commissioner of Consumer Protection may adopt regulations, in accordance with the provisions of chapter 54, establishing the use of electronic data processing systems or other electronic media systems for maintaining drug records. No such electronic data processing system

shall be implemented prior to the adoption of these regulations.

Sec. 21a-245. (Formerly Sec. 19-452). Manufacture, sale, administering of restricted substances regulated. No person shall manufacture, possess, have under his control, sell, prescribe, dispense, compound, process, deliver or administer to another person any restricted substance, except as authorized in this chapter and section 10-212a, except that no vendor of the volatile substances enumerated in subdivision (49) of section 21a-240 shall be deemed to have violated the provisions of this chapter insofar as sale, dispensing or delivering of one or more of said volatile substances or compounds containing said chemical substances is concerned, unless he knew or should have known of the improper purpose to which such substance was to be put. Insofar as substances containing said substances are possessed, sold, dispensed, compounded or delivered for licit purposes, i.e., other than to produce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system by breathing, inhaling, sniffing or drinking, such substances are expressly not restricted and neither the regulatory provisions, including but not limited to record keeping, licensing and the writing of prescriptions nor the criminal sanctions and proscriptions of this chapter shall apply.

Sec. 21a-246. (Formerly Sec. 19-453). License to manufacture, wholesale, supply, compound, etc. Exception. License fees. License to possess and supply marijuana. (a) No person within this state shall manufacture, wholesale, repackage, supply, compound, mix, cultivate or grow, or by other process produce or prepare, controlled substances without first obtaining a license to do so from the Commissioner of Consumer Protection and no person within this state shall operate a laboratory for the purpose of research or analysis using controlled

substances without first obtaining a license to do so from the Commissioner of Consumer Protection, except that such activities by pharmacists or pharmacies in the filling and dispensing of prescriptions or activities incident thereto, or the dispensing or administering of controlled substances by dentists, podiatrists, physicians or veterinarians, or other persons acting under their supervision, in the treatment of patients shall not be subject to the provisions of this section, and provided laboratories for instruction in dentistry, medicine, nursing, pharmacy, pharmacology and pharmacognosy in institutions duly licensed for such purposes in this state shall not be subject to the provisions of this section except with respect to narcotic drugs and schedule I and II controlled substances. Upon application of any physician licensed pursuant to chapter 370, the Commissioner of Consumer Protection shall without unnecessary delay, license such physician to possess and supply marijuana for the treatment of glaucoma or the side effects of chemotherapy. No person outside this state shall sell or supply controlled substances within this state without first obtaining a license to do so from the Commissioner of Consumer Protection, provided no such license shall be required of a manufacturer whose principal place of business is located outside this state and who is registered with the federal Drug Enforcement Administration or other federal agency, and who files a copy of such registration with the appropriate licensing authority under this chapter.

(b) Such licenses shall expire annually, and may be renewed by application to the licensing authority. The Commissioner of Consumer Protection following a hearing as prescribed in section 21a-275, may revoke or suspend any license granted by him pursuant to this section for violation of the provisions of any statute relative to controlled substances or of any regulation made hereunder. The licensing authority, upon application of any person whose license has been suspended or

revoked, may reinstate such license upon a showing of good cause.

(c) The fee for licenses provided pursuant to this section shall be according to the following schedule: For any wholesaler, one hundred ninety dollars per annum; for manufacturers employing not more than five licensed pharmacists or qualified chemists or both, two hundred eighty-five dollars per annum; for manufacturers employing six to ten licensed pharmacists or qualified chemists or both, three hundred seventy-five dollars per annum; for manufacturers employing more than ten licensed pharmacists or qualified chemists or both, nine hundred forty dollars per annum; for laboratories, eighty dollars per annum. A separate fee is required for each place of business or professional practice where the licensee uses, manufactures, stores, distributes, analyzes or dispenses controlled drugs.

(d) Controlled substances which are possessed, kept or stored at an address or location other than the address or location indicated on the registration required by chapter 420c or by federal laws and regulations shall be deemed to be possessed, kept or stored illegally and shall be subject to seizure and forfeited to the state. The following are subject to forfeitures: (1) All controlled substances which have been manufactured, distributed, dispensed or acquired in violation of this chapter; (2) all raw materials, products and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this chapter; (3) all property which is used, or intended for use, as a container for property described in paragraph (1) or (2); (4) all conveyances, including aircraft, vehicles or vessels, which are used, or intended for use, to transport or in any manner to facilitate the transportation, for the purpose of sale or receipt of property described in paragraph (1) or (2), but (i) no conveyance used by any person as a

common carrier is subject to forfeiture under this chapter unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this chapter; (ii) no conveyance is subject to forfeiture under this chapter by reason of any act or omission established by the owner thereof to have been committed or omitted without his knowledge or consent.

Sec. 21a-247. (Formerly Sec. 19-454). Qualifications of applicant for license. No license shall be issued under section 21a-246 until the applicant therefor has furnished proof satisfactory to the licensing authority (1) that the applicant is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character and (2) that the applicant is equipped as to facilities and apparatus properly to carry on the business described in his application and (3) that the applicant conforms to regulations adopted and promulgated pursuant to section 21a-243. No license shall be granted to any person who has, within five years of the date of application, been convicted of a violation of any law of the United States, or of any state, relating to a controlled drug.

Sec. 21a-248. (Formerly Sec. 19-456). Sale or dispensing of controlled drugs by licensed manufacturer or wholesaler. Records; orders. Scope of uses limited. (a) A licensed manufacturer or wholesaler may sell and dispense controlled drugs to any of the following-named persons, but in the case of schedule II drugs only on official written order: (1) To a manufacturer, wholesaler or pharmacist; (2) to a physician, dentist or veterinarian; (3) to a person in charge of a hospital, incorporated college or scientific institution, but only for use by

or in that hospital, incorporated college or scientific institution for medical or scientific purposes; (4) to a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to any registrant as defined in subdivision (47) of section 21a-240.

(b) A licensed manufacturer or wholesaler may sell controlled drugs only to registrants when permitted under federal and state laws and regulations.

(c) An official written order for any schedule I or II drug shall be signed in triplicate by the person giving such order or by his authorized agent and the original shall be presented to the person who sells or dispenses the drug or drugs named therein as provided by federal laws. If such order is accepted by such person, each party to the transaction shall preserve his copy of such order for a period of three years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

(d) The manufacturer or wholesaler shall keep records of all sales and dispensing of controlled drugs and shall comply fully with applicable provisions of the federal controlled drug laws and the federal food and drug laws, and the state food, drug and cosmetic laws in such sale or dispensing of controlled drugs.

(e) Possession or control of controlled drugs obtained as authorized by this section shall be lawful only if obtained in the regular course of the business, occupation, profession, employment or duty of the possessor.

(f) A person in charge of a hospital, incorporated college or scientific institution, or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled drugs under the provisions of this section or otherwise, shall not administer, or

dispense, or otherwise use such drugs within this state, except within the scope of his employment or official duty, and then only for scientific or medicinal purposes or for the purposes of research or analysis and subject to the provisions of this chapter.

Sec. 21a-249. (Formerly Sec. 19-457). Prescription requirements. (a) All prescriptions for controlled drugs shall include (1) the name and address of the patient, or the name and address of the owner of an animal and the species of the animal, (2) whether the patient is an adult or a child, or his specific age, (3) the compound or preparation prescribed and the amount thereof, (4) directions for use of the medication, (5) the name and address of the prescribing practitioner, (6) the date of issuance, and (7) the Federal Registry number of the practitioner. No prescription blank containing a prescription for a schedule II substance shall contain more than one prescription.

(b) Written prescriptions shall be written in ink or in indelible pencil or by typewriter. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter. No prescription or order for any controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.

(c) Prescriptions for schedule II substances, if in writing, shall be signed by the prescribing practitioner at the time of issuance and previously signed orders for such schedule II substances shall not be considered valid prescriptions within the meaning of this chapter. No practitioner shall prescribe, dispense or administer schedule II sympathomimetic amines as anorectics, except as may be authorized by

regulations adopted by the Departments of Public Health and Consumer Protection acting jointly. The Department of Public Health and the Department of Consumer Protection, acting jointly, may adopt regulations, in accordance with chapter 54, allowing practitioners to prescribe, dispense or administer schedule II sympathomimetic amines as anorectics under certain specific circumstances. Nothing in this subsection shall be construed to require a licensed pharmacist to determine the diagnosis of a patient prior to dispensing a prescription for such substances to a patient.

(d) To the extent permitted by the federal Controlled Substances Act, 21 USC 801, as from time to time amended, a prescribing practitioner may issue an oral order or an electronically transmitted prescription order and, except as otherwise provided by regulations adopted pursuant to sections 21a-243, 21a-244 and 21a-244a, such oral order or electronically transmitted prescription order shall be promptly reduced to writing on a prescription blank or a hardcopy printout or created as an electronic record and filed by the pharmacist filling it. For the purposes of subsections (d) and (h) of this section the term "electronically transmitted" means transmitted by facsimile machine, computer modem or other similar electronic device.

(e) To the extent permitted by the federal Controlled Substances Act, in an emergency the dispensing of schedule II substances may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist who shall promptly reduce the oral order to writing on a prescription blank, provided, in such cases such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the

temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter.

(f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, the federal Controlled Substances Act, and state laws and regulations adopted under this chapter.

(g) Repealed by P.A. 82-419, S. 46, 47.

(h) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under federal food and drug laws, shall not be dispensed without a written, electronically transmitted or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

(i) A controlled substance included in schedule V shall not be distributed or dispensed other than for a medical purpose.

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571.

(k) Pharmacies shall file filled prescriptions for controlled substances separately from other prescriptions. All schedule II prescriptions shall be filed in a separate file or in an electronic file. All schedule III, IV and V prescriptions shall be filed in another separate file or in an electronic file, except as otherwise provided for in regulations adopted pursuant to section 21a-243, 21a-244 or 21a-244a. All written controlled substance prescriptions shall, immediately upon filling, be filed chronologically

and consecutively.

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in the federal Controlled Substances Act 21 USC 801 et seq. and the regulations promulgated thereunder, as from time to time amended.

(m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.

Sec. 21a-250. (Formerly Sec. 19-458). Rights and duties of pharmacist. (a) A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a physician or dentist, podiatrist, optometrist, veterinarian, physician assistant licensed pursuant to section 20-12b, advanced practice registered nurse, or nurse-midwife to the extent that they are authorized to prescribe such controlled substances. Except as otherwise provided by regulations adopted pursuant to section 21a-244, the person filling or refilling the prescription shall include the date of filling and the person's signature or initials on any prescription for controlled substances, and the prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of three years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter. The prescription shall not be filled or refilled unless permitted by federal food and drug laws, the federal Controlled Substances Act and regulations adopted under this chapter.

(b) The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such substances, may sell

such stock to a manufacturer, distributor, practitioner, wholesaler or pharmacy, but schedule II substances may only be sold on such written order as is required by the federal Controlled Substances Act.

(c) A pharmacist, only upon an official written order, may sell to a registrant the kinds and quantities of aqueous or oleaginous schedule II substances which he has prepared and which are permitted by the federal Controlled Substances Act.

(d) (1) A retail pharmacy or pharmacy within a licensed hospital may distribute small quantities of schedule III, IV or V controlled substances to another pharmacy to provide for the immediate needs of a patient pursuant to a prescription or medication order of a practitioner. As used in this subsection "small quantities" means not more than one ounce of a powder or ointment, not more than sixteen ounces of a liquid and not more than one hundred dosage units of tablets, capsules, suppositories or injectables. (2) A retail pharmacy may distribute, in accordance with state and federal statutes and regulations, a schedule II, III, IV or V controlled substance to a practitioner who has a current federal and state registry number authorizing such practitioner to purchase such controlled substances, and who is the medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision or of a state correctional institution, for use as emergency stock within such facility. Such drugs shall be supplied in containers which bear labels specifying the name of the drug and its strength, expiration date, lot number and manufacturer. Drugs supplied pursuant to this subsection shall be limited in type and quantity to those specifically documented and authorized by such medical director for use as emergency stock in such facility. (3) Pharmacies distributing controlled substances in accordance with the provisions of subdivisions (1) and (2) of this subsection shall keep a written record of such transactions containing the

name of the receiving pharmacy, or the name and federal registry number of a medical director, date distributed and name, form, strength and quantity of such controlled substances distributed. Such records shall be kept on file separately, in accordance with subsection (h) of section 21a-254. Receiving pharmacies or medical directors, shall keep, in a separate file, a written record in accordance with subsections (f) and (h) of section 21a-254.

Sec. 21a-250a. Transferred to Chapter 417, Sec. 21a-70a.

Sec. 21a-251. (Formerly Sec. 19-459). Dispensing of controlled substances by hospitals, infirmaries or clinics. (a) No controlled substances shall be dispensed or administered by hospitals, infirmaries or clinics except upon written order signed or initialed by the prescribing practitioner or upon an oral order of a prescribing practitioner which shall be confirmed by a written order which shall be signed or initialed by such prescribing practitioner within twenty-four hours after the giving of such oral order for schedule II controlled substances and within seventy-two hours after the giving of such oral order for other controlled substances.

(b) Original and continuing orders for schedule II controlled substances shall be limited to a period not exceeding seven days from the time the order is entered, but may be extended for additional periods of seven days each by the signing or initialing of the order by a prescribing practitioner.

(c) Original and continuing orders for schedule III, IV or V controlled substances shall be limited in duration as designated in the written order

of the prescribing practitioner, but in no case shall such order be effective for more than thirty days.

(d) An original or continuing medication order for a controlled substance in a hospital, as defined in subsection (b) of section 19a-490, or a hospice licensed by the Department of Public Health or certified pursuant to 42 USC Section 1395x, may include a range of doses that may be administered by a physician assistant licensed pursuant to chapter 370, a licensed nurse or an advanced practice registered nurse licensed pursuant to chapter 378 or a nurse-midwife licensed pursuant to chapter 377. Each such hospital or hospice shall establish a written protocol that identifies the specific drugs that may be prescribed in ranges and that lists critical assessment parameters and guidelines to be considered in implementing such orders. The Commissioner of Consumer Protection, with the advice and assistance of the commissioner of any other state health care licensing authority having primary jurisdiction over such hospital or hospice, may require the modification of any protocol to meet the requirements of this subsection. Nothing in this subsection shall be construed to restrict the use of patient administered analgesia through the use of pumps or similar devices.

Sec. 21a-252. (Formerly Sec. 19-460). Prescription and dispensing of controlled substances by certain practitioners. Surrender of unused substances by patients. (a) A physician, in good faith and in the course of the physician's professional practice only, may prescribe, administer and dispense controlled substances, or may cause the same to be administered by a physician assistant, nurse or intern under the physician's direction and supervision, for demonstrable physical or mental disorders but not for drug dependence except in accordance with state and federal laws and regulations adopted thereunder.

Notwithstanding the provisions of this subsection the Department of Consumer Protection may approve protocols allowing the dispensing of take-home doses of methadone, by a registered nurse or licensed practical nurse, to outpatients in duly licensed substance abuse treatment facilities. Such dispensing shall be done pursuant to the order of a licensed prescribing practitioner and using computerized dispensing equipment into which bulk supplies of methadone are dispensed by a pharmacist. The quantity of methadone dispensed by such nurse shall not exceed at any one time that amount allowed under federal or state statutes or regulations governing the treatment of drug dependent patients. The Department of Consumer Protection shall conduct inspections of such treatment facilities to ensure that the computerized dispensing equipment and related dispensing procedures documented in the approved protocols are adhered to.

(b) A dentist, in good faith and in the course of the dentist's professional practice only, may prescribe, administer or dispense controlled substances, or may cause the same to be administered by a nurse under the dentist's direction and supervision, to the extent permitted by the federal Controlled Substances Act, federal food and drug laws and state laws and regulations relating to dentistry.

(c) A podiatrist, in good faith and in the course of the podiatrist's professional practice only, may prescribe, administer and dispense controlled substances in schedules II, III, IV or V, or may cause the same to be administered by a nurse under the podiatrist's direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to podiatry.

(d) A veterinarian, in good faith in the course of the veterinarian's professional practice only, and not for use by a human being, may

prescribe, administer and dispense controlled substances, and may cause them to be administered by an assistant or orderly under the veterinarian's direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to veterinary medicine.

(e) An advanced practice registered nurse licensed pursuant to section 20-94a, in good faith and in the course of such nurse's professional practice only, may prescribe, dispense, and administer controlled substances in schedule II, III, IV or V, or may cause the same to be administered by a registered nurse or licensed practical nurse under the advanced practice registered nurse's direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to advanced nursing practice.

(f) A nurse-midwife licensed under chapter 377, in good faith and in the course of the nurse-midwife's professional practice only, may prescribe, dispense, and administer controlled substances in schedules II, III, IV and V, or may cause the same to be administered by a registered nurse or licensed practical nurse under the nurse-midwife's direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws.

(g) A physician assistant licensed pursuant to section 20-12b, in good faith and in the course of the physician assistant's professional practice only, may prescribe, dispense, and administer controlled substances in schedule II, III, IV or V, or may cause the same to be administered by an advanced practice registered nurse, registered nurse, or licensed practical nurse who is acting under a physician's direction, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to physician assistant practice.

(h) An optometrist authorized to practice advanced optometrical care, in good faith and in the course of the optometrist's professional practice only and who is duly authorized by section 20-127, may prescribe, administer or dispense controlled substances in schedule II, III, IV or V to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to optometry.

(i) Any person who has obtained directly from a physician, dentist, podiatrist, optometrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife any controlled substance for self-administration or administration to a patient during the absence of such physician, dentist, podiatrist, optometrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife shall return to such physician, dentist, podiatrist, optometrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife any unused portion of such controlled substance, when it is no longer required by the person or the patient, or may surrender such controlled substance to the Commissioner of Consumer Protection for proper disposition.

Sec. 21a-253. Possession of marijuana pursuant to a prescription by a physician. Any person may possess or have under his control a quantity of marijuana less than or equal to that quantity supplied to him pursuant to a prescription made in accordance with the provisions of section 21a-249 by a physician licensed under the provisions of chapter 370 and further authorized by subsection (a) of section 21a-246 by the Commissioner of Consumer Protection to possess and supply marijuana for the treatment of glaucoma or the side effects of chemotherapy.

Sec. 21a-254. (Formerly Sec. 19-461). Designation of restricted drugs or substances by regulations. Records required by chapter. Establishment of electronic prescription drug monitoring program. Pharmacy and outpatient pharmacy controlled substance prescription reporting. Vendor collection of information. Confidentiality. Disclosure of information. Regulations. (a) The Commissioner of Consumer Protection, after investigation and hearing, may by regulation designate certain substances as restricted drugs or substances by reason of their exceptional danger to health or exceptional potential for abuse so as to require written records of receipt, use and dispensation, and may, after investigation and hearing, remove the designation as restricted drugs or substances from any substance so previously designated.

(b) Each physician, dentist, veterinarian or other person who is authorized to administer or professionally use schedule I substances shall keep a record of such schedule I substances received by him and a record of all such schedule I substances administered, dispensed or professionally used by him. The record of schedule I substances received shall in each case show the date of receipt, the name and address of the person from whom received and the kind and quantity of schedule I substances received. The record of all schedule I substances administered, dispensed or otherwise disposed of shall show the date of administering or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed and the kind and quantity of substances.

(c) Practitioners obtaining and dispensing controlled substances shall keep a record of all such controlled substances, received and dispensed

by them in accordance with the provisions of subsections (f) and (h) of this section.

(d) Manufacturers and wholesalers shall keep records of all controlled substances, compounded, mixed, cultivated or grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section.

(e) Pharmacies, hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision, clinics, infirmaries, free-standing ambulatory surgical centers and laboratories shall keep records of all controlled substances, received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section, except that hospitals and chronic and convalescent nursing homes using a unit dose drug distribution system may instead keep such records in accordance with the provisions of subsections (g) and (h) of this section, and except that hospitals and free-standing ambulatory surgical centers shall not be required to maintain separate disposition records for schedule V controlled substances or records of administering of individual doses for ultra-short-acting depressants, including but not limited to, Methohexital, Thiamylal and Thiopental.

(f) The form of record to be kept under subsection (c), (d) or (e) of this section shall in each case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of controlled substances received, or, when applicable, the kind and quantity of controlled substances produced or removed from process of manufacture and the date of such production or removal from process of manufacture; and the record shall in each case show the proportion of controlled substances. The record of all controlled substances sold, administered, dispensed or otherwise disposed of shall show the date of

selling, administering or dispensing, the name of the person to whom or for whose use, or the owner and species of animal for which, the substances were sold, administered or dispensed, the address of such person or owner in the instance of records of other than hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision and infirmaries, and the kind and quantity of substances. In addition, hospital and infirmary records shall show the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the substance. Each such record of controlled substances shall be separately maintained apart from other drug records and kept for a period of three years from the date of the transaction recorded.

(g) Hospitals using a unit dose drug distribution system shall maintain a record noting all dispositions of controlled substances from any area of the hospital to other hospital locations. Such record shall include, but need not be limited to, the name, form, strength and quantity of the drug dispensed, the date dispensed and the location within the hospital to which the drug was dispensed. Such dispensing record shall be separately maintained, apart from other drug or business records, for a period of three years. Such hospital shall, in addition, maintain for each patient a record which includes, but need not be limited to, the full name of the patient and a complete description of each dose of medication administered, including the name, form, strength and quantity of the drug administered, the date and time administered and identification of the nurse or practitioner administering each drug dose. Entries for controlled substances shall be specially marked in a manner which allows for ready identification. Such records shall be filed in chronological order and kept for a period of three years.

(h) A complete and accurate record of all stocks of controlled

substances on hand shall, on and after July 1, 1981, be prepared biennially within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the biennial inventory date, and kept on file for three years; and shall be made available to the commissioner or his authorized agents. The keeping of a record required by or under the federal Controlled Substances Act, or federal food and drug laws, containing substantially the same information as is specified above, shall constitute compliance with this section, provided each record shall in addition contain a detailed list of any controlled substances lost, destroyed or stolen, the kind and quantity of such substances and the date of the discovery of such loss, destruction or theft and provided such record shall be made available to the commissioner or his authorized agents. All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

(i) Whenever any record is removed by a person authorized to enforce the provisions of this chapter or the provisions of the state food, drug and cosmetic laws for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of three years.

(j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances, as defined in subdivision (9) of section

21a-240, that are dispensed by pharmacies, nonresident pharmacies, as defined in section 20-627, outpatient pharmacies in hospitals or institutions or by any other dispenser, as defined in section 21a-240. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

(2) The commissioner may identify other products or substances to be included in the electronic prescription drug monitoring program established pursuant to subdivision (1) of this subsection.

(3) Each pharmacy, nonresident pharmacies, as defined in section 20-627, outpatient pharmacy in a hospital or institution and dispenser, as defined in section 21a-240, shall report to the commissioner, at least weekly, by electronic means or, if a pharmacy or outpatient pharmacy does not maintain records electronically, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy: (A) Dispenser identification number; (B) the date the prescription for the controlled substance was filled; (C) the prescription number; (D) whether the prescription for the controlled substance is new or a refill; (E) the national drug code number for the drug dispensed; (F) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (G) a patient identification number; (H) the patient's first name, last name and street address, including postal code; (I) the date of birth of the patient; (J) the date the prescription for the controlled substance was issued by the prescribing practitioner and the prescribing practitioner's Drug Enforcement

Agency's identification number; and (K) the type of payment.

(4) The commissioner may contract with a vendor for purposes of electronically collecting such controlled substance prescription information. The commissioner and any such vendor shall maintain the information in accordance with the provisions of chapter 400j.

(5) The commissioner and any such vendor shall not disclose controlled substance prescription information reported pursuant to subdivision (3) of this subsection, except as authorized pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Any person who knowingly violates any provision of this subdivision or subdivision (4) of this subsection shall be guilty of a class D felony.

(6) The commissioner shall provide, upon request, controlled substance prescription information obtained in accordance with subdivision (3) of this subsection to the following: (A) The prescribing practitioner who is treating or has treated a specific patient, provided the information is obtained for purposes related to the treatment of the patient, including the monitoring of controlled substances obtained by the patient; (B) the prescribing practitioner with whom a patient has made contact for the purpose of seeking medical treatment, provided the request is accompanied by a written consent, signed by the prospective patient, for the release of controlled substance prescription information; or (C) the pharmacist who is dispensing controlled substances for a patient, provided the information is obtained for purposes related to the scope of the pharmacist's practice and management of the patient's drug therapy, including the monitoring of controlled substances obtained by the patient. The prescribing practitioner or pharmacist shall submit a written and signed request to the commissioner for controlled substance prescription information. Such prescribing practitioner or pharmacist shall not disclose any such request except as authorized pursuant to

sections 20-570 to 20-630, inclusive, or sections 21a-240 to 21a-283, inclusive.

(7) No person or employer shall prohibit, discourage or impede a prescribing practitioner or pharmacist from requesting controlled substance prescription information pursuant to this subsection.

(8) The commissioner shall adopt regulations, in accordance with chapter 54, concerning the reporting, evaluation, management and storage of electronic controlled substance prescription information.

(9) The provisions of this section shall not apply to samples of controlled substances dispensed by a physician to a patient.

Sec. 21a-254a. Appointment of prescription drug monitoring working group. Membership. The Commissioner of Consumer Protection shall appoint a prescription drug monitoring working group for the purpose of advising the commissioner on the implementation of the electronic prescription drug monitoring program established pursuant to section 21a-254, including the adoption of regulations by the commissioner. Such advice shall include, but not be limited to, recommendations on how to effectively use the data collected pursuant to such program to detect fraud while protecting the legitimate use of controlled substances. The working group shall include, but not be limited to: (1) A physician, licensed pursuant to chapter 370, specializing in internal medicine; (2) a board certified oncologist; (3) a person licensed to perform advanced level nursing practice activities pursuant to subsection (b) of section 20-87a; (4) a representative from an acute care hospital licensed pursuant to chapter 368v; (5) a state police officer appointed in accordance with section 29-4; (6) a municipal police

chief; (7) a representative from the Division of Criminal Justice; (8) a representative from a hospice licensed by the Department of Public Health or certified pursuant to 42 USC 1395x; (9) a pain management specialist, as defined in section 38a-492i; (10) a pharmacist licensed pursuant to section 20-590, 20-591 or 20-592; and (11) a representative from the Department of Mental Health and Addiction Services.

Sec. 21a-255. (Formerly Sec. 19-462). Penalty for failure to make, furnish or keep records, statements or information. General penalty. (a) Any person who, either as principal or agent, refuses or fails to make, furnish or keep any record, notification, order form, statement, invoice or information required by sections 21a-243 to 21a-282, inclusive, or regulations adopted pursuant to section 21a-244, for the first offense may be fined not more than five hundred dollars and for each subsequent offense may be fined not more than one thousand dollars or imprisoned not more than thirty days or be both fined and imprisoned.

(b) Any person who fails to keep any record required by said sections 21a-243 to 21a-282, inclusive, or said regulations, with an intent to defeat the purpose of this chapter or any person who violates any other provision of said sections, except as to such violations for which penalties are specifically provided in sections 21a-277 and 21a-279, may, for the first offense, be fined not more than one thousand dollars or be imprisoned for not more than two years or be both fined and imprisoned; and for the second and each subsequent offense may be fined not more than ten thousand dollars or be imprisoned not more than ten years or be both fined and imprisoned.

Sec. 21a-256. (Formerly Sec. 19-463). Labeling of package or

container of controlled substances. (a) When a manufacturer sells or dispenses a controlled substance and when a wholesaler sells, dispenses or distributes a controlled substance in a package prepared by him, he shall securely affix to each package in which that substance is contained a label showing in legible English the name and address of the vendor and the quantity, kind and form of controlled substance contained therein and any additional information required under the federal food and drug laws and the state food, drug and cosmetic laws. No person, except a practitioner dispensing a controlled substance under this chapter, shall alter, deface or remove any label so affixed.

(b) When a pharmacist sells or dispenses any controlled substance on prescription issued by a physician, advanced practice registered nurse, physician assistant, podiatrist, dentist or veterinarian, the pharmacist shall affix, to the container in which such substance is sold or dispensed, a label showing the name and address of the pharmacy for which the pharmacist is lawfully acting, the full name of the patient, or, if the patient is an animal, the name of the owner of the animal and the species of the animal, the last name of the physician, advanced practice registered nurse, physician assistant, podiatrist, dentist or veterinarian by whom the prescription was written, such directions as may be stated on the prescription, the serial number of the prescription, the date of filling or refilling and any cautionary statement in such prescription as may be required by law.

(c) When aqueous or oleaginous preparations are sold under subsection (c) of section 21a-250, a label shall be affixed to the container containing the preparation which bears the name, address and BNDD numbers of the vendor and vendee, the date of sale, the kind and quantity of substance sold and the serial number of the official written order. No person shall alter, deface or remove any label affixed pursuant

to subsection (b) or this subsection.

Sec. 21a-257. (Formerly Sec. 19-464). Person receiving narcotic drug to keep it in original container. A person to whom or for whose use any narcotic drug has been prescribed, sold or dispensed by a physician, dentist, pharmacist or other person authorized under the provisions of section 21a-248, and the owner of any animal for which any such drug has been prescribed, sold or dispensed may lawfully possess it only in the container in which it was delivered to the recipient by the person selling or dispensing the same except as may be authorized by regulations adopted hereunder.

Sec. 21a-258. (Formerly Sec. 19-465). Exceptions concerning possession and control. The provisions of this part restricting the possession and control of controlled substances shall not apply to common carriers or to warehousemen, while engaged in lawfully transporting or storing such substances, or to any employee of the same acting within the scope of his employment; or to public officers or employees in the performance of their official duties requiring possession or control of controlled substances; or to temporary incidental possession by employees or agents of persons lawfully entitled to possession or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

Sec. 21a-259. (Formerly Sec. 19-466). Common nuisances. Receivership of rental housing property development. (a) As used in this section, “rental housing property development” means any privately

owned multifamily dwelling consisting of not less than six units which are not owner-occupied and which has at least one unit available for rent. Any store, shop, warehouse, dwelling house, building, rental housing property development, vehicle, boat, aircraft or any place whatever, other than as authorized by law, which is frequently resorted to by drug-dependent persons for the purpose of using controlled substances or which is used for the illegal keeping or selling of the same, shall be deemed a common nuisance.

(b) Any such rental housing property development deemed a common nuisance under subsection (a) of this section may be subject to an action for private receivership by the Chief State's Attorney, a deputy chief state's attorney, a state's attorney or an assistant or deputy assistant state's attorney on behalf of all the tenants occupying such development by applying to the superior court for the judicial district where the property is situated for an order requiring the owner and any mortgagees or lienors of record to show cause why a receiver of rents, issues and profits should not be appointed and why said receiver should not remove or remedy such common nuisance and obtain a lien in favor of such tenants, having priority with respect to all existing mortgages or liens, to secure payment of the costs incurred by the receiver in removing or remedying such common nuisance. Such application shall contain (A) proof by affidavit that an order of the proper authority has been issued and served on the owner, mortgagees and lienors; and (B) a plan to manage and operate such property following the appointment of a receiver of rents, issues and profits.

Sec. 21a-260. (Formerly Sec. 19-467a). Narcotics control section in Department of Consumer Protection. The narcotics control section of the Department of Public Health shall be merged into the Department of

Consumer Protection.

Sec. 21a-261. (Formerly Sec. 19-468). Inspection of records. Entry on premises. Warrants and arrests. (a) Every person required by section 21a-254 to prepare or obtain and keep records of controlled substances, and any carrier maintaining records with respect to any shipment containing any controlled substance, and every person in charge, or having custody, of such records shall, upon request of the Commissioner of Consumer Protection and his authorized agents, permit said commissioner and his authorized agents at reasonable times to have access to and copy such records.

(b) For the purposes of verification of such records and of the enforcement of this part, said commissioner and his agents, are authorized to enter, at reasonable times, any place, clinic, infirmary, correctional institution, care-giving institution, pharmacy, drug room, office, hospital, laboratory, factory, warehouse, establishment or vehicle in which any controlled substance is held, manufactured, compounded, processed, sold, delivered or otherwise disposed of and to inspect, within reasonable limits and in a reasonable manner, such place, clinic, infirmary, correctional institution, care-giving institution, pharmacy, drug room, office, hospital, laboratory, factory, warehouse, establishment or vehicle, and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, papers, processes, controls and facilities, and to inventory any stock of any such controlled substance therein and obtain samples of any such substance, any labels or containers for such substance and of any finished and unfinished material.

(c) No inspection authorized by subsection (b) shall extend to (1) financial data, (2) sales data other than shipment data, (3) pricing data, (4) personnel data or (5) research data and secret processes or apparatus.

(d) The Commissioner of Consumer Protection and his authorized agents are authorized and empowered to obtain and serve search warrants and arrest warrants; to seize contraband controlled substances; and to make arrests without warrant for offenses under sections 21a-243 to 21a-282, inclusive, if the offense is committed in their presence or, in the case of a felony, if they have probable cause to believe that the person so arrested has committed, or is committing, such offense. The commissioner and his authorized agents when executing the powers authorized pursuant to this subsection, except when using deadly physical force, shall be deemed to be acting in the capacity of a peace officer as defined in subsection (9) of section 53a-3.

Sec. 21a-262. (Formerly Sec. 19-469). Commissioner's authority and duties re controlled substances. When seizing authority may destroy. Disposal by long-term care facilities and outpatient surgical facilities. (a) The Commissioner of Consumer Protection may receive, take into custody or destroy excess or undesired controlled substances and may in his discretion deliver, upon application, to any hospital, laboratory, incorporated college, scientific institution or any state or municipal agency or institution not operated for private gain, any controlled substances that have come into his custody by authority of this section. In the case of a care-giving or correctional or juvenile training institution having an institutional pharmacy, the Commissioner of Consumer Protection shall deliver such controlled substances only to the licensed pharmacist in charge of such pharmacy. The Commissioner of Consumer Protection may receive and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. Said commissioner shall keep a full

and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities and forms of such substances, the persons from whom received and to whom delivered, by whose authority received, delivered and destroyed, and the dates of the receipt, disposal or destruction. Controlled substances and preparations shall at all times be properly safeguarded and securely kept. Minimum security and safeguard standards for the storage, manufacture, sale or distribution of all controlled substances shall be established by regulations adopted hereunder. Controlled substances seized or held as contraband or controlled substances, the title to which cannot be resolved, which controlled substances are not held by law enforcement agencies or court officials as evidence in criminal proceedings, shall be, upon the order of the court, destroyed by the seizing authority or delivered to the Commissioner of Consumer Protection as soon as possible upon resolution of the case or upon ascertaining the status of the unclaimed substance. The agent of the Commissioner of Consumer Protection shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the Commissioner of Consumer Protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or destroyed and the circumstances involved, and immediately forward the statement to the Commissioner of Consumer Protection. A copy of such statement shall be retained by the registrant; (2) where controlled substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall, immediately upon ascertainment of the occurrence, file with the Commissioner of Consumer Protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and

documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, “care-giving institution”, “correctional or juvenile training institution”, “institutional pharmacy” and “pharmacist” shall have the same meaning as used in section 20-571.

(b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

Sec. 21a-263. (Formerly Sec. 19-469a). Power of commissioner to receive and destroy drug paraphernalia. Records. The Commissioner of Consumer Protection may receive, take into custody or destroy any drug paraphernalia as defined in subdivision (20) of section 21a-240. Said commissioner shall keep a full and complete record of all drug paraphernalia received and disposed of, showing the exact kinds, quantities and forms of such drug paraphernalia, the persons from whom received, by whose authority received and destroyed, and the dates of

the receipt or destruction. Drug paraphernalia held by law enforcement agencies or court officials as evidence in criminal proceedings, or drug paraphernalia seized or held as contraband shall be destroyed upon the order of the court by the seizing authority or delivered to the Commissioner of Consumer Protection as soon as possible upon termination of the proceedings or resolution of the case.

Sec. 21a-264. (Formerly Sec. 19-470). Notice to licensing boards of violations by licensees. On the conviction of any person of the violation of any provision of this part, a copy of the judgment and sentence and of the opinion of the court, if any opinion is filed, shall be sent by the clerk of the court, or by the judge, to the board or officer, if any, by whom such person has been licensed or registered to practice his profession or to carry on his business and the court may, in its discretion, recommend to the licensing or registering board or officer that the license or registration of such person to practice his profession or to carry on his business be suspended or revoked. On the application of any person whose license or registration has been so suspended or revoked, such board or officer may, for good cause shown, reinstate such license or registration.

Sec. 21a-265. (Formerly Sec. 19-471). Inspection of prescriptions, orders, records and stocks restricted to government officers and third-party payors. Confidentiality. Prescriptions, orders and records required by sections 21a-243 to 21a-282, inclusive, and stocks of controlled substances shall be open for inspection only to federal, state, county and municipal officers, whose duty it is to enforce the laws of this state or of the United States relating to controlled substances, and to

third party payors having a formal agreement or contract to audit such prescriptions, orders and records in connection with claims submitted to such payors. No such officer or third party payor having knowledge by virtue of his office of any such prescription, order or record shall divulge such knowledge, except in connection with a civil action or criminal prosecution in court or before a licensing or registration board or officer, to which action, prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.

Sec. 21a-266. (Formerly Sec. 19-472). Prohibited acts. (a) No person shall obtain or attempt to obtain a controlled substance or procure or attempt to procure the administration of a controlled substance (1) by fraud, deceit, misrepresentation or subterfuge, or (2) by the forgery or alteration of a prescription or of any written order, or (3) by the concealment of a material fact, or (4) by the use of a false name or the giving of a false address.

(b) Information communicated to a practitioner in an effort unlawfully to procure a controlled substance, or unlawfully to procure the administration of any such substance, shall not be deemed a privileged communication.

(c) No person shall wilfully make a false statement in any prescription, order, report or record required by this part.

(d) No person shall, for the purpose of obtaining a controlled substance, falsely assume the title of, or claim to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, podiatrist or other authorized person.

(e) No person shall make or utter any false or forged prescription or

false or forged written order.

(f) No person shall affix any false or forged label to a package or receptacle containing controlled substances.

(g) No person shall alter an otherwise valid written order or prescription except upon express authorization of the issuing practitioner.

(h) No person who, in the course of treatment, is supplied with controlled substances or a prescription therefor by one practitioner shall, knowingly, without disclosing such fact, accept during such treatment controlled substances or a prescription therefor from another practitioner with intent to obtain a quantity of controlled substances for abuse of such substances.

(i) The provisions of subsections (a), (d) and (e) shall not apply to manufacturers of controlled substances, or their agents or employees, when such manufacturers or their authorized agents or employees are actually engaged in investigative activities directed toward safeguarding of the manufacturer's trademark, provided prior written approval for such investigative activities is obtained from the Commissioner of Consumer Protection.

Sec. 21a-267. (Formerly Sec. 19-472a). Penalty for use, possession or delivery of drug paraphernalia. Immunity. (a) No person shall use or possess with intent to use drug paraphernalia, as defined in subdivision (20) of section 21a-240, to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to ingest, inhale

or otherwise introduce into the human body, any controlled substance, as defined in subdivision (9) of section 21a-240, other than a cannabis-type substance in a quantity of less than one-half ounce. Any person who violates any provision of this subsection shall be guilty of a class C misdemeanor.

(b) No person shall deliver, possess with intent to deliver or manufacture with intent to deliver drug paraphernalia knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to ingest, inhale or otherwise introduce into the human body, any controlled substance, other than a cannabis-type substance in a quantity of less than one-half ounce. Any person who violates any provision of this subsection shall be guilty of a class A misdemeanor.

(c) Any person who violates subsection (a) or (b) of this section in or on, or within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school and who is not enrolled as a student in such school shall be imprisoned for a term of one year which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of subsection (a) or (b) of this section.

(d) No person shall (1) use or possess with intent to use drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to ingest, inhale or otherwise introduce into the human body, less than one-half ounce of a cannabis-type substance, or (2) deliver, possess with intent to deliver or manufacture with intent to deliver drug paraphernalia knowing, or under

circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to ingest, inhale or otherwise introduce into the human body, less than one-half ounce of a cannabis-type substance. Any person who violates any provision of this subsection shall have committed an infraction.

(e) The provisions of subsection (a) of this section shall not apply to any person (1) who in good faith, seeks medical assistance for another person who such person reasonably believes is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance, (2) for whom another person, in good faith, seeks medical assistance, reasonably believing such person is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance, or (3) who reasonably believes he or she is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance and, in good faith, seeks medical assistance for himself or herself, if evidence of the use or possession of drug paraphernalia in violation of said subsection was obtained as a result of the seeking of such medical assistance. For the purposes of this subsection, "good faith" does not include seeking medical assistance during the course of the execution of an arrest warrant or search warrant or a lawful search.

Sec. 21a-268. (Formerly Sec. 19-473). Misrepresentation of substance as controlled substance. Exemption. (a) Any person who knowingly delivers or attempts to deliver a noncontrolled substance (1) upon the express representation that such substance is a controlled substance or (2) under circumstances which would lead a reasonable

person to believe that such substance is a controlled substance, shall be guilty of a class D felony.

(b) The provisions of subsection (a) of this section shall not apply to any transaction in the ordinary course of business by any licensed practitioner or licensed pharmacist.

Sec. 21a-269. (Formerly Sec. 19-474). Burden of proof of exception, excuse, proviso or exemption. In any complaint, information or indictment, and in any action or proceeding brought for the enforcement of any provision of this part, it shall not be necessary to negative any exception, excuse, proviso or exemption contained in said section, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

Sec. 21a-270. (Formerly Sec. 19-474a). Drug paraphernalia: Factors to be considered by court or other authority in determination. In determining whether any object or material listed in subdivision (20) of section 21a-240 shall be deemed "drug paraphernalia", a court or other authority shall, in addition to all other logically relevant factors, consider the following:

(1) Statements by an owner or by anyone in control of the object concerning its use;

(2) The proximity of the object to any controlled substances;

(3) The existence of any residue of controlled substances on the object;

(4) Evidence of the intent of an owner, or of anyone in control of the

object, to deliver it to persons whom he knows, or should reasonably know, intend to use the object to facilitate a violation of this section, subdivision (20) of section 21a-240, and sections 21a-263, 21a-267 and 21a-271;

(5) Instructions, oral or written, provided with the object concerning its use with a controlled substance;

(6) Descriptive materials accompanying the object which explain or depict its use with a controlled substance;

(7) National and local advertising concerning its use;

(8) The manner in which the object is displayed for sale;

(9) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

(10) Evidence of the ratio of sales of the object to the total sales of the business enterprise;

(11) The existence and scope of legitimate uses for the object in the community;

(12) Expert testimony concerning its use.

Sec. 21a-271. (Formerly Sec. 19-474b). Severability of provisions concerning drug paraphernalia. If any section, part, clause or phrase in subdivision (20) of section 21a-240, section 21a-263, 21a-267, 21a-270 or this section, is for any reason held to be invalid or unconstitutional, sections, parts, clauses and phrases in said sections not held to be invalid or unconstitutional shall not be affected and shall remain in full force and effect.

Sec. 21a-272. (Formerly Sec. 19-475). Preparations which may be sold and dispensed. Exceptions. (a) The following preparations may be sold at retail in pharmacies and dispensed by hospitals, dentists, veterinarians and physicians without a prescription or written order, in quantities of not more than the amounts stated to any one person, or for the use of any one person or animal within forty-eight consecutive hours: (1) Four fluid ounces of Stokes expectorant, (2) four fluid ounces of Brown mixture, (3) eight fluid ounces of any preparation which contains camphorated tincture of opium or the opium equivalent not to exceed 16.2 mg. of opium in one fluid ounce and from which the camphorated tincture of opium or the opium equivalent cannot be easily extracted.

(b) The exceptions authorized by this section shall be subject to the following conditions: (1) That the medicinal preparation administered, dispensed or sold shall contain, in addition to the morphine-type substance in it some drug or drugs conferring upon it medicinal qualities other than those possessed by the morphine-type substance alone; and (2) that such preparation shall be administered, dispensed and sold in good faith as a medicine and not for the purpose of evading the provisions of this part; and (3) that the purchaser of such preparations shall not purchase or attempt to obtain such preparations for the purpose of sustaining or satisfying a dependency upon controlled drugs; provided no vendor shall be deemed to have violated this subdivision unless he knew or should have known of such improper purpose; and (4) that the seller keep a schedule V record, as required by the Commissioner of Consumer Protection, of the full name and address of the person purchasing the medicinal preparation, in the handwriting of the purchaser, the name and quantity of the preparation sold and the time

and date of sale; and (5) that whenever a pharmacist sells or dispenses any schedule V substance which, under the provisions of this section, is excepted from prescriptions or written orders, the pharmacist shall securely affix to each package in which such drug is contained a label showing the name and address of the pharmacy. No person shall alter, deface or remove any label so affixed and no person shall have under his control or in his possession any such drug if not so labeled; and (6) that no provisions of this section shall be construed to permit the purchase, within any forty-eight-hour period by any one person or for use of any one person or animal of more than one excepted schedule V preparation specified in subsection (a) or in more than the maximum amounts allowed under subsection (a) except as authorized by other provisions of this part.

(c) (1) The Commissioner of Consumer Protection may, by regulation, exempt from the application of said sections to such extent as he determines to be consistent with the public welfare, pharmaceutical preparations containing schedule V substances found by said commissioner, after due notice and opportunity for hearing: (A) To possess no liability for drug abuse and dependency sufficient to warrant imposition of all of the requirements of said sections, and (B) not to permit recovery of a controlled substance having such liability for drug abuse and dependence with such relative technical simplicity and degree of yield as to create a risk of improper use. (2) In exercising the authority granted in subdivision (1) the Commissioner of Consumer Protection, by regulation pursuant to section 21a-243 and without special findings, may grant exempt status to such pharmaceutical preparations as are determined to be exempt under the federal Controlled Substances Act and regulations and permit the administering, dispensing or selling of such preparations under the same conditions as permitted by the federal regulations dealing therewith.

(d) After due notice and hearing, the Commissioner of Consumer Protection may determine that a pharmaceutical preparation exempted from the oral or written prescription requirement under the provisions of this section does possess a potential for drug abuse and dependence and may, by regulation pursuant to section 21a-243, withdraw the prior exemption. Such determination shall be final, and, after the expiration of a period of six months from the date of issuance of the regulation, the exempt status shall cease to apply to the particular pharmaceutical preparation.

Sec. 21a-273. (Formerly Sec. 19-476). Substances exempt under federal law. (a) No prescription or written order shall be required for those controlled substances and preparations which are permitted by federal food and drug laws to be sold or dispensed without a prescription or written order to the extent that the person selling or dispensing such controlled substances and preparations is authorized by licensure of the state of Connecticut to so sell or dispense.

(b) If, after due notice and hearing, the Commissioner of Consumer Protection determines that any pharmaceutical preparation exempted from the oral or written prescription requirement under the provisions of subsection (a) of this section does possess a degree of liability for drug abuse or dependence that, in his opinion is likely to result in abuse, he shall, by regulation pursuant to section 21a-243, so state. The determination shall be final and, after the expiration of a period of six months from the date of publication of the regulation, the exempt status shall cease to apply to the particular pharmaceutical preparation.

Sec. 21a-274. (Formerly Sec. 19-477). Cooperation in enforcement of law. (a) The Commissioners of Public Health and Consumer Protection and their authorized agents, police officers within their respective jurisdictions and all state's attorneys and prosecuting attorneys shall cooperate with each other and with other agencies charged with the enforcement of the laws of the United States, of this state and all other jurisdictions relative to controlled substances.

(b) Notwithstanding the provisions of section 21a-265 and chapter 55 said commissioners and their authorized agents may, in carrying out their duties under subsection (a), (1) exchange information relating to the issuance, suspension or revocation of a license issued by their respective agencies, or (2) exchange investigative information relating to violations of this chapter with each other, with state's attorneys and with other agencies charged with the enforcement of the laws of the United States, and of this state and all other jurisdictions relative to controlled substances.

Sec. 21a-274a. Drug enforcement grant program. Safe neighborhoods grant program. Community mobilization antidrug grant program. (a) There is established a drug enforcement grant program which shall be administered by the Office of Policy and Management. Grants may be made to municipalities, the Department of Emergency Services and Public Protection and the Division of Criminal Justice for the purpose of enforcing federal and state laws concerning controlled substances, undertaking crime prevention activities related to the enforcement of such laws, substance abuse prevention education or training related to such enforcement or education activities. The Secretary of the Office of Policy and Management shall adopt regulations in accordance with chapter 54 for the administration of this

subsection, including the establishment of priorities, program categories, eligibility requirements, funding limitations and the application process. Such regulations shall provide that the costs of a community-based police program, as defined in the regulations, may be paid from a grant made under this section.

(b) There is established a safe neighborhoods grant program which shall be administered by the Office of Policy and Management. Grants may be made, on a competitive basis, to the cities of Bridgeport, Danbury, Hartford, Meriden, Middletown, New Britain, New Haven, New London, Norwalk, Norwich, Stamford, Waterbury and Windham, and to the Police Officer Standards and Training Council within the Department of Emergency Services and Public Protection for the purpose of (1) improving public safety in urban neighborhoods through programs which increase police presence by hiring additional police officers and establishing police substations for those neighborhoods, (2) involving residents in crime prevention activities, including security enhancements to neighborhood residences and business establishments, and (3) improving public safety in urban neighborhoods through programs which increase police presence by increasing the hours worked by police officers during times when such increased presence is most needed to deter and control illegal use of firearms in those neighborhoods where there has been a high incidence of illegal use of firearms in the commission of crime. A grantee shall use the grant to increase police presence within the grantee's safe neighborhoods project area and, with the approval of the Office of Policy and Management, a grantee may use such grant to temporarily increase police presence in high crime areas outside such project area. The Secretary of the Office of Policy and Management shall adopt regulations in accordance with chapter 54 for the administration of this subsection. Such regulations shall include provisions for the establishment of programs, the allocation

of funds and the application process. For purposes of this subsection, the term “safe neighborhoods project area” means a single neighborhood within a municipality selected by the municipality to be eligible for a safe neighborhoods grant.

Sec. 21a-275. (Formerly Sec. 19-478). Revocation or suspension of licenses by commissioner. (a) If the Commissioner of Consumer Protection has reasonable cause to believe that a person licensed by him under section 21a-246, or any licensed practitioner, is violating or has violated any provision of sections 21a-243 to 21a-282, inclusive, relative to controlled substances, he may hold a hearing as to such violation upon reasonable notice and give opportunity to be heard to such licensee or practitioner.

(b) The commissioner may subpoena witnesses and papers on his own behalf and, if requested by the practitioner or licensee, may subpoena witnesses and papers in his behalf, may administer oaths, may compel the testimony of witnesses, may examine witnesses and may issue commissions to take testimony and testimony so taken and sworn to shall be admissible at such hearing. At such hearing the practitioner or licensee shall be entitled to representation by counsel.

(c) If the commissioner after a hearing finds that a person is violating or has violated any provision of sections 21a-243 to 21a-282, inclusive, he may revoke or suspend any license issued by him and forward his findings and the record upon which they are based to any other authority licensing such person with a recommendation that disciplinary action be taken.

Sec. 21a-276. (Formerly Sec. 19-479). Discretion of commissioner to issue warning. Nothing in sections 20-50, 20-576, 20-577, subdivision (3) of section 21a-92, subsection (e) of section 21a-115, sections 21a-240, 21a-243 to 21a-279, inclusive, and 21a-283, shall be construed as requiring the Commissioner of Consumer Protection to institute criminal or administrative action pursuant to said sections for violations thereof. In lieu of instituting criminal or administrative action pursuant to said sections, said commissioner may protect the public interest by serving suitable written notice or warning to the offending party or parties.

Sec. 21a-277. (Formerly Sec. 19-480). Penalty for illegal manufacture, distribution, sale, prescription, dispensing. (a) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person any controlled substance which is a hallucinogenic substance other than marijuana, or a narcotic substance, except as authorized in this chapter, for a first offense, shall be imprisoned not more than fifteen years and may be fined not more than fifty thousand dollars or be both fined and imprisoned; and for a second offense shall be imprisoned not more than thirty years and may be fined not more than one hundred thousand dollars, or be both fined and imprisoned; and for each subsequent offense, shall be imprisoned not more than thirty years and may be fined not more than two hundred fifty thousand dollars, or be both fined and imprisoned.

(b) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with intent to sell or dispense, possesses with intent to sell or dispense, offers, gives or administers to

another person any controlled substance, except a narcotic substance, or a hallucinogenic substance other than marijuana, except as authorized in this chapter, may, for the first offense, be fined not more than twenty-five thousand dollars or be imprisoned not more than seven years or be both fined and imprisoned; and, for each subsequent offense, may be fined not more than one hundred thousand dollars or be imprisoned not more than fifteen years, or be both fined and imprisoned.

(c) No person shall knowingly possess drug paraphernalia in a drug factory situation as defined by subdivision (20) of section 21a-240 for the unlawful mixing, compounding or otherwise preparing any controlled substance for purposes of violation of this chapter.

(d) As an alternative to the sentences specified in subsections (a) and (b) of this section, the court may sentence the person to the custody of the Commissioner of Correction for an indeterminate term not to exceed three years or the maximum term specified for the offense, whichever is the lesser, and, at any time within such indeterminate term and without regard to any other provision of law regarding minimum term of confinement, the Commissioner of Correction may release the convicted person so sentenced subject to such conditions as he may impose including, but not limited to, supervision by suitable authority. At any time during such indeterminate term, the Commissioner of Correction may revoke any such conditional release in his discretion for violation of the conditions imposed and return the convicted person to a correctional institution.

Sec. 21a-278. (Formerly Sec. 19-480a). Penalty for illegal manufacture, distribution, sale, prescription or administration by non-drug-dependent person. (a) Any person who manufactures,

distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person one or more preparations, compounds, mixtures or substances containing an aggregate weight of one ounce or more of heroin or methadone or an aggregate weight of one-half ounce or more of cocaine or one-half ounce or more of cocaine in a free-base form, or a substance containing five milligrams or more of lysergic acid diethylamide, except as authorized in this chapter, and who is not, at the time of such action, a drug-dependent person, shall be imprisoned for a minimum term of not less than five years or more than twenty years; and, a maximum term of life imprisonment. The execution of the mandatory minimum sentence imposed by the provisions of this subsection shall not be suspended, except the court may suspend the execution of such mandatory minimum sentence if at the time of the commission of the offense (1) such person was under the age of eighteen years, or (2) such person's mental capacity was significantly impaired, but not so impaired as to constitute a defense to prosecution.

(b) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person any narcotic substance, hallucinogenic substance other than marijuana, amphetamine-type substance, or one kilogram or more of a cannabis-type substance, except as authorized in this chapter, and who is not, at the time of such action, a drug-dependent person, for a first offense shall be imprisoned not less than five years or more than twenty years; and for each subsequent offense shall be imprisoned not less than ten years or more than twenty-five years. The execution of the mandatory minimum sentence imposed by the provisions of this subsection shall not be suspended, except the court may suspend the execution of such mandatory minimum sentence if at the time of the

commission of the offense (1) such person was under the age of eighteen years, or (2) such person's mental capacity was significantly impaired, but not so impaired as to constitute a defense to prosecution.

Sec. 21a-278a. Penalty for illegal manufacture, distribution, sale, prescription or administration. (a) Any person eighteen years of age or older who violates section 21a-277 or 21a-278, and who is not, at the time of such action, a drug-dependent person, by distributing, selling, prescribing, dispensing, offering, giving or administering any controlled substance to another person who is under eighteen years of age and is at least two years younger than such person who is in violation of section 21a-277 or 21a-278, shall be imprisoned for a term of two years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

(b) Any person who violates section 21a-277 or 21a-278 by manufacturing, distributing, selling, prescribing, dispensing, compounding, transporting with the intent to sell or dispense, possessing with the intent to sell or dispense, offering, giving or administering to another person any controlled substance in or on, or within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school, a public housing project or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place shall be imprisoned for a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278. To constitute a violation of this subsection, an act of transporting or possessing a controlled substance shall be with intent to sell or dispense in or on, or

within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school, a public housing project or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place. For the purposes of this subsection, "public housing project" means dwelling accommodations operated as a state or federally subsidized multifamily housing project by a housing authority, nonprofit corporation or municipal developer, as defined in section 8-39, pursuant to chapter 128 or by the Connecticut Housing Authority pursuant to chapter 129.

(c) Any person who employs, hires, uses, persuades, induces, entices or coerces a person under eighteen years of age to violate section 21a-277 or 21a-278 shall be imprisoned for a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

Sec. 21a-279. (Formerly Sec. 19-481). Penalty for illegal possession. Alternative sentences. Immunity. (a) Any person who possesses or has under his control any quantity of any narcotic substance, except as authorized in this chapter, for a first offense, may be imprisoned not more than seven years or be fined not more than fifty thousand dollars, or be both fined and imprisoned; and for a second offense, may be imprisoned not more than fifteen years or be fined not more than one hundred thousand dollars, or be both fined and imprisoned; and for any subsequent offense, may be imprisoned not more than twenty-five years or be fined not more than two hundred fifty thousand dollars, or be both fined and imprisoned.

(b) Any person who possesses or has under his control any quantity of

a hallucinogenic substance other than marijuana or four ounces or more of a cannabis-type substance, except as authorized in this chapter, for a first offense, may be imprisoned not more than five years or be fined not more than two thousand dollars or be both fined and imprisoned, and for a subsequent offense may be imprisoned not more than ten years or be fined not more than five thousand dollars or be both fined and imprisoned.

(c) Any person who possesses or has under his control any quantity of any controlled substance other than a narcotic substance, or a hallucinogenic substance other than marijuana or who possesses or has under his control one-half ounce or more but less than four ounces of a cannabis-type substance, except as authorized in this chapter, (1) for a first offense, may be fined not more than one thousand dollars or be imprisoned not more than one year, or be both fined and imprisoned; and (2) for a subsequent offense, may be fined not more than three thousand dollars or be imprisoned not more than five years, or be both fined and imprisoned.

(d) Any person who violates subsection (a), (b) or (c) of this section in or on, or within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school and who is not enrolled as a student in such school or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place shall be imprisoned for a term of two years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of subsection (a), (b) or (c) of this section.

(e) As an alternative to the sentences specified in subsections (a) and (b) and specified for a subsequent offense under subsection (c) of this section, the court may sentence the person to the custody of the

Commissioner of Correction for an indeterminate term not to exceed three years or the maximum term specified for the offense, whichever is the lesser, and at any time within such indeterminate term and without regard to any other provision of law regarding minimum term of confinement, the Commissioner of Correction may release the convicted person so sentenced subject to such conditions as he may impose including, but not limited to, supervision by suitable authority. At any time during such indeterminate term, the Commissioner of Correction may revoke any such conditional release in his discretion for violation of the conditions imposed and return the convicted person to a correctional institution.

(f) To the extent that it is possible, medical treatment rather than criminal sanctions shall be afforded individuals who breathe, inhale, sniff or drink the volatile substances defined in subdivision (49) of section 21a-240.

(g) The provisions of subsections (a) to (c), inclusive, of this section shall not apply to any person (1) who in good faith, seeks medical assistance for another person who such person reasonably believes is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance, (2) for whom another person, in good faith, seeks medical assistance, reasonably believing such person is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance, or (3) who reasonably believes he or she is experiencing an overdose from the ingestion, inhalation or injection of intoxicating liquor or any drug or substance and, in good faith, seeks medical assistance for himself or herself, if evidence of the possession or control of a controlled substance in violation of subsection (a), (b) or (c) of this section was obtained as a result of the seeking of such medical assistance. For the purposes of this

subsection, “good faith” does not include seeking medical assistance during the course of the execution of an arrest warrant or search warrant or a lawful search.

Sec. 21a-279a. Penalty for illegal possession of small amount of cannabis-type substance. (a) Any person who possesses or has under his control less than one-half ounce of a cannabis-type substance, as defined in section 21a-240, except as authorized in this chapter, shall (1) for a first offense, be fined one hundred fifty dollars, and (2) for a subsequent offense, be fined not less than two hundred dollars or more than five hundred dollars.

(b) The law enforcement officer issuing a complaint for a violation of subsection (a) of this section shall seize the cannabis-type substance and cause such substance to be destroyed as contraband in accordance with law.

(c) Any person who, at separate times, has twice entered a plea of nolo contendere to, or been found guilty after trial of, a violation of subsection (a) of this section shall, upon a subsequent plea of nolo contendere to, or finding of guilty of, a violation of said subsection, be referred for participation in a drug education program at such person’s own expense.

Sec. 21a-280. (Formerly Sec. 19-481a). Breathing of anesthesia not violation. The breathing, inhalation, sniffing or drinking of anesthesia for medical or dental purposes under the direction of a physician or dentist, acting in the course of his professional practice, is determined to be a licit purpose and not in contravention of the provisions of this

chapter.

Sec. 21a-281. (Formerly Sec. 19-481b). Presumption of psychological dependence on volatile substances. One who is found to have inhaled or to be under the influence of one or more of the volatile substances enumerated in subdivision (49) of section 21a-240 shall be presumed to be psychologically dependent upon such volatile substance or substances.

Sec. 21a-282. (Formerly Sec. 19-482). No prosecution where federal action has been taken. No person shall be prosecuted for a violation of any provision of sections 21a-243 to 21a-282, inclusive, if such person has been acquitted or convicted under the federal Controlled Substances Act or under the federal food and drug laws for the same act or omission which, it is alleged, constitutes a violation of said sections.

Sec. 21a-283. (Formerly Sec. 19-483). Analytical tests for presence of controlled drugs or alcohol. Standards and procedures. Convictions constituting prior offense. Imposition of cost when analysis performed. (a) The Division of Scientific Services within the Department of Emergency Services and Public Protection shall have primary responsibility for analysis of materials believed to contain controlled drugs, or of blood or urine believed to contain alcohol, for purposes of criminal prosecutions pursuant to this chapter; provided nothing herein shall be construed to preclude the use for such analyses of the services of other qualified toxicologists, pathologists and chemists, whether employed by the state or a municipality or a private

facility or engaged in private practice, if such toxicologists, pathologists and chemists are engaged in operation of or employed by laboratories licensed by the Commissioner of Public Health or the Commissioner of Consumer Protection pursuant to section 21a-246. A laboratory of the United States Bureau of Narcotics is not required to be licensed under this section if it is approved by the Division of Scientific Services within the Department of Emergency Services and Public Protection.

(b) The Division of Scientific Services within the Department of Emergency Services and Public Protection shall establish the standards for analytical tests to be conducted with respect to controlled drugs, or with respect to body fluids believed to contain alcohol, by qualified professional toxicologists and chemists operating under the division's direction and shall have the general responsibility for supervising such analytical personnel in the performance of such tests. The original report of an analysis made by such analytical personnel of the Division of Scientific Services or by a qualified toxicologist, pathologist or chemist of a laboratory of the United States Bureau of Narcotics shall be signed and dated by the analyst actually conducting the tests and shall state the nature of the analytical tests or procedures, the identification and number of samples tested and the results of the analytical tests. A copy of such report certified by the analyst shall be received in any court of this state as competent evidence of the matters and facts therein contained at any hearing in probable cause, pretrial hearing or trial. If such copy is to be offered in evidence at a trial, the attorney for the state shall send a copy thereof, by certified mail, to the attorney of the defendant who has filed an appearance of record or, if there is no such attorney, to the defendant if such defendant has filed an appearance pro se, and such attorney or defendant, as the case may be, shall, within five days of the receipt of such copy, notify the attorney for the state, in writing, if such attorney or defendant intends to contest the introduction of such certified copy. No

such trial shall commence until the expiration of such five-day period and, if such intention to contest has been filed, the usual rules of evidence shall obtain at such trial.

(c) In the case of any person charged with a violation of any provision of sections 21a-243 to 21a-279, inclusive, who has been previously convicted of a violation of the laws of the United States or of any other state, territory or the District of Columbia, relating to controlled drugs, such previous conviction shall, for the purpose of sections 21a-277 and 21a-279, be deemed a prior offense.

(d) In addition to any fine, fee or cost that may be imposed pursuant to any provision of the general statutes, the court shall impose a cost of fifty dollars upon any person convicted of a violation of this chapter if an analysis of a controlled substance in relation to the conviction was performed by or at the direction of the chief toxicologist of the Department of Public Health or the Division of Scientific Services within the Department of Emergency Services and Public Protection. Any cost imposed under this subsection shall be credited to the appropriation for the Department of Emergency Services and Public Protection and shall not be diverted for any other purpose than the provision of funds for the Division of Scientific Services.

Sec. 21a-283a. Court authorized to depart from imposing mandatory minimum sentence. Notwithstanding any provision of the general statutes, when sentencing a person convicted of a violation of any provision of this chapter, except a violation of subsection (a) or (c) of section 21a-278a, for which there is a mandatory minimum sentence, which did not involve the use, attempted use or threatened use of physical force against another person or result in the physical injury or

serious physical injury of another person, and in the commission of which such person neither was armed with nor threatened the use of or displayed or represented by word or conduct that such person possessed any firearm, deadly weapon or dangerous instrument, as those terms are defined in section 53a-3, the court may, upon a showing of good cause by the defendant, depart from the prescribed mandatory minimum sentence, provided the provisions of this section have not previously been invoked on the defendant's behalf and the court, at the time of sentencing, states in open court the reasons for imposing the particular sentence and the specific reason for imposing a sentence that departs from the prescribed mandatory minimum sentence.

Secs. 21a-284 and 21a-285. (Formerly Secs. 19-484 and 19-485). Suspension of prosecution for treatment for drug dependence; dismissal of charges. Order for treatment in addition to penalties on conviction; penalty for unauthorized departure from hospital. Sections 21a-284 and 21a-285 are repealed.

Secs. 21a-286 to 21a-300. Reserved for future use.

PART II

INSTITUTIONAL PHARMACIES AND PHARMACISTS' DRUG ROOMS

Secs. 21a-301 to 21a-305. (Formerly Secs. 19-504a, 19-504c to 19-504e, 19-504g). Definitions. Regulations. Inspections of: Institutional pharmacies, pharmacist's drug rooms and dispensing outpatient facilities; correctional and juvenile training institutions and care-giving institutions. Reports by care-giving, correctional and juvenile training institutions. Sections 21a-301 to 21a-305, inclusive, are

repealed.

Sec. 21a-306. Transferred to Chapter 400j, Part I, Sec. 20-578.

Sec. 21a-307. (Formerly Sec. 19-504i). Definitions re dispensing of drugs. Section 21a-307 is repealed.

Sec. 21a-308. Transferred to Chapter 400j, Part III, Sec. 20-613.

Secs. 21a-309 to 21a-315. Reserved for future use.

CHAPTER 420c*

CONTROLLED SUBSTANCE REGISTRATION

Table of Contents

Sec. 21a-316. (Formerly Sec. 19-504k). "Practitioner" defined.

Sec. 21a-317. (Formerly Sec. 19-504*l*). Registration required.

Sec. 21a-318. (Formerly Sec. 19-504m). Application form. Fee. Exemptions.

Sec. 21a-319. (Formerly Sec. 19-504n). Professional or institutional approval to precede registration.

Sec. 21a-320. (Formerly Sec. 19-504o). Public interest standard for registration.

Sec. 21a-321. (Formerly Sec. 19-504p). Renewal of registration. Fee.

Sec. 21a-322. (Formerly Sec. 19-504q). Grounds for disciplinary action. Civil penalty.

Sec. 21a-323. (Formerly Sec. 19-504r). Hearing re refusal to renew registration or re denial, suspension or revocation of registration.

Sec. 21a-324. (Formerly Sec. 19-504s). Voluntary surrender of certificate; effect upon registration.

Sec. 21a-325. (Formerly Sec. 19-504t). Disposal of controlled substances upon surrender of registration.

Sec. 21a-326. (Formerly Sec. 19-504u). Regulations.

Sec. 21a-327. (Formerly Sec. 19-504v). Pharmacies, pharmacists and nurses exempt from chapter.

Sec. 21a-328. (Formerly Sec. 19-504w). Penalty for failure to register.

Secs. 21a-329 to 21a-334. **Reserved**

Sec. 21a-316. (Formerly Sec. 19-504k). "Practitioner" defined. As used in this chapter, "practitioner" means: (1) A physician, dentist, veterinarian, podiatrist, optometrist, physician assistant licensed pursuant to section 20-12b, advanced practice registered nurse as defined in subsection (b) of section 20-87a, nurse-midwife, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (2) a hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

Sec. 21a-317. (Formerly Sec. 19-504*l*). Registration required. Every practitioner who distributes, administers or dispenses any controlled substance or who proposes to engage in distributing, prescribing, administering or dispensing any controlled substance within this state shall obtain (1) certificate of registration issued by the Commissioner of Consumer Protection in accordance with the provisions of this chapter, and (2) register for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254, as amended by this act. Registration for access to said program shall be in a

manner prescribed by said commissioner.

Sec. 21a-318. (Formerly Sec. 19-504m). Application form. Fee. Exemptions. An application for registration pursuant to this chapter shall be made upon a form provided by the Commissioner of Consumer Protection and shall be accompanied by a fee of twenty dollars for biennial registration, except that a practitioner who obtains such registration pursuant to the practitioner's employment with a municipality, this state or the federal government shall not be required to pay the fee.

Sec. 21a-319. (Formerly Sec. 19-504n). Professional or institutional approval to precede registration. No certificate of registration shall be issued, maintained or renewed under this chapter unless or until the applicant has furnished proof satisfactory to the Commissioner of Consumer Protection that he or she is licensed or duly authorized to practice his or her profession by the appropriate state licensing board, commission or registration agency; or, in the case of a hospital or other institution, by the appropriate state agency having jurisdiction over the licensure, registration or approval of such establishment.

Sec. 21a-320. (Formerly Sec. 19-504o). Public interest standard for registration. The commissioner shall register an applicant unless he or she determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider the following factors:

(1) Maintenance of effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels;

(2) Compliance with all applicable state and federal laws and regulations concerning controlled substances;

(3) Any conviction of the applicant under any state or federal law relating to controlled substances;

(4) Furnishing by the applicant of false or fraudulent information or material in any application filed under this chapter;

(5) Expiration, suspension, revocation, surrender or denial of the practitioner's federal controlled substance registration;

(6) Prescribing, distributing, administering or dispensing of controlled substances in schedules other than those specified in the practitioner's state or federal registration; and

(7) Suspension, revocation, expiration or surrender of, or other disciplinary action taken against, any professional license or registration held by the practitioner.

Sec. 21a-321. (Formerly Sec. 19-504p). Renewal of registration. Fee. Registration may be renewed by application to the Commissioner of Consumer Protection. Renewal applications shall be in such form as the commissioner shall prescribe and shall be accompanied by a biennial renewal fee of forty dollars. A separate fee shall be required for each place of business or professional practice where the practitioner stores, distributes or dispenses controlled substances.

Sec. 21a-322. (Formerly Sec. 19-504q). Grounds for disciplinary action. Civil penalty. The commissioner may suspend, revoke or refuse to renew a registration, place a registration on probation, place conditions on a registration and assess a civil penalty of not more than one thousand dollars per violation of this chapter, for sufficient cause. Any of the following shall be sufficient cause for such action by the commissioner: (1) The furnishing of false or fraudulent information in any application filed under this chapter; (2) conviction of a crime under any state or federal law relating to the registrant's profession, controlled substances or drugs or fraudulent practices, including, but not limited to, fraudulent billing practices; (3) failure to maintain effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels; (4) the suspension, revocation, expiration or surrender of the practitioner's federal controlled substance registration; (5) prescribing, distributing, administering or dispensing a controlled substance in schedules other than those specified in the practitioner's state or federal registration or in violation of any condition placed on the practitioner's registration; (6) suspension, revocation, expiration, surrender or other disciplinary action taken against any professional license or registration held by the practitioner; (7) abuse or excessive use of drugs; (8) possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose; (9) a practitioner's failure to account for disposition of controlled substances as determined by an audit of the receipt and disposition records of said practitioner; and (10) failure to keep records of medical evaluations of patients and all controlled substances dispensed, administered or prescribed to patients by a practitioner.

Sec. 21a-323. (Formerly Sec. 19-504r). Hearing re refusal to renew registration or re denial, suspension or revocation of registration. Before denying, suspending, revoking or refusing to renew a registration, the commissioner shall afford the applicant an opportunity for hearing in accordance with the provisions of chapter 54. Notice of such hearing shall be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

Sec. 21a-324. (Formerly Sec. 19-504s). Voluntary surrender of certificate; effect upon registration. A practitioner may at any time voluntarily surrender his or her state controlled substance certificate of registration for any or all schedules of controlled substances for any of the following reasons: (1) As an indication of his or her good faith in desiring to remedy any incorrect or unlawful practices or (2) as a voluntary act arising out of his or her desire to terminate prescribing or handling of controlled substances in any or all schedules. Any such voluntary surrender shall constitute authority for the Commissioner of Consumer Protection or his or her authorized agent to terminate and revoke any state controlled substance registration without a hearing or any other proceeding.

Sec. 21a-325. (Formerly Sec. 19-504t). Disposal of controlled substances upon surrender of registration. Upon the surrender of a controlled substance certificate of registration for any or all schedules of controlled substances, as defined in section 21a-243, the registrant shall dispose of stocks of controlled substances as provided in regulations

adopted under section 21a-262 or by following the procedure for disposition of controlled substances as outlined in Section 1307.21 of the Code of Federal Regulations or any successor regulation.

Sec. 21a-326. (Formerly Sec. 19-504u). Regulations. The Commissioner of Consumer Protection may adopt such regulations as may be necessary to administer and enforce the provisions of this chapter.

Sec. 21a-327. (Formerly Sec. 19-504v). Pharmacies, pharmacists and nurses exempt from chapter. Nothing in this chapter shall be construed to include pharmacies or pharmacists licensed under chapter 400j or nurses licensed under chapter 378 who are not advanced practice registered nurses.

Sec. 21a-328. (Formerly Sec. 19-504w). Penalty for failure to register. Upon the failure of a practitioner, as defined in section 21a-316, to comply with the provisions of this chapter the Attorney General at the request of the Commissioner of Consumer Protection is authorized to apply in the name of the state of Connecticut to the Superior Court for an order temporarily or permanently restraining and enjoining any practitioner from distributing, administering, dispensing or prescribing any controlled substance.

Secs. 21a-329 to 21a-334. Reserved for future use.

CHAPTER 420f

PALLIATIVE USE OF MARIJUANA

Table of Contents

Sec. 21a-408. Definitions.

Sec. 21a-408a. Qualifying patient not subject to arrest, prosecution or certain other penalties. Requirements. Exceptions.

Sec. 21a-408b. Primary caregiver not subject to arrest, prosecution or certain other penalties. Requirements. Exceptions.

Sec. 21a-408c. Physician not subject to arrest, prosecution or certain other penalties. Requirements. Written certifications. Exceptions.

Sec. 21a-408d. Qualifying patient and primary caregiver to register with Department of Consumer Protection. Change in information. Fee. Confidentiality of registry information.

Sec. 21a-408e. Person not subject to arrest or prosecution solely for being in presence or vicinity of palliative use of marijuana.

Sec. 21a-408f. Seizure and return of marijuana, paraphernalia or other property. Exception.

Sec. 21a-408g. Fradulent representation to law enforcement official re palliative use of marijuana or written certification. Penalty.

Sec. 21a-408h. Dispensaries. Licensure. Regulations. Fees.

Sec. 21a-408i. Producers. Licensure. Regulations. Fees.

Sec. 21a-408j. Licensed dispensaries and employees not subject to arrest, prosecution or certain other penalties. Exceptions.

Sec. 21a-408k. Licensed producers and employees not subject to arrest, prosecution or certain other penalties. Exceptions.

Sec. 21a-408*l*. Board of Physicians re palliative use of marijuana. Duties. Confidentiality of information.

Sec. 21a-408m. Regulations re palliative use of marijuana. Fees. Additional debilitating conditions.

Sec. 21a-408n. Temporary registration certificates. Qualifying patients, primary caregivers and physicians not subject to arrest, prosecution or certain other penalties. Exceptions. Confidentiality of registry information.

Sec. 21a-408o. Health insurance coverage not affected.

Sec. 21a-408p. Treatment of student, tenant or employee due to status as qualifying patient or primary caregiver.

Sec. 21a-408q. Palliative marijuana administration account.

Secs. 21a-409 to 21a-429. **Reserved**

Sec. 21a-408. Definitions. As used in sections 21a-408 to 21a-408o, inclusive, unless the context otherwise requires:

(1) "Cultivation" includes planting, propagating, cultivating, growing and harvesting;

(2) "Debilitating medical condition" means (A) cancer, glaucoma, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, cachexia, wasting

syndrome, Crohn's disease, posttraumatic stress disorder, or (B) any medical condition, medical treatment or disease approved by the Department of Consumer Protection pursuant to regulations adopted under section 21a-408m;

(3) "Licensed dispensary" or "dispensary" means a person licensed as a dispensary pursuant to section 21a-408h;

(4) "Licensed producer" or "producer" means a person licensed as a producer pursuant to section 21a-408i;

(5) "Marijuana" means marijuana, as defined in section 21a-240;

(6) "Palliative use" means the acquisition, distribution, transfer, possession, use or transportation of marijuana or paraphernalia relating to marijuana, including the transfer of marijuana and paraphernalia relating to marijuana from the patient's primary caregiver to the qualifying patient, to alleviate a qualifying patient's symptoms of a debilitating medical condition or the effects of such symptoms, but does not include any such use of marijuana by any person other than the qualifying patient;

(7) "Paraphernalia" means drug paraphernalia, as defined in section 21a-240;

(8) "Physician" means a person who is licensed under chapter 370, but does not include a physician assistant, as defined in section 20-12a;

(9) "Primary caregiver" means a person, other than the qualifying patient and the qualifying patient's physician, who is eighteen years of age or older and has agreed to undertake responsibility for managing the well-being of the qualifying patient with respect to the palliative use of marijuana, provided (A) in the case of a qualifying patient lacking legal capacity, such person shall be a parent, guardian or person having legal

custody of such qualifying patient, and (B) the need for such person shall be evaluated by the qualifying patient's physician and such need shall be documented in the written certification;

(10) "Qualifying patient" means a person who is eighteen years of age or older, is a resident of Connecticut and has been diagnosed by a physician as having a debilitating medical condition. "Qualifying patient" does not include an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(11) "Usable marijuana" means the dried leaves and flowers of the marijuana plant, and any mixtures or preparations of such leaves and flowers, that are appropriate for the palliative use of marijuana, but does not include the seeds, stalks and roots of the marijuana plant; and

(12) "Written certification" means a written certification issued by a physician pursuant to section 21a-408c.

Sec. 21a-408a. Qualifying patient not subject to arrest, prosecution or certain other penalties. Requirements. Exceptions. (a) A qualifying patient shall register with the Department of Consumer Protection pursuant to section 21a-408d prior to engaging in the palliative use of marijuana. A qualifying patient who has a valid registration certificate from the Department of Consumer Protection pursuant to subsection (a) of section 21a-408d and complies with the requirements of sections 21a-408 to 21a-408n, inclusive, shall not be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by a professional licensing board, for the palliative use of marijuana if:

(1) The qualifying patient's physician has issued a written certification to the qualifying patient for the palliative use of marijuana after the physician has prescribed, or determined it is not in the best interest of the patient to prescribe, prescription drugs to address the symptoms or effects for which the certification is being issued;

(2) The combined amount of marijuana possessed by the qualifying patient and the primary caregiver for palliative use does not exceed an amount of usable marijuana reasonably necessary to ensure uninterrupted availability for a period of one month, as determined by the Department of Consumer Protection pursuant to regulations adopted under section 21a-408m; and

(3) The qualifying patient has not more than one primary caregiver at any time.

(b) The provisions of subsection (a) of this section do not apply to:

(1) Any palliative use of marijuana that endangers the health or well-being of a person other than the qualifying patient or the primary caregiver; or

(2) The ingestion of marijuana (A) in a motor bus or a school bus or in any other moving vehicle, (B) in the workplace, (C) on any school grounds or any public or private school, dormitory, college or university property, (D) in any public place, or (E) in the presence of a person under the age of eighteen. For the purposes of this subdivision, (i) "presence" means within the direct line of sight of the palliative use of marijuana or exposure to second-hand marijuana smoke, or both; (ii) "public place" means any area that is used or held out for use by the public whether owned or operated by public or private interests; (iii) "vehicle" means a vehicle, as defined in section 14-1; (iv) "motor bus" means a motor bus, as defined in section 14-1; and (v) "school bus"

means a school bus, as defined in section 14-1.

Sec. 21a-408b. Primary caregiver not subject to arrest, prosecution or certain other penalties. Requirements. Exceptions. (a) No person may serve as a primary caregiver for a qualifying patient (1) unless such qualifying patient has a valid registration certificate from the Department of Consumer Protection pursuant to subsection (a) of section 21a-408d, and (2) if such person has been convicted of a violation of any law pertaining to the illegal manufacture, sale or distribution of a controlled substance. A primary caregiver may not be responsible for the care of more than one qualifying patient at any time, except that a primary caregiver may be responsible for the care of more than one qualifying patient if the primary caregiver and each qualifying patient have a parental, guardianship, conservatorship or sibling relationship.

(b) A primary caregiver who has a valid registration certificate from the Department of Consumer Protection pursuant to subsection (a) of section 21a-408d and complies with the requirements of sections 21a-408 to 21a-408n, inclusive, shall not be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by a professional licensing board, for the acquisition, distribution, possession or transportation of marijuana or paraphernalia related to marijuana on behalf of such primary caregiver's qualifying patient, provided (1) the amount of any marijuana so acquired, distributed, possessed or transported, together with the combined amount of usable marijuana possessed by the qualifying patient and the primary caregiver, does not exceed an amount reasonably necessary to ensure uninterrupted

availability for a period of one month, as determined by the Department of Consumer Protection pursuant to regulations adopted under section 21a-408m, and (2) such amount is obtained solely within this state from a licensed dispensary. For the purposes of this subsection, "distribution" or "distributed" means the transfer of marijuana and paraphernalia related to marijuana from the primary caregiver to the qualifying patient.

Sec. 21a-408c. Physician not subject to arrest, prosecution or certain other penalties. Requirements. Written certifications. Exceptions. (a) A physician may issue a written certification to a qualifying patient that authorizes the palliative use of marijuana by the qualifying patient. Such written certification shall be in the form prescribed by the Department of Consumer Protection and shall include a statement signed and dated by the qualifying patient's physician stating that, in such physician's professional opinion, the qualifying patient has a debilitating medical condition and the potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use to the qualifying patient.

(b) Any written certification for the palliative use of marijuana issued by a physician under subsection (a) of this section shall be valid for a period not to exceed one year from the date such written certification is signed and dated by the physician. Not later than ten calendar days after the expiration of such period, or at any time before the expiration of such period should the qualifying patient no longer wish to possess marijuana for palliative use, the qualifying patient or the primary caregiver shall destroy all usable marijuana possessed by the qualifying patient and the primary caregiver for palliative use.

(c) A physician shall not be subject to arrest or prosecution, penalized

in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by the Connecticut Medical Examining Board or other professional licensing board, for providing a written certification for the palliative use of marijuana under subdivision (1) of subsection (a) of section 21a-408a if:

(1) The physician has diagnosed the qualifying patient as having a debilitating medical condition;

(2) The physician has explained the potential risks and benefits of the palliative use of marijuana to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent, guardian or person having legal custody of the qualifying patient;

(3) The written certification issued by the physician is based upon the physician's professional opinion after having completed a medically reasonable assessment of the qualifying patient's medical history and current medical condition made in the course of a bona fide physician-patient relationship; and

(4) The physician has no financial interest in a dispensary licensed under section 21a-408h or a producer licensed under section 21a-408i.

Sec. 21a-408d. Qualifying patient and primary caregiver to register with Department of Consumer Protection. Change in information. Fee. Confidentiality of registry information. (a) Each qualifying patient who is issued a written certification for the palliative use of marijuana under subdivision (1) of subsection (a) of section 21a-408a, and the primary caregiver of such qualifying patient, shall register with the Department of Consumer Protection. Such registration shall be

effective from the date the Department of Consumer Protection issues a certificate of registration until the expiration of the written certification issued by the physician. The qualifying patient and the primary caregiver shall provide sufficient identifying information, as determined by the department, to establish the personal identity of the qualifying patient and the primary caregiver. The qualifying patient or the primary caregiver shall report any change in such information to the department not later than five business days after such change. The department shall issue a registration certificate to the qualifying patient and to the primary caregiver and may charge a reasonable fee, not to exceed twenty-five dollars, for each registration certificate issued under this subsection. Any registration fees collected by the department under this subsection shall be paid to the State Treasurer and credited to the account established pursuant to section 21a-408q.

(b) Information obtained under this section shall be confidential and shall not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200, except that reasonable access to registry information obtained under this section and temporary registration information obtained under section 21a-408n shall be provided to: (1) State agencies, federal agencies and local law enforcement agencies for the purpose of investigating or prosecuting a violation of law; (2) physicians and pharmacists for the purpose of providing patient care and drug therapy management and monitoring controlled substances obtained by the qualifying patient; (3) public or private entities for research or educational purposes, provided no individually identifiable health information may be disclosed; (4) a licensed dispensary for the purpose of complying with sections 21a-408 to 21a-408n, inclusive; (5) a qualifying patient, but only with respect to information related to such qualifying patient or such qualifying patient's primary caregiver; or (6) a primary caregiver, but only with respect to information related to such

primary caregiver's qualifying patient.

Sec. 21a-408e. Person not subject to arrest or prosecution solely for being in presence or vicinity of palliative use of marijuana. No person shall be subject to arrest or prosecution solely for being in the presence or vicinity of the palliative use of marijuana as permitted under sections 21a-408 to 21a-408n, inclusive.

Sec. 21a-408f. Seizure and return of marijuana, paraphernalia or other property. Exception. Any marijuana, paraphernalia relating to marijuana, or other property seized by law enforcement officials from a qualifying patient or a primary caregiver in connection with the claimed palliative use of marijuana under sections 21a-408 to 21a-408n, inclusive, shall be returned to the qualifying patient or the primary caregiver immediately upon the determination by a court that the qualifying patient or the primary caregiver is entitled to the palliative use of marijuana under sections 21a-408 to 21a-408n, inclusive, as evidenced by a decision not to prosecute, a dismissal of charges or an acquittal. The provisions of this section do not apply to any qualifying patient or primary caregiver who fails to comply with the requirements for the palliative use of marijuana under sections 21a-408 to 21a-408n, inclusive.

Sec. 21a-408g. Fradulent representation to law enforcement official re palliative use of marijuana or written certification. Penalty. (a) Any person who makes a fraudulent representation to a law enforcement official of any fact or circumstance relating to the palliative

use of marijuana in order to avoid arrest or prosecution under chapter 420b or any other provision of the general statutes shall be guilty of a class C misdemeanor.

(b) Any person who makes a fraudulent representation to a law enforcement official of any fact or circumstance relating to the issuance, contents or validity of a written certification for the palliative use of marijuana, or a document purporting to be such a written certification, shall be guilty of a class A misdemeanor.

Sec. 21a-408h. Dispensaries. Licensure. Regulations. Fees. (a) No person may act as a dispensary or represent that such person is a licensed dispensary unless such person has obtained a license from the Commissioner of Consumer Protection pursuant to this section.

(b) The Commissioner of Consumer Protection shall determine the number of dispensaries appropriate to meet the needs of qualifying patients in this state and shall adopt regulations, in accordance with chapter 54, to provide for the licensure and standards for dispensaries in this state and specify the maximum number of dispensaries that may be licensed in this state. On and after the effective date of such regulations, the commissioner may license any person who applies for a license in accordance with such regulations, provided (1) the commissioner deems such applicant qualified to acquire, possess, distribute and dispense marijuana pursuant to sections 21a-408 to 21a-408n, inclusive, (2) the applicant is a pharmacist licensed under chapter 400j, and (3) the number of dispensary licenses issued does not exceed the number appropriate to meet the needs of qualifying patients in this state, as determined by the commissioner pursuant to this subsection. At a minimum, such regulations shall:

(A) Indicate the maximum number of dispensaries that may be licensed in this state;

(B) Provide that only a pharmacist licensed under chapter 400j may apply for and receive a dispensary license;

(C) Provide that no marijuana may be dispensed from, obtained from or transferred to a location outside of this state;

(D) Establish a licensing fee and renewal fee for each licensed dispensary, provided such fees shall not be less than the amount necessary to cover the direct and indirect cost of licensing and regulating dispensaries pursuant to sections 21a-408 to 21a-408n, inclusive;

(E) Provide for renewal of such dispensary licenses at least every two years;

(F) Describe areas in this state where licensed dispensaries may not be located, after considering the criteria for the location of retail liquor permit premises set forth in subsection (a) of section 30-46;

(G) Establish health, safety and security requirements for licensed dispensaries, which may include, but need not be limited to: (i) The ability to maintain adequate control against the diversion, theft and loss of marijuana acquired or possessed by the licensed dispensary, and (ii) the ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the distributing, dispensing and use of palliative marijuana;

(H) Establish standards and procedures for revocation, suspension, summary suspension and nonrenewal of dispensary licenses, provided such standards and procedures are consistent with the provisions of subsection (c) of section 4-182; and

(I) Establish other licensing, renewal and operational standards deemed necessary by the commissioner.

(c) Any fees collected by the Department of Consumer Protection under this section shall be paid to the State Treasurer and credited to the account established pursuant to section 21a-408q.

Sec. 21a-408i. Producers. Licensure. Regulations. Fees. (a) No person may act as a producer or represent that such person is a licensed producer unless such person has obtained a license from the Commissioner of Consumer Protection pursuant to this section.

(b) The Commissioner of Consumer Protection shall determine the number of producers appropriate to meet the needs of qualifying patients in this state and shall adopt regulations, in accordance with chapter 54, to provide for the licensure, standards and locations for producers in this state and specify the maximum number of producers that may be licensed in this state at any time. On and after the effective date of such regulations, the commissioner may license any person who applies for a license in accordance with such regulations, provided (1) such person is organized for the purpose of cultivating marijuana for palliative use in this state, (2) the commissioner finds that such applicant has appropriate expertise in agriculture and that such applicant is qualified to cultivate marijuana and sell, deliver, transport or distribute marijuana solely within this state pursuant to sections 21a-408 to 21a-408n, inclusive, and (3) the number of producer licenses issued does not exceed the number appropriate to meet the needs of qualifying patients in this state, as determined by the commissioner pursuant to this subsection. At a minimum, such regulations shall:

(A) Indicate the maximum number of producers that may be licensed

in this state at any time, which number shall not be less than three nor more than ten producers;

(B) Provide that no marijuana may be sold, delivered, transported or distributed by a producer from or to a location outside of this state;

(C) Establish a nonrefundable application fee of not less than twenty-five thousand dollars for each application submitted for a producer license;

(D) Establish a license fee and renewal fee for each licensed producer, provided the aggregate amount of such license and renewal fees shall not be less than the amount necessary to cover the direct and indirect cost of licensing and regulating producers pursuant to sections 21a-408 to 21a-408n, inclusive;

(E) Provide for renewal of such producer licenses at least every five years;

(F) Provide that no producer may cultivate marijuana for palliative use outside of this state and designate permissible locations for licensed producers in this state;

(G) Establish financial requirements for producers, under which (i) each applicant demonstrates the financial capacity to build and operate a marijuana production facility, and (ii) each licensed producer may be required to maintain an escrow account in a financial institution in this state in an amount of two million dollars;

(H) Establish health, safety and security requirements for licensed producers, which shall include, but need not be limited to, a requirement that the applicant or licensed producer demonstrate: (i) The ability to maintain adequate control against the diversion, theft and loss of marijuana cultivated by the producer, and (ii) the ability to cultivate

pharmaceutical grade marijuana for palliative use in a secure indoor facility;

(I) Define "pharmaceutical grade marijuana for palliative use" for the purposes of this section;

(J) Establish standards and procedures for revocation, suspension, summary suspension and nonrenewal of producer licenses, provided such standards and procedures are consistent with the provisions of subsection (c) of section 4-182; and

(K) Establish other licensing, renewal and operational standards deemed necessary by the commissioner.

(c) Any fees collected by the Department of Consumer Protection under this section shall be paid to the State Treasurer and credited to the account established pursuant to section 21a-408q.

Sec. 21a-408j. Licensed dispensaries and employees not subject to arrest, prosecution or certain other penalties. Exceptions. (a) No licensed dispensary or employee of the dispensary may: (1) Acquire marijuana from a person other than a licensed producer; (2) distribute or dispense marijuana to a person who is not (A) a qualifying patient registered under section 21a-408d or 21a-408n, or (B) a primary caregiver of such qualifying patient; or (3) obtain or transport marijuana outside of this state in violation of state or federal law.

(b) No licensed dispensary or employee of the dispensary acting within the scope of his or her employment shall be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by

a professional licensing board, for acquiring, possessing, distributing or dispensing marijuana pursuant to sections 21a-408 to 21a-408n, inclusive.

Sec. 21a-408k. Licensed producers and employees not subject to arrest, prosecution or certain other penalties. Exceptions. (a) No licensed producer or employee of the producer may: (1) Sell, deliver, transport or distribute marijuana to a person who is not a licensed dispensary, or (2) obtain or transport marijuana outside of this state in violation of state or federal law.

(b) No licensed producer or employee of the producer acting within the scope of his or her employment shall be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by a professional licensing board, for cultivating marijuana or selling, delivering, transporting or distributing marijuana to licensed dispensaries under sections 21a-408 to 21a-408n, inclusive.

Sec. 21a-408*l*. Board of Physicians re palliative use of marijuana. Duties. Confidentiality of information. (a) The Commissioner of Consumer Protection shall establish a Board of Physicians consisting of eight physicians or surgeons who are knowledgeable about the palliative use of marijuana and certified by the appropriate American board in one of the following specialties: Neurology, pain medicine, pain management, medical oncology, psychiatry, infectious disease, family medicine or gynecology. Four of the members of the board first appointed shall serve for a term of three years and four of the members

of the board first appointed shall serve for a term of four years. Thereafter, members of the board shall serve for a term of four years and shall be eligible for reappointment. Any member of the board may serve until a successor is appointed. The Commissioner of Consumer Protection shall serve as an ex-officio member of the board, and shall select a chairperson from among the members of the board.

(b) A quorum of the Board of Physicians shall consist of three members.

(c) The Board of Physicians shall:

(1) Review and recommend to the Department of Consumer Protection for approval the debilitating medical conditions, medical treatments or diseases to be added to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(2) Accept and review petitions to add medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(3) Convene at least twice per year to conduct public hearings and to evaluate petitions, which shall be maintained as confidential pursuant to subsection (d) of this section, for the purpose of adding medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(4) Review and recommend to the Department of Consumer Protection protocols for determining the amounts of marijuana that may be reasonably necessary to ensure uninterrupted availability for a period of one month for qualifying patients, including amounts for topical treatments; and

(5) Perform other duties related to the palliative use of marijuana upon

the request of the Commissioner of Consumer Protection.

(d) Any individually identifiable health information contained in a petition received under this section shall be confidential and shall not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200.

Sec. 21a-408m. Regulations re palliative use of marijuana. Fees. Additional debilitating conditions. (a) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, to establish (1) a standard form for written certifications for the palliative use of marijuana issued by physicians under subdivision (1) of subsection (a) of section 21a-408a, and (2) procedures for registrations under section 21a-408d. Such regulations, if any, shall be adopted after consultation with the Board of Physicians established in section 21a-408*l*.

(b) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to establish a reasonable fee to be collected from each qualifying patient to whom a written certification for the palliative use of marijuana is issued under subdivision (1) of subsection (a) of section 21a-408a, for the purpose of offsetting the direct and indirect costs of administering the provisions of sections 21a-408 to 21a-408n, inclusive. The commissioner shall collect such fee at the time the qualifying patient registers with the Department of Consumer Protection under subsection (a) of section 21a-408d. Such fee shall be in addition to any registration fee that may be charged under said subsection. The fees required to be collected by the commissioner from qualifying patients under this subsection shall be paid to the State Treasurer and credited to the account established pursuant to section

21a-408q.

(c) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to implement the provisions of sections 21a-408 to 21a-408g, inclusive, and section 21a-408*l*. At a minimum, such regulations shall:

(1) Govern the manner in which the department considers applications for the issuance and renewal of registration certificates for qualifying patients and primary caregivers, and establish any additional information to be contained in such registration certificates;

(2) Define the protocols for determining the amount of usable marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amounts for topical treatments;

(3) Establish criteria for adding medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(4) Establish a petition process under which members of the public may submit petitions, in such manner and in such form as prescribed in the regulations, regarding the addition of medical conditions, medical treatments or diseases to the list of debilitating medical conditions;

(5) Establish a process for public comment and public hearings before the board regarding the addition of medical conditions, medical treatments or diseases to the list of debilitating medical conditions, medical treatments or diseases;

(6) Add additional medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana as recommended by the board; and

(7) Develop a distribution system for marijuana for palliative use that provides for:

(A) Marijuana production facilities within this state that are housed on secured grounds and operated by licensed producers; and

(B) Distribution of marijuana for palliative use to qualifying patients or their primary caregivers by licensed dispensaries.

(d) The commissioner shall submit regulations pursuant to subsections (b) and (c) of this section to the standing legislative regulation review committee not later than July 1, 2013.

Sec. 21a-408n. Temporary registration certificates. Qualifying patients, primary caregivers and physicians not subject to arrest, prosecution or certain other penalties. Exceptions. Confidentiality of registry information. (a) During the period beginning on October 1, 2012, and ending thirty calendar days after the effective date of regulations adopted pursuant to section 21a-408m, a qualifying patient who would be determined to be eligible for a registration certificate pursuant to subsection (a) of section 21a-408d, except for the lack of effective regulations concerning licensed dispensaries, licensed producers, distribution systems and amounts of marijuana, may obtain a written certification from a physician and upon presenting the written certification to the Department of Consumer Protection, the department shall issue a temporary registration certificate for the palliative use of marijuana. The department shall indicate on such temporary registration certificate the amount of usable marijuana that constitutes a one month supply which may be possessed pursuant to such temporary registration certificate. The department shall maintain a list of all temporary registration certificates issued pursuant to this section and the

information on such list shall be confidential and shall not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200, except that such information may be disclosed in the manner set forth in subsection (b) of section 21a-408d.

(b) A qualifying patient possessing a temporary registration certificate and the qualifying patient's primary caregiver shall not be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by a professional licensing board, for possessing marijuana if the amount of usable marijuana possessed by the qualifying patient and the primary caregiver is not more than the amount specified in the temporary registration certificate.

(c) A physician shall not be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty, or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by the Connecticut Medical Examining Board or other professional licensing board, for providing a written certification for the palliative use of marijuana pursuant to this section.

Sec. 21a-408o. Health insurance coverage not affected. Nothing in sections 21a-408 to 21a-408n, inclusive, or section 21a-243 shall be construed to require health insurance coverage for the palliative use of marijuana.

Sec. 21a-408p. Treatment of student, tenant or employee due to

status as qualifying patient or primary caregiver. (a) For the purposes of this section:

(1) "Action" has the meaning provided in section 47a-1;

(2) "Dwelling unit" has the meaning provided in section 47a-1;

(3) "Employer" means a person engaged in business who has one or more employees, including the state and any political subdivision of the state;

(4) "Landlord" has the meaning provided in section 47a-1;

(5) "Palliative use" has the meaning provided in section 21a-408;

(6) "Primary caregiver" has the meaning provided in section 21a-408;

(7) "Qualifying patient" has the meaning provided in section 21a-408;

(8) "School" means a public or private elementary or secondary school in this state or a public or private institution of higher education in this state; and

(9) "Tenant" has the meaning provided in section 47a-1.

(b) Unless required by federal law or required to obtain federal funding:

(1) No school may refuse to enroll any person or discriminate against any student solely on the basis of such person's or student's status as a qualifying patient or primary caregiver under sections 21a-408 to 21a-408n, inclusive;

(2) No landlord may refuse to rent a dwelling unit to a person or take action against a tenant solely on the basis of such person's or tenant's status as a qualifying patient or primary caregiver under sections 21a-408 to 21a-408n, inclusive; and

(3) No employer may refuse to hire a person or may discharge, penalize or threaten an employee solely on the basis of such person's or employee's status as a qualifying patient or primary caregiver under sections 21a-408 to 21a-408n, inclusive. Nothing in this subdivision shall restrict an employer's ability to prohibit the use of intoxicating substances during work hours or restrict an employer's ability to discipline an employee for being under the influence of intoxicating substances during work hours.

(c) Nothing in this section shall be construed to permit the palliative use of marijuana in violation of subsection (b) of section 21a-408a.

Sec. 21a-408q. Palliative marijuana administration account. There is established a palliative marijuana administration account which shall be a separate, nonlapsing account within the General Fund. The account shall contain any fees collected pursuant to subsection (a) of section 21a-408d, any fees collected pursuant to sections 21a-408h and 21a-408i, any fees collected pursuant to subsection (b) of section 21a-408m, and any other moneys required by law to be deposited in the account, and shall be held in trust separate and apart from all other moneys, funds and accounts. Any balance remaining in the account at the end of any fiscal year shall be carried forward in the account for the fiscal year next succeeding. Investment earnings credited to the account shall become part of the account. Amounts in the account shall be expended only for the purpose of providing funds to the Department of Consumer Protection for administering the provisions of sections 21a-408 to 21a-408o, inclusive.

Secs. 21a-409 to 21a-429. Reserved for future use.

Note: Chapters 420g to 420k are also reserved for future use.

S E C T I O N II

CONNECTICUT PUBLIC ACTS

Substitute House Bill No. 5767

Public Act No. 13-131

AN ACT CONCERNING SYNCHRONIZING PRESCRIPTION REFILLS.

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

Section 1. (NEW) (*Effective January 1, 2014*) No individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11), (12) and (16) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state that provides coverage for prescription drugs shall deny coverage for the refill of any drug prescribed for the treatment of a chronic illness that is made in accordance with a plan among the insured, a practitioner and a pharmacist to synchronize the refilling of multiple prescriptions for the insured.

Sec. 2. (NEW) (*Effective January 1, 2014*) No group health insurance policy providing coverage of the type specified in

subdivisions (1), (2), (4), (11), (12) and (16) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state that provides coverage for prescription drugs, shall deny coverage for the refill of any drug prescribed for the treatment of a chronic illness that is made in accordance with a plan among the insured, a practitioner and a pharmacist to synchronize the refilling of multiple prescriptions for the insured.

Approved June 18, 2013

Senate Bill No. 320

Public Act No. 13-175

AN ACT PROHIBITING PRICE GOUGING DURING SEVERE WEATHER EVENTS.

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

Section 1. (NEW) (*Effective from passage*) (a) For purposes of this section, "consumer goods and services" means goods and services that are vital and necessary for the health, safety or welfare of consumers and are used, bought or rendered primarily for personal, family or household purposes, including, but not limited to, the provision of lodging, snow removal, flood abatement and post-storm cleanup or repair services.

(b) In the event that adverse weather conditions create an unusually high demand for consumer goods and services, the Governor may proclaim that a severe weather event emergency exists. Upon the proclamation of such emergency, the Governor shall post notice of such proclamation on the home page of the Internet web site of the office of the Governor. Upon determining that such severe weather event emergency has ended, the Governor shall post the end date of such emergency on such web site.

(c) During such severe weather event emergency, no person within the chain of distribution of consumer goods and services shall sell or offer to sell consumer goods or services for a price that is unconscionably excessive.

(d) (1) A determination that a violation of subsection (c) of this section has occurred shall be based, among other factors, on the following: (A) That the price for which consumer goods and services were sold or offered to be sold was unconscionably excessive, (B) that there was an exercise of unfair leverage or unconscionable means, or (C) a combination of both factors in subparagraphs (A) and (B) of this subdivision. (2) Evidence that: (A) The price for which consumer goods and services were sold or offered to be sold represents a gross disparity between the price of the goods or services that were the subject of the transaction and their value measured by the average price at which such consumer goods or services were sold or offered to be sold by the defendant in the usual course of business during the thirty-day period prior to a severe weather event proclamation

made by the Governor pursuant to subsection (b) of this section, or (B) the price for which consumer goods and services were sold or offered to be sold grossly exceeded the price at which the same or similar goods or services were readily obtainable by other consumers in the trade area shall constitute prima facie evidence that the price is unconscionably excessive. A defendant may rebut a prima facie case with evidence that additional costs not within the control of the defendant were imposed on the defendant for such goods or services.

(e) A seller of an energy resource, as defined in subsection (a) of section 42-234 of the general statutes, shall be exempt from the provisions of this section.

(f) A violation of subsection (c) of this section shall constitute an unfair trade or deceptive practice under subsection (a) of section 42-110b of the general statutes.

(g) Each violation and each day on which the violation occurs or continues shall be a separate offense.

(h) The provisions of this section shall not be construed to limit the ability of the Commissioner of Consumer Protection or the court from finding certain acts or practices unfair or deceptive pursuant to chapter 735a of the general statutes in the absence of a severe weather event emergency proclamation made by the Governor pursuant to subsection (b) of this section.

Approved June 21, 2013

Senate Bill No. 918

Public Act No. 13-230

AN ACT CONCERNING DISCIPLINARY ACTION AGAINST VETERINARIANS.

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

Section 1. Section 20-202 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2013*):

After notice and opportunity for hearing as provided in the regulations established by the Commissioner of Public Health, said board may take any of the actions set forth in section 19a-17 for any of the following causes: (1) The presentation to the board of any diploma, license or certificate illegally or fraudulently obtained; (2) proof that the holder of such license or certificate has become unfit or incompetent or has been guilty of cruelty, unskillfulness or negligence towards animals and birds. In determining whether the holder of such license has acted with negligence, the board may consider standards of care and guidelines published by the American Veterinary Medical Association including, but not limited to, guidelines for the use, distribution and prescribing of prescription drugs; (3) conviction of the violation of any of the provisions of this chapter by any court of criminal jurisdiction, provided no license or registration shall be revoked or suspended because of such conviction if an

appeal to a higher court has been filed until such appeal has been determined by the higher court and the conviction sustained; (4) the violation of any of the provisions of this chapter or the refusal to comply with any of said provisions; (5) the publication or circulation of any statement of a character tending to deceive or mislead the public; (6) the supplying of drugs, biologics, instruments or any substances or devices by which unqualified persons may practice veterinary medicine, surgery and dentistry, except that such drugs, biologics, instruments, substances or devices may be supplied to a farmer for his own animals or birds; (7) fraudulent issue or use of any health certificate, vaccination certificate, test chart or other blank form used in the practice of veterinary medicine relating to the dissemination of animal disease, transportation of diseased animals or the sale of inedible products of animal origin for human consumption; (8) knowingly having professional association with, or knowingly employing any person who is unlawfully practicing veterinary medicine; (9) failure to keep veterinary premises and equipment in a clean and sanitary condition; (10) physical or mental illness, emotional disorder or loss of motor skill, including but not limited to, deterioration through the aging process; (11) abuse or excessive use of drugs, including alcohol, narcotics or chemicals; or (12) failure to comply with the continuing education requirements prescribed in section 20-201a. A violation of any of the provisions of this chapter by any unlicensed employee in the practice of veterinary medicine, with the knowledge of his employer, shall be deemed a violation thereof by his employer. The Commissioner of Public Health may order a license holder to

submit to a reasonable physical or mental examination if his physical or mental capacity to practice safely is the subject of an investigation. Said commissioner may petition the superior court for the judicial district of Hartford to enforce such order or any action taken pursuant to section 19a-17.

Approved June 24, 2013

S E C T I O N III - REGULATIONS

The Practice of Pharmacy

Sec. 20-576-1. Definitions

For the purpose of sections 20-576-1 through 20-576-53 of the Regulations of
Connecticut State Agencies, the following terms shall have the meanings indicated:

(a) ‘‘Commission’’ means the Commission of Pharmacy;

(b) ‘‘Department’’ means the Department of Consumer Protection;

(c) ‘‘Legend drug’’ has the meaning given to this term by Section 20-571 of the General Statutes;

(d) ‘‘Prescribing practitioner’’ has the meaning given to this term by Section 20-571 of the General Statutes; and

(e) ‘‘Prescription department’’ means that area within a pharmacy where drugs are compounded and dispensed pursuant to the order of a prescribing practitioner.

Sec. 20-576-2. Applications

(a) All applications for licenses or permits shall be made on forms furnished by the department. All such forms shall be signed by the applicant thereby indicating that all information contained in the application is true and accurate.

(b) Proper proof of all requirements for applications for admission to examinations and for applications for licenses and permits shall be provided to the department with each such application.

(c) Applications for licenses for which an examination is required shall be submitted to the department at least forty-five days prior to the date on which the examination is to be taken unless this is deemed by the commission to be unnecessary based upon the manner in which the exam is to be administered.

(d) Applications for new pharmacy licenses and applications for the relocation of a pharmacy shall be made at least fifteen days prior to the next scheduled meeting of the commission.

Sec. 20-576-3. Applications for pharmacist license
(a) An applicant for a license to practice pharmacy other than by reciprocity shall be required to take a two part examination consisting of the following:
(1) Part I. The North American Pharmacist Licensure Exam or such other examination as may be required by the commission and approved by the Commissioner of Consumer Protection; and
(2) Part II. Pharmaceutical jurisprudence.
(b) The applicant must achieve a grade of not less than 75 in each designated part.

Sec. 20-576-4. Eligibility for examination
(a) An applicant who is a graduate of a school or college of pharmacy accredited by the American Council on Pharmaceutical Education and approved by the commission, and who has had at least fifteen hundred hours of the practical experience required of a pharmacy intern shall be eligible to take the required examination, except as provided in section 20-576-6 of the Regulations of Connecticut State Agencies.
(b) An applicant who is a graduate of a foreign college or school of pharmacy shall be eligible to take the required examination if the following requirements are met:
(1) Documentation of date and place of birth;
(2) Proof of having passed the paper-based, computer-based or internet-based Test of English as a Foreign Language with the minimum score approved by the National Association of Boards of Pharmacy;
(3) Proof of having passed the Test of Spoken English with a minimum score of fifty-five (55) if the applicant has taken either the paper-based or the computer based Test of English as a Foreign Language;
(4) Proof of United States citizenship or a visa permitting employment in the United States;
(5) Proof of at least fifteen hundred hours of the practical experience required of a pharmacy intern as provided by section 20-576-8 of the Regulations of Connecticut State Agencies;

(6) Proof of passage of the Foreign Pharmacy Graduate Equivalency Examination; and
(7) Appearance before the commission for a personal interview prior to the commencement of the practical experience required of a pharmacy intern in subsection
(b)(5) of this section, at which time such training requirement as well as the other criteria established in this subsection will be reviewed.

Sec. 20-576-5. Examination conduct
Any candidate committing a fraudulent or deceitful act related to the taking of the examination shall be prohibited from further examination for a minimum period of one year.

Sec. 20-576-6. Exception to intern requirements
If a candidate for the examination for licensure to practice pharmacy as a pharmacist in Connecticut as prescribed by section 20-590 of the General Statutes and section 20-576-3 of the Regulations of Connecticut State Agencies has not fulfilled the law as required by section 20-598 of the General Statutes, the candidate, upon completion of the examination, shall immediately register and fulfill the requirements of said section 20-598, or, submit to the commission evidence of the completion of a program as described in section 20-576-8(b) of the Regulations of Connecticut State Agencies.

Sec. 20-576-7. Reciprocity
A pharmacist who is licensed as such in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States, may be licensed to practice as such in this state provided:
(1) the qualifications necessary to secure such license in the state or jurisdiction in which the pharmacist is licensed were, at the time of first

securing such license, at least equal to those required in this state at that time;
(2) the pharmacist is a graduate with a professional undergraduate degree from those schools of pharmacy that are accredited by the American Council on Pharmaceutical Education, or is a graduate with a professional undergraduate degree from a foreign college or school of pharmacy and has complied with the requirements of section 20-576-4(b) of the Regulations of Connecticut State Agencies;
(3) the pharmacist is a resident of the state of Connecticut at the time of making application to be licensed as a pharmacist or has indicated an intention to practice pharmacy within the state of Connecticut;
(4) the pharmacist has practiced the profession of pharmacy for at least one year in any other state or jurisdiction within the last five years at the time of application or has been licensed by examination in another state or jurisdiction within the previous twelve months. In lieu of the practice requirement, the commission may accept, in its discretion, equivalent experience as determined by the commission;
(5) the pharmacy board or commission in the state or jurisdiction from which the pharmacist is reciprocating grants similar reciprocal privileges to pharmacists licensed in this state;
(6) the pharmacist passes that portion of the commission's licensure examination relating to pharmacy law; and
(7) the pharmacist appears before the commission for a personal interview in which the criteria established in this section will be reviewed.

Sec. 20-576-8. Registration of pharmacy interns
(a) As used in this section: ''pharmacy intern'' has the meaning given to this term by Section 20-571 of the General Statutes; ''intern training pharmacy'' means a Connecticut pharmacy or an institutional pharmacy approved by the commission, providing training for a pharmacy intern in contemporary pharmacy practice; and ''pharmacy intern preceptor'' means a Connecticut pharmacist supervising a pharmacy intern.

(b) The professional experience required by section 20-590 of the General Statutes shall consist of the satisfactory fulfillment of a series of objectives approved by the commission, completed during fifteen hundred clock hours as a registered pharmacy intern. The professional experience may be obtained by completing any combination of the following:

(1) employment or voluntary work in a Connecticut pharmacy or an institutional pharmacy approved by the commission, but no more than 40 clock hours may be obtained in any one week;

(2) completion of an educational experiential program established and monitored by a school or college of pharmacy accredited by the Accreditation Council for Pharmacy Education, or its successor organization recognized by the United States Department of Education as the accrediting body for professional degree programs in pharmacy, and approved by the commission;

(3) an out of state practical experience program approved by the appropriate licensing agency in the state wherein the experience is attained; or

(4) an industrial, research or other professional experience program established by a school or college of pharmacy accredited by the Accreditation Council for Pharmacy Education, or its successor organization recognized by the United States Department of Education as the accrediting body for professional degree programs in pharmacy, and approved by the commission. Hours accumulated under this subdivision shall be limited to a maximum of 400 hours.

(c) The following requirements shall apply only to experience hours acquired by a pharmacy intern employed or volunteering in a Connecticut pharmacy or institutional pharmacy approved by the commission pursuant to subsection (b)(1) of this section:

(1) No pharmacy intern preceptor shall supervise the training of more than one pharmacy intern at any one time;

(2) A pharmacy intern preceptor's statement supplied by the department shall be completed and signed by the preceptor and the intern, certifying that the stated hours and content of the professional experience are true;

(3) The pharmacy intern shall within five days of the event, notify the commission of any of the following changes in his internship training:
(A) the commencement of his internship training;
(B) a change in the place of supervision;
(C) a change of the pharmacy intern preceptor;
(D) a change in the hours of supervision; or
(E) cessation of supervision; and
(4) The department shall issue to each pharmacy intern, registering in accordance with section 20-598 of the General Statutes, an identification number and card except to those individuals obtaining internship training in an out of state practical experience program approved by the licensing agency in the state wherein the experience is attained.

Sec. 20-576-9. Authority of registered pharmacy intern
A registered pharmacy intern may compound and dispense drugs and devices and otherwise perform contemporary pharmacy services only when a pharmacist is physically present in the pharmacy or institutional pharmacy and personally supervising such compounding, dispensing or delivery of contemporary pharmacy services.

Sec. 20-576-10. Information to be reported
Every pharmacist who commences the practice of pharmacy or changes the pharmacist's place of employment within the state of Connecticut shall report to the department within five days the following information:
(1) the date of commencement of the practice of pharmacy;
(2) the name of the pharmacist's employer;
(3) the address of the practice location; and
(4) the type of practice.

Sec. 20-576-11. Change of name or address
Any pharmacist or registered pharmacy technician changing the pharmacist's or technician's name or home address shall notify the commission of such change within five days.

Sec. 20-576-12. Required pharmacy equipment and references
Every pharmacy and institutional pharmacy shall have proper pharmaceutical equipment and appropriate pharmaceutical reference materials to insure that prescriptions can be properly dispensed and that contemporary pharmacy services can be properly provided.

Sec. 20-576-13. Hours of operation of a pharmacy
A pharmacy shall be open at least thirty-five hours per week, except as otherwise authorized in regulations concerning classes of pharmacies promulgated pursuant to Section 20-576(a)(2) of the General Statutes.

Sec. 20-576-14. Security of the prescription department during momentary absences of a pharmacist
During times when the pharmacist leaves the prescription department, or leaves the area operated as the pharmacy in accordance with sections 20-576-15 and 20- 576-16 of the Regulations of Connecticut State Agencies, for a few moments, measures shall be taken to insure that adequate security of the prescription department is provided and that entry by unauthorized personnel is prevented or immediately detected. The presence of a pharmacy intern or a pharmacy technician in the prescription department, or in the area operated as the pharmacy in accordance with section 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, during these times shall be considered to be providing adequate security. If no such personnel are available for this purpose, and the prescription department, or the area licensed as the pharmacy in accordance with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, is not within the view of the

pharmacist, a method shall be employed to physically or electronically secure the prescription department through the use of mechanisms such as a locked barrier or an alarm system that will prevent or immediately detect access to that area.

Sec. 20-576-15. Licensing as a pharmacy the entire premises of a business not primarily devoted to the operation of a pharmacy

The commission shall not be required to license as a pharmacy, the entire premises of a business that is not devoted primarily to the operation of a pharmacy. In determining whether to license the entire premises the commission shall consider, but shall not be limited to the following factors:

(1) the primary nature of the business and the type of products sold, especially the relationship of the products sold to the practice of pharmacy; and

(2) the percentage of the floor space of the business devoted to the sale of drugs, medical devices and other health related products.

Sec. 20-576-16. Physical construction and operation of pharmacies located in
businesses not devoted primarily to the operation of a pharmacy

When a pharmacy is operated in any store, firm or other business not devoted primarily to the operation of a pharmacy, the following provisions shall be met:

(1) The area which is licensed as a pharmacy shall be completely separated from other business operations by partitions approved by the commission and the entire pharmacy shall be arranged or constructed to prevent the public from having unauthorized or illegal access to any drugs or medical devices;

(2) Such pharmacy shall be constructed so that it can be completely secured and locked to prevent unauthorized entry during times when the pharmacy is closed and the pharmacist is not present;

(3) The hours of operation of the pharmacy shall be conspicuously displayed at the main outside entrance of the business, store or firm;
(4) Access to the pharmacy by an authorized pharmacist shall be provided twentyfour hours daily;
(5) Exterior and interior signs exhibited by such business which use words such as ‘‘pharmacy,’’ ‘‘drug store,’’ ‘‘apothecary’’ or other words indicating that such place of business houses a pharmacy shall not be positioned in such a way, or be of such size, as to imply that the entire premises is a pharmacy;
(6) The portion of the premises occupied by a pharmacy may have a door admitting the public directly into said pharmacy from outside of the building, from a public way within a shopping mall or plaza or from a lobby which leads directly to the outside; and
(7) In a business, store or firm where there is no access providing direct access to the pharmacy in accordance with subdivision (6) of this section, the pharmacy shall be located in an area which is approved by the commission and which provides for convenience and ease of access to patients.

Sec. 20-576-17. Closing of prescription department
(a) The pharmacist manager of a pharmacy may apply to the commission for permission to close the prescription department during specified hours. Prior to granting the applicant’s request, the commission shall request that the Commissioner of Consumer Protection inspect the pharmacy for compliance with sections 20-576-17 through 20-576-19, inclusive, of the Regulations f Connecticut State Agencies. Upon confirmation from the Commissioner of Consumer Protection that the pharmacy is in compliance with those regulations, the commission shall grant such permission. A record of such application and its approval shall be maintained on file by the commission.
(b) After approval is granted pursuant to subsection (a) of this section, a pharmacy may reduce the hours the prescription department is open if:

(1) the pharmacist manager files notice of such reduction of hours with the Department of Consumer Protection at least thirty days prior to such change; and
(2) the pharmacy posts a conspicuous notice to the public at least thirty days prior to such reduction of hours.
(c) After approval is granted pursuant to subsection (a) of this section, a pharmacy may increase the hours the prescription department is open. The pharmacist manager shall file notice of such increase of hours with the Department of Consumer Protection not later than five days after such change.
(d) The prescription department of a pharmacy shall be open to provide pharmaceutical services not less than thirty-five hours per week.

Sec. 20-576-18. Procedures when prescription department closed
(a) During times that the prescription department is closed, it shall be securely locked and equipped with an alarm system. Such alarm shall be activated and operated separately from any other alarm system at the pharmacy, and shall be able to detect entrance to the prescription department at times when it is closed. Keys and access codes to the alarm system shall be controlled in such a manner so as to prevent access to the prescription department by other than authorized pharmacy personnel. Only a pharmacist shall have the authority to deactivate the alarm system.
(b) Original written prescriptions, prescription containers to be refilled or written requests for prescription refills may be left at the pharmacy at times when the prescription department is closed only if they are deposited directly into a drop box by a patient or his agent. Such box shall be a one-way container constructed in a manner which ensures that deposited items are not retrievable other than from inside the pharmacy by the pharmacist or his designee and only at times when the pharmacist is present in the pharmacy.
(c) Prescriptions which have been prepared for pickup, legend drugs, controlled substances, legend devices and products whose sale is limited

to pharmacies or shall be carried out by or under the supervision of a pharmacist, shall be stored within the prescription department or in a separate locked storage area and no sales of such products shall take place when the prescription department is closed.
(d) When the prescription department is closed, deliveries from manufacturers, wholesalers or other drug distributors of legend drugs, controlled substances, legend devices and products whose sale is limited to pharmacies or shall be carried out by or under the supervision of a pharmacist, shall be stored in a secure locked area until such time that a pharmacist is present in the pharmacy and the orders can be processed under a pharmacist's supervision.

Sec. 20-576-18a. Unscheduled closing of the prescription department or the pharmacy
(a)(1) A pharmacy that has received approval from the commission, in accordance with section 20-576-17 of the Regulations of Connecticut State Agencies, to close the prescription department during specified hours, may close the prescription department during its posted hours of operation only if the pharmacist who was scheduled to work cannot do so and a replacement pharmacist cannot reasonably be scheduled to work.
(2) If the prescription department of a pharmacy is closed under the provisions of subsection (a)(1) of this section, the pharmacy shall comply with the requirements of section 20-576-18 of the Regulations of Connecticut State Agencies and the following:
(A) The pharmacy shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs;
(B) the prescription department of a pharmacy shall not be closed more than one calendar day for any one such closing;

(C) the prescription department of a pharmacy shall not be closed more than eighteen times in a three hundred sixty-five day period or more than twice in any thirty-day period; and
(D) the pharmacist manager shall report each such closing of the prescription department to the commission not later than seventy-two hours after the closing.
(b)(1) A pharmacy that is operated in a store, firm or other business not devoted primarily to the operation of a pharmacy, in accordance with section 20-576-16 of the Regulations of Connecticut State Agencies, may close the pharmacy during its posted hours of operation only if the pharmacist who was scheduled to work cannot do so and a replacement pharmacist cannot reasonably be scheduled to work.
(2) If the pharmacy is closed under the provisions of subsection (b)(1) of this section, the pharmacy shall comply with the requirements of section 20-576-16 of the Regulations of Connecticut State Agencies and the following:
(A) The pharmacy shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs;
(B) the pharmacy shall not be closed more than one calendar day for any one such closing;
(C) the pharmacy shall not be closed more than eighteen times in a three hundred sixty-five day period or more than twice in any thirty-day period; and
(D) the pharmacist manager shall report each such closing of the pharmacy to the commission not later than seventy-two hours after the closing.
(c) A pharmacy that is not required to post its hours of operation, but closes the pharmacy during its normal hours of operation, shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.

Sec. 20-576-19. Disclosure of times of operation of prescription department

Pharmacies which have received approval from the commission to operate when the prescription department is closed shall comply with the following requirements:

(1) The hours of operation of the prescription department shall be posted at all entrances to the pharmacy in block letters at least one-half inch in height;

(2) All advertising for a specific pharmacy shall clearly state the hours of operation
of the prescription department; and

(3) All advertising containing multiple listings of specific pharmacies may contain the statement ‘‘The services of a pharmacist may not be available at all times when stores are open’’ in lieu of stating the hours of operation of each pharmacy’s prescription department.

Sec. 20-576-20. New pharmacy or relocation of existing pharmacy

(a) The pharmacist manager and applicant for a new pharmacy premise, or the pharmacist manager and licensee of a pharmacy premise which moves its location to a new premise location, or the pharmacist manager and licensee of a pharmacy which complies with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies and which moves the area, or any portion thereof, licensed as a pharmacy, to a different area within the business premises, shall appear in person at a meeting of the commission and present a completed new pharmacy premise application or a completed transfer pharmacy premise application with the proper fee and a detailed sketch drawn to scale or a blueprint of the proposed new pharmacy premise location or re-location with its dimensions. The sketch or blueprint shall show at least the following data:

(1) the square footage of the area which will be licensed as the pharmacy premise;

(2) for pharmacies which comply with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, the total square footage of the entire business entity;
(3) the square footage of the prescription department;
(4) the square footage and location of areas used as storerooms or stockrooms;
(5) the size of the prescription counter;
(6) the location of the prescription department sink and refrigerator;
(7) the location of the controlled drug safe;
(8) the location of the toilet facilities;
(9) the location and size of patient counseling areas, if any; and
(10) any other information, related to the physical plant, required by the commission in regulations adopted pursuant to section 20-576(a)(2) of the General Statutes, concerning the licensing of various classes of pharmacies.
(b) Whenever the applicant or the licensee is a person other than the pharmacist manager, the applicant or licensee may designate an individual to act as the applicant's or licensee's agent for purposes of this section.
(c) Applications to move the area, or any portion thereof, licensed as a pharmacy, to a different area within the business premises, for pharmacies which comply with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, shall require the fee for the relocation of a pharmacy.

Sec. 20-576-21. Name of pharmacist manager to be posted
The name of the pharmacist manager shall be conspicuously posted within the prescription department of a pharmacy, or in immediate proximity to it. The manager's name shall be displayed in a location and in a manner so as to be clearly and readily identifiable to patients and customers. Nothing in this section shall be construed to prevent the display of the name of the pharmacist manager at other locations within the pharmacy in addition to the above location.

Sec. 20-576-22. Report of absence of pharmacist manager
(a) If a pharmacist manager is absent from the pharmacy for any reason for more than sixteen consecutive days, the licensee shall immediately report such absence to the commission. The licensee shall provide the commission with the name of the pharmacist designated to be the acting pharmacist manager within five days following the sixteenth consecutive day of the pharmacist manager's absence.
(b) If the absence of the pharmacist manager exceeds forty-two consecutive days such person shall be deemed to have ceased to be the pharmacist manager of the pharmacy. In such case, the licensee shall, in accordance with section 20-597 of the General Statutes, immediately notify the commission and shall immediately enroll with the commission the name, address and license number of the pharmacist who is assuming management of the pharmacy. This notice of change of pharmacist manager shall be accompanied by the filing fee required by section 20-601 of the General Statutes. The pharmacist who ceases management of the pharmacy shall also immediately notify the commission of this fact.

Sec. 20-576-23. Newly designated pharmacist managers
A pharmacist who is designated to be a pharmacist manager and has not previously managed a Connecticut pharmacy, shall appear before the commission for a personal interview related to the pharmacist's knowledge and responsibilities as a pharmacist manager. Such interview shall take place before the pharmacist is authorized to manage the pharmacy except that, in cases of hardship, the pharmacist shall appear at the first commission meeting held after the date the pharmacist commences work as the pharmacist manager.

Sec. 20-576-24. Provision of prescription blanks to prescribing practitioners prohibited
No pharmacist or pharmacy shall provide any prescribing practitioner with prescription blanks bearing a pharmacist's or pharmacy's name thereon.

Sec. 20-576-25. Labeling of prescriptions
All prescriptions dispensed in pharmacies and all outpatient prescriptions dispensed in institutional pharmacies shall be labeled and such labels shall contain all information required by federal and state statutes and regulations.

Sec. 20-576-26. Prescription procedures
(a) Oral orders from a prescribing practitioner or his agent for new prescriptions or oral authorizations for prescription refills shall be communicated directly to a pharmacist. Nothing in this subsection shall be construed to prevent a pharmacy technician from obtaining prescription renewal authorizations in accordance with sections 20-576-35 and 20-576-39 of the Regulations of Connecticut State Agencies.
(b) All electronically transmitted prescriptions shall be received directly in the prescription department of a pharmacy.

Sec. 20-576-27. Substitution of drugs. Definitions
As used in sections 20-576-27 through 20-576-30, inclusive, of the Regulations of Connecticut State Agencies, ''Purchaser'' means the patient for whom the drug product is prescribed, or the patient's authorized agent, or, in the case of a minor or incompetent person, the patient's parent or guardian except that for subsection (e) of section 20-619 of the General Statutes the word ''Purchaser'' means the Payor of a prescription drug; and ''Substitution'' means the dispensing of a different drug, biological, medicinal substance, device or brand of the same in place of the drug, biological, medicinal substance, device or

brand of the same prescribed without the express permission of the prescribing practitioner, except as provided in section 20-619 of the General Statutes, or in hospitals without the express approval of the medical staff pharmacy committee.

Sec. 20-576-28. Notification to patient concerning substitution
The pharmacist, prior to any substitution of a drug product pursuant to section 20-619 of the General Statutes, shall notify the patient or the patient's agent of any such substitution. The patient may indicate that no substitution is to be made and that the drug product appearing on the prescription shall be used to the exclusion of all other drug products.

Sec. 20-576-29. Recording of drug substitution
Whenever a pharmacist substitutes a drug product pursuant to section 20-619 of the General Statutes, the pharmacist shall:
(1) Record on the face of the prescription form of a written prescription the brand name of the drug product substituted or if the drug product substituted has no brand name, the generic name and name of the manufacturer of the drug product substituted; or in the case of an oral or electronically transmitted prescription, he shall record both the brand name of the drug product ordered by the prescribing practitioner and the brand name of the drug product substituted or, if the drug product substituted has no brand name, the generic name and name of the manufacturer of the drug product substituted; and
(2) Record on the face of the prescription form the retail price (at the time of dispensing) of the drug product substituted.

Sec. 20-576-30. Disclosing the price of legend drugs
(a) As used in section 20-611 of the General Statutes, and in this section, ''prospective purchaser'' means a person for whom a prescription has been issued in compliance with section 20-614 of the General Statutes,

or the patient's authorized agent or, in the case of a minor or incompetent person, the patient's parent or guardian, and who is making an inquiry either in person or by telephone to a pharmacist for the price of said prescription.
(b) For the purpose of complying with section 20-611 of the General Statutes, and in order to have sufficient information to disclose a prescription price, a pharmacist may ask a prospective purchaser making an inquiry in person or by telephone, or any other person making such an inquiry on behalf of the prospective purchaser for the following:
(1) The name of the medication (brand or generic);
(2) Dose or strength, if applicable; and
(3) Quantity.
(c) In the event that the prospective purchaser or other person making such an inquiry on his or her behalf cannot provide any of the information listed in subsection
(b) of this section, and such information is necessary for the requested price to be determined, then the pharmacist may contact the prescribing practitioner in order to obtain the necessary information prior to disclosing the prescription price.
(d) Where substitution of a generic drug product is authorized pursuant to section 20-619 of the General Statutes, the pharmacist shall disclose the price of the substituted drug product. In so doing, however, the pharmacist shall also disclose the brand name or the generic name of said substituted drug product. The pharmacist shall also disclose the name of the drug manufacturer of the substituted drug product and otherwise comply with the provisions of section 20-619 of the General Statutes.

Sec. 20-576-31. Sale of nonlegend drugs in vending machines
No nonlegend drug shall be sold or offered or exposed for sale or dispensed by any means in any type of vending machines.

Sec. 20-576-32. Pharmacy technicians. Definitions

(a) The definitions in section 20-571 of the Connecticut General Statutes and this section shall apply to sections 20-576-33 to 20-576-39 inclusive, of the Regulations of Connecticut State Agencies. The term pharmacy technician does not include:

(1) persons working in an institutional pharmacy who are not engaged in the compounding and dispensing of medications, such as stock clerks and clerical personnel; and

(2) persons working in a pharmacy who are not engaged in the compounding and dispensing of medications, such as stock clerks, cashiers, clerical personnel and data entry personnel performing routine functions such as entering and retrieving basic information not directly related to dispensing as defined in subdivision (9) of section 20-571 of the Connecticut General Statutes, getting prescription files and other manual records from storage, generating computer records such as refill logs and inventories of dispensing for the signature or initials of the pharmacist, handling or delivering completed prescriptions to the patient or the patient's agent, and ringing up or receiving sales. Data entry of demographic and insurance information shall not be considered to be directly related to dispensing.

(b) ''Supervising pharmacist'' means a pharmacist who supervises pharmacy technicians; who is fully aware of and responsible for all activities pertinent to drug preparation, dispensing and distribution in which pharmacy technicians are engaged; and who conducts in-process and final checks on the performance of such pharmacy technicians.

(c) ''Certified pharmacy technician'' means a person who holds an active certification from the Pharmacy Technician Certification Board, or any other equivalent pharmacy technician certification approved by the Commission of Pharmacy.

(d) ''Director of pharmacy'' means the pharmacist designated by the facility administrator in a care-giving, correctional or juvenile training institution as being in direct charge of, and having overall responsibility for the operation and management of pharmacy services of that institution.

(e) ‘‘Inpatient pharmacy’’ means that area of an institutional pharmacy which is engaged in the manufacture, production, sale and distribution of drugs, devices and other pharmaceutical related materials used in the diagnosis and treatment of registered inpatients of a care-giving, correctional or juvenile training institution.
(f) ‘‘Satellite pharmacy’’ means an extension of an inpatient pharmacy which provides decentralized pharmaceutical care to persons in specific locations within a care-giving, correctional or juvenile training institution, including but not limited to specific patient care areas, nursing units, operating rooms and critical care units.
(g) ‘‘Outpatient pharmacy’’ means that area of an institutional pharmacy which provides pharmaceutical care to registered outpatients receiving treatment at a caregiving institution.

Pharmacy Technicians in Institutional Pharmacies

Sec. 20-576-33. Ratio
The ratio of pharmacy technicians to pharmacists in an institutional pharmacy shall be as follows:
(1) In an outpatient pharmacy, the ratio shall not exceed two pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed three pharmacy technicians to one supervising pharmacist;
(2) In an inpatient pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist; and
(3) In a satellite pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from

any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist.

Sec. 20-576-34. Supervision and responsibility

The pharmacist providing direct supervision of pharmacy technicians shall be responsible for their actions. Any violations relating to the dispensing of drugs resulting from the actions of pharmacy technicians, or the use of pharmacy technicians in the performance of tasks in a manner not in conformance with section 20-613 of the General Statutes or section 20-576-35 of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the supervising pharmacist in accordance with section 20-579 of the General Statutes.

Sec. 20-576-35. Limitations. Name tags

(a) Pharmacy technicians shall not:

(1) receive new prescription orders verbally from a prescribing practitioner or the practitioner's agent;

(2) consult with a patient or the patient's agent regarding medication, either before or after it has been dispensed, or regarding any medical information contained in a patient medication record system;

(3) perform any identification, evaluation, interpretation or needed clarification of a prescription;

(4) consult with the prescribing practitioner or the practitioner's agent regarding a patient or any medical information pertaining to the patient's prescription;

(5) interpret the clinical data in a patient medication record system;

(6) perform professional consultation with prescribing practitioners, nurses or other health care professionals or their authorized agents;

(7) verify a prescription prior to its release for patient use; and

(8) determine generically and therapeutically equivalent drug products to be substituted for brand name drug products in accordance with section 20-619 of the General Statutes.

(b) Nothing in this section shall be construed to limit a pharmacy technician from communicating with a prescribing practitioner or his agent to obtain an authorization for the renewal of an existing prescription for a drug other than a controlled substance that can no longer be refilled, provided the following conditions are met:
(1) the supervising pharmacist is aware that such an authorization is being requested;
(2) the refill for which the authorization is being requested is identical to the original prescription and there is no change in the prescribed drug, its strength, form, quantity, dose, route of administration or in any other element of the prescription; and
(3) all refill authorizations obtained by the pharmacy technician are reviewed by the supervising pharmacist to insure that there is no change in the prescription.
(c) Pharmacy technicians shall wear name tags or similar forms of identification that clearly identify them to the public as pharmacy technicians.

Pharmacy Technicians in Pharmacies

Sec. 20-576-36. Ratio
(a) The ratio of pharmacy technicians to pharmacists shall not exceed two pharmacy technicians to one supervising pharmacist, except that the ratio shall not exceed three pharmacy technicians to one supervising pharmacist:
(1) for intravenous admixtures and other sterile products preparation, unit dose and unit of use dispensing and bulk compounding; ; or
(2)(A) if at least one of the three pharmacy technicians is a Certified Pharmacy Technician; and
(B) the supervising pharmacist has not, pursuant to the provisions of subsection
(b) of this section, provided notice to the pharmacist manager that the pharmacist

refuses to supervise three pharmacy technicians.
(b) Except for intravenous admixtures and other sterile products preparation, unit dose and unit of use dispensing and bulk compounding, a pharmacist may refuse to supervise three pharmacy technicians at one time. The pharmacist shall put any such refusal in writing and give it to the pharmacist manager. Any refusal shall include a specific statement that the pharmacist refuses to supervise three pharmacy technicians, the names and addresses of the pharmacies involved, the date and the signature of the pharmacist. A pharmacist may rescind any refusal by providing the pharmacist manager with a signed, dated statement. A pharmacy shall keep all refusals or rescissions on file in the pharmacy or a place where they can be readily retrieved and provided to the department.

Sec. 20-576-37. Training and registration

(a) Pharmacy technicians shall complete initial training as determined by the pharmacist manager of each pharmacy. Such training shall include, but not be limited to, on-the-job and other related education and shall be commensurate with the tasks pharmacy technicians are to perform. This training shall be completed prior to the regular performance of such tasks. The pharmacy technician shall be registered with the department no more than thirty days after the start of such training.
(b) The pharmacist manager shall assure the continued competency of pharmacy technicians through continuing in-service training designed to supplement initial training.
(c) The pharmacist manager shall be responsible for maintaining a written record documenting the initial and continuing training of pharmacy technicians and it shall contain the following information:
(1) the name of the individual receiving the training;
(2) the date(s) of the training;
(3) a general description of the topics covered;
(4) the name of the person supervising the training; and
(5) the signature of the individual receiving the training and

the pharmacist manager. When a change of pharmacist manager occurs, the new manager shall review the document and sign it, indicating that he understands its contents. This record shall be readily available for inspection and may be copied by the Commissioner of Consumer Protection or his authorized agents.

Sec. 20-576-38. Supervision and responsibility

The pharmacist providing direct supervision of pharmacy technicians shall be responsible for their actions. Any violations relating to the dispensing of drugs resulting from the actions of pharmacy technicians, or the use of pharmacy technicians in the performance of tasks in a manner not in conformance with section 20-613 of the General Statutes or section 20-576-39 of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the supervising pharmacist in accordance with section 20-579 of the General Statutes.

Sec. 20-576-39. Limitations. Name tags

(a) Pharmacy technicians shall not:
(1) receive new prescription orders verbally from a prescribing practitioner or the practitioner's agent;
(2) consult with a patient or the patient's agent regarding medication, either before or after it has been dispensed, or regarding any medical information contained in a patient medication record system;
(3) perform any identification, evaluation, interpretation or needed clarification of a prescription;
(4) consult with the prescribing practitioner or the practitioner's agent regarding a patient or any medical information pertaining to the patient's prescription;
(5) interpret the clinical data in a patient medication record system;
(6) perform professional consultation with prescribing practitioners, nurses or other health care professionals or their authorized agents;

(7) verify a prescription prior to its release for patient use; or
(8) determine generically and therapeutically equivalent drug products to be substituted for brand name products in accordance with section 20-619 of the Connecticut General Statutes.
(b) Nothing in this section shall be construed to limit a pharmacy technician from communicating with a prescribing practitioner or his agent to obtain an authorization for the renewal of an existing prescription for a drug other than a controlled substance that can no longer be refilled, provided the following conditions are met:
(1) the supervising pharmacist is aware that such an authorization is being requested;
(2) the refill for which the authorization is being requested is identical to the original prescription and there is no change in the prescribed drug, its strength, form, quantity, dose, route of administration or in any other element of the prescription; and
(3) all refill authorizations obtained by the pharmacy technician are reviewed by the supervising pharmacist to insure that there is no change in the prescription.
(c) Pharmacy technicians shall wear name tags or similar forms of identification that clearly identify them to the public as either pharmacy technicians or certified pharmacy technicians.

Sec. 20-576-40. Prescriptions transmitted by facsimile machine
No pharmacist or pharmacy shall dispense legend drugs which are not controlled substances upon a prescription transmitted by means of a facsimile machine unless such prescription fully complies with sections 20-576-41 through 20-576-43, inclusive, of the Regulations of Connecticut State Agencies. For the purposes of Sections 20-576-40 through 20-576-43, inclusive, of the Regulations of Connecticut State Agencies, ‘‘facsimile machine’’ means a machine that electronically transmits facsimiles through connection with a telephone network.

Sec. 20-576-41. Requirements

Prescriptions for legend drugs which are not controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine. All such prescriptions must comply with the following in addition to any other requirement of federal or state statute or regulation:

(a) The facsimile prescription shall clearly contain the name of the pharmacy to which the facsimile is being transmitted and the name of the facility from which it is being transmitted if the prescription is written for an inpatient of a chronic or convalescent nursing home or a rest home with nursing supervision;

(b) The facsimile prescription shall clearly display a statement in substantially the following form: ‘‘This prescription is valid only if transmitted by means of a facsimile machine’’; and

(c) The facsimile document received may be maintained as the actual prescription only if the nature of the equipment and paper ensures that the document will remain non-fading and durable for the minimum amount of time required for the maintenance of prescription records under federal and state statute or regulation. If the document will not remain non-fading or durable, the document transmitted by facsimile machine shall be reduced to writing, photocopied or converted into an individual hard copy printout.

Sec. 20-576-42. Accuracy of prescriptions

If a pharmacist questions the accuracy or authenticity of a prescription order transmitted by facsimile machine, the pharmacist shall contact the prescribing practitioner for verification before dispensing the prescription.

Sec. 20-576-43. Relationship with prescribing practitioners and health care facilities

(a) No pharmacist or pharmacy shall maintain direct telephone, facsimile machine or computer lines to any health care facility or prescribing practitioner's office.

(b) No pharmacist shall enter into any agreement with a prescribing practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

Sec. 20-576-44. Computer system requirements for non-controlled legend drugs

(a) Original written prescriptions for non-controlled substances shall be received, executed and filed in accordance with sections 20-614 and 20-615 of the General Statutes. In the case of original oral prescriptions which shall be received by a pharmacist, an individual or continuous hard copy printout containing all the required information may be used to satisfy the requirement of sections 20-614 and 20-615 of the General Statutes provided that such hard copy prescriptions are maintained in numerical order.

(b) In the case of refills of prescriptions for non-controlled substances an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system must provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual display device or hard-copy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

(1) the original prescription number;

(2) date of issuance of the original prescription order by the prescribing practitioner;

(3) full name and complete address of the patient;

(4) name and address of the prescribing practitioner;

(5) the name, strength, dosage form, quantity of the substance prescribed and quantity dispensed if different from the quantity prescribed; and

(6) the total number of refills authorized by the prescribing practitioner.

Sec. 20-576-45. Refill history capability requirements
Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for all prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:
(1) the full name and address of the patient;
(2) the full name and complete address of the prescribing practitioner;
(3) the name, strength and dosage form of the substance dispensed;
(4) the date of refill;
(5) the quantity dispensed;
(6) the date on which the prescription was first dispensed;
(7) the original number assigned to said prescription;
(8) the name or initials of the dispensing pharmacists for each refill; and
(9) the total number of refills dispensed to date for that prescription order.

Sec. 20-576-46. Documentation of data requirements
Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for non-controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation a pharmacy using such a computerized system must:
(1) provide a separate hardcopy printout of non-controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 20-576-45 of the Regulations of Connecticut State Agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. The individual pharmacist must verify that the data is correct and sign the document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This

printout of the noncontrolled substance prescription order refill data for each day must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who effected such dispensing as soon as possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document; or

(2) In lieu of producing a separate hardcopy printout of non-controlled drug prescription refill data for each day, such data may be maintained in electronic form. If daily refill data is maintained electronically, the electronic data processing system must provide for ready retrieval of this information for a period of three years from the date of the last recorded dispensing. The system must provide online retrieval of prescription refill data, via visual display device, for at least six months from the date of the last recorded dispensing. The remaining refill data that must be stored for the required time period may be archived. The name or initials of the pharmacist associated with a prescription refill in the electronic system shall be construed to indicate that such pharmacist was the person responsible for dispensing that prescription. It shall be the responsibility of each dispensing pharmacist to insure that the daily refill information attributed to them is accurate.

Sec. 20-576-47. Information available upon request

Any computerized system shall have the capability of producing a printout of any refill data, for a three year period following the last date of dispensing, which the utilizing pharmacy is responsible for maintaining under Chapter 400j of the General Statutes and the regulations promulgated thereunder. The printout shall be produced within 48 hours of the request, and shall include the following:

(1) the name of the prescribing practitioner;

(2) the name of the patient;

(3) the name, dosage form, strength and quantity of the drug;

(4) the date of dispensing for each refill;

(5) the name or initials of the dispensing pharmacist; and

(6) the number of the original prescription order.
Any pharmacy utilizing a computerized system, and authorized to maintain records at a central record keeping location, must be capable of obtaining the requested printout within 48 hours.

Sec. 20-576-48. Auxiliary system provision
In the event that a pharmacy which employs such a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure to be used for documentation of refills of non-controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, and that all of the appropriate data are retained for on-line entry as soon as the computer system is available for use again. All prescriptions refilled during the down time shall be confirmed as being authorized upon the resumption of online service.

Sec. 20-576-49. When handwritten system allowed
If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, the pharmacy may use a traditional handwritten system only to satisfy the requirements of section 20- 576-48 of the Regulations of Connecticut State Agencies.

Sec. 20-576-50. Notice to commission upon commencement of use or change
Any pharmacy instituting an automated data processing system, or changing to an entirely new system, for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder shall

notify the commission at least 30 days prior to the commencement of usage of said system.

Sec. 20-576-51. Requirement of safeguards
If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, it shall:
(1) guarantee the confidentiality of the information contained in the data bank; and
(2) be capable of providing safeguards against erasures and/or unauthorized changes in data after the information has been entered and verified by the pharmacist.

Sec. 20-576-52. Reconstruction of data in case of accident
If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Sec. 20-576-53. Discontinuance of data processing system
In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:
(1) Notify the commission in writing at least 30 days prior to discontinuance of said system;

(2) Provide an up-to-date hardcopy printout of all prescriptions stored in the automated system for three years as part of the final records of that pharmacy prior to a change over to a manual system; and
(3) Make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the General Statutes.

Classes of Pharmacies

Sec. 20-576-54. Definitions
As used in sections 20-576-54 to 20-576-59, inclusive, of the Regulations of Connecticut State Agencies:
(1) ‘‘Commission’’ means the Commission of Pharmacy;
(2) ‘‘Community pharmacy’’ means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs and legend devices are stored and dispensed and from which related pharmaceutical care services are provided, primarily to non-institutionalized patients living in a community setting;
(3) ‘‘Infusion therapy pharmacy’’ means a pharmacy licensed under section 20- 594 of the Connecticut General Statutes wherein legend drugs, in the form of parenteral, enteral and infusion therapies, and legend devices are stored, dispensed or sold and from which related pharmaceutical care services are provided;
(4) ‘‘Long-term care pharmacy’’ means a pharmacy licensed under section 20- 594 of the Connecticut General Statutes wherein legend drugs and legend devices are stored and dispensed to patients or residents of licensed nursing homes, rest homes, homes for the aged, or other supervised residential facilities and from which related pharmaceutical care services are provided. This includes pharmacies located both inside and outside of such facilities but does not include those that are part of a licensed hospital;
(5) ‘‘Nuclear pharmacy’’ means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs, in the

form of radiopharmaceuticals, and legend devices are stored, prepared or dispensed and from which related radiopharmaceutical care services are provided;
(6) ‘‘Specialized drug pharmacy’’ means a pharmacy licensed under section 20- 594 of the Connecticut General Statutes wherein specialized legend drugs and legend devices are stored and dispensed and from which related pharmaceutical care services are provided including, but not limited to, those relating to the treatment of diabetes, hemophilia and infertility; and
(7) ‘‘Specialty pharmacy’’ means a pharmacy licensed under section 20-594 of the Connecticut General Statutes that does not meet any of the other definitions listed in subdivisions (2) through (6), inclusive, of this section.

Sec. 20-576-55. Classes of pharmacies
The commission shall approve a pharmacy for licensure in one or more of the following classes:
(1) Community pharmacy;
(2) Infusion therapy pharmacy;
(3) Long-term care pharmacy;
(4) Nuclear pharmacy;
(5) Specialized drug pharmacy; or
(6) Specialty pharmacy.

Sec. 20-576-56. Practice of pharmacy in classes
The commission shall approve each pharmacy to practice in one or more classes, as listed in section 20-576-55 of the Regulations of Connecticut State Agencies. No pharmacy shall conduct any substantial portion of its business in a class or classes until it is approved to do so by the commission, except that no pharmacy licensed prior to the effective date of this section shall be in violation of this section if the commission has not yet approved the pharmacy to practice in one or more classes.

Sec. 20-576-57. Designation of class
(a) The commission shall, when approving a new pharmacy license application, designate the class or classes, as listed in section 20-576-55 of the Regulations of Connecticut State Agencies, in which the pharmacy is approved for licensure. The commission has complete discretion to determine in which class or classes a pharmacy shall be licensed. In making its determination, the commission shall take into consideration the proportion of the business that the class of service represents as it relates to the total business of the pharmacy.
(b) For pharmacies licensed prior to the adoption of sections 20-576-54 to 20- 576-59, inclusive, of the Regulations of Connecticut State Agencies, the commission shall review the operation of each such pharmacy and designate the class or classes in which it is approved for licensure not later than one hundred eighty days after the effective date of section 20-576-56 of the Regulations of Connecticut State Agencies.
(c) The licensing of a pharmacy in more than one class, simultaneously, shall not result in an increase in the licensing fee.

Sec. 20-576-58. Request for reconsideration. Modifications
(a) A pharmacy may request the commission to reconsider the pharmacy's initial designation of class not later than thirty days after the notice of such classification.
(b) A pharmacy that is licensed to operate in a particular class or classes may apply to the commission for a modification of such status.
(c) No fee shall be charged for a request for reconsideration or modification.

Sec. 20-576-59. Waivers and modifications
(a) Upon written request, the commission may grant a waiver or modification of any regulation pertaining to the operation of a pharmacy

within a designated class or classes. The commission may approve such a request if it finds that:
(1) The waiver or modification will not adversely affect the health, safety or welfare of the public;
(2) The basis for the request has been clearly substantiated; and
(3) Compliance with the particular regulation is, or will be, impractical or unduly burdensome.
(b) For the purpose of requesting the waiver or modification described in subsection
(a) of this section, the pharmacist manager, as designated under the provisions of section 20-597 of the Connecticut General Statutes, shall submit a written request to the commission which documents:
(1) The specific regulation for which the waiver or modification is requested;
(2) The reason for the request;
(3) A description of any alternative measures that will be employed;
(4) Any other relevant information that will assist the commission in properly evaluating the request; and
(5) Any additional information that may be requested by the commission for purposes of evaluating the request.
(c) Upon approving or denying the request, the commission shall notify the pharmacist manager of its decision. Any approval shall state the specific regulation or regulations being waived or modified, and any contingent conditions the pharmacy is required to meet in order to obtain the waiver or modification.

Nuclear Pharmacies

Sec. 20-576-60. Definitions
As used in sections 20-576-60 to 20-576-63, inclusive, of the Regulations of Connecticut State Agencies:

(1) ‘‘Agreement state’’ means any state that has entered into an agreement with the United States Nuclear Regulatory Commission or the Atomic Energy Commission under 42 U.S.C. § 2021;
(2) ‘‘Commission’’ means the Commission of Pharmacy;
(3) ‘‘Component’’ means any active or non-active ingredient of a drug product;
(4) ‘‘Department’’ means the Department of Consumer Protection;
(5) ‘‘Nuclear pharmacist’’ or ‘‘authorized nuclear pharmacist’’ means a pharmacist who holds a current pharmacist license issued by the commission, and who meets the following standards:
(A) has a current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
(B) is identified as an authorized nuclear pharmacist on a United States Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy;
(6) ‘‘Nuclear pharmacy technician’’ means a person who:
(A) works under the direct supervision of a nuclear pharmacist;
(B) is currently registered as a pharmacy technician with the department; and
(C)(i) has successfully completed a nuclear pharmacy technician training program provided by an accredited college program or an equivalent company sponsored program approved by the commission, or
(ii) is listed as an ‘‘Authorized User of Radioactive Materials’’ on the nuclear pharmacy’s United States Nuclear Regulatory Commission or agreement state license;
(7) ‘‘Nuclear pharmacy’’ means a pharmacy that provides radiopharmaceutical services and holds a Connecticut pharmacy license;
(8) ‘‘Practice of nuclear pharmacy’’ means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs;
(9) ‘‘Quality assurance procedures’’ means all activities necessary to assure the quality of the process used to provide radiopharmaceutical

services, including authentication of the product history, internal test assessment, and maintenance of all required records;
(10) ‘‘Quality control testing’’ means the performance of appropriate chemical, biological and physical tests on compounded and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals;
(11) ‘‘Radiopharmaceutical’’ means any drug that exhibits spontaneous disintegration of unstable nuclides with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator or eluates derived therefrom, which is intended to be used in preparation of any such substance. The term ‘‘radiopharmaceutical’’ includes, but is not limited to, positron-emission tomography agents, any biological product, including, but not limited to, blood formed element, antibody or peptide, that is labeled with a radionuclide or solely intended to be labeled with a radionuclide;
(12) ‘‘Radiopharmaceutical compounding’’ means the preparation, mixing, assembling, packaging, or labeling of a radiopharmaceutical that:
(A) is the result of a practitioner’s drug prescription order in the course of professional practice;
(B) is for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing;
(C) includes use of reagent kits and radiopharmaceuticals in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
(D) is performed in accordance with the preparation instructions contained in the approved drug product labeling or other preparation directions as provided by the manufacturer;
(E) is performed in consideration of patient safety and efficacy, with validated procedures which deviate from the preparation instructions specified in the approved drug product labeling; or
(F) may utilize professional judgment, scientific knowledge, literature evidence and other reference materials according to current standards of practice as the basis for employing any deviations from the labeled preparation instructions or modifications to a radiopharmaceutical, if the

final drug product, created as a result of any such deviations or modifications, is subjected to appropriate quality control testing necessary to confirm the presence of the desired radiopharmaceutical qualities;
(13) ‘‘Radiopharmaceutical services’’ means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping, and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for the provision of pharmaceutical care; and
(14) ‘‘Reagent kit’’ means a sterile and pyrogen-free reaction vial containing nonradioactive chemicals, including, but not limited to, complexing agent (ligand), reducing agent, stabilizer, or dispersing agent.

Sec. 20-576-61. General requirements for pharmacies providing radiopharmaceutical services
(a) A license to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, a nuclear pharmacist.
(b)(1) A nuclear pharmacist shall:
(A) be responsible for all operations of the nuclear pharmacy;
(B) supervise the operation of only one nuclear pharmacy; and
(C) be present at all times that radiopharmaceutical services are being performed and at all times that the nuclear pharmacy is open for business.
(2) The license to operate a nuclear pharmacy shall be effective only if the pharmacy also holds appropriate federal and state licenses and permits to possess and distribute radioactive materials. Copies of all inspection reports prepared by any nuclear licensing agency shall be made available for department or commission inspection upon request.
(c) Nuclear pharmacies shall:

(1) have adequate space and equipment, commensurate with the scope of services required and provided;
(2) include, but are not limited to, the following areas: radiopharmaceutical preparation and dispensing area; radioactive material shipping and receiving area; radioactive material storage area and radioactive waste decay area;
(3) be secured from entry by unauthorized personnel;
(4) maintain records, including, but not limited to, the acquisition, inventory and disposition of all radiopharmaceuticals;
(5) compound and dispense radiopharmaceuticals that meet accepted standards of radiopharmaceutical quality, including, but not limited to, standards established by the United States Nuclear Regulatory Commission; and
(6) dispense radiopharmaceuticals only upon receipt of an order from a licensed practitioner or the practitioner's agent, or from a person authorized by the United States Nuclear Regulatory Commission or agreement state agency to possess such radiopharmaceuticals.
(d)(1) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission and the Regulations of Connecticut State Agencies. A nuclear pharmacy may also furnish radiopharmaceuticals and other drug products for office use to these practitioners for individual patient use.
(2) Nuclear pharmacies may redistribute United States Food and Drug Administration approved radioactive drugs if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the product packaging. Drugs dispensed in this manner are not subject to the labeling requirements of section 20-576-62(c) of the Regulations of Connecticut State Agencies.

Sec. 20-576-62. Records and labeling
(a) Upon receiving an order for a radiopharmaceutical, a nuclear pharmacy shall immediately reduce the prescription to writing or record

the order in an automated data processing system. The written or electronic record shall contain at least the following:
(1) the name of the institution and prescribing practitioner or the practitioner's agent;
(2) the requested date of dispensing and the calibration time of the radiopharmaceutical;
(3) the name of the procedure;
(4) the name of the radiopharmaceutical;
(5) the dose or quantity of the radiopharmaceutical;
(6) the prescription number assigned to the order;
(7) any specific instructions;
(8) the identity of the person who dispenses the prescription or medication order; and
(9) the patient's name if the prescription or medication order is for a therapeutic or blood-product radiopharmaceutical.
(b) The outer container (consisting of the radiation shielding) containing a radiopharmaceutical to be dispensed shall be labeled with:
(1) the name and address of the pharmacy;
(2) the name of the prescribing practitioner;
(3) the date of dispensing;
(4) the prescription number;
(5) if radioactive, the standard radiation symbol and the words ''Caution: Radioactive Material'';
(6) the name of the procedure;
(7) the radionuclide and chemical form;
(8) the amount of radioactivity and the calibration date and time;
(9) the expiration time;
(10) the appropriate dosage units;
(11) if a solid, the number of items or weight;
(12) if a gas, the number of ampoules or vials; and
(13) the patient name when intended for individual therapeutic use, or the words ''For Physician Use'' or ''For Physician Use Only.''
(c) The immediate inner container (containing the dose) of a radiopharmaceutical to be dispensed shall be labeled with:
(1) the name of the radiopharmaceutical;

(2) the serial number assigned to the prescription or medication order of the radiopharmaceutical;
(3) the standard radiation symbol; and
(4) the words ‘‘Caution: Radioactive Material.’’

Sec. 20-576-63. Minimum equipment and supplies
(a) Each nuclear pharmacy shall have the following equipment and supplies:
(1) radiation detection and measuring instruments capable of accurately measuring quantities of radioactivity and radiation;
(2) radiation shielding;
(3) appropriate supplies and equipment for performing quality assurance testing; (4) a refrigerator;
(5) materials for decontamination of accidental spills of radioactive materials; and
(6) appropriate supplies and equipment necessary for compounding and dispensing sterile parenteral radiopharmaceuticals.
(b) Each nuclear pharmacy shall have access to, or maintain on the premises, a copy of:
(1) the *United States Pharmacopoeia/National Formulary* (USP/NF), or *Remington: The Science and Practice of Pharmacy;* and
(2) the current rules and regulations of the Nuclear Regulatory Commission or agreement state.

Sterile Compounding

Sec. 20-576-64. Definitions
As used in sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies:
(1) ‘‘Sterile compounding pharmacy’’ means a pharmacy licensed pursuant to section 20-594 of the general statutes that dispenses sterile

pharmaceutical products, but does not include a pharmacy that is part of a licensed hospital; and
(2) ‘‘Sterile pharmaceutical’’ means any dosage form of a drug, including, but not limited to, parenterals (e.g., injectables, surgical irrigants, and ophthalmics), devoid of viable microorganisms.

Sec. 20-576-65. Purpose
The purpose of sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies is to ensure positive patient outcomes through the provision of standards for (1) pharmacist care; (2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies licensed pursuant to section 20-594 of the general statutes; and (3) product quality and characteristics.

Sec. 20-576-66. Standards
(a) Sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies shall apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor’s office).
(b) A sterile compounding pharmacy shall comply with sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies, and the current United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations. The United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations may be obtained via the Internet at the following location:
http://www.usp.org/products/797Guidebook/.
(c) A sterile compounding pharmacy may provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and

immediate supervision, except that the quantity of such compounded products shall be limited to a two-week supply.

Sec. 20-576-67. Policy and procedure manual

A sterile compounding pharmacy shall prepare and maintain a policy and procedure manual for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceuticals. The policy and procedure manual shall be in compliance with the United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Sec. 20-576-68. Hours

A sterile compounding pharmacy shall be open at least thirty-five (35) hours per week unless granted a waiver by the Commission of Pharmacy pursuant to section 20-576-59 of the Regulations of Connecticut State Agencies.

(Adopted effective July 12, 2011)

Regulations Concerning Non-Sterile Compounding

Section 20-576-69. Definitions.

As used in sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Commission" means Commission of Pharmacy;

(2) "Non-sterile compounding pharmacy" means a pharmacy licensed pursuant to section 20-594 of the General Statutes that dispenses non-sterile compounded pharmaceutical products; but does not include a pharmacy that is part of licensed hospital; and

(3) "Non-sterile compounded pharmaceutical product" means a drug dosage form, a dietary supplement or a finished device made from the preparation of one or more substances.

Section 20-576-70. Purpose.

The purpose of sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies is to ensure positive patient outcomes through the provision of standards for (1) pharmacist care; (2) the preparation, labeling, and distribution of non-sterile compounded pharmaceutical products by pharmacies licensed pursuant to section 20-594 of the General Statutes; and (3) product quality and characteristics.

Section 20-576-71. Standards.

(a) Sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies shall apply to all non-sterile compounded pharmaceutical products, notwithstanding the location of the patient for example: Home, hospital, nursing home, hospice, or doctor's office.

(b) A non-sterile compounding pharmacy shall comply with sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies, and the current United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations. The United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations may be obtained at http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html.

(c) A non-sterile compounding pharmacy may provide non-sterile compounded pharmaceutical products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision, except that the quantity shall be limited to a thirty day supply.

Section 20-576-72. Policy and Procedure Manual.

A non-sterile compounding pharmacy shall prepare and maintain a policy and procedure manual for the compounding, dispensing, delivery,

administration, storage, and use of non-sterile compounded pharmaceutical products. The policy and procedure manual shall be in compliance with the United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations.

Section 20-576-73. Hours.

A non-sterile compounding pharmacy shall be open thirty-five hours per week unless granted a waiver by the commission pursuant to section 20-576-59 of the Regulations of Connecticut State Agencies.

Electronic Data Intermediaries

Sec. 20-614-1. Definitions

(1) ‘‘Commission’’ means the Commission of Pharmacy;
(2) ‘‘Department’’ means the Department of Consumer Protection; and
(3) ‘‘Electronic data intermediary’’ means ‘‘electronic data intermediary’’ as defined by section 20-614 of the Connecticut General Statutes.

Sec. 20-614-2. Application for approval

(a) Each electronic data intermediary shall file an application for approval of its system with the commission on a form prescribed by the department. The form shall include but not be limited to the following information:
(1) the name and address of the applicant; and
(2) the business status of the applicant (sole proprietorship, partnership, corporation, limited liability company, etc.); and
(3) a description of the type of electronic data intermediary system to be used that describes:
(A) the security safeguards;
(B) the retention and retrieval capabilities of the system; and
(C) the safeguards designed to protect patient confidentiality.

(b) The commission, in its discretion, may require the applicant to provide a protocol that describes in detail the applicant's intended plan of operation. No applicant may change its protocol without review by the commission and approval by the department.
(c) The department shall approve any application filed by electronic data intermediaries that the commission has reviewed and accepted as being in compliance with the provisions of sections 20-614-3 though 20-614-6, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 20-614-3. Procedures for transmission of prescription information

Each electronic data intermediary system shall have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information in accordance with current electronic transmission standards. Each system established by an electronic data intermediary shall include procedures to:
(1) select and execute security measures;
(2) establish physical safeguards to protect computer systems and other pertinent equipment from intrusion;
(3) protect and control confidential patient information;
(4) prevent unauthorized access to the data when transmitted over communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives, CD media or any other means of data
storage; and
(5) authenticate the sender's authority and credentials to transmit a prescription.

Sec. 20-614-4. Retention of information

Each system established by an electronic data intermediary shall provide an audit trail of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including the authorized delegation of a transmission. Such

audit trail shall be maintained for three years from the date of last activity and made available for review by investigators of the department.

Sec. 20-614-5. Mechanisms for confidentiality of prescription information

Each electronic data intermediary system shall maintain the confidentiality of patient information in accordance with any applicable federal or state statute or regulation, including but not limited to 45 C.F.R. Part 160 and Part 164. Each electronic data intermediary system shall establish mechanisms in accordance with current electronic transmission standards that contain:

(1) encryption technology to maintain security;
(2) controls on employee access;
(3) protections against unauthorized access by outsiders;
(4) procedures for the permanent deletion of patient information.

Sec. 20-614-6. Patient's access to pharmacies

No electronic data intermediary shall restrict a patient's access to the patient's pharmacy of choice.

Sec. 20-631-1. Competency requirements

To qualify for participation in a collaborative drug therapy management agreement, a pharmacist shall be licensed in this state and shall meet at least one of the following qualifications:

(1) Bachelor of Science degree in pharmacy with 10 years of clinical experience, or a Pharm. D. degree;

(2) Certification by the Board of Pharmaceutical Specialties;

(3) Certification by the Commission for Certification in Geriatric Pharmacy;

(4) A credential in disease state management from the National

Institute for Standards in Pharmacist Credentialing;

(5) Pharmacy residency accredited by the American Society of Health-System Pharmacists; or

(6) Completion of a disease state management certification program approved by the Accreditation Council for Pharmacy Education.

Sec. 20-631-2. Content of a collaborative drug therapy management agreement

A collaborative drug therapy management agreement shall include:

(1) The types of prescriptive authority decisions the pharmacist may make (e.g., initiation, continuation or modification);

(2) Patients who are eligible for treatment;

(3) The types of diseases, drugs, or drug categories involved (there are no limitations on disease states or conditions);

(4) The procedures, decision criteria, plans, or guidelines the pharmacist is to follow when making therapeutic decisions, particularly when initiating or modifying drug therapy;

(5) Required training;

(6) A plan for periodic review, feedback and quality assurance; and

(7) Procedures for documenting prescribing decisions.

Sec. 20-631-3. Content of patient protocol

A written protocol for a specific patient established pursuant to a collaborative drug therapy management agreement shall include, but need not be limited to, the following:

(1) The specific drug or drugs to be managed by the pharmacist;

(2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;

(3) The conditions and events that the pharmacist is required to report to the physician;
(4) The laboratory tests that may be ordered by the pharmacist; and
(5) The drugs that may be administered by the pharmacist.

Administration of Vaccine by Pharmacists

Sec. 20-633-1. Definitions
As used in sections 20-633-1 to 20-633-5, inclusive, of the Regulations of Connecticut State Agencies:
(1) ‘‘Administer’’ means ‘‘administer’’ as defined in section 20-571 of the Connecticut General Statutes; and
(2) ‘‘Health care provider’’ means a licensed practitioner authorized to order or prescribe legend drugs.

Sec. 20-633-2. General requirements
A licensed pharmacist may administer a vaccine listed in section 20-633(a) of the Connecticut General Statutes to an adult if:
(a) The administration of the vaccine is conducted pursuant to an order of a licensed health care provider; and
(b) the pharmacist has successfully completed an immunization training program that complies with the requirements of section 20-633-3 and section 20-633-4 of the Regulations of Connecticut State Agencies.

Sec. 20-633-3. Qualifying training programs
Each immunization training program shall be accredited by the National Centers for Disease Control Prevention or the Accreditation Council for Pharmacy Education.

Sec. 20-633-4. Requirements of training programs
(a) The course of study for the immunization training program shall include current guidelines and recommendations of the National Centers for Disease Control Prevention for adult patients or be accredited by the Accreditation Council for Pharmacy Education.
(b) The course of study shall include, but not be limited to, the following:
(1) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
(2) subcutaneous and intramuscular injections;
(3) immunization screening questions, informed consent forms, recordkeeping, registries and reporting mechanisms;
(4) vaccine storage;
(5) biohazard waste disposal and sterile techniques;
(6) establishing protocols;
(7) immunization coalitions and other community resources available;
(8) mechanisms for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);
(9) reimbursement procedures and vaccine coverage by federal, state and local entities;
(10) administration techniques;
(11) current cardiopulmonary resuscitation certification; and
(12) annual continuing education in immunizations.

Sec. 20-633-5. Systems for control and reporting
(a) A health care provider shall establish a protocol with a pharmacist or a pharmacy. The protocol shall establish which vaccines may be administered, recordkeeping and reporting requirements, and emergency procedures.
(b) Written protocols shall include, but not be limited to, the following:
(1) The name of the health care provider authorized to order or prescribe drugs;
(2) the name of the pharmacist or pharmacists authorized to administer the vaccine;

(3) the types of vaccines that the pharmacist or pharmacists are authorized to administer;
(4) the procedures, decision criteria or plan the pharmacist or pharmacists shall follow when exercising the administration authority, including when to refer the patient to the physician;
(5) the procedures for emergency situations; and
(6) record keeping and documentation procedures, which shall include a requirement that the name of the pharmacist who administered the vaccine be recorded.

Quality Assurance Programs for Pharmacies
Sec. 20-635-1. Definitions
As used in section 20-635-1 to section 20-635-6, inclusive, of the Regulations of Connecticut State Agencies:
(1) ‘‘Department’’ means the Department of Consumer Protection;
(2) ‘‘Pharmacy personnel’’ means pharmacist, pharmacy intern, pharmacy technician, and pharmacy support personnel; and
(3) ‘‘Prescription error’’ means ‘‘prescription error’’ as defined by section 20-635 of the Connecticut General Statutes.

Sec. 20-635-2. Quality assurance program
(a) Each pharmacy shall implement a quality assurance program to detect, identify and prevent prescription errors. The quality assurance program shall document and assess prescription errors to determine the cause and an appropriate response.
(b) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.
(c) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors.

Sec. 20-635-3. Notification to patient and prescribing practitioner
(a) Unless informed of a prescription error by the prescribing practitioner or the patient, a pharmacist who has discovered or been informed of a prescription error, shall immediately notify the patient and the prescribing practitioner that a prescription error has occurred. If the patient is deceased or unable to fully comprehend the notification of the error, the pharmacist shall notify the patient's caregiver or appropriate family member.
(b) The pharmacist shall communicate to the patient and prescribing practitioner the methods for correcting the error and reducing the negative impact of the error on the patient.

Sec. 20-635-4. Review of prescription errors
(a) Each pharmacy shall perform a quality assurance review for each prescription error. This review shall commence as soon as is reasonably possible, but no later than two business days from the date the prescription error is discovered.
(b) Each pharmacy shall create a record of every quality assurance review. This record shall contain at least the following:
(1) the date or dates of the quality assurance review and the names and titles of the persons performing the review;
(2) the pertinent data and other information relating to the prescription error reviewed;
(3) documentation of the patient and prescribing practitioner contact required by section 20-635-3 of the Regulations of Connecticut State Agencies;
(4) the findings and determinations generated by the quality assurance review; and
(5) recommended changes to pharmacy policy, procedure, systems, or processes, if any.

Sec. 20-635-5. Records
(a) Each pharmacy shall maintain a written copy of the quality assurance program on the pharmacy premises. This copy shall be readily available to all pharmacy personnel and the department.
(b) Each pharmacy shall maintain a record of the quality assurance review for all prescription errors for a minimum of three years. These records shall be maintained in an orderly manner and filed by date. These records, which may be stored outside of the pharmacy, shall be made available for inspection by the department within forty-eight (48) hours of request.

Sec. 20-635-6. Notice to pharmacy personnel
(a) A pharmacy shall make available a copy of its quality assurance program to each pharmacist employed at the pharmacy.
(b) Each pharmacy shall notify all pharmacy personnel that the discovery or reporting of a prescription error shall be relayed immediately to a pharmacist on duty.
(c) Each pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

DESCRIPTION OF ORGANIZATION Part I
Definitions

Sec. 21a-1-1. Definitions

(a) The term ‘‘Commissioner,’’ as used in these regulations, means the commis- sioner of consumer protection.

(b) ‘‘Department’’ means the department of consumer protection.

(c) ‘‘Division chief’’ means any departmental employee or employees designated by the commissioner as the head of a particular division of the department.

(d) ‘‘License’’ includes the whole or part of any permit, certification, approval, registration, charter, or similar form of permission required by law to be issued by the department.

(e) ‘‘Regulation’’ means any departmental rule of general applicability that imple- ments, interprets, or prescribes law or policy, or describes the organization, proce- dure, or practice requirements of the department. The term does not include

(i) rules governing the internal management of the department and not affecting private rights or procedures available to the public, and

(ii) declaratory rulings issued pursuant to section 21a-1-10 of these regulations.

Part II
Structure and Responsibilities

Sec. 21a-1-2. Creation and authority

The department was established as a separate agency of the state government by public Act 412 of the 1959 General Assembly (Section 21a-1 of the Connecticut General Statutes). The department’s powers are derived from the various statutes which it is charged with administering. These statutes deal generally with food and drugs, pharmacies, weights and measures, and consumer deception.

Sec. 21a-1-3. Commissioner of consumer protection

The commissioner has the overall responsibility for the operation of the depart- ment. The deputy commissioner assists the commissioner and is the acting commis- sioner in his absence. In discharging his responsibilities, the commissioner may delegate certain of his functions to a division of the department, to an individual division chief, to an independent hearing examiner, or to an employee of the department.

Sec. 21a-1-4. Official address

The principal office of the department is located at Hartford, Connecticut. All communications should be addressed to the Department of Consumer Protection, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106, unless otherwise specifically directed.

Sec. 21a-1-5. General duties and responsibilities

The department is charged with enforcing legislation intended to protect consum- ers from injury by product use or merchandising deceit. In connection with this Department of Consumer Protection responsibility, the department administers a statewide consumer education program designed to alert the public of potentially hazardous products and deceptive trade practices.

Sec. 21a-1-6. Organizational structure and division of responsibilities

The department is composed of the following divisions, the principal duties of which are as follows:

(a) **Administration division.** This division is responsible for all functions relating to budget and fiscal services, payroll and personnel procedures, the ordering of supplies and related support activities.

(b) **Food division — general section.** This division is responsible for safeguarding consumers from injury, filth, and deception pertaining to the manufacture, storage and sale of foods in intrastate commerce. The laws administered by this division include the Pure Food and Drug statutes, the Unit Pricing Act, and certain provisions of the Uniform Food, Drug, and Cosmetic Act.

(c) **Drug, device and cosmetic division.** This division is responsible for insuring that drug products, medical devices, cosmetic products, and children's toys are accurately labeled and suitable for the purposes intended. The laws administered by this division include the Child Protection Act, the Dependency-Producing Drug statutes, and certain provisions of the Uniform Food, Drug and Cosmetics Act.

(d) **Weights and measures division.** This division is responsible for safeguarding the public in all matters involving commercial determinations of quantity. The provisions contained in Title 43 of the General Statutes are administered by this division.

(e) **Consumer frauds division.** This division processes and investigates consumer complaints regarding deceptive trade practices and untrue or misleading advertise- ments. It also licenses or otherwise regulates itinerant vendors, going out of business sales, and the sale of cigarettes. The Unfair Sales Practices Act and the Uniform Deceptive Trade Practices Act are administered by this division.

(f) **Consumer education division.** This division is responsible for keeping the public abreast of the activities of the department and

informing consumers of potentially hazardous products and deceptive trade practices. All written information is disseminated in both the English and Spanish languages, whenever practicable.

RULES OF PRACTICE Part III
Dealings with the General Public

Sec. 21a-1-7. Departmental policy on public information

(a) The policy of the department is to make available for public inspection all files, records, documents and other materials within its possession, unless prohibited by law. A compilation of all regulations, policy statements, final orders, decisions, and official opinions is available for public inspection at the office of the commis- sioner.

(b) Departmental employees are not permitted to release information about a particular individual or firm unless a complaint has been issued or an order has been secured against such individual or firm. Information may be released concerning

(i) the allegations contained in a complaint issued pursuant to Section 21a-1-21 of these regulations;

(ii) a final decision or order secured by the department in a contested case;

(iii) the contents of a complaint issued by a consumer affairs agency in another state or by the Federal Trade Commission; and

(iv) an order secured against a particular individual or firm by any state or federal court, by a consumer affairs agency in another state, by the Federal Trade Commission, or by any other federal agency.

Personal Data Systems Sec. 21a-1-7a (a). Authority

These regulations are promulgated pursuant to the provisions of section 4-196 of the General Statutes.

Sec. 21a-1-7a (b). Definitions

(a) The terms set forth in section 4-190 of the General Statutes, as amended, shall have the same meanings in this regulation as therein defined.

(b) ‘‘Department’’ means the Department of Consumer Protection, 165 Capitol Avenue, Hartford, Connecticut 06106, and includes all boards and commissions within said department as defined by section 21a-6 of the General Statutes.

Sec. 21a-1-7a (c). Categories

(a) **Licensee files.** The licensee personal data system consists of financial, employment, criminal history and other personal background data and information secured and maintained by the department for individuals licensed by the department.

(b) **Complaint files.** The complaint file personal data system consists of corre- spondence files relating to complaints or inquiries received by the department concerning the conduct or method of doing business of individuals, companies or other organizations regulated or licensed by the department. Active complaint files are maintained separately from the file containing the licensee licensure data; closed out or resolved complaint files are subsequently consolidated, as appropriate, into the licensee personal data system.

(c) **Personnel files.** The personnel files personal data system consists of payroll and personnel data. Said data consists of payroll data, personnel status, attendance records, addresses, telephone numbers, educational data, financial data, medical data and employment data.

(d) **Agency financial files.** The agency financial file personal data system con- sists of payments to vendors, travel records of agency employees, expense statements of agency employees, mileage reports of agency employees and all other routine financial data.

Sec. 21a-1-7a (d). Nature and purpose of personal data systems

(a) The nature and purpose of the licensee personal data system is to maintain an accurate and current information base upon which to determine and ascertain that all licensees licensed or to be licensed by the department are qualified, fit and suitable to be licensed for the particular activity authorized by the department.

(b) The nature and purpose of the complaint file personal data system is to receive, maintain, investigate and act upon complaints concerning the

conduct or method of doing business of all persons regulated by the department.

(c) The nature and purpose of the personnel file personal data system is to maintain an accurate and current information base needed to fulfill the department's responsibility in the proper administration of said department. Said information is used to substantiate payrolls; to substantiate leave balances and/or retirement; to substantiate health/life/disability insurance, social security and retirement benefits; to substantiate affirmative action policies; and other areas as directed by state statutes and regulations.

(d) The nature and purpose of the agency financial file personal data system is to maintain an accurate and current information base needed to fulfill the department's responsibility in the proper fiscal administration of the department.

Sec. 21a-1-7a (e). Procedures regarding the maintenance of personal data

(a) All employees who function as custodians of the department's personal data systems or who have access thereto shall be given a copy of the provisions of Chapters 3 and 55 of the General Statutes together with a copy of these regulations.

(b) All such departmental employees shall take reasonable precautions to protect personal data under their supervision from the danger of fire, theft, flood, natural disaster and other physical threats.

(c) Except for departmental employees a record shall be maintained of each person, individual, agency or organization who has obtained access

to or to whom disclosure has been made of personal data, pursuant to Chapter fifty-five of the Connecticut General Statutes, together with a reason for each disclosure or access. Upon written request this record shall be made available to the individual who is the subject of the personal data disclosure.

(d) The department shall maintain only such personal data as is relevant and necessary in order to accomplish the statutory authorization to maintain such infor- mation.

(e) Upon receipt of a written request, the department shall, within four business days thereafter, mail or deliver to individuals a written response to the question of whether the department maintains personal data concerning such individual.

(f) Except where precluded by law, the department shall disclose to any person upon request, all personal data, concerning him which is maintained by the depart- ment. Such disclosure shall be conducted so as not to disclose any personal data concerning persons other than the individual requesting such information.

(g) If the department refuses to disclose personal medical data to a person and the non-disclosure is not mandated by law, the department shall, at the written request of such person, permit a qualified medical doctor to review the personal medical data contained in the person's record to determine if the personal medical data should be disclosed. If disclosure is recommended by the person's medical doctor, the department shall disclose the personal medical data to such person; if non-disclosure is recommended by such person's medical doctor, the department shall not disclose the personal medical data and shall inform such person of the judicial relief provided under section 4-195 of the General Statutes.

Sec. 21a-1-7a (f). Procedures for contesting content

The following procedure shall be used in order to provide an opportunity to contest the accuracy, completeness or relevancy of personal data:

(a) Any individual may file a request with this department for correction of personal data pertaining to him.

(b) Within thirty days of receipt of such request, the department shall notify such individual that it will make the correction or, if the correction is not to be made as submitted, shall state the reason for its denial of such request.

(c) Following such denial by the department, the individual requesting such correction shall be permitted to add a statement to his personal data record setting forth what he believes to be an accurate or complete version of the personal data in question. Such statements shall become a permanent part of the department's personal data system and shall be disclosed to any individual, agency or organization to which the disputed personal data is disclosed.

Dealings with the General Public

Sec. 21a-1-8. Departmental proceedings open to the public

(a) All rule-making and licensing proceedings shall be open to the public. Prior to any proceedings to adopt or promulgate new rules and regulations, a public hearing will be held and the time and place of such

hearing will be duly publicized. A special effort will be made to contact any person or firm whose rights or duties would be most directly affected by the proposed regulations.

(b) All investigational proceedings prior to the issuance of a formal complaint by the department are not open to the public. The contents of investigational files and inspection reports shall remain confidential unless made a part of the record in an adjudicative proceeding or unless provided otherwise by statute.

(c) The issuance of a complaint by the department, as provided in section 21a- 1-21 of these regulations, is a matter of public record. All adjudicative proceedings after the issuance of a complaint are open to the public.

Sec. 21a-1-9. Consumer complaints and requests for information

(a) Consumer complaints regarding allegedly unfair trade practices or regarding allegedly false or misleading advertisements should be addressed to the Department of Consumer Protection, Consumer Frauds Division, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106.

(b) Consumer complaints concerning foods, drugs, pharmacies, or weights and measures, should be addressed to the Food Division, the Drug Division, the Pharmacy Division, or the Weights and Measures Division, respectively. All of these divisions are located in the State Office Building, 165 Capitol Avenue, Hartford, Connecti- cut 06106.

(c) Requests for information should be directed preferably to the appropriate division in possession of the information. Requests for

information about the depart- ment generally should be addressed to the Department of Consumer Protection, Consumer Education Division, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106. A nominal fee may be charged for copies of certain statutes and regulations.

Sec. 21a-1-10. Requests for declaratory rulings

(a) Any interested person may present a request for a declaratory ruling from the department regarding the applicability of any statute or regulation administered by the department to any practice described in such request. The request must be in writing and submitted by mail or hand-delivered to the office of the commissioner. The facts relating to such request should be in complete and detailed form; the department may demand such additional facts as may be relevant to the requested ruling. The ruling will be made by the department within a reasonable time after the submission of the request and a copy of such ruling will be mailed to the petitioner. In its discretion, the department may hold an informal conference for factfinding purposes relating to such request.

(b) Within 30 days following the receipt of a petition, the commissioner shall determine whether to deny or to grant it. If he denies the petition, he shall notify the petitioner of his decision in writing. If the petition is granted, the commissioner shall make a ruling and send it to the petitioner. Any such ruling shall have the same effect as a final decision in a contested case.

Part IV
Rule Making Functions

Sec. 21a-1-11. Authority to promulgate regulations

Statutory authority to adopt, amend, or repeal regulations is derived from 4 the various laws administered by the department. These laws include, but are not limited to, the following sections of the General Statutes: 21a-43, 21a-156, 21a-336, and 43-3.

Sec. 21a-1-12. Petition for the promulgation, amendment or repeal of a regu- lation

Petitions by interested persons requesting the promulgation, amendment, or repeal of a regulation of the department must be submitted to the department in writing. Such petition shall contain an explanation of the person's interest in the particular subject matter and the reasons for the proposal. Within thirty days of the receipt of the petition, the department will either deny the petition in writing, stating its reasons for the denial, or initiate proceedings to effect the requested action.

Sec. 21a-1-13. Procedure for the issuance, amendment or repeal of a regulation

(a) Proceedings for the issuance, amendment, or repeal of a regulation, including proceedings for the exemption of certain products or classes of products from statutory requirements, may be commenced by the department on its own initiative or pursuant to a petition submitted by an interested person.

(b) Notice of the proposed issuance, amendment, or repeal of a regulation will appear in the Connecticut Law Journal at least twenty days prior to the proposed action. The notice will contain:

(i) a statement of the purpose of the proposed action;
(ii) a statement of the time, date and place of the public hearing or other opportunity for the presentation of views;
(iii) reference to the statutory authority under which the department is acting; and
(iv) a statement of the terms or substance of the intended action.
(c) Adequate publicity will be provided by the department to assure that all interested parties have notice of the time, date and place of the public hearing or other opportunity for the presentation of views. The purpose is to afford an opportunity for all interested parties to participate in the proceedings through the submission of written or oral data, views, arguments, or suggestions.

(d) After any necessary revisions have been made, the proposed regulations will be forwarded to the attorney general and to the legislative review committee of the General Assembly for approval, as required under sections 4-169 and 4-170 of the General Statutes.

(e) The new regulation or the amendment or repeal of an existing regulation will become final following approval by the attorney general and the legislative review committee and certification thereof to the secretary of state.

(f) When the department finds that an imminent peril to the public health, safety, or welfare so requires, it may adopt emergency regulations, as provided in section 4-168 (b) of the General Statutes.

Part V Licensing Function

Sec. 21a-1-14. Authority to issue and revoke licenses

Statutory authority to issue, renew, suspend, or revoke licenses, permits, or regis- trations is derived from various laws administered by the department. These laws include, but are not limited to, the following sections of the General Statutes: 21a- 18, 21a-35, 21a-53, 21a-152, 21-28, and 43-10.

Sec. 21a-1-15. Form, contents and filing of applications

All applications shall include
(i) the name and address of the applicant;
(ii) the name and address of the applicant's counsel, agent, or other representative, if any;
(iii) the purpose for which the application is made;
(iv) any statutes and rules which support the application;
(v) a complete and concise description of the activities, facilities, projects, or other actions for which the license, permit or registration is sought;
(vi) any other information which the department may require; and
(vii) any additional information which the applicant considers relevant.
Applications shall be addressed to the appropriate division of the department and shall be sent by mail or hand-delivered during normal business hours.

Sec. 21a-1-16. Revocation or suspension of licenses

(a) No license, permit, or registration may be suspended or revoked without a prior notice to the licensee detailing the reasons for the proposed suspension or revocation. The licensee shall further be afforded an opportunity to appear for a hearing before the commissioner to show cause why the proposed suspension or revocation is not warranted. Any such hearing shall be conducted as a contested case, as defined in section 21a-1-20 of these regulations.

(b) If the commissioner finds that the public health, safety, or welfare imperatively requires emergency action, a license, permit, or registration may be suspended or revoked without the necessity of a prior hearing. The notice to the licensee shall detail the reasons for the emergency action and shall afford the licensee an opportunity for a subsequent hearing to contest the suspension or revocation.

(c) Any person aggrieved by the decision of the commissioner or his representative in connection with any licensing proceedings may seek review of the decision by initiating an appropriate action in the Superior Court for the Judicial District of Hartford.

Part VI Investigations and Inspections

Sec. 21a-1-17. Authority to conduct investigations and inspections

Statutory authority to conduct investigations and inspections is derived from various laws administered by the department. Section 21a-11 of the General Statutes confers upon the commissioner of consumer protection and his agents the general authority to enter upon private premises during regular business hours for the purposes of conducting necessary

investigations and purchasing samples for analysis. Laws conferring specific authority to conduct investigations and inspections include, but are not limited to, the following sections of the General Statutes: 21a-40, 21a- 70, 21a-116, 21a-118, 21a-235, 21a-261, 21a-265, 21a-343, 42-112, and 43-3.

Sec. 21a-1-18. Seizures and condemnations

(a) Statutory authority to seize and/or condemn products which are allegedly adulterated or misbranded is derived from sections 21a-39 and 21a-96 of the Gen- eral Statutes.

(b) Statutory authority to detain or embargo in intrastate commerce household products which are allegedly banned or misbranded hazardous substances is derived from section 21a-340 of the General Statutes.

(c) Statutory authority to seize and destroy any incorrect weight, measure, or weighing and measuring device is derived from section 43-3 of the General Statutes. (d) Whenever an inspector or an investigator obtains a sample of any product for further analysis, he shall pay or offer to pay the owner, operator, or agent in charge for such sample and give a receipt describing the sample obtained. Laws conferring the specific authority to obtain samples include, but are not limited to, the following sections of the General Statutes: 21a-39, 21a-116, and 21a-343.

Secs. 21a-1-19—21a-1-27.

Repealed, June 27, 1985.

Part VII Hearings Procedures

Sec. 21a-1-19a. Applicability

(a) These hearing procedures shall apply to all Compliance Meetings and Con- tested Cases held by the Department of Consumer Protection.

(b) As used herein, ‘‘agency’’ means the Department of Consumer Protection.

(c) As used herein, ‘‘certificate’’ includes the whole or part of any Department of Consumer Protection permit which the Department issues under authority of the General Statutes and which (1) authorizes practice of the profession by certified persons but does not prohibit the practice of the profession by others, not certified, (2) prohibits a person from falsely representing that he is certified to practice the profession unless the person holds a certificate issued by the Department, and (3) requires as a condition of certification that a person submit specified credentials to the Department which attest to qualifications to practice the profession.

(d) As used herein, ‘‘License’’ includes the whole or part of any Department of Consumer Protection permit, approval, or similar form of permission which the Department issues under authority of the General Statutes and which requires: (1) practice of the profession by licensed persons only, (2) demonstration of competence to practice by examination or other means and meeting of certain minimum standards, and (3) enforcement of standards by the Department.

(e) As used here in, ‘‘registration’’includes the whole or part of any permit which the Department issues under authority of the General Statutes and which: (1) requires persons to place their names on a list

maintained by the Department before they can engage in the practice of a specified profession or occupation, (2) does not require a person to demonstrate competence by examination or other means, and (3) may be revoked or suspended by the Department for cause.

Sec. 21a-1-20a. Opportunity to show compliance

(a) No revocation, suspension, annulment or with drawal of any certificate, license or registration is lawful unless prior to the institution of agency proceedings, the agency gave notice by mail to the holder thereof of facts or conduct which warrant the intended action, and the holder thereof was given the opportunity to show compliance with all lawful requirements for the retention of the certificate, license or registration.

(b) The notice of the opportunity to show compliance shall contain:
(1) A statement of the time, date and method for responding to the agency;
(2) A reference to the statute(s) or regulation(s) allegedly violated;
(3) A clear and concise factual statement sufficient to inform each respondent

of the acts or practices alleged to be in violation of the law. This requirement may be met by including a copy of the investigation report with the notice; and

(4) A statement that each respondent may be represented by counsel.

(c) The agency may request the respondent to attend a compliance conference as the method for responding to the agency. Compliance

conferences shall be informal and the rules of evidence shall not apply. Compliance conferences may be recorded but need not be transcribed.

(d) The Commissioner may, in his or her discretion, designate a person to preside at such compliance conference. After said compliance conference, the designated presiding officer shall report in writing his or her recommendations to the Commis- sioner.

Sec. 21a-1-21a. Summary suspension procedures

If the agency finds that public health, safety or welfare imperatively requires emergency action, and incorporates a finding to that effect in its order, summary suspension of a certificate, license, or registration may be ordered pending proceed- ings for revocation or other action. These proceedings shall be promptly instituted and determined.

Sec. 21a-1-22a. Contested cases

(a) A ‘‘Contested Case’’ means a proceeding, including but not restricted to rate- making, price fixing, and licensing, in which the legal rights, duties or privileges of a party are required by statute to be determined by an agency after an opportunity for hearing or in which a hearing is in fact held, but does not include hearings referred to in Section 4-168 of the Connecticut General Statutes.

(b) When an agency has reason to believe there has been a violation of the statute(s) or regulation(s) it administers, it shall issue a complaint by certified mail to the respondent.

(c) The notice in contested cases shall contain:

(1) A statement of the statutory authority and jurisdiction for instituting the pro- ceedings;

(2) A reference to the specific statutory section(s) or regulations alleged to be violated;

(3) A short and plain statement of the matters asserted sufficient to inform each respondent of the acts or practices alleged to be in violation of the law;

(4) Notice of the time, date, place and nature of the hearing; and

(5) A statement that each respondent may, if he desires, be represented by an attorney.

(d) If a respondent can reasonably show a need for additional time to prepare a defense to the alleged statutory violations, an extension of time may be granted by moving the scheduled hearing to a later date. The granting of such a request is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(e) If a respondent can reasonably show that the complaint is unclear or ambiguous as to the nature of the acts in violation of the law, he may file with the agency a written motion for a more detailed statement of the nature of the charges against him. The granting or denial of such a motion is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(f) Appearances, Admissionsand Denials, Answers, Motions and any other pleading which a Respondent wishes considered by the

Commissioner prior to the conven- ing of a contested case proceeding may be filed up to seven days prior to the hearing date. Failure to file any pleadings may allow the agency to proceed with the matter. However, if a Respondent can reasonably show a need for additional time to submit documentation, an extension of time may be granted. The granting of such a request is within the complete discretion of the Commissioner or such presiding officer as has been designated by the Commissioner.

Sec. 21a-1-23a. Pre-hearing procedure in contested cases

(a) Any time after the issuance of a complaint and before the scheduled hearing date, the commissioner may order or a respondent may request an informal pre- hearing conference. The granting or denial of a request for a pre-hearing conference is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(b) A pre-hearing conference may be held for any of the following purposes:
(1) to narrow the scope of the issues in dispute;
(2) to obtain stipulations as to matters of fact;
(3) to stipulate as to the authenticity of documents which are to be offered in evidence;
(4) to stipulate as to the qualifications of any expert witnesses who are to testify at the hearing; and
(5) to discuss the possibility of an informal disposition of the complaint.
(c) A pre-hearing conference need not be recorded, but a written record will be made of any stipulations as to matters of fact, as to the authenticity of documents, or as to the qualifications of expert witnesses.

Any such written record will be signed by each of the individual respondents or his counsel and by the commissioner or his authorized representative.

Sec. 21a-1-24a. Conduct of adjudicative hearings in contested cases

(a) Hearings in contested cases shall be presided over by the commissioner or his designated hearing officer.

(b) Said commissioner or hearing officer shall have the power to:
(1) Regulate the course of the hearing and the conduct of the parties and their counsel therein;
(2) Insure that all testimony is given under oath;
(3) Rule upon offers of proof and to receive evidence;
(4) Consider and rule upon all motions; and
(5) Require any additional written and/or oral argument.

(c) Each party in an adjudicative hearing shall have the right to present evidence, cross examine witnesses, enter motions and objections, and assert all other rights essential to a fair hear.

(d) Intervention by interested parties shall be permitted in any contested case, as provided by applicable statute or otherwise within the discretion of the commis- sioner or hearing officer.

(e) All adjudicative hearings in contested cases shall be recorded and shall be conducted in accordance with the provisions of chapter 54 of the General Statutes.

Sec. 21a-1-25a. Transcript of the proceedings

(a) At the close of the reception of evidence, the respondent or any other party of record may file a written request addressed to the agency for a written transcript of the proceedings. If no such written request is filed, the agency may order that a written transcript be prepared.

(b) Ifanypartyofrecorddesiresacopyofthetranscript,itwillbemadeavailable to him upon written request and the tendering of the appropriate cost.

Sec. 21a-1-26a. Informal disposition in contested cases

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, or default. A respondent may agree to enter an agreement containing a consent order in lieu of a hearing on the issue(s). Such agreement may be negotiated by the respondent and the complaint counsel or authorized representative of said agency. The acceptance of a consent agreement is within the complete discretion of the commissioner.

(b) A consent agreement shall contain:
(1) An admission of all jurisdictional facts;
(2) An express waiver of the right to seek judicial review or otherwise challenge or contest the validity of the order;

(3) An express waiver of the requirement that the decision of said commissioner contain findings of fact and conclusion of law;
(4) A provision that the complaint may be used in construing the terms of the order;
(5) A statement that the order contained therein shall have the same force and effect as an order entered after a full hearing and shall become

final when issued; (6) A statement that said order shall not be effective unless and until accepted and approved by the commissioner;
(7) The signature of each respondent or his attorney and the complaint counsel; and
(8) The signature of the commissioner accepting and approving the consent agreement.

Sec. 21a-1-27a. Proposal for decision

When in a contested case the Commissioner has not heard the case or read the record, the decision, if adverse to a party to the proceeding other than the agency itself, shall not be made until a proposal for decision is served upon the parties and an opportunity is afforded to each party adversely affected to file exceptions and present briefs and oral argument to the commissioner. The proposal for decision shall contain a statement of the reasons therefore, and of each issue of fact or law necessary to the proposed decision, prepared by the person who conducted the hearing or one who has read the record. The parties by written stipulation may waive compliance with this section.

Sec. 21a-1-28a. Final decision in a contested case

(a) The final decision or order in a contested case shall be rendered by the commissioner after due consideration of the entire record. If no written request was filed for the preparation of a transcript, a final decision may be rendered at any time following the close of the hearing. If a transcript was requested in writing, the final decision may be

rendered within a reasonable time following preparation of the transcript.

(b) A final decision or order adverse to a party in a contested case shall be in writing or stated in the record.

(c) Parties shall be notified either personally or by mail of any decision or order. Upon request, a copy of the text of the final decision or order shall be sent by mail to each of the respondents and respondent's counsel, and to any other party of record.

(d) The agency shall proceed with reasonable dispatch to conclude any matter pending before it and shall render a final decision in all contested cases within ninety days following the close of evidence and filing of briefs in such proceedings.

Sec. 21a-1-29a. Inconsistent regulations

Unless precluded by law, the regulations appearing as Sections 21a-1-19a through 21a-1-28a inclusive, shall take precedence over any other conflicting or inconsistent regulation pertaining to hearing procedures within the Department of Consumer Protection.

Uniform Rules of Procedure Concerning Boards and Commissions within Its Jurisdiction

Sec. 21a-9-1. Applicability

(a) The uniform hearing procedures shall apply to all boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(b) As used herein, ‘‘agency’’ means the boards or commissions transferred to the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(c) As used herein, ‘‘certificate’’ includes the whole or part of any Department of Consumer Protection permit which the Department issues under authority of the General Statutes and which (1) authorizes practice of the profession by certified persons but does not prohibit the practice of the profession by others, not certified, (2) prohibits a person from falsely representing that he is certified to practice the profession unless the person holds a certificate issued by the Department and (3) requires as a condition of certification that a person submit specified credentials to the Department which attest to qualifications to practice the profession.

(d) As used herein, ‘‘License’’ includes the whole or part of any Department of Consumer Protection permit, approval, or similar form of permission which the Department issues under authority of the General Statutes and which requires; (1) practice of the profession by licensed persons only, (2) demonstration of competence to practice by examination or other means and meeting of certain minimum standards and (3) enforcement of standards by the Department or Agency.

(e) As used herein, ‘‘registration’’ includes the whole or part of any permit which the Department issues under authority of the General Statutes and which; (1) requires persons to place their names on a list maintained by the Department before they can engage in the practice of a specified profession or occupation, (2) does not require a person to

demonstrate competence by examination or other means and (3) may be revoked or suspended by the Agency for cause.

(f) As used herein, ‘‘practitioner’’ includes any person possessing a certificate, license, or registration which the Department issues under authority of Section 21a- 8 (5) of the General Statutes pertaining to the boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

Sec. 21a-9-2. Opportunity to show compliance

(a) No revocation, suspension, annulment or withdrawal of any certificate, license or registration is lawful unless prior to the institution of agency proceedings, the agency gave notice by mail to the practitioner of facts or conduct which warrant the intended action, and the practitioner was given the opportunity to show compli- ance with all lawful requirements for the retention of the certificate, license or regis- tration.

(b) The notice of the opportunity to show compliance shall contain:
(1) A statement of the time, date and method for responding to the agency;
(2) A reference to the statute(s) or regulation(s) allegedly violated;
(3) A clear and concise factual statement sufficient to inform each respondent of the acts or practices alleged to be in violation of the law. This requirement may be met by including a copy of the investigation report with the notice; and
(4) A statement that each respondent may be represented by counsel.

(c) The agency may request the respondent to attend a compliance conference as the method for responding to the agency. Compliance conferences shall be informal and the rules of evidence shall not apply. Compliance conferences may be recorded but need not be transcribed.

(d) The agency may, in its discretion, designate a person, other than a member of said agency, to preside at such compliance conference. After said compliance conference, the designated presiding officer shall report in writing his or her recom- mendations to the agency.

Sec. 21a-9-3. Summary suspension procedures

If the agency finds that public health, safety or welfare imperatively requires emergency action, and incorporates a finding to that effect in its order, summary suspension of a certificate, license, or registration may be ordered pending proceed- ings for revocation or other action. These proceedings shall be promptly instituted and determined.

Sec. 21a-9-4. Contested cases

(a) A ‘‘Contested Case’’means a proceeding, including but not restricted to rate- making price fixing and licensing, in which the legal rights, duties or privileges of a party are required by statute to be determined by an agency after an opportunity for hearing or in which a hearing is in fact held, but does not include hearings referred to in Section 4-168 of the Connecticut General Statutes.

(b) When an agency has reason to believe there has been a violation of the statute(s) or regulation(s) it administers, it shall issue a complaint by certified mail to the respondent.

(c) The notice in contested cases shall contain:

(1) A statement of the statutory authority and jurisdiction for instituting the pro- ceedings;

(2) A reference to the specific statutory section(s) or regulations alleged to be violated;

(3) A short and plain statement of the matters asserted sufficient to inform each respondent of the acts or practices alleged to be in violation of the law;

(4) Notice of the time, date, place and nature of the hearing; and

(5) A statement that each respondent may, if he desires, be represented by an attorney.

(d) (1) If a respondent can show a need for additional time to prepare a defense to the alleged violations, an extension of time may be granted by moving the scheduled hearing to a later date. The granting of such a request is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

(2) If a respondent can show that the complaint is unclear or ambiguous as to the nature of the acts in violation of the law, he may file with the agency a written motion for a more detailed statement of the nature of the charges against him. The granting or denial of such a motion is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

(3) Any pleading which a Respondent wishes considered by the agency prior to the convening of a contested case proceeding may be filed up to seven days prior to the hearing date. If a Respondent can show a need for additional time to submit documentation, an extension of time may be granted. The granting of such a request is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

Sec. 21a-9-5. Conduct of adjudicative hearings in contested cases

(a) Hearings in contested cases shall be presided over by the appropriate agency, its designated hearing panel, or hearing officer.

(b) Said agency, designated hearing panel or hearing officer shall have the power to:
(1) Regulate the course of the hearing and the conduct of the parties and their counsel therein;
(2) Insure that all testimony is given under oath;
(3) Rule upon offers of proof and to receive evidence;
(4) Consider and rule upon all motions; and
(5) Require any additional written and/or oral argument.
(c) Each party in an adjudicative hearing shall have the right to present evidence, cross examine witnesses, enter motions and objections, and assert all other rights essential to a fair hearing.

(d) Intervention by interested parties shall be permitted in any contested case, as provided by applicable statute or otherwise within the discretion of the agency, designated hearing panel or hearing officer.

(e) All adjudicative hearings in contested cases shall be recorded and shall be conducted in accordance with the provisions of chapter 54 of the General Statutes.

Sec. 21a-9-6. Transcript of the proceedings

(a) At the close of the reception of evidence, the respondent or any other party of record may file a written request addressed to the agency for a written transcript of the proceedings. If no such written request is filed, the agency may order that a written transcript be prepared.

(b) Ifanypartyofrecorddesiresacopyofthetranscript,itwillbemadeavailable to him upon written request and the tendering of the appropriate cost.

Sec. 21a-9-7. Informal disposition in contested cases

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, or default. A respondent may agree to enter an agreement containing a consent order in lieu of a hearing on the issue(s). Such agreement may be negotiated by the respondent and the complaint counsel or authorized representative of said agency provided that said authorized representative shall not be a member of said agency. The acceptance of a consent agreement is within the complete discretion of the agency and prior to exercising such discretion the agency may designate a member independently to confer with the parties and then present to the agency hearing panel a recommendation whether to accept or reject such

agreement, provided that in order to avoid prejudice the reasons forming the basis for such recommendation shall not be disclosed to such panel, and such member making the recommendation shall not be a member of the agency hearing panel rendering the decision.

(b) A consent agreement shall contain:
(1) An admission of all jurisdictional facts;
(2) An express waiver of the right to seek judicial review or otherwise challenge or contest the validity of the order;
(3) An express waiver of the requirement that the decision of said board or commission contain findings of fact and conclusion of law;
(4) A provision that the complaint may be used in construing the terms of the order;
(5) A statement that the order contained therein shall have the same force and effect as an order entered after a full hearing and shall become final when issued; (6) A statement that said order shall not be effective unless and until accepted
and approved by said agency;
(7) The signature of each respondent or his attorney; and
(8) The signature of said agency chairman-accepting and approving the consent agreement.

Sec. 21a-9-8. Proposal for decision

When in a contested case a majority of the officials of the agency who are to render the final decision have not heard the case or read the record, the decision if adverse to a party to the proceeding other than the agency itself, shall not be made until a proposal for decision is served upon the parties and an opportunity is afforded to each party adversely affected to file exceptions and present briefs and oral argument to the

officials who are to render the decision. The proposal for decision shall contain a statement of the reasons therefore, and of each issue of fact or law necessary to the proposed decision, prepared by the person who conducted the hearing or one who has read the record. The parties by written stipulation may waive compliance with this section.

Sec. 21a-9-9. Final decision in a contested case

(a) The final decision or order in a contested case shall be rendered by an agency after due consideration of the entire record. If no written request was filed for the preparation of a transcript, a final decision may be rendered at any time following the close of the hearing. If a transcript was requested in writing, the final decision may be rendered within a reasonable time following preparation of the transcript.

(b) A final decision or order adverse to a party in a contested case shall be in writing or stated in the record.

(c) Parties shall be notified either personally or by mail of any decision or order. Upon request, a copy of the text of the final decision or order shall be sent by mail to each of the respondents and respondent's counsel, and to any other party of record.

(d) The agency shall proceed with reasonable dispatch to conclude any matter pending before it and shall render a final decision in all contested cases within ninety days following the close of evidence and filing of briefs in such proceedings.

Sec. 21a-9-10. Petitions

(a) Any interested person may petition the commissioner of consumer protection requesting the promulgation, amendment or repeal of a regulation pursuant to Section 4-174 of the General Statutes and Section 19-170a-12 of the Regulations of Connecti- cut State Agencies pertaining to an agency within the jurisdiction of the Department of Consumer Protection. Only written petitions will be considered. The petition shall set forth clearly the reasons for its submission.

(b) Petitions for declaratory rulings on the applicability of any statutory provision within the Department of Consumer Protection pertaining to boards or commissions shall be submitted in writing to the appropriate board or commission pursuant to Section 4-176 of the General Statutes. A copy of such request shall also be simultaneously made to the Commissioner of Consumer Protection.

Sec. 21a-9-11. Inconsistent regulations

Unless precluded by law the regulations appearing as Sections 21a-9-1 through 21a-9-10, inclusive, shall take precedence over any other conflicting or inconsistent regulation pertaining to hearing procedures of all boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

Schedule for License Renewal Sec. 21a-10-1. Schedule for license renewal

Licenses, certificates, registrations, and permits issued by the Department of Consumer Protection shall be renewed and expire annually pursuant to the follow- ing schedule.

(a) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of December and renew on the first day of the month of January:

(1) frozen dessert manufacturer-retail;
(2) frozen dessert manufacturer-wholesale;
(3) interior designer;
(4) license to advertise and sell property in another state;
(5) mobile manufactured home park;
(6) mobile manufactured home seller;
(7) sale of nonlegend drugs;
(8) refrigerated locker; and
(9) weights and measures dealer and repairer.
(b) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of January and renew on the first day of the month of February: (1) arborist;
(2) community association manager;
(3) controlled substance laboratory;
(4) land surveyor;
(5) pharmacist;
(6) professional engineer; and
(7) professional engineer and land surveyor.
(c) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of February and renew on the first day of

the month of March: (1) controlled substance registration for practitioner.
(d) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of March and renew on the first day of the month of April: (1) pharmacy technician; and
(2) real estate broker.
(e) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of April and renew on the first day of the month of May: (1) architect and land surveyor corporation;
(2) automatic fire sprinkler system layout technician;
(3) bedding — manufacturer;
(4) bedding — renovator;
(5) bedding — secondhand dealer;
(6) bedding — sterilization;
(7) bedding — supply dealer;
(8) non water well contractor;
(9) non water well driller;
(10) professional engineer and architect corporation;
(11) professional engineer, architect, and land surveyor corporation; (12) professional engineer and land surveyor corporation;
(13) real estate appraiser — certified;
(14) real estate appraiser — licensed;
(15) real estate appraiser — provisional licensed;
(16) real estate appraiser — tenured licensed;
(17) water well driller; and
(18) water well contractor.
(f) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of May and renew on the first day of the month of June: (1) real estate salesperson.
(g) Licenses, certificates, registrations, and permits that expire annually

on the last day of the month of June and renew on the first day of the month of July: (1) apple juice and cider;
(2) bakery;
(3) general contractor;
(4) major subcontractor;
(5) manufacturer of controlled substances;
(6) manufacturer of drugs, medical devices or cosmetics;
(7) non-alcoholic beverage;
(8) public weigher;
(9) vending;
(10) wholesaler of controlled substances; and
(11) wholesaler of drugs, medical devices or cosmetics.
(h) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of July and renew on the first day of the month of August: (1) architect;
(2) architect corporation;
(3) landscape architect; and
(4) weights and measurers device.
(i) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of August and renew on the first day of the month of September:
(1) elevator contractor — all categories and types;
(2) elevator journeyman — all categories and types;
(3) heating, cooling and piping contractor — all categories and types;
(4) heating, cooling and piping journeyman — all categories and types;
(5) mechanical contractor;
(6) pharmacy;
(7) television and radio repair dealer — all categories and types; and
(8) television and radio repair technician — all categories and types.
(j) Licenses, certificates, registrations, and permits that expire annually

on the last day of the month of September and renew on the first day of the month of October: (1) electrical contractor — all categories and types;
(2) electrical journeyman — all categories and types; and
(3) health club.
(k) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of October and renew on the first day of the month of November:
(1) fire protection contractor — all categories and types;
(2) fire protection journeyman — all categories and types;
(3) plumbing contractor — all categories and types;
(4) plumbing journeyman — all categories and types;
(5) motor fuel quality; and
(6) retail gasoline dealer.
(*l*) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of November and renew on the first day of the month of December:

Specifications and Test Standards for Clinical Thermometers

Sec. 21a-63-1. Application for permit to sell clinical thermometers in the state of Connecticut

Each manufacturer applying for authority to sell thermometers in the state of Connecticut shall comply with the following requirements before a permit is granted: (a) Such application shall be made to the State Department of Consumer Protection on application forms to be furnished by the department.
(b) At the time of making application the manufacturer shall submit are presentative sample of his clinical thermometers, which shall be taken at

random from his stock. Such representative sample shall consist of two hundred clinical thermometers. More clinical thermometers may be requested for examination before the permit is granted.

Sec. 21a-63-2. Granting of permit

After any manufacturer of mercury-in-glass clinical thermometers has fulfilled all the requirements of section 21a-63-1, the State Commissioner of Consumer Protection shall grant a permit to such manufacturer to sell clinical thermometers of his manufacture that meet the specifications and tolerances herein established. For the purposes of these requirements, specifications and tolerances, an individual, a firm or a corporation shall not be considered a manufacturer unless engaged in the business of engraving, either by etching and filling or by staining, and testing clinical thermometers.

Sec. 21a-63-3. Factory records

Each permittee shall keep on file for at least two years complete records of each clinical thermometer which has been sold in the state of Connecticut, the record to include either a serial number or code which indicates the specific period, not to exceed 90 days, in which the thermometers were calibrated, name and address of the purchaser, and the date of sale of each lot of thermometers sold. These records shall be available to a representative of the State Department of Consumer Protection at any time upon request.

Sec. 21a-63-4. Guarantee

Each manufacturer of clinical thermometers shall furnish to the Chief of the Weights and Measures Division of the State Department of Consumer Protection, within thirty days of the date of sale, a sales record for thermometers sold in this state. This record shall include the name and address of the purchaser, the date of sale and the variety name of each lot of thermometers, together with the number of thermometers in each consignment.

Sec. 21a-63-5. Forfeiture of permit by manufacturer

The testing records of a manufacturer shall show that he has been actively engaged in the business of selling clinical thermometers for use in the state of Connecticut within the previous two-year period in order to entitle him, at any time, to retain a

Sec. 21a-63-6. Termination of permit

Any permit granted under sections 21a-63-1 to 21a-63-12, inclusive, and all rights and privileges pertaining thereto, shall terminate if the holder of the permit at any time or for any cause ceases to be a manufacturer of clinical thermometers.

Sec. 21a-63-7. Manufacturer's standards and certificates

A manufacturer holding or applying for a Connecticut permit may at any time be required to submit to the State Department of Consumer

Protection for test or examination such clinical thermometer standards or certificates as may be deemed necessary for carrying out any of the provisions of section 21a-63 of the General Statutes.

Sec. 21a-63-8. Purpose

The purpose of this standard is to provide a specification and methods of testing clinical thermometers as a basis for certification of quality and accuracy; to assure the purchaser that the thermometer has been tested and found to meet the requirements of a recognized standard.

Sec. 21a-63-9. Scope

This standard applies to maximum self-registering mercury-in-glass thermometers of the types commonly used for measuring body temperatures. Each clinical ther- mometer legal for sale in Connecticut shall meet the requirements and tests for: bulb and stem glasses, mercury, legibility and permanency of markings, dimensions, temperature scale ranges, graduations, thermometer stability, ease of resetting, reten- tion of temperature indication, and accuracy of scale reading.

Sec. 21a-63-10. Markings

Each clinical thermometer marked by the manufacturer shall be engraved with the legible characters in the following order: Serial number or code; and manufactur- er's name, initials or trade-mark. If a

variety name is engraved on the thermometer, it shall follow the manufacturer's name, initials or trademark. A cap may be attached to the top of the stem, provided it shall not cover up any markings, graduations or imperfections.

Sec. 21a-63-11. Adoption of standards

Standard specification ASTM E 667-79 of the American Society of Testing and Materials, except for section 5.6, 7 and 7.1 of said specification, is adopted and herein incorporated by reference as setting forth standards for the manufacture and testing of clinical thermometers in this state.

Sec. 21a-63-12. Test for entrapped gas

Gas in bulb. Thermometers in which inspection shows the presence of gas in the bulb shall be rejected. (Effective July 27, 1984)

Safe Handling and Disposal of Hypodermic Needles and Syringes

Sec. 21a-66-1. Definitions

(a) **Hypodermic needles and syringes** means needles, syringes and any other types of intravascular device including but not limited to indwelling catheters and introducers, except that needles which are specifically used to administer antineoplastic agents shall be handled in

accordance with existing Department of Environmental Protection Regulations for the handling of such wastes.

(b) **Biomedical Waste** means untreated solid waste which requires special handling as defined in Sec. 22a-207 (17) of the Connecticut General Statutes.

(c) **Treatment** when used in connection with biomedical waste, means any method, technique, or process which is designed to change the character or composition of any biomedical waste so as to render such waste non-infectious, non-injurious, safer for storage, for transport, and reduced in volume.

Sec. 21a-66-2. Safety procedures concerning hypodermic needles and syringes

Each health-care institution licensed pursuant to Chapter 368v of the Connecticut General Statutes, each laboratory licensed pursuant to Section 19a-30 of the Connect- icut General Statutes, and all other generators of biomedical waste as defined in Section 22a-207 of the Connecticut General Statutes, as amended, shall forthwith establish and implement procedures for the handling and disposal of hypodermic needles and syringes in accordance with the following safety and control measures.

(a) Used hypodermic needles and syringes shall be placed intact directly into rigid puncture-resistant containers and the following procedure shall be followed:
(1) Needles shall not be resheathed, purposely bent, broken, removed from disposable syringes, or otherwise manipulated by hand;

(2) Notwithstanding the requirement set forth in Subsection (a) (1), injectable equipment having self-contained secondary precautionary type sheathing devices may be utilized in accordance with its manufacturer's directions, and re-sheathing may occur when technical procedure involved requires re-sheathing as part of that procedure;
(3) Containers shall be located in close proximity to the area in which hypodermic needles and syringes are used to minimize the hazards of injury or transmission of infection during transport;
(4) The container lid opening shall be a one way system to prevent spillage, and this shall render the items contained therein non-reuseable;
(5) Containers shall be maintained under secure conditions at all times; and
(6) Prior to treatment, containers shall be stored in a designated area accessible only to authorized personnel.

(b) Containers of hypodermic needles and syringes shall be considered to be biomedical waste, and shall be treated to render them non-recoverable in accordance with any existing Department of Enviromental Protection Regulations regarding biomedical waste or in accordance with any other methods specifically approved by the Commissioner of Consumer Protection in consultation with the Commissioners of Health Services and Environmental Protection.

(c) If treatment is not done onsite, these wastes shall be safely transported in sealed, impervious containers to another facility for appropriate treatment.

(d) Personnel involved in the handling and disposal of hypodermic needles and syringes shall be informed of the potential health and safety hazards, and trained in the appropriate handling and disposal procedures.

(e) Each facility shall monitor staff performance for adherence to the established handling and disposal procedures.

(f) Policy for disposal of these wastes by a health care facility shall be available for review by the Department of Health Services or the Commissioner of Con- sumer Protection.

Sec. 21a-66-3. Purchase, possession, control and use of hypodermic needles and syringes

(a) The purchase, possession, control, and use of hypodermic needles and syringes by commercial or industrial firms pursuant to Section 21a-65 (a) (6) of the Connecti- cut General Statutes shall be considered to be authorized by the Commissioner of Consumer Protection provided that such businesses attest to the following in a written statement which they shall provide to the commissioner:
(1) that there exists an essential need for such devices in any function of their operation;
(2) that there are no devices, tools, or equipment modifications which may be used as an alternative to the use of hypodermic needles and syringes;
(3) that there shall be maintained only those quantities of hypodermic needles and syringes which are essential for normal efficient operations;
(4) that security safeguards and inventory control systems have been established which are adequate to detect any loss or diversion of hypodermic needles and syringes; and
(5) that access to stocks of hypodermic needles and syringes is limited to only those employees who have a legitimate need to handle these devices in the normal course of business.

(b) It shall be within the discretion of the Commissioner to determine whether such firms meet the requirements of subsection (a) of this section.

Sec. 21a-115-15. Names of drugs; difference from standards to be indicated

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term ‘‘drug defined in an official compendium’’ means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality or purity from the standard of strength, quality or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

Sec. 21a-115-16. Labeling of drugs and devices; false or misleading represen- tations

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Sec. 21a-115-17. Labeling of drugs and devices; information re manufacturer, packer or distributor; statement of quantity

(a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as ‘‘Manufactured for and Packed by . . . . . .,’’ ‘‘Distributed by . . . . . ,’’ ‘‘Retailed by . . . . . ,’’ or other similar word or phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug. (2) The statement shall be expressed in the terms of weight, measure or numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul or other unit form shall be in terms of weight if the drug is solid, semi-solid or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement, in such terms, manner and form as are not misleading, of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information. (3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint, fluid ounce and fluid dram subdivisions thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume at 68□F. (20□C.).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not

be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subdivision (2) of this subsection, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of subsection (e) (2) of this section, shall express the number of the largest unit specified in subsection (f) of this section which is contained in the package (for example, the statement on the label of a package which contains one pint of a drug shall be ‘‘1 pint,’’ and not ‘‘16 fluid ounces’’). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is may be expressed as ‘‘1 pound 4 4
ounces’’). The stated number of any unit which is smaller than the largest unit, specified in said subsection (f), contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, quart 1 pint’’). (2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by any official compendium for filling of ampuls.

(k) Where the statement does not express the minimum quantity (1) variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure; (2) variations from the stated weight, measure or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring or counting the contents of individual packages which occur in good packing practices. But under this subdivision (2) variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(*l*) The extent of variations from the stated quantity of the contents permissible under subsections (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of subsection (b) (2) of section 21a-106 of the general statutes if (1) the statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of subsection (e) (2) of this section, together with all other words, statements and information required by or under authority of the act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the labels as to comply with the requirements of said section

21a-106 and regulations promulgated thereunder; or (2) the quantity of the contents of the package, as expressed in terms of numerical count in compliance with subsection (e) (2) or (3) of this section is less than six units and such units can be easily counted without opening the package.

Sec. 21a-115-18. Inadequate labeling. Language

(a) A word, statement or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 21a-106 (c) of the general statutes by reason, among other reasons, of (1) the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; (2) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; (3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or informa- tion; (4)

insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space for any word, state- ment, design or device which is not required by or under authority of the act to appear on the label; (5) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or (6) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 21a-106 of the general statutes, shall apply if such insufficiency is caused by (1) the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (2) the use of label space to give greater conspicuousness to any word, statement or other information than is required by section 21a-106 (c) of the general statutes, or (3) the use of label space for any representation in a foreign language.

(c)(1) All words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. (2) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. (3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear

on the label or labeling shall appear on the labeling in the foreign language.

Sec. 21a-115-19. Labeling of drugs; names; quantity; warning

(a) (1) The name of a substance or derivative required by or under authority of section 21a-106 of the general statutes to be borne on the label of a drug shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of said section 21a-106. (2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in said section 21a-106 shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) (1) If the drug is in tablet, capsul, ampul or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug. (2) The statement of the percentage of such substance or derivative contained in a drug shall express the percentage by weight; except that, if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at 68□F. (20□C.), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement ‘‘Warning—May be habit forming,’’ shall immediately precede or immediately follow, without intervening written, printed or graphic matter, the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement ‘‘Warning—May be habit forming’’ (1) if such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or (2) if the only substance or derivative subject to section 21a-106 (d) of the general statutes contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 per cent by weight, and such drug is for parenteral use only; or (3) if the only substance or derivative subject to said section 21a-106 (d) contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 per cent and such drug contains one or more active ingredients and is for parenteral use only.

Sec. 21a-115-20. Name and quantity statement requirements; derivatives or preparations of substances

(a) (1) The name of an ingredient, substance, derivative or preparation required by said section 21a-106 of the general statutes to be borne on the label of a drug shall be the name thereof which is listed in said section, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the

specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth. (2) Where an ingredient contains a substance the quantity or proportion of which is required by said section 21a-106 to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in subsection (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug. (3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name ‘‘acetophenetidin’’ shall be considered to be the same as the name ‘‘acetphenetidin,’’ ‘‘aminopyrine’’ the same as ‘‘amidopyrine.’’ The name ‘‘alcohol,’’ without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 21a-106 of the general statutes is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action. (2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in said section 21a-106 shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportion of a substance, derivative or preparation contained therein shall express the weight or measure of such substance, derivative or prepara- tion in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance, derivative or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative or preparation in such drug. Such statement shall be in terms

which are informative to the ordinary consumer and user of the drug. (2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol by volume at 60°F. (15.56°C.). A statement of the percentage of a substance, derivative or preparation other than alcohol shall express the percentage by weight; except that, if both the substances, derivative or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68°F. (20°C.), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason, among other reasons, of (1) the order in which the names of ingredients, substances, derivatives or preparations appear thereon, or the relative prominence otherwise given such names; or (2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of subparagraph (A) (ii) of subdivision (1) of subsection (E) of section 21a-106 of the general statutes if all words, statements, and other information required by or under authority of the act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as

to comply with the requirements of said section 21a-106 and regulations promulgated thereunder. But such exemption shall be on the condi- tion that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by said subparagraph (A) (ii), such statement of the quantity of the contents shall be omitted as authorized by section 21a-115-17 (m) (1), and the information required by said subparagraph (A) (ii) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase. (2) A drug shall be exempt from the requirements of said subparagraph (A) (ii) with respect to the alkaloids, atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, stramo- nium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

Sec. 21a-115-21. Directions for use; exemptions

(a) Directions for use may be inadequate by reason, among other reasons, of omission, in whole or in part, or incorrect specification of (1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any, for which

such drug or device is commonly and effectively used; (2) quantity of dose, including quantities for persons of different ages and different physical conditions; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration or application, in relation to time of meals, time of onset of symptoms or other time factor; (6) route or method of administration or application; or (7) preparation for use (shaking, dilution, adjustment of temperature or other manipulation or process).

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of section 21a-106 of the general statutes in the following cases: (1) A drug or device which because of its toxicity or because of the degree of skill required in its administration cannot be used with safety except by or under the supervision of a physician, dentist or veterinarian; provided the label of such drug or device shall bear the statement ‘‘Caution—to be used only by or on the prescription of a physician’’ (dentist or veterinarian as the case may be); (2) official drugs which are dispensed only after compounding with other substances in filling prescriptions of physicians, dentists or veterinarians; (3) inactive ingredients of drugs such as solvents, colorings and flavorings; (4) drugs and devices shipped to physicians, dentists or veterinarians, hospitals or clinics, for use in professional practice and under professional supervision; (5) a drug or device intended solely for use in the manufacture of other drugs and devices; provided the label of such drug or device bears the statement ‘‘for manufacturing purposes only.’’ The term ‘‘manufacture’’ does not include compounding of a prescription issued by a physician, dentist or veterinarian, in his professional practice; (6) common household preparations, adequate directions for the use of which are known by the ordinary individual.

Sec. 21a-115-22. New drugs

Newness of a drug may arise by reason, among other reasons, of (a) the newness for drug use of any substance which composes such drug, in whole or in part, whether it is an active substance or a menstruum, excipient, carrier, coating or other component; (b) the newness for drug use of a combination of two or more substances, none of which is a new drug; (c) the newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug; (d) the newness of use of such drug in diagnosing, curing, mitigating, treating or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or (e) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

Sec. 21a-115-23. Application for sale of new drugs

An application which is on its face incomplete in that it does not contain all the matter required by subparagraphs (A), (B), (C), (D) and (F) of subdivision (2) of subsection (a) of section 21a-110 of the general statutes shall not be accepted for filing. The date on which an application is received by the commissioner of consumer protection shall be considered to be the date on which such application is filed, and the commissioner shall notify the applicant of such date. If the applicant

withdraws his application, such application shall be considered as not having been filed.

Sec. 21a-115-24. Adulterated cosmetics; ‘‘coal-tar hair dye’’ defined

The term ‘‘coal-tar hair dye’’ includes all articles containing any coal-tar color or intermediate, which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

Sec. 21a-115-25. Misbranded cosmetics; false or misleading representations

(a) Among representations in the labeling of a cosmetic which render such cos- metic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such cosmetic in such labeling by a name which includes or suggests the names of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Sec. 21a-115-26. Labeling of cosmetics; information re manufacturer, packer or distributor; statement of quantity

(a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic, such as, ‘‘Manufactured for and Packed by . . . . . ,’’ ‘‘Distributed by . . . . . ’’ or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic. (2) The statement shall be expressed in the terms of weight, measure or numerical count, or a combination of numerical count and weight or measure, which are generally used by the consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semi-solid or viscous, or in such terms of numerical count, or

numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint and fluid ounce subdivisions thereof, and shall express the volume at 68°F. (20°C.). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which shipment is exported. (2) A statement of weight or measure in the terms specified in subdivision (1) of this subsection may be supplemented by a sement in terms of the metric system of weight or measure. (3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used inexpressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in subsection (f) of this section, and which is applicable to such cosmetic under the provisions of subsection
(e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be ‘‘1 pint’’ and not ‘‘16 fluid ounces’’), unless the statement is made in accordance with the provisions of subdivision (2) of this

subsection. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is as 24 ‘‘1 pound 4 ounces’’). The stated number of any unit which is smaller than the largest unit, specified in subsection (f), contained in the package shall not equal or exceed in number of such smaller units in the next larger unit so specified (for 2 or ‘‘1 pound 8 ounces’’). (2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity (1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur

in good distribution practice and which unavoidably result in change of weight or measure; (2) variations from the stated weight, measure or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring or counting individual packages which occur in good packing practice. But under this subdivision variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(*l*) The extent of variations from the stated quantity of the contents permissible under subsections (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of subdivision (2) of subsection (b) of section 21a-112 of the general statutes if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of subsection (e) (2) of this section, is less than one- fourth ounce avoirdupois, or less than one-eighth fluid ounce, or, in case the units of the cosmetic can be easily counted without opening the package, less than six units.

Sec. 21a-115-27. Inadequate labeling. Language

(a) A word, statement or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 21a-112 (c) of the general statutes by reason, among other reasons, of (1) the failure of such word,

statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; (2) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; (3) the failure of the label to extend over the area of the container or package available for such extension so as to provide sufficient label space for the prominent placing of such word, statement or information; (4) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (5) insufficiency of label space, for the prominent placing of such word, statement or information resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or (6) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b)(1) All words, statements and other in formation required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. (2) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. (3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

APPENDIX (excluded-applicable to food only)

Sec. 21a-115-28. Definitions

Drug Wholesalers

For the purpose of Sections 21a-115-28 through Sections 21a-115-32 the following terms shall have the meanings indicated:

(1) ‘‘Commissioner’’ means the Commissioner of Consumer Protection;

(2) ‘‘Controlled substance’’ means a drug as defined in Chapter 420b, Section 21a-240 (9) of the general statutes;

(3) ‘‘Drug’’ means an article defined in Chapter 418, Section 21a-92 (8) of the general statutes;

(4) ‘‘Drug sample’’ means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;

(5) ‘‘Legend drug’’ shall have the definition stated in Chapter 382, Section 20- 184a of the general statutes;

(6) ‘‘Over the counter drug’’ means a drug which is not a legend drug;

(7) ‘‘Registration’’ means a wholesaler certificate of registration issued in accord- ance with Chapter 417, Section 21a-70 (b) of the general statutes; and

(8) ‘‘Wholesaler’’ means a person or firm defined in Chapter 417, Section 21a- 70 (a) (1) of the general statutes who distributes a drug, except that for the purposes of these regulations such distribution does

not include intracompany sales or the distribution of drug samples by manufacturers.

Sec. 21a-115-29. Minimum information required for registration as a wholesaler

The following information shall be required for each application for a registration or a renewal of a registration:

(1) The name, full business address, and telephone number of the registrant; (2) All trade or business names used by the registrant;
(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the registrant for the storage, handling, and distribution of prescription drugs;
(4) The type of ownership or operation (i.e. ,partnership, corporation, or sole proprietorship);
(5) The name(s) of the owner and/or operator of the registrant, including:
(A) If a person, the name of the person;
(B) If a partnership, the name of each partner, and the name of the partnership; (C) If a corporation, the name and title of each corporate officer and director, the corporate name, and the name of the State of incorporation; and
(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
(6) An indication as to whether the registrant will distribute controlled substances, legend drugs and/or over the counter drugs as well as a statement concerning the types of drugs to be distributed; and
(7) A change in any information in this section shall be submitted to the Commissioner within 30 days of such change.

Sec. 21a-115-30. Multiple locations

A wholesaler operating facilities at more than one location need only obtain a single registration provided that it does not store or distribute controlled substances and there is joint ownership and control of all the facilities. The registrant shall provide the names and addresses of all facilities operating under the single registra- tion and all locations shall be subject to inspection in accordance with Chapter 418, Section 21a-118 of the general statutes. If a wholesaler stores or distributes controlled substances, it shall register each facility separately.

Sec. 21a-115-31. Personnel

Personnel employed by wholesalers shall have appropriate education and/or expe- rience to assume responsibility for positions related to compliance with registra- tion requirements.

Sec. 21a-115-32. Minimum requirements for the storage and handling of drugs and for the establishment and maintenance of drug distribution records by wholesalers

(a) **Facilities.** All facilities at which drugs are stored, warehoused, handled, offered, markted, or displayed shall:
(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
(4) Be maintained in a clean and orderly condition; and
(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.
(b) **Security.**
(1) All facilities operated by wholesalers shall be secure from unauthorized entry. (2) Access from outside the premises shall be kept to a minimum and well controlled.
(3) The outside perimeter of the premises shall be well-lighted.
(4) Entry into areas where drugs are held shall be limited to authorized personnel. (5) All facilities shall be equipped with an alarm system to detect entry after business hours.
(6) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(7) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, subdivisions (2) and (4) of this subsection shall apply only to areas where legend drugs are stored.
(c) **Storage.**
(1) All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United State Pharmacopoeia/National Formulary (USP/NF).

(2) If no storage requirements are established for a drug, the drug may be held at ‘‘controlled’’ room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(3) Appropriate measures shall be undertaken to ensure that drugs are stored under conditions of proper temperature and humidity and that such storage conditions are adequately documented.
(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all stored drugs.

(d) **Examination of materials.**

(1) Upon receipt each outside shipping container shall be visibly examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal con- tainer damage that would suggest possible contamination or other damage to the contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.
(3) The recordkeeping requirements in subsection (f) of this section shall be followed for all incoming and outgoing drugs.

(e) **Returned, damaged, and outdated drugs.**

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.
(2) Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(f) **Recordkeeping.**

(1) Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the source of the drugs, including the name and principal address of the seller or transferor, the address of the location from which the drugs were shipped or in the case of distribution the name and address of the purchaser; the identity and quantity of the drugs received and distributed or disposed of; and the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local officials for a period of 3 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local agency.

(g) **Written Policies and Procedures.** Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and proce- dures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesalers shall include in their written policies and procedures the following:
(1) A procedure where by the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;
(2) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: any action initiated at the request of the U. S. Food and Drug Administration or other Federal, State, or local law enforcement or government agency; any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the wholesaler prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;
(4) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This docu- mentation shall be maintained for 3 years after disposition of the outdated drugs; and
(5) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, the requirements of this subsection shall apply to legend drugs only.

(h) **Responsible Persons.** Wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Designation of Controlled Drugs Sec. 21a-243-1. Volatile substances

(a) The following volatile substances are hereby designated as controlled drugs to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person, with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depres- sant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; toluol; trichloroethylene; isopropanol; methanol; ether; methyl cellosolve acetate; toluene; hexane; butyl alcohol; benzene;

methyl ethyl ketone; cyclohexa- none; pentochlorophenol; ethyl acetate; methyl isobutyl ketone; trichloroethane, and dichlorodifluoromethane.

(b) Insofar as it is the express intent of these regulations to provide medical treatment whenever possible, there is hereby created the presumption that one who is found to have inhaled or to be under the influence of the above-described volatile substances shall be deemed to be psychologically dependent upon said volatile sub- stances.

(c) To the extent that it is possible, medical treatment rather than criminal sanc- tions shall be afforded individuals who breathe, inhale, sniff or drink the above- named volatile substances.

Sec. 21a-243-2. Criminal liability of vendor

No vendor of the aforementioned volatile substances shall be deemed to have violated the provisions of chapter 420b of the general statutes insofar as sale, dispensing or delivering of one or more of said volatile substances or compounds containing said chemical substances is concerned, unless he knew or should have known of the improper purpose to which said substance was to be put.

Sec. 21a-243-3. When volatile substances not controlled drug

The above drugs are designated as controlled drugs only for the limited purpose stated in section 21a-243-1. Insofar as substances containing said drugs are possessed, sold, dispensed, compounded or delivered for licit purposes, i.e., other than to produce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous

system by breathing, inhaling, sniffing or drinking, such substances are expressly not controlled and neither the regulatory provisions, including but not limited to record keeping, licensing, and the writing of prescriptions nor the criminal sanctions and proscriptions of chapter 420b of the general statutes shall apply.

Sec. 21a-243-4. Anesthesia

The breathing, inhalation, sniffing or drinking of anesthesia for medical or dental purposes under the direction of a physician, dentist or osteopath acting in the course of his professional practice, is determined to be a licit purpose and not in contravention of these regulations or the provisions of chapter 420b of the
general statutes.

Sec. 21a-243-5. Controlled drugs

The following substances are hereby designated as controlled drugs for all pur- poses of chapter 420b of the general statutes: Datura stramonium, hyoscyamus niger, atropa belladonna or the alkaloids atropine, hyoscyamine, belladonnine, apoatropine, or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids. Any drug or preparation containing any of the above- mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled drug.

Sec. 21a-243-6. Amyl nitrate

Amyl nitrate is hereby designated as a controlled drug as defined under chapter 420b of the general statutes.

Schedules of Controlled Substances

Sec. 21a-243-7. Controlled substances in schedule I

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule I:

(a) Any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, unless specifically excepted, whenever the exis- tence of these isomers, esters, ethers and salts is possible within the specific chemi- cal designation:

(1) Acetylalpha-methylfentanyl;
(2) Acetylmethadol;
(3) Allylprodine;
(4) Alphacetylmethadol (except Levo-alphacetylmethadol or LAAM);
(5) Alphameprodine;
(6) Alphamethadol;
(7) Alpha-methylfentanyl;
(8) Alphamethylthiofentanyl;
(9) Benzethidine;
(10) Betacetylmethadol;
(11) Beta-hydroxy-fentanyl;
(12) Beta-hydroxy-3-methylfentanyl; (13) Betameprodine;
(14) Betamethadol;

(15) Betaprodine;
(16) Clonitazene;
(17) Dextromoramide;
(18) Diampromide;
(19) Diethylthiambutene;
(20) Difenoxin;
(21) Dimenoxadol;
(22) Dimepheptanol;
(23) Dimethylthiambutene;
(24) Dioxaphetyl Butyrate;
(25) Dipipanone;
(26) Ethylmethylthiambutene;
(27) Etonitazene;
(28) Etoxeridine;
(29) Furethidine;
(30) Hydroxypethidine;
(31) Ketobemidone;
(32) Levomoramide;
(33) Levophenacylmorphan;
(34) 3-methylfentanyl;
(35) 3-methylthiofentanyl;
(36) Morpheridine;
(37) Noracymethadol;
(38) Norlevorphanol;
(39) Normethadone;
(40) Norpipanone;
(41) Para-fluorofentanyl;
(42) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);
(43) Phenadoxone;
(44) Phenampromide;
(45) Phenomorphan;
(46) Phenoperidine;
(47) Piritramide;

(48) Proheptazine;
(49) Properidine;
(50) Propiram;
(51) Racemoramide;
(52) Thiofentanyl;
(53) Tilidine;
(54) Trimeperidine.
(b) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:
(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-oxide;
(6) Cyprenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Drotebanol;
(10) Etorphine, except hydrochloride salts; (11) Heroin;
(12) Hydromorphinol;
(13) Methyldesorphine;
(14) Methyldihydromorphine;
(15) Morphine methylbromide;
(16) Morphine methylsulfonate;
(17) Morphine-N-oxide;
(18) Myrophine;
(19) Nicocodeine;
(20) Nicomorphine;
(21) Normorphine;
(22) Pholcodine;
(23) Thebacon.
(c) Any material, compound, mixture or preparation which contains their salts,

isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemi- cal designation:
(1) Alpha-ethyltryptamine;
(2) 4-bromo-2,5-dimethoxyamphetamine; or 4-bromo-2,5-DMA;
(3) 2,5-dimethoxyamphetamine; or 2,5-DMA;
(4) 2,5-Dimethoxy-4-ethylamphetamone or DOET;
(5) 3,4-M ethylenedioxy-N-ethylamphetamine;
(6) 1-methyl-4-phenyl-4-propionoxypiperidine; or MPPP;
(7) 3,4-methylenedioxymethamphetamine; or MDMA;
(8) 2,5-dimethoxy-4-(n)-propylthiopenenthylamine (2C-T-7);
(9) 4-methoxyamphetamine; or PMA;
(10) 5-methoxy-3,4-methylenedioxy-amphetamine;
(11) 5-Methoxy-nn-Diisopropyltryptamine(5-methoxy-dipt);
(12) 4-methyl-2,5-dimethoxyamphetamine; or DOM; or STP
(13) 3,4-methylenedioxy amphetamine; or MDA;
(14) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy- alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA; (15) 3,4,5-trimethoxy amphetamine;
(16) benzylpiperazine or BZP;
(17) Bufotenine or Mappine;
(18) Alphaethyltryptamine;
(19) Diethyltryptamine or DET;
(20) Dimethyltryptamine or DMT;
(21) Ibogaine;
(22) Lysergic acid diethylamide;
(23) MDVP (3,4-methylenedioxypyrovalerone);
(24) 3,4-methylenedioxy-N-methycathione (methylone)
(25) Mephedrone (4-methylmethcathinone);
(26) Mescaline;

(27) Parahexyl or Synhexyl;
(28) Peyote, meaning all parts of the plants;
(29) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine; or PEPAP;
(30) N-ethyl-3-piperidyl benzilate;
(31) N-methyl-3-piperidyl benzilate;
(32) Psilocybin;
(33) Psilocyn;
(34) Tetrahydrocannabinols except Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved product;
(35) Salvia divinorum;
(36) Salvinorin A;
(37) Ethylamine analog of phencyclidine, Cyclohexamine or PCE;
(38) 4-Bromo-2,5-dimethoxyphenethylamine;
(39) Pyrrolidine analog of phencyclidine, PCP or PHP;
(40) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine;
(41) Thiophene analog of phencyclidine, TPCP or TCP;
(42) Tiletamine or 2-(ethylamino)-2-(2-thienyl)-cyclohexanone;
(43) Trifluoromethylphenylpiperazine or TFMPP.

(d) Any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, their salts, isomers and salts of isomers unless specifically excepted, wherever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Gamma-hydroxy butyric acid, except if contained in a drug product for which an application has been approved under section 505 of the federal food, drug and cosmetic act;

(2) Gamma-butyrolactone; (3) Mecloqualone;
(4) Methaqualone; or
(5) Zolazepam.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex;
(2) N-benzylpiperazine (some other names: BZP; 1-benzylpiperazine);
(3) 4-Methylaminorex;
(4) Cathinone;
(5) Fenethylline;
(6) Methcathinone;
(7) N-ethylamphetamine;
(8) N,N-Dimethylamphetamine.
(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of a substance having a psychotropic response primarily by agonist activity at cannabinoid-specific receptors affecting the central nervous system. Specific compounds include, but are not limited to:
(1) 1-pentyl-3-(1-naphthoyl)indole (JWH-018);
(2) 1-butyl-3-(1-naphthoyl)indole (JWH-073);
(3) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
(4) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP- 47,497);
(5) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabi-cyclohexanol CP-47,497 C8 homologue).

Sec. 21a-243-8. Controlled substances in schedule II

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule II:

(a) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:
(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding Apomorphine, Dextrorphan, Nalbuphine, Naloxone, Nal- trexone, and their salts, but including the following: Raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, tincture of opium, codeine, dihydroetorphine, ethylmorphine, etorphine hydrochloride, hydrocodone, hydromor- hone, metopon, morphine, oripavine, oxycodone, oxymorphone and thebaine;
(2) any salt, compound,isomer, derivative or preparation thereof which is chemi- cally equivalent or identical with any of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium;
(3) opium poppy and poppy straw;
(4) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine;
(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of opium poppy). (b) Any of the following opiates, including

their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, Dextrorphan and Levopropoxy-phene excepted:

(1) Alfentanil;
(2) Alphaprodine;
(3) Anileridine;
(4) Bezitramide;
(5) bulk Dextropropoxyphene (nondosage forms);
(6) Carfentanil;
(7) Dihydrocodeine;
(8) Diphenoxylate;
(9) Fentanyl;
(10) Isomethadone;
(11) Levo-alphacetylmethadol or LAAM;
(12) Levomethorphan;
(13) Levorphanol;
(14) Metazocine;
(15) Methadone;
(16) Methadone-intermediate,4-cyano-2-dimethylamino-4,4-diphenylbutane;
(17) Moramide-Intermediate,2-methyl-3-morpholino-1,1-diphenyl-propane-carboxylic acid;
(18) Pethidine (Meperidine);
(19) Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine;
(20) Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate;
(21) Pethidine-Intermediate-C, 1-methyl 4-phenylpiperidine-4-carboxylic acid;
(22) Phenazocine;
(23) Piminodine;

(24) Racemethorphan;
(25) Racemorphan;
(26) Remifentanil;
(27) Sufentanil;
(28) Tapentadol.

(c) Unless excepted or placed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central ner- vous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
(2) any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;
(3) Methylphenidate;
(4) Phenmetrazine and its salts;
(5) Lisdexamfetamine and its salts, isomers and salts of isomers.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Amobarbital;
(2) Glutethimide;
(3) Pentobarbital;
(4) Phencyclidine; and
(5) Secobarbital.

(e) Hallucinogenic Substances:
(1) Nabilone.

(f) Unless specifically excepted or unless listed in another schedule, any material,
compound, mixture or preparation which contains any quantity of the following sub- stances:
(1) Immediate precursor to Amphetamine and Methamphetamine; Phenylacetone (some trade names or other names); phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;
(2) immediate precursors to phencyclidine (PCP);
(A) 1-phencylohexylamine;
(B) 1-piperidinocyclohaxanecarbonitrile (PCC).

(g) Marijuana, including any material, compound, mixture ore preparation which contains its salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation.

Sec. 21a-243-9. Controlled substances in schedule III

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule III:

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Benzphetamine;
(2) Chlorphentermine;
(3) Clortermine;
(4) Phendimetrazine.

(b) Unless listed in another schedule, any material, compound, mixture or prepara- tion which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:
(1) Any compound, mixture or preparation containing: Amobarbital, Secobarbital, Pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;
(2) Any suppository dosage form containing Amobarbital, Secobarbital, Pentobar- bital or any salt of any of these drugs and approved by the Food and Drug Administra- tion for marketing only as a suppository;
(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules, except that the following analgesic products shall not be considered to be controlled substances:

(A) Products containing a ratio of fifteen milligrams of long or intermediate acting barbiturates combined with at least one of the following:

(i) 188 mg aspirin;
(ii) 375 mg salicylamide; or
(iii) 70 mg phenacetin, acetanilid or acetaminophen;
(B) Products containing a ratio of fifteen milligrams of short acting

barbiturates combined with at least one of the following:
(i) 307 mg aspirin;
(ii) 614 mg salicylamide; or
(iii) 106 mg phenacetin, acetanilid or acetaminophen;
(4) Any compound, mixture or preparation containing equal weights of both tiletamine and zolazepam or any salt thereof and not mixed with other psychoac- tive substances;
(5) Chlorhexadol;
(6) Embutramide;
(7) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product;
(8) Ketamine or any salt thereof;
(9) Lysergic acid;
(10) Lysergic acid amide;
(11) Methyprylon;
(12) Sulfondiethylmethane;
(13) Sulfonethylmethane;
(14) Sulfonmethane.
(c) Buprenorphine.
(d) Nalorphine.
(e) Any material, compound, mixture or preparation containing limited quantities
of any of the following narcotic drugs or any salts thereof:
(1) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit,with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredi- ents in recognized therapeutic amounts;

(7) not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Unless expressly intended for administration through implants to nonhuman species and approved for such use by the Federal Food and Drug Administration, any anabolic steroid including but not limited to, any of the following, or any isomer, ester, salt or derivative of the following that acts in the same manner on the human body:

(1) 3[beta],17-dihydroxy-5a-androstane;
(2) 3[alpha],17[beta]-dihydroxy-5a-androstane;
(3) 5[alpha]-androstan-3,17-dione;
(4) 1-androstenediol (3[beta],17[beta]-dihydroxy-5[alpha]-androst-1-ene);
(5) 1-androstenediol (3[alpha],17[beta]-dihydroxy-5[alpha]-androst-1-ene);
(6) 4-androstenediol (3[beta],17[beta]-dihydroxy-androst-4-ene);
(7) 5-androstenediol (3[beta],17[beta]-dihydroxy-androst-5-ene);
(8) 1-androstenedione ([5[alpha]]-androst-1-en-3,17-dione);
(9) 4-androstenedione (androst-4-en-3,17-dione);
(10) 5-androstenedione (androst-5-en-3,17-dione;
(11) Boldenone;
(12) Boldione;
(13) Chlorotestosterone;
(14) Clostebol;
(15) Dehydrochlormethyltestosterone;
(16) [Delta]1-dihydrotestosterone (a.k.a. ‘1-testosterone’) (17[beta]-hydroxy- 5[alpha]-androst-1-en-3-one); (17) desoxymethltestosterone;
(18) Dihydrotesterone;
(19) Drostanolone;
(20) Ethylestrenol;
(21) Fluoxymesterone;
(22) Formebulone;
(23) Furazabol (17[alpha]-methyl-17[beta]-hydroxyandrostano[2,3-c]-furazan); (24) 13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one;
(25) 4-hydroxytestosterone (4,17[beta]-dihydroxy-androst-4-en-3-one);
(26) 4-hydroxy-19-nortestosterone (4,17[beta]-dihydroxy-estr-4-en-3-one);

(27) Mestanolone (17[alpha]-methyl-17[beta]-hydroxy-5-androstan-3-one);
(28) Mesterolone;
(29) Methandienone;
(30) Methandranone;
(31) Methandriol;
(32) Methandrostenolone;
(33) Methenolone;
(34) 17[alpha]-methyl-3[beta], 17[beta]-dihydroxy-5a-androstane;
(35) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy-5a-androstane;
(36) 17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-4-ene;
(37) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-methyl-4-hydroxy- 17[beta]-hydroxyestr-4-en-3-one);
(38) one);
(39) one);
(40) (41) (42)
(43) Nandrolone;
(44) 19-nor-4,9 (10)-androstadienedione;
(45) 19-nor-4-androstenediol (3[beta], 17[beta]-dihydroxyestr-4-ene);
(46) 19-nor-4-androstenediol (3[alpha], 17[beta]-dihydroxyestr-4-ene);
(47) 19-nor-5-androstenediol (3[beta], 17[beta]-dihydroxyestr-5-ene);
(48) 19-nor-5-androstenediol (3[alpha], 17[beta]-dihydroxyestr-5-ene);
(49) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
(50) 19-nor-5-androstenedione (estr-5-en-3,17-dione;
(51) Norbolethone (13[beta], 17[alpha]-diethyl-17[beta]-hydroxygon- 4-en-3- one);
(52) Norclostebol (4-chloro-17[beta]-hydroxyestr-4-en-3-one);
(53) Norethandrolone;
(54) Norethandrolone (17[alpha]-ethyl-17[beta]-hydroxyestr-4-en-3-one);

(55) Normethandrolone (17[alpha]-methyl-17[beta]-hydroxyestr-4-en-3-one); (56) Oxandrolone;
(57) Oxymesterone;
(58) Oxymetholone;
(59) Stenbolone (17[beta]-hydroxy-2-methyl-[5[alpha]]-androst-1-en-3-one); (60) Stanolone;
(61) Stanozolol;
(62) Testolactone;
(63) Testosterone;
(64) Tetrahydrogestrinone (13[beta], 17[alpha]-diethyl-17[beta]-hydroxygon-
4,9,11-trien-3-one);
(65) Trenbolone.
(g) Chorionic gonadotropin.
(h) Any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of such isomers, and esters:
(1) Gamma-hydroxy butyric acid if contained in a product for which an application has been approved under section 505 of the federal food, drug and cosmetic act; or
(2) Gamma-butyrolactone.

Sec. 21a-243-10. Controlled substances in schedule IV

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule IV:
Methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3- Methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-Methyltesterone;

Mibolerone;
17[alpha]-methyl-[Delta]1-dihydrotestosterone (17b[beta]- hydroxy-17[alpha]-methyl-5[alpha]-androst-1-en-3-one) (a.k.a. '17- [alpha]-methyl-1-testos- terone');

(a) Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Alprazolam;
(2) Barbital;
(3) Bromazepam;
(4) Camazepam;
(5) Carisoprodol;
(6) Chloral betaine; (7) Chloral hydrate; (8) Chlordiazepoxide; (9) Clobazam;
(10) Clonazepam;
(11) Clorazepate;
(12) Clotiazepam;
(13) Cloxazolam;
(14) Delorazepam;
(15) Diazepam;
(16) Dochloralphenazone; (17) Estazolam;
(18) Etholorvynol; (19) Ethinamate;
(20) Ethyl-lofiazepate; (21) Fludiazepam; (22) Flunitrazepam; (23) Flurazepam;
(24) Halazepam;
(25) Haloxazolam;
(26) Ketazolam;
(27) Loprazolam;
(28) Lorazepam;

(29) Lormetazepam;
(30) Mebutamate;
(31) Medazepam;
(32) Meprobamate;
(33) Methohexital;
(34) Methylphenobarbital (mephobarbital); (35) Midazolam;
(36) Nimetazepam;
(37) Nitrazepam;
(38) Nordiazepam;
(39) Oxazepam;
(40) Oxazolam;
(41) Paraldehyde;
(42) Petrichloral;
(43) Phenobarbital;
(44) Pinazepam;
(45) Prazepam;
(46) Quazepam;
(47) Temazepam;
(48) Tetrazepam;
(49) Triazolam;
(50) Zaleplon;
(51) Zolpidem;
(52) Zopiclone.
(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cathine;
(2) Diethylpropion;
(3) Fencamfamin;
(4) Fenproporex;
(5) Mazindol;
(6) Mefenorex;
(7) Modafinil;
(8) Pemoline
(9) Phentermine
(10) Pipradol;
(11) Sibutramine;
(12) SPA [(-)dimethylamino-1,2-diphenylethane].
(c) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers when- ever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Fenfluramine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the follow- ing narcotic drugs, or any salts thereof:

(1) Not more than 1 milligram of Difenoxin and not less than 25 micrograms of Atropine Sulfate per dosage unit;

(2) Dextropropoxyphene.

(e) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Butorphanol; or
(2) Pentazocine.

Sec. 21a-243-11. Controlled substances in schedule V

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule V:

(a) Any compound, mixture, or preparation containing limited quantities of any of the following controlled drugs, which also contain one or more noncontrolled active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the controlled drug alone:

(1) not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers:

(1) Pyrovalerone

Drug Prescriptions Transmitted by Facsimile Machines Sec. 21a-243-12. Definitions

For the purpose of Sections 21a-243-12 through 21a-243-17 of the Regulations of Connecticut State Agencies, the following terms shall have the meanings indicated: (a) ‘‘Controlled substance’’ has the meaning given to this term by Connecticut General Statutes, Section 21a-240(9);
(b) ‘‘Facsimile machine’’ means a machine that electronically transmits facsimiles
through connection with a telephone network;
(c) ‘‘Prescribing Practitioner’’ means any person licensed by the state of Connecticut, any other state, the District of Columbia or the Commonwealth of Puerto Rico and authorized to prescribe controlled substances within the scope of his or her practice; and

(d) ‘‘Long Term Care Facility’’ means a facility or institution as defined by the federal government in 21 CFR 1300.01.

Sec. 21a-243-13. Dispensing of prescriptions transmitted by means of a facsimile machine

No pharmacist or pharmacy may dispense controlled substances upon a prescription transmitted by means of a facsimile machine unless such prescription fully complies with Sections 21a-243-14 through 21a-243-18, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 21a-243-14. Schedule II controlled substances

(a) Prescriptions for Schedule II controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine provided the original written, signed prescription is provided to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided for in subsections (b) and (c) of this section. The original written prescription, once received by the pharmacist, shall be reviewed to ensure that it conforms with the requirements of section 21a-249 of the Connecticut General Statutes and shall be maintained as the original record of dispensing. The facsimile prescription order shall not be considered to be the actual prescription, but only a record of the transmission of the prescription order.

(b) Prescriptions for Schedule II narcotic substances to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the prescribing practitioner or his agent to a pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(c) Prescriptions for Schedule II controlled substances for patients of a long term care facility may be transmitted by a prescribing practitioner or his agent to the dispensing pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(d) Prescriptions transmitted by facsimile machine in accordance with subsections (b) and (c) of this section shall comply with the requirements set forth in subsection (b) of Section 21a-243-15 of the Regulations of Connecticut State Agencies.

Sec. 21a-243-15. Schedule III, IV and V controlled substances

(a) Prescriptions for Schedule III, IV and V controlled substances may be transmit- ted by a prescribing practitioner or his agent to a pharmacy by means of a facsim- ile machine.

(b) All prescriptions transmitted pursuant to subsection (a) of this section must comply with the following in addition to any other requirement of federal or state statute or regulation:
(1) The facsimile prescription shall clearly contain the name of the pharmacy to which the facsimile is being transmitted and the name of the facility from which it is transmitted if the prescription is written for an inpatient of a chronic or convalescent nursing home or a rest home with nursing supervision;
(2) The facsimile prescription shall clearly display a statement in substantially the following form: ‘‘This prescription is valid only if transmitted by means of a facsimile machine’’; and
(3) The facsimile document may be maintained as the actual prescription only if the nature of the equipment and paper ensures that the

prescription will remain non-fading and durable for the minimum amount of time required for the maintenance of prescription records under federal and state statute or regulation. If the document will not remain non-fading or durable, the prescription transmitted by facsimile machine shall be reduced to writing, photocopied or converted to an individual printout.

Sec. 21a-243-16. Accuracy of prescription

If a pharmacist questions the accuracy or authenticity of a prescription transmitted by facsimile machine, he or she shall contact the prescribing practitioner for verifica- tion before dispensing the prescription.

Sec. 21a-243-17. Relationship with prescribing practitioners and health care facilities

(a) No pharmacist or pharmacy shall maintain direct telephone, facsimile machine or computer lines to any health care facility or prescribing practitioner's office.

(b) No pharmacist shall enter into any agreement with a prescribing practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

Sec. 21a-243-18. Control of prescription forms

It shall be the responsibility of the prescribing practitioner to ensure that the prescription form that is used to transmit a prescription by facsimile machine is either destroyed immediately or marked or controlled in such a manner that prevents the use of such form to obtain controlled substances other than as authorized by these regulations.

Storage and Retrieval of Prescription Information for Controlled Substances

Sec. 21a-244-1. Computer systems requirements

(a) All prescriptions for schedule II controlled substances, and original written and oral prescriptions for schedule III, IV and V controlled substances shall be received, executed and filed in accordance with sections 21a-249 and 21a-250 of the Connecticut General Statutes and all applicable federal laws and regulations. In the case of original oral prescriptions for schedule III, IV and V controlled substances, which shall be received by a pharmacist, an individual hard copy printout of the prescription containing all required information may be used to satisfy the require- ments of section 21a-249 (d) of the Connecticut General Statutes.

(b) In the case of refills of prescriptions for schedule III, IV and V controlled substances, an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system shall provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual

display device or hardcopy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

(1) the original prescription number;
(2) the date of issuance of the original prescription order by the prescribing practitioner;
(3) the full name and complete address of the patient;
(4) the full name, full address, and Drug Enforcement Administration, United States Department of Justice, or its successor agency registration number of the prescribing practitioner;
(5) the name, strength, dosage form, quantity of the controlled substance prescribed and quantity dispensed if different from the quantity prescribed; and
(6) the total number of refills authorized by the prescribing practitioner.

Sec. 21a-244-2. Refill history capability requirement

Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for Schedule III, IV, or V controlled substance prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:

(a) the full name and address of patient;
(b) the full name and complete address of the prescribing practitioner;
(c) the name, strength and dosage form of the controlled substance;
(d) the date of refill;
(e) the quantity dispensed;

(f) the date on which the prescription was first dispensed;
(g) the original number assigned to said prescription;
(h) the name or initials of the dispensing pharmacist for each refill; and
(i) the total number of refills dispensed to date for that prescription order.

Sec. 21a-244-3. Documentation of data requirement

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation, a pharmacy using such a computerized system must provide either:

(1) a separate hard-copy printout of controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 21a-244-2 of the Regulations of Connecticut State Agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. Each prescription on said printout shall be reviewed by each individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This printout of the controlled substance prescription order refill data must be provided by each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed and must be verified and signed by each pharmacist who effected such dispensing as soon as

possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document; or

(2) In lieu of producing a hardcopy printout of daily refill information signed by each dispensing pharmacist, the pharmacy shall maintain a bound log book or separate file which each pharmacist involved in such dispensing shall sign in the same manner as he would sign a check or legal document. The signature of the dispensing pharmacist shall indicate that he has reviewed the refill information entered into the computer, which is attributed to him, for each date of dispensing and that it is correct as shown. Whenever possible, this log book or separate file shall be signed by each pharmacist on the date of dispensing but in no case shall it be signed later than the pharmacist's first work period in that pharmacy after such date.

Sec. 21a-244-4. Information available to commissioner upon request

Any computerized system shall have the capability of producing a printout of any refill data which the utilizing pharmacy is responsible for maintaining under Chapter 420b of the general statutes and the regulations promulgated thereunder. This shall include the capability to produce a refill by refill audit trail for any specified strength and dosage form of any controlled substance by either brand or generic name or both. Said printout shall be produced within 48 hours and shall indicate the following:

(a) the name of the prescribing practitioner;
(b) the name and address of the patient;
(c) the name, dosage form, strength, and quantity of the drug dispensed

on each refill;
(d) the name or initials of the dispensing pharmacist and the date of dispensing for each refill; and
(f) the number of the original prescription order.
Any pharmacy utilizing a computerized system and authorized to maintain records at a central record-keeping location, must be capable of obtaining the requested printout within 48 hours.

Sec. 21a-244-5. Auxiliary system provision

In the event that a pharmacy which employs such a computerized system experi- ences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, IV or V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again. All prescriptions refilled during the down-time shall be confirmed as being authorized upon resumption of on-line service.

Sec. 21a-244-6. When handwritten system is allowed

If an automated data processing system is used for the storage and retrieval or refill information for prescription orders as authorized by Section 21a-244 of the general statutes, and the regulations promulgated thereunder, the pharmacy may use a traditional, handwritten system only to satisfy the requirement of Section 21a- 244-5 of the regulations of State agencies.

Sec. 21a-244-7. Notice to commissioner upon commencement of use

Any pharmacy instituting an automated data processing system for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder shall notify in writing the Drug Control Division of the Department of Consumer Protec- tion at least 30 days prior to the commencement of usage of said system.

Sec. 21a-244-8. Compliance with federal law

Notwithstanding the provisions of Section 21a-244 of the general statutes and the regulations promulgated thereunder, there must be compliance with all applicable federal laws.

Sec. 21a-244-9. Requirement of safeguards

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, it shall:

(a) guarantee the confidentiality of the information contained in the data bank;and

(b) be capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.

Sec. 21a-244-10. Reconstruction of data in case of accident

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Sec. 21a-244-11. Discontinuance of data processing system

In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:

(a) notify the Drug Control Division of the Department of Consumer Protection in writing at least 30 days prior to discontinuance of said system;

(b) provide an up-date hard-copy printout of all prescriptions stored in the auto- mated system for the three years immediately preceding as part of the final records of that pharmacy prior to a change over to a manual system; and

(c) make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the general statutes

Electronic Drug Records in Hospitals

Sec. 21a-244a-1. Definitions

As used in section 21a-244a-2 to section 21a-244a-4, inclusive, of the Regulations of Connecticut State Agencies:

(1) ‘‘Drug record’’ means ‘‘drug record’’ as defined in section 21a-244a of the Connecticut General Statutes; and

(2) ‘‘Hospital’’ means ‘‘hospital’’ as defined in section 19a-490 of the Connecticut General Statutes.

Sec. 21a-244a-2. Use of electronic data processing system

Hospitals may create and maintain drug records using an electronic data processing system, provided they comply with the requirements of sections 21a-244a-3 and 21a-244a-4 of the Regulations of Connecticut State Agencies.

Sec. 21a-244a-3. Establishment of policy

Hospitals shall establish and comply with a policy in creating and maintaining electronic drug records. This policy shall be maintained electronically or in writing, shall be dated and shall accurately reflect the manner in which electronic drug records are currently created and maintained at the hospital. This policy shall be readily available for

inspection by the Department of Consumer Protection for a period of three years from its last effective date.

Sec. 21a-244a-4. Content of policy

A hospital, in establishing the policy required by section 21a-244a-3 of the Regulations of Connecticut State Agencies, shall include:

(1) a description of the electronic data processing system being used by the hospital to create and maintain records. This description shall include at least the following information:

(A) the specific types of drug records being maintained electronically on the system; and

(B) the hospital's patient populations and physical locations for which the elec- tronic drug record system is being utilized;

(2) the specific types of electronic identifiers, including but not limited to those listed in section 21a-244a(c) of the Connecticut General Statutes, that are utilized to access the hospital's electronic system, or used in place of written signatures or initials where required. All electronic identifiers described in the system shall be unique to an individual and shall be controlled in a secure manner;

(3) the manner in which access to the electronic drug record system is controlled. This shall, at a minimum, include:

(A) a description of the general levels of access into the system; and

(B) the mechanism by which the hospital identifies all individuals having access to the electronic system, their level of access and a description of how this access data is maintained by the hospital;

(4) the method by which individual electronic identifiers allowing access to the system are issued, maintained and terminated. This shall include, at a minimum, the following information:

(A) the specific individual or group at the hospital responsible for issuing, main- taining or terminating electronic identifiers;

(B) the procedure by which electronic identifiers are issued, maintained and terminated; and

(C) the method by which the uniqueness of electronic identifiers is established and their security maintained;

(5) the system by which electronic drug records are stored on-line, archived or maintained in some other manner that ensures that they are readily retrievable for a period of not less than three years;

(6) the recovery procedure utilized to reconstruct electronic drug records in the event the system experiences unscheduled downtime;

(7) the procedure utilized to routinely backup data stored on the electronic system to prevent the loss or destruction of electronic drug records;

(8) the method employed to prevent or detect unauthorized alteration or erasure of electronic drug records maintained on the system; and

(9) the procedure employed to ensure that all information contained in electronic drug records that is deemed to be confidential is appropriately

protected from unauthorized access and dissemination. Such confidential information shall, at a minimum, include the names of patients and prescribing practitioners. The electronic data processing system shall comply with all federal and state statutes and regulations pertaining to the confidentiality of patient drug records.

Record Keeping for Controlled Drugs Sec. 21a-254-1. Records

(a) In general, special and long-term hospitals there shall be a separate proof of use sheet as required in subsection (e) of section 21a-254 of the general statutes for controlled drugs which are not dispensed or administered directly to patients from the hospital's pharmacy but are administered or dispensed from each floor stock. Such proof of use record shall show the date of administering or dispensing, the name of the person to whom or for whose use the drug is administered or dispensed, the kind and quantity of drug, the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the drug.

(b) In general, special and long-term hospitals where controlled drugs are dis- pensed or administered directly to patients from the hospital's pharmacy in quantities not exceeding four days' supply, the hospital may use a duplicate copy of the patient's medication record to record the drug administration or dispensing in lieu of a separate proof of use record as required by said subsection (e) of section 21a- 254.

Electronic Prescription Drug Monitoring Program Sec. 21a-254-2. Definitions

As used in sections 21a-254-2 to 21a-254-7, inclusive, of the Regulations of Connecticut State Agencies:

(1) ‘‘Controlled substance’’ means ‘‘controlled substance’’ as defined in section 21a-240 of the Connecticut General Statutes;

(2) ‘‘Department’’ means the Department of Consumer Protection;

(3) ‘‘Pharmacy’’ means ‘‘pharmacy’’ as defined in section 20-571 of the Connecti- cut General Statutes, or a pharmacy located in a hospital, long term care facility or correctional facility; and

(4) ‘‘Practitioner’’ means ‘‘Prescribing practitioner’’ as defined in section 20- 571 of the Connecticut General Statutes.

Sec. 21a-254-3. General requirements

A pharmacy that dispenses schedule II, III, IV, and V controlled substances shall transmit the prescription information for these controlled substances to the department. A hospital pharmacy, long term care facility pharmacy or correctional facility pharmacy shall transmit controlled prescription information for outpa- tients only.

Sec. 21a-254-4. Reporting

(a) A pharmacy that maintains prescription information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a

person who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Electronic Reporting Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy. A pharmacy shall transmit to the department the fields listed in said reporting standard, including, but not limited to, the following:

(1) Drug Enforcement Administration Pharmacy number; (2) Birth date;
(3) Sex code;
(4) Date prescription filled;
(5) Prescription number; (6) New-refill code;
(7) Quantity;
(8) Days supply;
(9) National Drug Code number;
(10) Drug Enforcement Administration Prescriber identification number;
(11) Date prescription written;
(12) Number of refills authorized;
(13) Prescription origin code;
(14) Patient last name;
(15) Patient first name;
(16) Patient street address;
(17) State;
(18) Payment code for either cash or third-party provider; and
(19) Drug name.
(b) A copy of the Electronic Reporting Standard for Prescription Monitoring Programs may be obtained from the American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160, Blue Bell, Pennsylvania 19422. Telephone: (610) 825-7783. Website: www.asapnet.org.

(c) A pharmacy that maintains prescription information electronically shall transmit the required information by means of one of the following methods:
(1) Electronic data transmission through a computer modem that can transmit information at a rate of 2400 baud or more;
(2) Computer disc; or
(3) Magnetic tape of the kind that is used to transmit information between computerized systems.
(d) A pharmacy that does not maintain prescription information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a person who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit to the Drug Control Division of the department the information set forth in subsection (a) of this section on a paper form provided by the department.

(e)(1) A pharmacy shall transmit to the department the information required pursuant to this section not later than month for all prescriptions dispensed on and between * for current requirements please see statute.

(2) If the reporting date falls on weekend or a holiday, a pharmacy shall transmit the required information by the next state of Connecticut workday.

(f) A pharmacy shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996.

Sec. 21a-254-5. Evaluation

Agents of the Drug Control Division of the department, and any department employee authorized to work with the Drug Control Division, shall evaluate the controlled substance prescription information received from pharmacies. The depart- ment shall evaluate the prescription information for the purposes of preventing controlled substance diversion, public health initiatives, and statistical reporting.

Sec. 21a-254-6. Management of information

The department may provide prescription information obtained from pharmacies to:

(a) Other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes;

(b) Practitioners, for the purpose of education in lieu of disciplinary, civil or criminal action;

(c) Practitioners and pharmacists, for the purposes of patient care, drug therapy management and monitoring of controlled substances obtained by the patient; and (d) Public or private entities, for statistical, research, or educational purposes, provided that the privacy of patients and confidentiality of patient information is not compromised.

Sec. 21a-254-7. Storage of information

(a) The department shall ensure the privacy of patients and confidentiality of patient information transmitted or obtained pursuant to sections 21a-254-2 to 21a- 254-6, inclusive, of the Regulations of Connecticut State Agencies, and shall ensure that the patient information

collected, recorded, transmitted, and stored is maintained in accordance with applicable state and federal laws, rules and regulations.

(b) The department shall retain the prescription information collected pursuant to sections 21a-254-2 to 21a-254-6, inclusive, of the Regulations of Connecticut State Agencies,for a minimum of three years.

Minimum Security and Safeguard Requirements for Storage and Handling of Controlled Substances

Sec. 21a-262-1. Definitions

(a) Controlled Substances means a drug, substance, or immediate precursor so designated as a controlled drug or controlled substance pursuant to state and/or federal drug laws and regulations.

(b) **Schedules of Controlled Substances.** For security purposes, each particular controlled substance shall be considered to be in the schedule as designated in each particular instance by applicable state and/or federal drug laws or regulations. In instances of conflict between state and federal drug laws or regulations, the controlled substances shall be considered to be in the schedule providing the highest degree of control.

(c) Registrant means any person of firm registered with the federal government for conduct of any business activity with controlled substances. The person signing the federal application for registration for controlled substances shall be considered to be the registrant for security purposes.

(d) **Classification of Registrants.** For security purposes, registrants shall be classified according to the business activity for which they are registered under the federal controlled substances act.

(e) **Controlled Substance(s) Units:** A controlled substance unit shall be a unit consisting of a quantity of controlled substance(s) which shall be determined according to the following formula:

#100 Tablets or Capsules—shall be 1 unit
One pint of a liquid—shall be 1 unit
One multiple dose vial—shall be 1 unit
Ten suppositories—shall be 1 unit
Ten single dose Ampules, Tubexes, Dosettes, Hyporettes, or other single dose package forms for injection whether powder or in solution—shall be 1 unit The quantity of controlled substance(s) stocked by any registrant shall be determined for security purposes by totaling the number of controlled substance(s) units currently on hand. Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger pack- age sizes shall be counted according to the number of controlled substance units they contain. Package sizes less than a full controlled substance unit shall be counted as the fraction of a controlled substance unit which the package size contains, i.e., #50 Tablets shall be counted as .5 controlled substance units.
(f) An approved safe or safe(s) as used in sections 21a-262-1 to 21a-262-10, inclusive, of the Regulations of Connecticut State Agencies means any safe(s) that has been approved prior to January 1, 1975 or any safe(s) which conforms to or exceeds all of the following standards:
(1) A minimum of a B Burglary Rate;
(2) Equipped with a relocking device;

(3) Weight of 750 pounds or more or rendered immobile by being securely anchored to a permanent structure of the building; and
(4) Adequate interior space to store all controlled substances required to be kept within the safe.

(g) An approved vault as used in sections 21a-262-1 to 21a-262-4 inclusive, means a vault approved prior to January 1, 1975 or a vault constructed after January 1, 1975 and meeting the following specifications or equivalent:

(1) Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings.

(2) The door of the vault must contain a multiple-position combination lock or the equivalent, a relocking device or equivalent and steel plate with a thickness of at the vault door.)

(3) The vault, if operations require it to remain open for frequent access, must be equipped with a ‘‘day gate’’ which is self-closing and self-locking or the equiva- lent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always relocked immediately after use, a ‘‘day gate’’ is not required.

(4) The walls, floor, and ceiling of the vault must be equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant. If necessary, due to local conditions or

other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.

(5) The vault door must be equipped with a contact switch.

(6) The vault must have at least one of the following:
a. Complete electrical lacing of the walls, floor and ceiling or
b. Sensitive ultrasonic equipment within the vault or
c. A sensitive sound accumulator system or
d. Such other device designed to detect illegal entry as may be approved by the Commissioner of Consumer Protection.

(7) The electrical alarm system must be certified as being an Underwriters Laboratories, Inc., approved system and installation.

Sec. 21a-262-2. Security requirements

(a) Requirements for minimum security and safeguard standards for storage and handling of controlled substances may be determined for each registrant by the Commissioner of Consumer Protection after consideration of the protection offered from an overall standpoint in instances wherein other security measures provided exceed those specifically stated. If the registrant has provided other safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such registrant such as supervised watchman service, full electrical protection of the building, electric alarms, etc., such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the

Commissioner of Consumer Protection which may include approved vault(s), approved safe(s), electrical alarm protection, and/or hold up button(s).

(b) In all instances, registrants shall maintain all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel. Such specific authorization should be given by registrants only to the minimum number of employees absolutely essential for efficient operation. All controlled substances should be stored in such a manner as to prevent theft or diversion of these preparations.

(c) In all instances, registrants shall maintain all equipment used for storage of controlled substances such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc., securely locked except for the actual time required to remove or replace needed items. Locks shall be kept in good working order with keys removed therefrom. Keys to the locks shall not be left in a location accessible to other than specifically authorized personnel.

(d) Any controlled substance(s) stored at any location not stored in compliance with section 21a-262-1 through section 21a-262-10 inclusive, or at a location other than that for which the person, firm, or business activity is registered under the Federal Controlled Substances Act shall be subject to seizure by the Commissioner of Consumer Protection. This action of seizure shall be considered as being in the best interests of the general public and said Commissioner shall not be held liable for any loss of revenues suffered by the person surrendering the drugs.

(e) Any wholesaler, manufacturer, or laboratory licensed by the Commissioner of Consumer Protection, who after due process, has his

license revoked or suspended by said Commissioner, or who does not within 30 days apply for relicensure shall upon loss of said license dispose of his entire stock of controlled substances under conditions approved by the Commissioner or surrender his entire supply of controlled substances to said Commissioner. Any Licensed Pharmacy or any Practitioner who has his license revoked or suspended by his respective Licensing Board or who does not apply for relicensure, shall dispose of his entire stock of Controlled Sub- stances under conditions approved by the Commissioner of Consumer Protection or shall surrender his entire stock of Controlled Substances to said Commissioner. This action of surrender shall be considered as being in the best interest of the general public, and said Commissioner shall not be held liable in any way for any loss of revenue suffered by the person surrendering these drugs.

(f) If any case where a loss, theft, burglary, or diversion of controlled substances has occurred, the Commissioner of Consumer Protection may require additional security safeguards which may include storage of any controlled substance(s) in an approved vault, approved safe, separate locked caged area, locked room or enclosure, or a substantially constructed locked steel or wood cabinet, or under effective electrical protection within 90 days of any such occurrence. In the case of hospitals, 180 days shall be allowed for this purpose.

(g) Registrants shall not maintain any stock of controlled substance(s) in excess of the quantity actually required for normal, efficient operation.

Sec. 21a-262-3. Disposition of drugs

(a) Disposal of undesired, excess, unauthorized, obsolete, or deteriorated con- trolled substances shall be made by a registrant, person having title to, enforcement or court official, executor of an estate, or any other person in the following manner:

(1) By transfer to a person or firm registered under the Federal Controlled Sub- stances Act and authorized to possess such controlled substances providing all state and federal required procedures are complied with.

(2) By following procedures as outlined in Sections 307.21 of the Code of Federal Regulations.

(3) By the following manner in the case of hospital pharmacies where small quantities of less than No. 10 controlled substance units are involved on any separate occasion:

(a) By destruction in such a manner as to render the controlled substance(s)non-recoverable.

(b) By destruction conducted by a Connecticut licensed pharmacist in the presence of another Connecticut licensed pharmacist acting as a witness.

(c) By maintaining a separate record of each such destruction indicating the date, time, manner of destruction, the type, strength, form, and quantity of controlled substance(s) destroyed, and the signatures of the pharmacist destroying the controlled substance(s) and the pharmacist witness.

(4) By a manner rendering the controlled substance(s) nonrecoverable in cases where such controlled substance(s) are legally possessed by a person for his/her own personal use pursuant to a bonafide medical condition.

(5) By surrender without compensation of such controlled substance(s) to the Commissioner of Consumer Protection in all other instances.

(b) Reporting of loss, theft, or unauthorized destruction of controlled substances. Any loss, theft, or unauthorized destruction of any controlled substance(s) must be reported by a registrant within 72 hours of discovery of any such occurrence to the Commissioner of Consumer Protection as follows:

(1) Where through breakage of the container or other accident, otherwise than in transit, controlled substance(s) are lost or destroyed, the registrant shall make a signed statement as to the kinds and quantities of controlled substance(s) lost or destroyed and the circumstances involved. The statement shall be forwarded to the Commissioner of Consumer Protection and a copy retained by the registrant.

(2) Where controlled substance(s) are lost by theft or otherwise lost or destroyed in transit, the consignee, and the consignor if within this state, shall forward to the Commissioner of Consumer Protection a signed statement which details the facts, includes an accurate listing of the controlled substance(s) stolen, lost, or destroyed and specifies that the local authorities were notified. A copy of the statement shall be retained by the registrant.

Sec. 21a-262-4. Manufacturers, wholesalers, distributors, importers, and exporters

(a) Schedule II Stock if less than No. 250 controlled substance units shall be stored in an approved safe equipped with a separate effective electrical alarm system. Schedule II Stock, if 250 or more controlled substance units all schedule II controlled substances shall be stored in an approved vault equipped with a separate effective electrical alarm system.

(b) Schedule III, IV, V Stock shall be stored in an approved vault, approved safe equipped with a separate effective electrical alarm system, or separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system. If a caged area or enclosure is used, such caged area or enclosure must be completely enclosed. If a caged area is used, construction must be of heavy gauge wire mesh having openings smaller than the smallest controlled substance(s) contain- ers stocked.

(c) All controlled substances in the process of manufacturing, distribution, transfer, or analysis shall be stored in such a manner as to prevent diversion; shall be accessible only to the minimum number of specifically authorized personnel essential for efficient operation; and shall be returned to the required security location immedi- ately after completion of the procedure or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing controlled

Sec. 21a-262-5. Licensed pharmacies

(a) Schedule II Stock, if less than No. 150 controlled substance units a substan- tially constructed completely enclosed locked wood or metal cabinet shall be used for storage of all schedule II controlled substance stock. If No. 150 or more controlled substance units an approved safe shall be used for storage of all schedule II controlled substance stock. Pharmacies newly licensed and/or relocating after Jan. 1, 1975 shall be required to store all schedule II controlled substances in an approved safe.

(b) Schedule III, IV, V Stock shall be stored in an approved safe, substantially constructed locked metal or wood cabinet, or dispersed throughout stock within the pharmacy prescription compounding area providing requirements of Section 21a- 262-2 (b) are complied with and a loss, theft, or diversion of any controlled substance in any schedule has not occurred.

(c) In every case where loss, theft, burglary, or diversion other than armed robbery during regular scheduled business hours of any controlled substance in any schedule has occurred from a licensed pharmacy, the Commissioner of Consumer protection shall determine the appropriate storage and security requirements for all controlled substances, and shall require additional safeguards to ensure the security of the controlled substances.

(d) The Commissioner of Consumer Protection may require any licensed pharma- cy(ies) to store any controlled substance stock in an approved safe, or locked substantially constructed cabinet for security purposes when overall conditions warrant additional safeguards.

Sec. 21a-262-6. Practitioners including but not limited to medical doctors, dentists, veterinarians, osteopaths, and podiatrists

(a) Schedule II and III Controlled Substance Stock, if total is No. 15 controlled substance units or less shall be stored in a locked substantially constructed steel or wood cabinet in a securely safeguarded location. If the total quantity of schedule II and III controlled substance stock is more than 15 controlled substance units, such stock shall be stored in an approved safe. In the case of veterinary practitioners an additional No. 25 controlled substance units of schedule II or III controlled substance stock of the barbiturate-type, for use solely for animal anesthesia or animal euthenasia, may be stored in a locked substantially constructed steel or wood cabinet.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a locked substantially constructed steel or wood cabinet or in a securely safeguarded location. (c) In no case shall a practitioner's controlled substance stock be left unsecured or unattended in an examining room, treatment room, automobile, or in any other location assessible to nonauthorized persons. (Effective July 27, 1984)

Sec. 21a-262-7. Laboratories other than hospital clinical laboratories

(a) Schedule I and II Controlled Substance Stock shall be stored in an approved safe except where schedule II stock of the barbiturate type is used solely for its sedative or anesthetic effect on animals and not more than No. 10 Controlled Substance units are stocked, in which cases security as outlined for schedule III controlled substances in Section 21a-262-7 (b) will apply. In instances in laboratories where schedule I or II stock may be unstable, of extremely small quantity, or of such a nature

as to require special storage conditions, the Commissioner of Consumer Protection may approve of other security safeguards on an individual basis in lieu of those required by section 21a-262-1 through 21a-262-10 inclusive.

(b) Schedule III, IV or V Controlled Substances Stock shall be stored separately from other drugs and substances in an approved safe or separate secure locked location accessible only to the minimum number of specifically authorized personnel essential for efficient operation.

(c) Controlled Substances in the process of testing, use, or research shall be immediately returned to the required storage location upon completion of each such process.

Sec. 21a-262-8. Pharmacies or other areas wherein controlled substances are stored, prepared, or dispensed exclusive of those specifically referred to in section 21a-262-9 and section 21a-262-10 located within licensed hospitals, mental health hospitals, mental retardation facilities, training schools, correctional institutions, juvenile training or youth services facilities, edu- cational institutions, health maintenance organizations, health facilities, and within other care giving institutions or establishments including those which are private, state, or municipally operated, and including hospital drug rooms, hospital satellite pharmacies, and hospital clinical labora- tories

(a) Schedule II and III Controlled Substance Stock in quantities of less than No. 150 controlled substance units shall be stored separately from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. In the case of Hospital Clinical

Laboratories, Schedule II Controlled Sub- stance stock shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 150 controlled substance units or more but less than No. 1000 controlled substance units shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 1000 controlled substance units or more shall be stored in a completely enclosed masonry room or equivalent equipped with a vault-type steel door with horizontal or vertical locking bolts, having a three-tumbler combination lock and a relocking device. The com- pletely enclosed masonry room or equivalent, if operations require it to be opened for frequent access, must be equipped with a ‘‘day gate’’ which is self-closing and self-locking or the vault type steel door must be equipped with a key locking device or an equivalent day locking device.

Completely enclosed masonry rooms or equivalents constructed after January 1, 1975, must be equipped with an electrical alarm system which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a secure location within the pharmacy prescription compounding area or drug room.

Schedule IV and V Controlled Substance Stock stored within hospital clinical laboratories shall be kept in a separate secure locked location.

(c) Controlled Substance Stock within any such pharmacy shall not be accessible to other than specifically authorized pharmacy personnel, and shall be handled by authorized pharmacy personnel only.

Sec. 21a-262-9. Hospital patient care areas, hospital nursing stations, other hospital drug storage locations, chronic and convalescent nursing homes, rest homes with nursing supervision, children's nursing homes, and areas and locations within correctional and/or juvenile training facilities, youth service facilities, mentally retarded facilities, and any other location other than pharmacies, hospital clinical laboratories, satellite pharmacies, or drug rooms, wherein drugs are stored, prepared, or dispensed not specifi- cally referred to in section 21a-262-1 through section 21a-262-10 inclusive

(a) ScheduleII Controlled Substances in small amounts not exceeding the quantity necessary for efficient operation kept at any specific individual area or location shall be stored in a locked substantially constructed nonportable and immobile metal cabinet or metal container within another separate locked enclosure. Keys shall not be the same for each of these locks and such keys shall be kept on two separated key rings or holders. Not more than one set of keys for the schedule II controlled substance cabinets shall be available to nonsupervisory personnel.

(b) At the beginning of each work period or shift, a nurse must be assigned responsibility for the security of schedule II controlled substance stock. Such respon- sibility shall be assumed by each said nurse who shall prepare a signed inventory indicating each kind and quantity of schedule II controlled substance received, the time and date

received, and from whom received. This responsibility shall not be transferred or assigned to another nurse or person during the course of each work period or shift unless another signed inventory transferring responsibility is first prepared. For systems regulated under subsection (h) of this section, the requirements of this subsection shall be extended to include schedule III, IV and V controlled substance stock in addition to schedule II controlled substance stock.

(c) Schedule III, IV, V Controlled Substance Stock in small amounts not exceeding the quantity necessary for normal efficient operation of each individual unit shall be stored with Schedule II Controlled Substances in compliance with security measures as required per Section 21a-262-9 (a) or separately from other drugs and/or substances in a separate secure locked nonportable immobile substan- tially constructed cabinet or container. Access to such cabinet or container shall be limited to a minimum number of personnel essential for efficient operation.

(d) Schedule III, IV, V Controlled Substance Stock in small quantities intended for emergency use only, may be stored within an emergency drug kit or on emergency crash carts equipped with disposable locking or sealing devices, provided adequate security measures for such controlled substance stock are maintained and required record-keeping procedures are complied with.

(e) The same security requirements shall apply for controlled substances obtained pursuant to individual patient(s) prescriptions as for stock controlled substances as outlined under this section 21a-262-9 inclusive. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient, shall be securely kept and safeguarded until properly disposed of.

(f) In cases involving Unit Dose or experimental, trial, new, or innovative drug distribution procedures, the Commissioner of Consumer Protection may approve of other controlled substance(s) security safeguards for a specific time period, in lieu of any required by section 21a-262-1 through section 21a-262-10 inclusive, on an individual basis after evaluating each such drug distribution procedure. Such approval may be extended indefinitely by said Commissioner upon such successful completion of the trial period. If approval is not given by said Commissioner prior to the implementation of any such drug distribution procedure, controlled substance security requirements as outlined in section 21a-262-1 through section 21a-262-10 inclusive shall apply.

(g) Where unwanted partial or individual doses of Controlled Substances are discarded by nursing personnel, a record of each such destruction must be made indicating the date and time of each such destruction; the name, form, strength, and quantity of Controlled Substance destroyed; the signature of the nurse destroying the Controlled Substance, and the signature of another nurse who witnesses such destruction. In other than hospital locations, an authorized person may witness such destruction.

(h) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, the following security safeguards shall be approved in lieu of any required by section 21a-262-9 (a) and (c); except that compliance with this subsection shall not be required of a facility using a mobile medication cart system previously approved for use in that facility by the commissioner of consumer protection. Compliance with this subsec- tion by facilities with previously approved systems shall be in lieu of the requirements of such previously approved systems.

(1) Mobile medication carts shall be of substantial construction and shall incorporate the following security features:

(A) A separate, lockable, non-removable drawer or compartment for storage of all controlled substances,

(B) The key which locks the controlled substance drawer or compartment shall be different from the key(s) to all other locking devices on each cart and such keys shall not be interchangeable between carts within the same facility, and

(C) Locking mechanism(s) which will secure the entire contents of the cart without requiring the use of a key;

(2) Mobile medication carts when not in use shall be locked and stored within a limited access locked and enclosed medication room or closet or other substantially constructed enclosed structure;

(3) Mobile medication carts shall be securely locked at all times when unattended. All medication and injection equipment shall be stored within the locked cart. Locking devices shall be maintained in good working order;

(4) The separate controlled substance drawer or compartment shall be securely locked at all times except for the actual time required to remove or replace needed items or to conduct an audit;

(5) The keys to the controlled substance drawer or compartment of each mobile cart shall be separated from the keys to the other locking devices of that cart and shall be carried personally by the nurse responsible for the required controlled substance audit during each nursing shift and no duplicate keys shall be available to other than specifically designated supervisory personnel;

(6) Requirements of section 21a-262-9 (b) concerning audits of controlled sub- stance stocks shall be extended to include schedule III, IV, and V controlled substance stock in addition to schedule II controlled substance stock;

(7) Record keeping entries of controlled substances administered shall be made at the time of administration;

(8) The director of nursing or his/her nursing supervisor designee shall conduct unannounced documented audits of all controlled substance stocks on all units at least twice a month; and

(9) All controlled substance medications shall be inventoried when received and immediately placed into the controlled substance drawer or compartment within the mobile cart. Quantities of patients' controlled substance medications stored within mobile medication carts shall be limited to the minimum quantities necessary to provide for normal efficient operation and shall be promptly removed for proper disposition when no longer needed by the patient.

(i) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, other security safeguards in lieu of any required by section 21a-262-9 (h) may be approved by the commissioner of consumer protection on an individual basis after evaluating the drug distribution procedure of the applicant for approval pursuant to this subsection.

Sec. 21a-262-10. Industrial health facilities, educational institution infirmar- ies, clinics, summer camps, and other institutions or establishments provid- ing health care services including those which are group, private, state, and/or municipally operated

(a) ScheduleII and III Controlled Substance Stock, if No.15 controlled substance units or less shall be stored separate from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. Schedule II and III Controlled Substance Stock if in excess of No. 15 controlled substance units shall be stored in an approved safe.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a separate secure locked location or with Schedule II and III Controlled Substances in compli- ance with security measures as required per section 21a-262-10 (a).

(c) Controlled Substances for Stock use shall be purchased or obtained by the medical director or physician in charge from a wholesaler or manufacturer of drugs, and shall be handled only by an authorized physician, Connecticut licensed pharma- cist, or Connecticut licensed nurse. Controlled substances shall be the property of the medical director or physician in charge who shall be responsible for security requirements and record keeping procedures.

(d)The same security requirements shall apply for controlled substances obtained pursuant to patient(s) prescriptions as for stock controlled substances. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient shall be securely kept and safeguarded until properly disposed of.

Registration of Practitioners for Controlled Substances Sec. 21a-326-1. Definitions

(a) ‘‘Abuse or Excessive Use of Drugs’’ means the personal use of controlled substances by a practitioner or other registrant in such dosage and frequency not warranted by an existing medical condition or use of controlled substances solely for a stimulant, depressant, or hallucinogenic effect which use is not within the medical consensus or stated in the medical literature as acceptable or proper.

(b) ‘‘Controlled Substance Schedules’’ means the grouping of drugs, schedules 1 through 5, as delineated in Section 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation. Any particular controlled substance shall be deemed to be in the schedule wherein such controlled substance appears by its chemical or generic name within Sec. 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation.

(c) ‘‘Course of Professional Practice’’ means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the ‘‘course of professional practice.’’

(d) ‘‘Effective Controls Against Diversion’’ means the implementation of the following controls on a regular basis necessary for the prevention of diversion of controlled substances:

(1) Prescribing, dispensing, or administering of controlled substances only after a proper medical evaluation.

(2) Maintaining of controlled substance record keeping and security requirements pursuant to Chapter 420b of the Connecticut General Statutes.

(3) Providing for adequate security of prescription blanks to prevent thefts and/ or illegal use.

(4) Regular monitoring of patient(s) conditions in instances wherein continued or prolonged treatment with controlled substances is indicated.

(5) Refraining from knowingly prescribing controlled substances for persons abusing such controlled substances and/or using such controlled substances for purposes of maintenance of drug dependency unless pursuant to state and federal regulations pertaining to treatment of drug dependent persons.

(6) Compliance with all state and federal statutes and regulations concerning controlled substances.

(e) ‘‘Therapeutic or Other Proper Medical or Scientific Purposes’’ means the following:

(1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the

manufacturers of the controlled substances as being the purposes for which the controlled substance is intended.

(2) Investigational use of a controlled substance by a researcher or scientist wherein documentation of necessity of use of such controlled substances is maintained.

(f) ‘‘Legend drug’’ is any article, substance, preparation or device which bears the legend: ‘‘CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.’’

Sec. 21a-326-2. Registration applications and renewals

Registration applications and renewals shall be on such forms as furnished by the Commissioner of Consumer Protection and shall whenever so indicated be signed by the applicant.

(a) All registration applications shall contain all information required by the Commissioner of Consumer Protection. Applications not inclusive of required data or those which are illegibly executed may be returned for correction.

(b) It shall be the responsibility of all practitioners, hospitals, or other institutions who propose to engage in distributing, prescribing, administering, dispensing, or using any controlled substance within this state to submit an application for registration with the appropriate fee to the Commissioner of Consumer Protection. The Commissioner shall issue a certificate of registration in accordance with the provisions of Chapter 420c of the General Statutes.

(c) It shall be the responsibility of the applicant to submit his/her registration renewal application to the Commissioner at least one month prior to the expiration of his/her current registration.

(d) All practitioners, hospitals, clinics, or other authorized persons or facilities wishing to prescribe, administer, or dispense controlled substances shall obtain a certificate of registration issued by the commissioner of consumer protection as mated by Section 21a-317 of the General Statutes. No controlled substance shall be prescribed, administered, or dispensed until such registration has been approved by the commissioner. Regulation fees shall not be prorated.

(e) For registration purposes applicants shall be classified as follows:
(1) Practitioner;
(2) Hospital;
(3) Clinic;
(4) Others.

All practitioners shall designate their specific professional practice; e.g., M.D., dentist, veterinarian, osteopath or podiatrist on their application for registration. Other applicants shall designate their appropriate title; i.e., Ph.D., Director, Director of Pharmacy, Administrator, President, Manager, etc.

Sec. 21a-326-3. Notification of failure to obtain or renew registration

The Commissioner of Consumer Protection shall notify the Federal Drug Enforcement Administration or its successor, of the failure of any practitioner or researcher to obtain or renew a valid state registration; or of any administrative action taken by the Commissioner resulting in the

denial, surrender, suspension, or revocation of a registration or the limitation of the controlled substance schedules of a registration.

Sec. 21a-326-4. Responsibility of registrant

(a) It shall be the responsibility of a registrant who ceases to practice or who goes out of business to notify the Commissioner in writing five (5) days before such occurrence.

(b) It shall be the responsibility of the registrant to notify the Commissioner within thirty (30) days of any changes in information or data required on the registration application pursuant to which any registration is issued.

Sec. 21a-326-5. Registration of controlled substances

(a) It shall be the responsibility of the registrant to be registered in accordance with state and federal controlled substance laws for those particular controlled substance schedules incorporating those drugs used or to be used within the scope of his/her professional practice.

(b) A registrant may voluntarily surrender his/her controlled substance registration privileges in any or all controlled substance schedules to the Commissioner of Consumer Protection or may voluntarily refrain from registering in those controlled substance schedules not applicable to his/her professional practice or scientific research.

(c) The Commissioner of Consumer Protection may in accordance with Sections 21a-323 and 21a-324 of the General Statutes limit the schedules for which the practitioner is registered.

STATE OF CONNECTICUT REGULATION
of the
DEPARTMENT OF CONSUMER PROTECTION concerning
PALLIATIVE USE OF MARIJUANA

The Regulations of Connecticut State Agencies are amended by adding sections 21a-408-1 to 21a-408-70, inclusive, as follows:

(NEW) **Sec. 21a-408-1. Definitions**

As used in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies:

(1) “Abuse of drugs" means the use of controlled substances solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent prescribed in the course of medical treatment or in a program of research operated under the direction of a physician or pharmacologist;

(2) “Act” means Sections 21a-408 to 21a-408q, inclusive, of the Connecticut General Statutes;

(3) “Administer" means the direct application of marijuana to the body of a qualifying patient by inhalation, ingestion or any other means;

(4) “Adulterated” has the same meaning as described in section 21a-105 of the Connecticut General Statutes;

(5) “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 marijuana;

(6) “Agent" means an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(7) “Approved safe” has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(8) “Approved vault” has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(9) “Batch” means a specific harvest of marijuana or marijuana products that are identifiable by a batch number, every portion or package of which is uniform within recognized tolerances for the factors that were subject to a laboratory test and that appear in the labeling;

(10) “Board” means the Board of Physicians appointed under the provisions of section 21a-408l of the Connecticut General Statutes;

(11) “Bona fide physician-patient relationship” means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient’s debilitating medical condition, or a symptom of the patient’s debilitating medical condition, for which the physician has certified to the department that the patient would benefit from the palliative use of marijuana;

(12) “Commissioner” means the Commissioner of Consumer Protection;

(13) “Compounding” means to combine, mix or put together two or more ingredients and includes the preparation of a marijuana product in anticipation of a qualifying patient, primary caregiver or physician request;

(14) "Controlled substance" means a drug, substance, or immediate precursor listed in sections 21a-243-7 through 21a-243-11, inclusive, of the Regulations of Connecticut State Agencies;

(15) “Cultivation” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(16) “Debilitating” means a chronic medical condition that causes weakness or impairs the strength or ability of an individual and has progressed to such an extent that it substantially limits one or more major life activities of such individual. An assessment of whether a major life activity has been substantially limited shall be guided by interpretations of the term “disability” as set forth in 42 USC 12102(1)(A);

(17) “Debilitating medical condition" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(18) “Deliver” or “delivery" means the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship;

(19) “Department” means the Department of Consumer Protection;

(20) “Dietary supplement” has the same meaning as provided in 21 U.S.C. 321; (21) "Dispensary" has the same meaning as provided in

section 21a-408 of the Connecticut General Statutes;

(22) “Dispensary department” means that area within a dispensary facility where marijuana is stored, dispensed and sold. If a dispensary facility does not offer any products or services other than marijuana and paraphernalia, the entire dispensary facility is a dispensary department for purposes of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(23) “Dispensary facility” means a place of business where marijuana may be dispensed or sold at retail to qualifying patients and primary caregivers and for which the department has issued a dispensary facility license to an applicant under the Act and section 21a-408-14 of the Regulations of Connecticut State Agencies;

(24) “Dispensary facility backer” means, except in cases where the dispensary is the sole proprietor of a dispensary facility, any person with a direct or indirect financial interest in a dispensary facility, except “dispensary facility backer” does not include a person with an investment interest in a dispensary facility provided the interest held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, do not exceed five per cent of the total ownership or interest rights in such dispensary facility and such person does not participate directly or indirectly in the control, management or operation of the dispensary facility;

(25) “Dispensary facility manager” means the dispensary who has complete control and management over the dispensary facility;

(26) “Dispensary facility employee” means a dispensary, dispensary technician, dispensary facility staff and all other persons employed by a dispensary facility or who otherwise have access to the dispensary

facility, including independent contractors who are routinely on the facility premises;

(27) “Dispensary technician" means an individual who has had an active pharmacy technician registration in Connecticut within the past five years, is affiliated with a licensed dispensary and is registered with the department in accordance with section 21a-408-24 of the Regulations of Connecticut State Agencies;

(28) “Dispense” or “dispensing" means those acts of processing marijuana for delivery or for administration for a qualifying patient pursuant to a written certification consisting of:

(A) Comparing the directions on the label with the instructions on the written certification, if any, to determine accuracy;
(B) the selection of the appropriate marijuana product from stock;
(C) the affixing of a label to the container; and
(D) the provision of any instructions regarding the use of the marijuana;

(29) “Dispensing error" means an act or omission relating to the dispensing of marijuana that results in, or may reasonably be expected to result in, injury to or death of a qualifying patient or results in any detrimental change to the medical treatment for the patient;

(30) “Disqualifying conviction” means a conviction for the violation of any statute or regulation pertaining to the illegal manufacture, sale or distribution of a controlled substance or controlled substance analog unless the violation resulting in the conviction occurred when the person held a valid license or registration certificate from the department and the violation was of a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the

Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(31) “Drug Control Division” means the division within the department responsible for overseeing the medical marijuana program;

(32) “Drug” has the same meaning as provided in section 20-571 of Connecticut General Statutes;

(33) "Electronic data intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by dispensaries with those used by physicians or the department in order to facilitate the secure transmission of qualifying patient or primary caregiver information;

(34) “Financial interest" means any actual, or a future right to, ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment or family. “Financial interest” does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, do not exceed one-half of one per cent of the total number of shares issued by the corporation;

(35) “Forms” means applications, registrations, written certifications or other documents prescribed by the commissioner in either hardcopy or electronic format;

(36) “Good standing” means a person has a license or registration with the department that is not on probation or subject to any other restriction or oversight by the department beyond others in the same class;

(37) “Label" means a display of written, printed or graphic matter upon the immediate container of any product containing marijuana;

(38) “Laboratory" means a laboratory located in Connecticut that is licensed by the department to provide analysis of controlled substances pursuant to section 21a- 246 of the Connecticut General Statutes;

(39) “Legend drug” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(40) “Manufacture” or “manufacturing” means any process by which marijuana is converted to a marijuana product and that involves heating, mixing marijuana with any other ingredient or otherwise altering the raw material;

(41) “Marijuana” has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

(42) “Marijuana product” means any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to dispensaries, qualifying patients and primary caregivers;

(43) “One-month supply” means the amount of marijuana reasonably necessary to ensure an uninterrupted availability of supply for a thirty-day period for qualifying patients, which amounts, including amounts for topical treatments, shall be determined by the commissioner on the basis of practical administration of the Act, available research and recommendations from the Board of Physicians;

(44) “Palliative use” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(45) “Paraphernalia” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(46) “Person” includes any corporation, limited liability company, association or partnership, or one or more individuals, government or governmental subdivisions or agency, estate, trust, or any other legal entity;

(47) “Pesticide chemical” has the same meaning as provided in section 21a-92 of the Connecticut General Statutes;

(48) “Petition” means a written request submitted pursuant to the Act and section 21a-408-12 of the Regulations of Connecticut State Agencies that recommends adding a medical condition, medical treatment or disease to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(49) “Pharmaceutical grade marijuana” means marijuana or marijuana products that are not adulterated and are:

(A) processed, packaged and labeled according to the Food and Drug Administration’s “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” 21 CFR 111;

(B) labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and

(C) where each step of the production, cultivating, trimming, curing, manufacturing, processing and packaging method has been documented

by using established standard operation procedures approved by the commissioner;

(50) “Pharmacist” has the same meaning as provided in section 20-571 of Connecticut’s General Statutes;

(51) “Pharmacy technician” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(52) “Physician” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(53) “Prescription monitoring program” means the electronic prescription drug monitoring program established by section 21a-254(j) of the Connecticut General Statutes;

(54) “Primary caregiver” or “caregiver” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes for “primary caregiver”;

(55) “Producer” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(56) “Producer backer” means any person with a direct or indirect financial interest in an entity licensed as a producer, except it shall not include a person with an investment interest in a producer, provided the interest held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, does not exceed five per cent of the total ownership or interest rights in such producer and such person does not participate directly or indirectly in the control, management or operation of the production facility;

(57) "Production" or “produce” means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient’s use;

(58) “Production facility” means a secure, indoor facility where the production of marijuana occurs and that is operated by a person to whom the department has issued a producer license under the Act and sections 21a-408-20 of the Regulations of Connecticut State Agencies;

(59) “Production facility employee” means any person employed by a producer or who otherwise has access to the production facility, including independent contractors who are routinely on the production facility premises;

(60) “Qualifying patient” or “patient” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(61) “Registration certificate” means an identification card or other document issued by the department that identifies a person as a registered qualifying patient or primary caregiver;

(62) "Sale" is any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant or employee;

(63) "State", when applied to a part of the United States, includes any state, district, commonwealth, territory or insular possession thereof, and any area subject to the legal authority of the United States of America;

(64) "Usable marijuana" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes; and

(65) "Written certification" means a written or electronically submitted statement issued by a physician to the department certifying a patient for the palliative use of marijuana, which shall be submitted on a form and in a manner prescribed by the commissioner.

Sec. 21a-408-2. Physician requirements for issuing written certifications to the department

(a) The department shall only accept written certifications from physicians for the palliative use of marijuana when the physician:

(1) Holds an active license under chapter 370 of the Connecticut General Statutes and is in good standing;

(2) Holds an active department controlled substance practitioner registration, is in good standing and is eligible to prescribe schedule II controlled substances;

(3) Holds an active federal Drug Enforcement Administration controlled substance registration, is in good standing and is eligible to prescribe schedule II controlled substances;

(4) Is registered with, and able to access, the Prescription Monitoring Program; and

(5) Is not engaged in any conduct prohibited by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(b) A physician issuing a written certification shall:
(1) Have a bona fide physician-patient relationship with the qualifying patient;

(2) Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history and current medical condition, including an in-person physical examination;

(3) Diagnose the patient as having a debilitating medical condition;

(4) Be of the opinion that the potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use to the qualifying patient;

(5) Have prescribed, or have had a reasonable basis for determining that it is not in the best interest of the patient to prescribe, prescription drugs to address the symptoms or effects for which the written certification is being issued;

(6) Be reasonably available to provide follow-up care and treatment to the qualifying patient including, but not limited to, physical examinations, to determine the efficacy of marijuana for treating the qualifying patient's debilitating medical condition or the symptom of the debilitating medical condition for which the written certification was issued;

(7) Comply with generally accepted standards of medical practice except to the extent such standards would counsel against certifying a qualifying patient for marijuana; and

(8) Explain the potential risks and benefits of the palliative use of marijuana to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent, guardian or person having legal custody of the qualifying patient, prior to submitting the written certification.

(c) A physician shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a written certification. Employees under the direct supervision of the physician may assist with preparing a written certification so long as the final written certification is reviewed and approved by the physician before it is submitted to the department.

(d) If a physician provides instructions for the use of marijuana to the patient, or includes instructions as part of the written certification, the physician shall also securely transmit such instructions to the qualifying patient's designated dispensary facility.

Sec. 21a-408-3. Physician requirements for maintaining patient medical records

(a) A physician shall maintain medical records, as described in section 19a-14-40 of the Regulations of Connecticut State Agencies, for all patients for whom the physician has issued a written certification.

(b) A physician shall make a copy of such medical records reasonably available to the commissioner or the commissioner's authorized representative, to other state agencies and to state and local law

enforcement agencies for the purpose of enabling the department or other agency to ensure compliance with the Act and sections 21a- 408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or for the purpose of investigating or prosecuting a violation of any provision of the Connecticut General Statutes or the Regulations of Connecticut State Agencies.

Sec. 21a-408-4. Physician prohibitions

(a) A physician that has issued or intends to issue a written certification shall not:

(1) Directly or indirectly accept, solicit, or receive anything of value from a dispensary, dispensary facility backer, dispensary facility employee, producer, producer backer, production facility employee, provider of paraphernalia or any other person associated with a dispensary facility or production facility, except as permitted by section 21a-70e of the Connecticut General Statutes;

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular primary caregiver, dispensary, dispensary facility or marijuana product;

(3) Examine a qualifying patient for purposes of diagnosing a debilitating medical condition at a location where marijuana or paraphernalia is acquired, distributed, dispensed, manufactured, sold, or produced; or

(4) Directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a physician from charging an appropriate fee for the patient visit.

(b) A physician that issues written certifications, and such physician's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, provider of paraphernalia, or any other entity that may benefit from a qualifying patient's or primary caregiver's acquisition, purchase or use of marijuana, including any formal or informal agreement whereby a producer, dispensary, or other person provides compensation if the physician issues a written certification for a qualifying patient or steers a qualifying patient to a specific dispensary facility, paraphernalia provider, or marijuana product.

(c) A physician shall not issue a written certification for such physician or for the physician's family members, employees or co-workers.

(d) A physician shall not provide product samples containing marijuana other than those approved by the federal Food and Drug Administration.

Sec 21a-408-5. Enforcement actions against physicians

(a) The commissioner may, after a hearing conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, issue an order to revoke or suspend a physician's controlled substance practitioner registration or to restrict a physician's controlled substance practitioner registration so as to prohibit the physician from issuing written certifications if the physician has:

(1) Failed to comply with any provision of the Act or sections 21a-408-1 to 21a- 408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Failed to comply with any provision of state statute or regulation concerning legend drugs or controlled substances; or

(3) Intentionally or negligently permitted another person to issue written certifications under the physician's name.

(b) If the commissioner has reason to believe that the public health, safety or welfare imperatively requires emergency action, the commissioner may issue an order restricting the physician's controlled substance practitioner registration to summarily prohibit the physician from issuing written certifications pending a hearing. Such hearing shall be conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(c) The commissioner may enter into an agreement with a physician placing conditions on the physician's controlled substance practitioner registration that prohibit or restrict the issuing of written certifications.

(d) In addition to any other action permitted in this section, the commissioner may refer any case involving an alleged violation by a physician of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, to the Connecticut Medical Examining Board or to a Connecticut state or local law enforcement agency.

Sec. 21a-408-6. Patient and primary caregiver registration

(a) A qualifying patient for whom a physician has issued a written certification, and the qualifying patient's primary caregiver where applicable, shall register with the department on forms, and in a manner,

prescribed by the commissioner. For a registration application to be considered complete, the following items shall be submitted:

(1) Written certification issued by a physician who meets the requirements set forth in the Act and section 21a-408-2 of the Regulations of Connecticut State Agencies; (2) Proof of residency of the qualifying patient acceptable to the department; (3) Proof of identity of the qualifying patient acceptable to the department;
(4) Proof of the qualifying patient's age acceptable to the department;
(5) A photograph of the qualifying patient meeting the following requirements: (A) A current, digital, passport-size image, taken no more than thirty calendar days before the submission of the application;
(B) Taken against a plain white or off-white background or backdrop;
(C) At least two inches by two inches in size;
(D) In natural color;
(E) Provides a front, unobstructed view of the full face;
(F) Has between one and one and three-eighths inches from the bottom of the chin to the top of the head; and
(G) Is in "jpeg" format or such other format as the department may authorize; (6) A caregiver form, if applicable;
(7) Proof of identity of the caregiver in a manner acceptable to the department; (8) Proof of the primary caregiver's age acceptable to the department;
(9) A photograph of the caregiver meeting the requirements set forth in subsection (a)(5) of this section;
(10) Permission for the department to determine whether the patient is an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(11) Permission for the department to conduct a background check of the primary caregiver for the purpose of determining if such applicant has

been convicted of a violation of any law pertaining to the illegal manufacture, sale or distribution of a controlled substance;

(12) Payment of the appropriate fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies;

(13) The name, address and telephone number of the dispensary facility from which the qualifying patient or the patient's primary caregiver will purchase marijuana; and

(14) Such other information as the department may reasonably require to determine the applicant's suitability for registration or to protect public health and safety.

(b) If a registration application is determined to be inaccurate or incomplete, the department shall send the applicant a notice of deficiency. If the applicant corrects the deficiencies sixty days or less after receiving notice from the department, the department shall not charge any additional fees.

(c) The department shall deny an application if an applicant submits corrections or supplies the missing information more than sixty days after receiving a notice of deficiency from the department, or if the applicant fails to provide correct and complete information on their second attempt. Any such applicant may resubmit the registration application materials with all applicable fees for a new registration.

(d) A qualifying patient shall only designate, and the department shall only register, one primary caregiver for the patient at any given time.

(e) Absent permission from the commissioner for good cause shown, a qualifying patient may only change primary caregivers once per year at the time of renewal. A qualifying patient may change primary caregivers

at the time of their registration renewal by requesting a different primary caregiver, who shall meet the requirements of the Act and this section, and be approved by the commissioner prior to the patient's registration certificate being renewed. If the qualifying patient requests permission to change primary caregiver prior to renewal, the qualifying patient shall submit a change of caregiver request form to the department, which shall set forth the reasons the qualifying patient seeks to change primary caregivers. If the department approves such change of primary caregiver request, the new primary caregiver shall register with the department and shall submit the non-refundable primary caregiver application fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The department shall approve a new primary caregiver only if such person meets the requirements of the Act and this section.

(f) A qualifying patient who lacked legal capacity at the time of the most recent application or renewal may not change primary caregivers unless:

(1) The qualifying patient provides a court order, or other proof acceptable to the department, indicating that the qualifying patient no longer lacks legal capacity, in which case the qualifying patient may change caregivers in accordance with subsection (e) of this section; or

(2) The primary caregiver is no longer willing or able to serve as a caregiver, in which case the qualifying patient's new primary caregiver applicant shall:

(A) Certify to the department that the current primary caregiver can no longer serve or no longer wishes to serve as a caregiver; and

(B) Submit an application and registration fee that meets the requirements of the Act and this section.

Sec. 21a-408-7. Denial of a qualifying patient or primary caregiver registration application

(a) The department may deny an application or renewal of a qualifying patient's registration certificate if the applicant:

(1) Does not meet the requirements set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Fails to properly complete the application form;

(3) Does not provide acceptable proof of identity, residency or age to the department;

(4) Provides false, misleading or incorrect information to the department;

(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has had a qualifying patient's registration denied, suspended or revoked by the department in the previous six months;

(7) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(8) Has a written certification issued by a physician who is not authorized to certify patients for marijuana; or

(9) Needs a primary caregiver according to the written certification issued by the physician and:

(A) The applicant has not designated a primary caregiver; or

(B) The department has denied the application of the primary caregiver designated by the qualifying patient.

(b) The department may deny an application or the renewal of a primary caregiver's registration certificate if the qualifying patient's physician has not certified the need for the patient to have a primary caregiver or if the primary caregiver applicant:

(1) Does not meet the qualifications set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Has a disqualifying conviction;
(3) Fails to properly complete the primary caregiver application form;
(4) Does not provide acceptable proof of identity or age to the department;
(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(7) Provides false, misleading or incorrect information to the department;

(8) Has had a primary caregiver registration denied, suspended or revoked in the previous six months;

(9) Is already a primary caregiver, or has already applied to be a primary caregiver, for a different qualifying patient, unless the primary caregiver provides proof acceptable to the department demonstrating that the

primary caregiver has a parental, guardianship, conservatorship or sibling relationship with each qualifying patient; or

(10) Is designated as a primary caregiver for a qualifying patient whose application is denied by the department or whose qualifying patient registration certificate has been suspended or revoked.

(c) If the commissioner denies an application or renewal of a qualifying patient applicant or primary caregiver applicant, the commissioner shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing.

(1) Upon receipt of such notice, the applicant may request a hearing, which request shall be submitted to the department in writing not more than twenty calendar days after the date of the notice.

(2) If the applicant makes a timely request for a hearing, the commissioner shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant does not request a hearing in writing in a timely manner, the applicant shall be deemed to have waived the right to a hearing.

Sec. 21a-408-8. Revocation or suspension of a qualifying patient or primary caregiver registration

(a) The commissioner may revoke or suspend the registration certificate of a qualifying patient, in accordance with the Uniform Administrative

Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

(1) The qualifying patient becomes an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(2) The qualifying patient's physician notifies the department that the physician is withdrawing the written certification submitted on behalf of the qualifying patient and, thirty days after the physician's withdrawal of the written certification, the patient has not obtained a valid written certification from a different physician;

(3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;

(4) The qualifying patient is no longer a resident of Connecticut;

(5) The qualifying patient, together with the qualifying patient's caregiver where applicable, obtains more than a one-month supply of marijuana in a one-month period;

(6) The qualifying patient provides or sells marijuana to any person, including another registered qualifying patient or primary caregiver;

(7) The qualifying patient uses marijuana in a place or manner not permitted by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(8) The qualifying patient uses marijuana in a manner that puts others at risk or fails to take reasonable precautions to avoid putting others at risk;

(9) The qualifying patient permits another person to use the qualifying patient's registration certificate;

(10) The qualifying patient tampers, falsifies, alters, modifies or allows another person to tamper, falsify, alter or modify, the qualifying patient's registration certificate;

(11) The qualifying patient's physician is no longer available to provide care to the patient and, after thirty days from the physician notifying the department of the physician's unavailability, the patient has not established a bona-fide relationship with a different physician;

(12) The primary caregiver notifies the department that the primary caregiver is no longer willing to serve as a primary caregiver for the qualifying patient, or the primary caregiver's registration certification has been suspended or revoked, in which case the qualifying patient shall have thirty days to register an acceptable primary caregiver with the department before the department may commence an action to suspend or revoke the qualifying patient's registration;

(13) The qualifying patient's registration certificate is lost, stolen or destroyed and the patient or the patient's primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;

(14) The qualifying patient fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or

(15) The qualifying patient has violated any section of the Act or sections 21a- 408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(b) The department may revoke or suspend the registration certificate of a primary caregiver, in accordance with the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

(1) The registration certification of the qualifying patient has been revoked or suspended;

(2) The qualifying patient's physician notifies the department that the qualifying patient is no longer in need of a primary caregiver;

(3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;

(4) The qualifying patient registers a different person to serve as the primary caregiver in accordance with the procedure set forth in section 21a-408-6 of the Regulations of Connecticut State Agencies;

(5) The primary caregiver obtains more than a one-month supply of marijuana in a one-month period on behalf of a single qualifying patient;

(6) The primary caregiver obtains marijuana for, or provides or sells marijuana to, any person other than the qualifying patient of the primary caregiver, including a different qualifying patient or primary caregiver;

(7) The primary caregiver permits another person to use the primary caregiver's registration certificate;

(8) The primary caregiver has tampered, altered, modified, falsified, or allowed any person to tamper, alter, modify or falsify, the primary caregiver's registration certificate or the registration certificate of the qualifying patient;

(9) The primary caregiver has permitted the use of marijuana that endangers the health or well-being of a person other than the qualifying patient or primary caregiver;

(10) The primary caregiver has a disqualifying conviction;

(11) The primary caregiver's registration certificate is lost, stolen or destroyed and the primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;

(12) The primary caregiver fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or

(13) The primary caregiver has violated any section of the Act or sections 21a- 408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 21a-408-9. Reporting requirements for physicians, patients and caregivers

(a) A physician shall report to the department, in a manner prescribed by the commissioner, the death of a qualifying patient or change in status of a debilitating medical condition involving a qualifying patient for whom

the physician has issued a written certification if such change may affect the patient's continued eligibility to use marijuana. A physician shall report such death or change of status not more than five business days after the physician becomes aware of such fact.

(b) A qualifying patient or primary caregiver, who has been issued a registration certificate, shall notify the department of any change in the information provided to the department not later than five business days after such change. A qualifying patient or primary caregiver shall report changes that include, but are not limited to, a change in the qualifying patient's name, address, contact information, medical status, or status with the Department of Corrections. A qualifying patient or primary caregiver shall report such changes on a form, and in a manner, prescribed by the commissioner.

(c) A qualifying patient or primary caregiver may change the patient's designated dispensary facility no more than four times per year without good cause shown and prior approval by the commissioner or the commissioner's authorized representative. A qualifying patient or primary caregiver shall report the change on a form and in a manner prescribed by the commissioner. A change in the designated dispensary facility shall not be effective until five business days after the qualifying patient or primary caregiver notifies the department of such change. A qualifying patient or primary caregiver shall only purchase marijuana from the dispensary facility currently designated by the patient or caregiver with the department.

(d) If a qualifying patient's or primary caregiver's appearance has substantially changed such that the photograph submitted to the department does not accurately resemble such qualifying patient or primary caregiver, such person shall submit, in a timely manner, an

updated photograph that meets the requirements set forth in section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies.

(e) If a qualifying patient has a primary caregiver, that primary caregiver may notify the department of any changes on behalf of the qualifying patient using the same forms and process prescribed for qualifying patients.

(f) If a qualifying patient or primary caregiver notifies the department of any change that results in information on the registration certificate being inaccurate or the photograph needing to be replaced, the qualifying patient or primary caregiver shall submit the fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall thereafter issue the qualifying patient or primary caregiver a new registration certificate provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies. Upon receipt of a new registration certificate, the qualifying patient or primary caregiver shall destroy in a non-recoverable manner the registration certificate that was replaced.

(g) If a qualifying patient or primary caregiver becomes aware of the loss, theft or destruction of the registration certificate of such qualifying patient or primary caregiver, the qualifying patient or primary caregiver shall notify the department, on a form and in a manner prescribed by the commissioner, not later than five business days of becoming aware of the loss, theft or destruction, and submit the fee required by section 21a-408- 28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall inactivate the initial registration certificate upon receiving such notice and issue a

replacement registration certificate upon receiving the applicable fee provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 21a-408-10. Precautions for preventing the loss, theft or misuse of marijuana by patients and caregivers

(a) A qualifying patient and primary caregiver shall store marijuana in a secure location to prevent theft, loss or access by unauthorized persons.

(b) Qualifying patients and primary caregivers shall carry their registration certificate with them whenever they are in possession of marijuana.

Sec. 21a-408-11. Proper disposal of marijuana by patients or caregivers

A patient or caregiver shall dispose of all usable marijuana in the patient's or caregiver's possession no later than ten calendar days after the expiration of the patient's registration certificate, if such certificate is not renewed, or sooner should the patient no longer wish to possess marijuana for palliative use. A patient or caregiver shall complete such disposal by one of the following methods:

(1) By rendering the marijuana non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site at www.ct.gov/dcp/drugdisposal;

(2) By depositing it in a Connecticut police department medication drop-box; or

(3) By disposing of the marijuana at a government-recognized drug take-back program located in Connecticut.

Sec. 21a-408-12. Establishment of additional debilitating medical conditions, medical treatments or diseases

(a) The commissioner shall not add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act unless the appropriateness of adding the condition, treatment or disease has been considered by the board, the board has submitted a written recommendation to the commissioner in accordance with this section and the commissioner has adopted a regulation in accordance with subsection (k) of this section.

(b) Persons seeking to add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act shall submit a written petition to the commissioner and request that the commissioner present the petition to the board.

(c) Absent a showing of good cause, the commissioner shall only present a petition to the board if it includes the following information:

(1) The extent to which the medical condition, medical treatment or disease is generally accepted by the medical community and other experts as a valid, existing medical condition, medical treatment or disease;

(2) If one or more treatments for the condition, rather than the condition itself, are alleged to be the cause of a patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;

(3) The extent to which the condition or the treatments thereof cause severe or chronic pain, severe nausea, spasticity or otherwise substantially limits one or more major life activities of the patient;

(4) The availability of conventional medical therapies, other than those that cause suffering, to alleviate suffering caused by the condition or the treatment thereof;

(5) The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or the treatment thereof;

(6) Any information or studies known to the petitioner regarding any beneficial or adverse effects from the use of marijuana in patients with the medical condition, medical treatment or disease that is the subject of the petition; and

(7) Letters of support from physicians or other licensed health care professionals knowledgeable about the condition, treatment or disease.

(d) If a medical condition, medical treatment or disease in a petition has been previously considered and rejected by the commissioner, or is determined by the commissioner to be substantially similar to such a rejected condition, treatment or disease, the commissioner may deny the

petition without first submitting it to the board unless new scientific research supporting the request is included in the petition.

(e) If a written petition meets the requirements of this section, the commissioner shall refer the written petition to the board for a public hearing at the next board meeting that is at least sixty days after the date the petition was submitted and at which the board will be considering petitions.

(f) At least twice per year, the board shall conduct a public hearing to evaluate any petitions referred to it by the commissioner and to consider any other medical conditions, medical treatments or diseases that the board, on its own initiative, believes should be reviewed for possible inclusion on the list of debilitating medical conditions under the Act.

(g) No less than twenty days before each public hearing at which the board will consider petitions or the inclusion of debilitating conditions on its own initiative, the department shall publish on its Internet web site a list of the debilitating medical conditions, medical treatments and diseases that the board will be considering at its upcoming hearing so that the petitioner, where applicable, and other members of the public may offer public comments before the board.

(h) In addition to information provided in a petition, the board may examine scientific, medical or other evidence and research pertaining to the petition, and may gather information, in person or in writing, from other persons knowledgeable about the medical condition, medical treatment or disease being considered.

(i) Following the public hearing, the board shall consider the public comments and any additional information or expertise made available to the board for each proposed debilitating medical condition considered at

the hearing. The board shall issue a written recommendation to the commissioner as to whether the medical condition, medical treatment or disease should be added to the list of debilitating medical conditions that qualify for the palliative use of marijuana. The board shall include in its recommendation the following:

(1) Whether the medical condition, medical treatment or disease is debilitating;

(2) Whether marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition, medical treatment or disease; and

(3) Other matters that the board considers relevant to the approval or the denial of the petition.

(j) At least three members of the board, which shall constitute a quorum, shall consider each proposed debilitating medical condition. A majority of the board members present at the hearing where each proposed debilitating medical condition was presented for public comment shall concur in the recommendation submitted to the commissioner and that recommendation shall be considered the official recommendation of the board. Any board member who disagrees with the board's official recommendation may submit a dissenting or concurring recommendation to the commissioner.

(k) If, after receiving the board's official recommendation and any dissenting or concurring recommendation, the commissioner concludes that the medical condition, medical treatment or disease that was under consideration should be added to the list of debilitating medical conditions under the Act, the commissioner shall proceed to adopt regulations, in accordance with section 21a-408m of the Connecticut

General Statutes and the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, expanding the list of debilitating medical conditions accordingly.

Sec. 21a-408-13. Number of dispensaries and dispensary facilities

(a) Only a dispensary at a dispensary department may dispense marijuana.

(b) The commissioner shall issue at least one dispensary facility license and may issue additional dispensary facility licenses upon a determination that additional dispensary facilities are desirable to assure access to marijuana for qualifying patients. Such determination shall be made based on the size and location of the dispensary facilities in operation, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients.

(c) Each dispensary facility may employ no more than five dispensaries at a time without prior approval from the commissioner, one of whom shall be designated as the dispensary facility manager.

Sec. 21a-408-14. Dispensary facility license selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for dispensary facility licenses. Such notice shall include, but not be limited to:

(1) The maximum number of licenses to be awarded;
(2) Information on how to obtain an application;
(3) The deadline for receipt of applications;
(4) Acceptable methods for submitting an application;
(5) The preferred locations, if any, for the dispensary facility licenses; and
(6) The criteria that shall be considered in awarding the dispensary facility licenses.

(b) Following the deadline for receipt of applications, the commissioner shall evaluate each complete and timely submitted application and award dispensary facility licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the dispensary facility licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for dispensary facility licenses.

(c) The commissioner shall consider, but is not limited to, the following criteria in evaluating dispensary facility license applications:

(1) The character and fitness of the dispensary, dispensary facility backers and any other person who may have control or influence over the operation of the proposed dispensary facility;

(2) The location for the proposed dispensary facility including, but not limited to:

(A) Its proximity to previously approved dispensary facilities or pending dispensary facility applications;

(B) Whether the registered patient population in the area proposed by the dispensary facility applicant justifies the need for a dispensary facility, or an additional dispensary facility, in that area;

(C) Whether the proximity of the proposed dispensary facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(D) Whether the number of dispensary facilities in the locality is such that the granting of a license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned, the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood;

(3) The applicant’s ability to maintain adequate control against the diversion, theft and loss of marijuana;

(4) The applicant’s ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and

(5) The extent to which the applicant or any of the applicant’s dispensary facility backers have a financial interest in another licensee, registrant or applicant under the Act or sections 21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies.

(6) Any other reason provided by Connecticut state or federal statute or Connecticut state or federal regulation that is not inconsistent with the

Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrants consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a dispensary facility license.

(f) The commissioner may disqualify any applicant who:
(1) Submits an incomplete, false, inaccurate or misleading application;
(2) Fails to submit an application by the published deadline; or
(3) Fails to pay all applicable fees;

(g) The decision of the commissioner not to award a dispensary facility license to an applicant shall be final.

(h) If an applicant has been awarded a dispensary facility license and has not commenced operation of such facility within one hundred twenty days of being notified of the dispensary facility license award, the commissioner may, in the commissioner's discretion, rescind such dispensary facility license, unless such delay was caused by a force majeure. A dispensary facility shall be deemed to have commenced operation if the dispensary facility is capable of operating in accordance with the dispensary facility applicant's approved application. In the event a dispensary facility license is rescinded pursuant to this subsection, the commissioner shall award a dispensary facility license by selecting among the qualified applicants who applied for the dispensary facility license subject to rescission. If no other qualified applicant applied for such dispensary facility license or satisfied the criteria for

awarding a license, the department shall publish, in accordance with this section, a notice of open applications for dispensary facility licenses.

Sec. 21a-408-15. Dispensary facility license applications

(a) Only a dispensary facility that has obtained a license from the department may sell marijuana to qualified patients and primary caregivers that have a registration certificate from the department.

(b) A dispensary facility license applicant shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required documentation on forms prescribed by the commissioner.

(c) The applicant shall provide the following information and records in the application process:

(1) The name and address of the applicant, the applicant's dispensary facility backers, if any, and the person who will serve as the dispensary facility manager if the application is approved;

(2) The location for the dispensary facility that is to be operated under such license;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) A detailed description of any other services or products to be offered by the dispensary facility;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;

(6) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;

(7) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met;

(8) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any, for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a dispensary facility;

(9) Any business and marketing plans related to the operation of the dispensary facility or the sale of marijuana;

(10) Text and graphic materials showing the exterior appearance of the proposed dispensary facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(11) A blueprint of the proposed dispensary facility, which shall, at a minimum, show and identify:

(A) The square footage of the area which will constitute the dispensary department;
(B) The square footage of the overall dispensary facility;
(C) The square footage and location of areas used as storerooms or stockrooms; (D) The size of the counter that will be used for selling marijuana;
(E) The location of the dispensary facility sink and refrigerator, if any;
(F) The location of all approved safes and approved vaults that will be

used to store marijuana;
(G) The location of the toilet facilities;
(H) The location of a break room and location of personal belonging lockers;
(I) The location and size of patient counseling areas, if any;
(J) The locations where any other products or services will be offered; and
(K) The location of all areas that may contain marijuana showing the location of walls, partitions, counters and all areas of ingress and egress;
(12) Documents related to any compassionate need program the dispensary facility intends to offer; and
(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for registration or to protect public health and safety.

(d) In the event any information contained in the application or accompanying documents changes after being submitted to the department, the applicant shall immediately notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(e) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a dispensary facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

(1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;

(2) Conducting an on-site visit of the proposed dispensary facility location or other dispensary facility locations associated with the applicant or the applicant's dispensary facility backers;

(3) Conducting background checks or contacting references of the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors;

(4) Contacting state regulators in any other states where the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and

(5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

Sec. 21a-408-16. Dispensary facility employee licenses and registrations

(a) No person shall act as a dispensary without a license issued by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(b) No person shall act as a dispensary technician without being registered with the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(c) No person shall be employed or retained as any other type of dispensary facility employee without being at least 18 years of age and

being registered by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(d) Any dispensary facility backer, or other person who will exercise control over, or have management responsibility for, a dispensary facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

(e) Only a pharmacist who is in good standing and has an active pharmacist license issued by the department may apply for and receive a dispensary license.

(f) Only a person who has held an active pharmacy technician registration in Connecticut within the five years prior to the application, who is 18 years of age or older, and is currently in good standing, or was in good standing at the time his or her registration lapsed, may apply for and receive a dispensary technician registration.

Sec. 21a-408-17. Notification of changes by dispensary facility

(a) Unless otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary facility manager shall provide any notification or information that is required from a dispensary facility pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that if the notification or information relates to a change in the dispensary facility manager, or if the dispensary facility manager is otherwise not available to provide the notification or information to the department, a dispensary facility backer shall provide such notification or information.

(b) Prior to any person becoming affiliated with a dispensary facility, including any change associated with a change in ownership, such person shall comply with the licensing and registration requirements set forth in section 21a-408-16 of the Regulations of Connecticut State Agencies. No person shall commence such affiliation until approved by the commissioner.

(c) Prior to making any change to the dispensary facility name, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(d) Prior to changing a dispensary facility location, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(e) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a dispensary facility or a dispensary department, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(f) Prior to designating a new dispensary facility manager, the dispensary facility shall submit a change of dispensary facility manager form to the department and pay the fee set forth in section 21a-408-28 of

the Regulations of Connecticut State Agencies. No dispensary facility shall make such change in dispensary facility manager until approved by the commissioner. In the event of an emergency such that the designated dispensary facility manager is no longer able or willing to continue managing the dispensary department, the dispensary facility backer or current dispensary facility manager shall immediately notify the department that the dispensary facility manager has ceased such management and shall immediately notify the department of the name, address and dispensary license number of the dispensary who assumes management of the dispensary facility. Such person shall serve as the acting dispensary facility manager until such time as the commissioner approves a new dispensary facility manager. The dispensary facility shall submit a change of dispensary facility manager form and accompanying fee to the department to designate a permanent dispensary facility manager not more than fifteen business days after the previously designated dispensary facility manager has ceased management responsibilities.

(g) The dispensary facility shall notify the department no later than ten business days after the date that a dispensary facility backer or dispensary facility employee ceases to work for, or be affiliated with, the dispensary facility.

(h) If a dispensary facility will be closing, the dispensary facility manager for the facility shall notify the department of the closing not less than fifteen days prior to the closing.

Sec. 21a-408-18. Notification of changes by dispensary and dispensary technician

(a) Every dispensary and dispensary technician whose place of employment changes shall report to the department the following information regarding the dispensary or dispensary technician's new employment. Such notification shall be made, on a form prescribed by the commissioner, no less than five business days after the change in employment becomes effective.

(b) Any dispensary or dispensary technician whose name or home address changes shall notify the department of such change, on a form prescribed by the commissioner, no less than five business days after the change.

Sec. 21a-408-19. Number of producers

(a) The department shall issue at least three, but no more than ten, producer licenses.

(b) Prior to issuing any additional producer licenses, the commissioner shall determine that additional producers are desirable to assure access to marijuana for qualifying patients, which determination shall be made based on the size and location of the production facilities in operation, the amount of marijuana each production facility is producing, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients or dispensary facilities.

Sec. 21a-408-20. Producer selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for producer licenses. Such notice shall include, but not be limited to:

(1) The maximum number of producer licenses to be awarded;
(2) Information on how to obtain an application;
(3) The deadline for receipt of applications;
(4) Acceptable methods for submitting an application; and
(5) The criteria that shall be considered in awarding the producer license.

(b) Following the deadline for receipt of applications, the department shall evaluate each complete and timely submitted application and award producer licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the producer licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for producer licenses.

(c) The department shall consider, but is not limited to, the following criteria in evaluating producer license applications:

(1) The location for the proposed production facility to be owned or leased and operated by the producer including, but not limited to:

(A) Whether the proximity of the proposed production facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether

supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(B) Whether the number of production facilities in the locality is such that the granting of an additional license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned and the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood; and

(C) If the production facility is leased, whether the lease agreement limits access to the facility by the owner of the facility, or a representative or agent of the owner, except on conditions permitted by the Act and section 21a-408-53 of the Regulations of Connecticut State Agencies;

(2) The character and fitness of the producer, producer backers, and any other person who may have control or influence over the producer or production facility;

(3) Detailed information regarding the applicant’s financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a production facility;

(4) The applicant’s ability to maintain adequate control against the diversion, theft and loss of marijuana produced or manufactured at the production facility;

(5) The applicant's ability to produce pharmaceutical grade marijuana for palliative use in a secure, indoor facility;

(6) The applicant's expertise in agriculture and other production techniques required to produce pharmaceutical grade marijuana or to manufacture marijuana products;

(7) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, in the secured amount of two million dollars. Any escrow account agreement, letter of credit or surety bond shall adhere to the terms and conditions set forth by the commissioner in the request for applications. The establishment of such escrow account, letter of credit or surety bond shall be required prior to issuance of a producer license;

(8) The extent to which the applicant or any of the applicant's producer backers have a financial interest in another licensee, registrant or applicant under the Act or sections 21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies; and

(9) Any other factors provided by Connecticut state or federal statute or Connecticut or federal regulation that are not inconsistent with the Act or sections 21a- 408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrant consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. The

commissioner shall publish such amended notice in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a producer license.

(f) The commissioner may disqualify any applicant who:
(1) Submits an incomplete, false, inaccurate or misleading application;
(2) Fails to submit an application by the published deadline; or
(3) Fails to pay all applicable fees.
(g) The decision of the commissioner not to award a producer license to an applicant shall be final.

(h) If an applicant has been awarded a producer license and has not commenced operation of a production facility within 180 days of being notified of the producer license award, the commissioner may, in the commissioner's discretion, rescind such producer license unless such delay was caused by force majeure. A producer shall be deemed to have commenced operation if the production facility is fully constructed and capable of operating in accordance with the producer's approved application. In the event a producer license is rescinded pursuant to this subsection, the commissioner shall award a producer license by selecting among the qualified applicants who applied for the producer license subject to rescission. If no other qualified applicant applied for such producer license or satisfied the criteria for awarding a license, the department shall publish, in accordance with this section, a notice of open applications for producer license.

Sec. 21a-408-21. Producer applications

(a) A producer shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required documentation on forms prescribed by the commissioner.

(b) The applicant shall provide the following information in the application process and maintain the following records, as applicable:

(1) The name and address of the applicant and the applicant's producer backers, if any;

(2) The location for the production facility that is to be operated under such producer license;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;

(6) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met; with regard to zoning, it shall be sufficient to establish that the proposed location is in a zone where a pharmaceutical manufacturing facility would be allowed;

(7) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a producer or production facility;

(8) Any proposed business and marketing plans, including expected production capacity;

(9) Text and graphic materials showing the exterior appearance of the proposed production facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(10) A blueprint of the proposed production facility to be operated by the licensee, which shall, at a minimum, show and identify:

(A) The square footage of the areas where marijuana is to be grown;
(B) The square footage of the areas where marijuana is to be harvested;
(C) The square footage of the areas where marijuana is to be packaged and labeled;
(D) The square footage of the areas where marijuana is to be produced and manufactured;
(E) The square footage of the overall production facility;
(F) The square footage and location of areas to be used as storerooms or stockrooms;
(G) The location of any approved safes or approved vaults that are to be used to store marijuana;
(H) The location of the toilet facilities;
(I) The location of a break room and location of personal belonging lockers; and (J) The location of all areas that may contain marijuana that shows walls, partitions, counters and all areas of ingress and egress. The

blueprint shall also reflect all production, propagation, vegetation, flowering, harvesting, and manufacturing areas;

(11) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner;

(12) Documents related to any compassionate need program the producer intends to offer; and

(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for licensing or to protect public health and safety.

(c) In the event any information contained in the producer license application or accompanying documents changes after being submitted to the department, the applicant shall notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(d) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a production facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

(1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;

(2) Conducting an on-site visit of the proposed production facility location or other production facility locations associated with the applicant or the applicant's producer backers;

(3) Conducting background checks or contacting references of the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors;

(4) Contacting state regulators in any other states where the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and

(5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

Sec. 21a-408-22. Production facility employee registrations

(a) A production facility employee shall be at least 18 years of age and shall be registered by the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies before being employed by a producer.

(b) Any producer backer or other person who will exercise control over, or have management responsibility for, a production facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-23. Notification of changes by producers

(a) Prior to adding any person as a producer backer or making any other change to the ownership of the production facility, the producer shall register such additional person, on forms prescribed by the commissioner, with the department pursuant to sections 21a-408-24 to 21a-408-25, inclusive, of the Regulations of Connecticut State Agencies, and pay the accompanying registration fee set forth for producer backers in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such addition or change until approved by the commissioner.

(b) Prior to making any change to the producer name or production facility name, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(c) Prior to changing a production facility location, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(d) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a production facility, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(e) The producer shall notify the department no later than ten business days after the date that a producer backer or production facility employee ceases to work for or be affiliated with the producer.

(f) The producer shall notify the department if the producer's production facility will be closing or if the producer does not intend to renew the producer's license immediately after such decision has been made. In no event shall such notification be given less than six months prior to the effective date of such closing.

Sec. 21a-408-24 Licenses and registrations for dispensary facilities, dispensary facility employees, producers, producer backers and production facility employees

(a) Applicants for any of the licenses or registrations set forth in sections 21a- 408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall be required to supply information to the department sufficient for the department to conduct a background check and determine the character and fitness of the applicant for the license or registration, which information may include, but is not limited to:

(1) Name;
(2) Address;
(3) Social security number or federal employee identification number;
(4) Date of birth or formation;
(5) Name and address of the producer, production facility or dispensary facility that the applicant seeks to work for, invest in or otherwise be associated with; (6) Past employment history;
(7) Pharmacist or pharmacy technician license or registration number, if

applicable;
(8) Previous or current involvement in the medical marijuana industry;
(9) Personal references;
(10) Any criminal record;
(11) Whether the person has ever applied for a license or registration related to medical marijuana in any state and, if so, the status of that application, license or registration;
(12) Percent ownership or nature of the financial interest in the producer or dispensary facility, where applicable;
(13) Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a marijuana production facility or dispensary facility; and
(14) Such other information as the department may reasonably require to determine the applicant's suitability for licensing or registration or to protect public health and safety.

(b) All licenses and registrations issued pursuant to sections 21a-408-13 to 21a- 408-24 inclusive, of the Regulations of Connecticut State Agencies, shall expire one year after the date of issuance and annually thereafter if renewed.

(c) Any person who receives a license or registration pursuant to sections 21a- 408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall notify the department of any changes to the information supplied on the application for such license or registration no later than five business days after such change.

Sec. 21a-408-25. Department issuance of identification cards; expiration

(a) The department shall issue each person licensed or registered pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies an identification card that shall expire one year after the date of issuance.

(b) No person shall begin working at a dispensary facility or production facility prior to receiving their identification card.

(c) All licensees and registrants shall conspicuously display the identification cards issued by the department while on the premises of a dispensary facility or production facility.

(d) The dispensary facility manager or producer shall return to the department the identification card of any dispensary facility employee or production facility employee whose employment has been terminated no later than five business days after such termination.

Sec. 21a-408-26. Non-transferability of licenses and registrations

No person issued a license or registration pursuant to 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies shall assign or transfer such license, or registration without the commissioner's prior approval.

Sec. 21a-408-27. Renewal applications

(a) Every person issued a license or registration pursuant to sections 21a-408- 13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies shall file a renewal application and the proper fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies with the department at least 45 days prior to the date the existing license or registration expires.

(b) If a renewal application is not filed prior to the expiration date of the applicable license or registration, the license or registration shall expire and become void until the licensee or registrant files a renewal application and pays all applicable fees, and the renewal application is approved by the commissioner.

(c) If a renewal application and all applicable fees are submitted to the department more than thirty calendar days after the expiration of the license or registration, the commissioner shall not renew such license or registration and the applicant shall reapply for such license or registration.

Sec. 21a-408-28. Fees

An applicant shall submit the following fees with each license and registration application submitted, in the form of a certified check or money order payable to the "Treasurer, State of Connecticut," or by such other means as approved by the commissioner:

(1) The non-refundable application fee and each renewal fee for each qualifying patient and for each primary caregiver application shall be twenty-five dollars. In addition, there shall be a non-refundable fee of

seventy-five dollars for administrative costs for each qualifying patient application, for a total non-refundable fee of one hundred dollars per qualifying patient application and for each renewal.

(2) The non-refundable fee for a replacement registration certificate for a qualifying patient or primary caregiver whose information has changed or whose original registration certificate has been lost, stolen or destroyed shall be ten dollars;

(3) The non-refundable fee for a dispensary facility license application shall be one thousand dollars. In addition, upon approval of the applicant's dispensary facility license, the applicant shall pay an additional fee of five thousand dollars prior to receiving a license;

(4) The non-refundable fee for each renewal of a dispensary facility license shall be five thousand dollars;

(5) The non-refundable fee for a dispensary license and for each renewal shall be one hundred dollars;

(6) The non-refundable fee for a dispensary technician and dispensary employee registration and each renewal shall be fifty dollars;

(7) The non-refundable registration fee and each renewal fee for a dispensary facility backer shall be one hundred dollars;

(8) The non-refundable fee for an application to change a dispensary facility name shall be one hundred dollars;

(9) The non-refundable fee for a change of dispensary facility manager form shall be fifty dollars;

(10) The non-refundable fee for an application to expand or change the location of a dispensary facility shall be one thousand dollars. If the application is approved, the applicant shall pay an additional one thousand five hundred dollars upon such approval;

(11) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a dispensary facility or a dispensary facility department, other than an expansion, shall be five hundred dollars;

(12) The non-refundable application fee for a producer license shall be twenty- five thousand dollars. In addition, if an application for a producer license is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving a license;

(13) The non-refundable fee for each renewal of a producer license shall be seventy-five thousand dollars per production facility location;

(14) The non-refundable application fee for a producer to open an additional production facility location shall be twenty-five thousand dollars. In addition, if an application for an additional location is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving permission to open an additional production facility.

(15) The non-refundable fee for a production facility employee registration and for each renewal shall be one hundred dollars;

(16) The non-refundable fee for a producer backer registration and for each renewal shall be one hundred dollars;

(17) The non-refundable fee for an application to change a producer name or production facility name shall be one hundred dollars;

(18) The non-refundable fee for an application to expand or change the location of a production facility shall be three thousand five hundred dollars. In addition, upon approval of the application, the applicant shall pay an additional fee of one thousand five hundred dollars;

(19) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a production facility, other than an expansion, shall be five hundred dollars; and

(20) The non-refundable fee for a producer to register a marijuana brand name with the department shall be twenty five dollars per brand name.

Sec. 21a-408-29. Escrow Account Terms

(a) The producer's two million dollar escrow account, letter of credit or surety bond shall be payable to the state of Connecticut in the event the commissioner determines, after a hearing pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, that the producer has failed to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides a substantially uninterrupted supply to its usual dispensary facility customers during the term of the license.

(b) In addition to the other terms and conditions permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the commissioner shall permit the producer's two million dollar escrow account, letter of credit or surety bond to be reduced by five-hundred thousand dollars upon the successful

achievement of each of the following milestones, resulting in a potential elimination in the escrow account, letter of credit or surety bond:

(1) A determination by the commissioner that the production facility is fully operational and able to commence production of marijuana as provided for in the license application of the producer;

(2) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a one year period;

(3) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for an additional two consecutive years; and

(4) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a second period of two consecutive years.

(c) If a producer voluntarily chooses not to renew the producer license and provides notice of this decision in accordance with section 21a-408-23(f) of the Regulations of Connecticut State Agencies, the commissioner shall extinguish the obligations under the escrow account, letter of credit or surety bond at the end of the license term.

Sec. 21a-408-30. Refusal to renew or issue a license or registration of a dispensary facility, dispensary facility employee, producer or production facility employee

(a) If the commissioner refuses to renew a dispensary facility license or producer license, the department shall, in accordance with the Uniform Administrative Procedure Act , sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, notify the licensee of its refusal and set a day and place of a hearing thereon giving the licensee reasonable notice in advance thereof. If, at or after such hearing, the commissioner refuses to renew the license, the department shall promptly provide notice of such decision to such licensee.

(b) Upon refusal to issue or renew a license or registration required under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, other than dispensary facility licenses and producer licenses, the department shall provide the applicant, licensee or registrant with notice of the grounds for the refusal to issue or renew such person's license or registration and shall inform the person of the right to request a hearing.

(1) Upon receipt of such notice, the applicant, licensee or registrant may request a hearing, which request shall be submitted to the department in writing not more than ten calendar days after the date of the notice.

(2) If a request for a hearing is made within the ten-day period, the department shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant, licensee or registrant does not request a hearing in writing within the ten-day period, the applicant shall be deemed to have waived the right to a hearing.

Sec. 21a-408-31. Disciplinary action against dispensary facility, dispensary facility employee, producer or production facility employee

(a) For sufficient cause found in accordance with subsection (b) of this section, the commissioner may, in the commissioner's discretion, suspend, revoke or refuse to grant or renew a license or registration issued pursuant to sections 21a-408-13 to 21a- 408-24, inclusive, of the Regulations of Connecticut State Agencies, or place such license or registration on probation, place conditions on such license or registration, or take other actions permitted by statute or regulation. For purposes of this section, each instance of qualifying patient or primary caregiver contact or consultation that is in violation of any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall be deemed a separate offense. Failure to renew any license or registration in a timely manner is not a violation for purposes of this section.

(b) Any of the following shall be sufficient cause for such action by the commissioner:

(1) Furnishing of false or fraudulent information in any application;

(2) Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the act subject to the conviction occurred when the person held a valid license or registration certificate issued

pursuant to the Act and sections 21a-408- 1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and the conviction was based on a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(3) Any civil action under any federal or state statute or regulation or local ordinance relating to the applicant's, licensee's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices;

(4) Failure to maintain effective controls against diversion, theft or loss of marijuana or other controlled substances;

(5) Discipline by, or a pending disciplinary action or unresolved complaint, with regard to any professional license or registration of any federal, state or local government;

(6) Abuse or excessive use of drugs or alcohol;

(7) Possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose;

(8) Failure to account for the disposition of marijuana;

(9) Failure to keep accurate records of all marijuana dispensed, administered or sold to qualifying patients or primary caregivers;

(10) Failure to keep accurate records of all marijuana produced, manufactured, packaged or sold to a dispensary or dispensary facility;

(11) Denial, suspension or revocation of a license or registration, or the denial of a renewal of a license or registration, by any federal, state or local government or a foreign jurisdiction;

(12) False, misleading or deceptive representations to the public or the commissioner or the commissioner's authorized representative;

(13) Return to regular stock of any marijuana where:

(A) The package or container containing the marijuana has been opened, breached or tampered with; or

(B) The marijuana has been sold to a patient or caregiver;
(14) Involvement in a fraudulent or deceitful practice or transaction;
(15) Performance of incompetent or negligent work;
(16) Failure to maintain the entire dispensary facility or production facility and contents in a clean, orderly and sanitary condition;
(17) Intentionally, or through negligence, obscuring, damaging, or defacing a license or registration card;
(18) A determination by the commissioner that the applicant or holder of the license or registration has a condition, including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of dispensing, operation of a dispensary facility or activities as a dispensary, dispensary technician, dispensary facility employee, producer or production facility employee, provided the department shall not, in taking action against a license or registration holder on the basis of such a condition, violate the provisions of section 46a-73 of the Connecticut General Statutes, or 42 USC 12132 of the federal Americans with Disabilities Act;

(19) Permitting another person to use the licensee's or registrant's license or registration;

(20) Failure to cooperate or give information to the department, local law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at a dispensary facility or production facility;

(21) Discontinuance of business for more than sixty days, unless the commissioner approves an extension of such period for good cause shown, upon a written request from a dispensary facility or producer. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the dispensary facility or production facility;

(22) A violation of any provision of the Connecticut General Statutes, or any regulation established thereunder, related to the person's profession or occupation; or

(23) Failure to comply with any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(c) No person whose application for a license or registration has been denied due to the applicant's character and fitness may make another application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of denial.

(d) No person whose license or registration has been revoked may make an application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of such revocation.

(e) If a license or registration is voluntarily surrendered or is not renewed, the commissioner shall not be prohibited from suspending, revoking or imposing other penalties permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, on any such license or registration.

Sec. 21a-408-32. Suspension of dispensary facility license or producer license

During the period of any suspension of a dispensary facility license or producer license as a result of disciplinary action by the department:

(1) No person issued a dispensary facility license shall alter the dispensary facility, unless the alterations have been expressly approved in writing by the commissioner, or attach to the exterior or any other part of the facility any sign indicating that the premises are "closed for repairs," "closed for alterations" or any like signs.

(2) The dispensary facility manager shall place on the dispensary facility in the front window, or on the front door facing the street, a notice indicating the length of the suspension and the reasons therefor. The sign shall measure a minimum of eight inches in height by ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by persons standing outside the dispensary facility. The dispensary facility manager shall maintain the sign in place until the period of suspension has terminated.

(3) A dispensary facility shall not offer, sell, order or receive marijuana products unless expressly approved by the commissioner.

(4) The dispensary facility manager shall close the entire dispensary facility for business and shall securely lock all marijuana products. Dispensary facility employees may visit the facility only for the necessary care and maintenance of the premises.

(5) A producer whose license has been suspended shall not sell, offer for sale, or deliver marijuana to any dispensary facility. Production facility employees may enter the premises of the production facility for the necessary care and maintenance of the premises and of any marijuana and marijuana products.

(6) The commissioner may, in the commissioner's discretion, accept a monetary payment as an offer in compromise in lieu of, or so as to reduce a suspension, from a licensee or registrant whose license or registration is subject to a hearing that may result in a suspension or whose license or registration has been suspended after due hearing. Such offer shall include a waiver of appeal and judicial review and a certified check in the amount designated by the commissioner.

Sec. 21a-408-33. Confidentiality of information

(a) Except as provided by section 21a-408-50 of the Regulations of Connecticut State Agencies, a dispensary facility employee, producer, production facility employee, or any other person associated with a dispensary facility or producer, shall not disclose patient-specific information received and records kept pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that such person shall disclose patient treatment or dispensing information to:

(1) The department or state and local law enforcement for purposes of investigating and enforcing the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Physicians, pharmacists or other dispensaries for the purpose of providing patient care and drug therapy management and monitoring controlled substances obtained by the qualifying patient;

(3) A qualifying patient but only with respect to information related to such patient;

(4) A primary caregiver, but only with respect to the qualifying patient of such primary caregiver;

(5) Third party payors who pay claims for dispensary services rendered to a qualifying patient or who have a formal agreement or contract to audit any records or information in connection with such claims;

(6) Any person, the state or federal government or any agency thereof pursuant to an order of a court of competent jurisdiction or pursuant to a search warrant; and

(7) Any person upon the express written consent of the patient and only with respect to information related to such patient. Such written consent shall clearly identify the specific person and purpose for which consent is being granted, but in no event shall such information be disclosed to an electronic data intermediary.

(b) An electronic data intermediary shall not have access to any data involving marijuana, qualifying patients, primary caregivers or other data from a dispensary facility or an agent of the dispensary facility.

(c) No electronic equipment utilized by a dispensary department shall collect patient-specific data for use outside the dispensary department, except that such data shall be disclosed to the commissioner or the commissioner's authorized representative for purposes of an inspection or investigation.

Sec. 21a-408-34. Operation of dispensary facility

(a) No person may operate a dispensary facility without a dispensary facility license issued by the department.

(b) A dispensary facility shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Connecticut.

(c) A dispensary facility shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:

(1) It may acquire marijuana from a producer; and

(2) It may dispense and sell marijuana to a qualifying patient or primary caregiver who is registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies.

(d) No person at a dispensary facility shall provide marijuana samples or engage in marijuana compounding.

(e) A dispensary facility shall sell marijuana products only in the original sealed containers or packaging as delivered by the producer, except that a dispensary may remove the marijuana product from the producer's child-resistant container or package and place the marijuana

product in a non-child-resistant, secure and light-resistant container upon a written request from the qualifying patient or primary caregiver so long as all original labeling is maintained with the product.

(f) Only a dispensary may dispense marijuana, and only a dispensary or dispensary technician may sell marijuana, to qualifying patients and primary caregivers who are registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies. A dispensary technician may assist, under the direct supervision of a dispensary, in the dispensing of marijuana.

(g) A dispensary facility shall place all products sold to the qualifying patient or primary caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.

(h) A dispensary facility shall not permit any person to enter the dispensary department unless:

(1) Such person is licensed or registered by the department pursuant to 21a-408- 1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Such person's responsibilities necessitate access to the dispensary department and then for only as long as necessary to perform the person's job duties; or

(3) Such person has a patient or caregiver registration certificate, in which case such person shall not be permitted behind the service counter or in other areas where marijuana is stored.

(i) All dispensary facility employees shall, at all times while at the dispensary facility, have their current dispensary license, dispensary

technician registration or dispensary facility employee registration available for inspection by the commissioner or the commissioner's authorized representative.

(j) While inside the dispensary facility, all dispensary facility employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the dispensary facility.

(k) A dispensary department shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of thirty-five hours a week, except as otherwise authorized by the commissioner.

(l) A dispensary department that closes during its normal hours of operation shall implement procedures to notify qualifying patients and primary caregivers of when the dispensary department will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs. If the dispensary department is, or will be, closed during its normal hours of operation for longer than two business days, the dispensary facility shall immediately notify the department.

(m) A dispensary facility that operates at times when the dispensary department is closed shall:

(1) Conspicuously post the hours of operation of the dispensary department at all entrances to the dispensary facility in block letters at least one-half inch in height; and

(2) Clearly state the hours of operation of the dispensary department in all advertising for the specific dispensary department or dispensary facility.

(n) A dispensary facility shall make publicly available the price of all marijuana products offered by the dispensary facility to prospective qualifying patients and primary caregivers. Such disclosure may include posting the information on the dispensary facility Internet web site.

(o) A dispensary facility shall provide information to qualifying patients and primary caregivers regarding the possession and use of marijuana. The dispensary facility manager shall submit all informational material to the commissioner for approval prior to being provided to qualifying patients and primary caregivers. Such informational material shall include information related to:

(1) Limitations on the right to possess and use marijuana pursuant to the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Safe techniques for proper use of marijuana and paraphernalia;

(3) Alternative methods and forms of consumption or inhalation by which one can use marijuana;

(4) Signs and symptoms of substance abuse; and

(5) Opportunities to participate in substance abuse programs.

(p) The dispensary facility shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the commissioner or the commissioner's authorized representative upon request.

(q) All deliveries from producers shall be carried out under the direct supervision of a dispensary who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the dispensary department where marijuana is stored.

Sec. 21a-408-35. Dispensary facility prohibitions

(a) No dispensary department shall be open or in operation, and no person shall be in the dispensary department, unless a dispensary is on the premises and directly supervising the activity within the dispensary department. At all other times, the dispensary department shall be closed and properly secured, in accordance with sections 21a-408-51 and 21a-408-62 of the Regulations of Connecticut State Agencies.

(b) No dispensary facility shall sell anything other than marijuana products and paraphernalia from the dispensary department.

(c) No marijuana shall be consumed on the premises of a dispensary facility.

(d) No food or beverages shall be consumed by qualifying patients or primary caregivers on the premises of a dispensary facility, except that complimentary food and non-alcoholic beverages may be available for qualifying patients and primary caregivers who are at the dispensary facility for a pre-scheduled education, counseling or therapy program.

(e) No person, except for a qualifying patient or primary caregiver, shall open or break the seal placed on a marijuana product packaged by a producer except that a dispensary may remove marijuana from a child-

resistant container or package under the conditions set forth in sections 21a-408-34(e) of the Regulations of Connecticut State Agencies.

(f) Except as provided in subsection (g) of this section, no person, except a dispensary facility employee, or a production facility employee who is delivering marijuana products, shall be allowed on the premises of a dispensary facility without a qualifying patient or primary caregiver registration certificate issued by the department.

(g) (1) Upon prior written request, the commissioner or the commissioner's authorized representative may waive the provisions of subsection (f) of this section.

(2) All persons not permitted on the premises of a dispensary facility pursuant to subsection (f) of this section, but who have been authorized, in writing, to enter the facility by the commissioner or the commissioner's authorized representative shall obtain a visitor identification badge from a dispensary facility employee, prior to entering the dispensary facility. A dispensary or dispensary technician shall escort and monitor such a visitor at all times the visitor is in the dispensary department. A visitor shall visibly display the visitor identification badge at all times the visitor is in the dispensary facility and shall return the visitor identification badge to a dispensary facility employee upon exiting the dispensary facility.

(3) All visitors shall log in and out. The dispensary facility shall maintain the visitor log, which shall include the date, time and purpose of the visit and which shall be available to the commissioner in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(4) If an emergency requires the presence of a visitor and makes it impractical for the dispensary facility to obtain a waiver pursuant to subsection (g)(1) of this section, the dispensary facility shall provide written notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A dispensary facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

(h) No person associated with a dispensary facility shall enter into any agreement with a certifying physician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensary facility at which the qualifying patient or primary caregiver will purchase marijuana.

(i) No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a dispensary facility, except that a primary caregiver may deliver marijuana to the caregiver’s qualified patient.

(j) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a dispensary facility if necessary to perform their governmental duties.

Sec. 21a-408-36. Procedures when dispensary department is closed

(a) During times that the dispensary department is closed, it shall be securely locked and equipped with an alarm system. Such alarm shall be activated and operated separately from any other alarm system at the dispensary facility and shall be able to immediately detect entrance to the dispensary department at times when it is closed. Keys and access codes to the alarm system shall be controlled in such a manner so as to prevent access to the dispensary department by other than authorized dispensary facility employees. Only a dispensary shall have the authority to deactivate the alarm system.

(b) A dispensary facility shall store marijuana in an approved safe or approved vault within the dispensary department and shall not sell marijuana products when the dispensary department is closed.

Sec. 21a-408-37. Security of the dispensary department during momentary absences of a dispensary

During times when the dispensary leaves the dispensary department for a few moments, the dispensary shall take measures to ensure that adequate security of the dispensary department is provided and that entry by unauthorized persons is prevented or immediately detected. The presence of a dispensary technician in the dispensary department during these times shall be considered adequate security. If no such dispensary technician is available for this purpose, and the dispensary department is not within the view of the dispensary, the dispensary shall physically or electronically secure the dispensary department through the use of mechanisms such as a locked barrier or an alarm system that will prevent or immediately detect access to such department.

Sec. 21a-408-38. Rights and responsibilities of dispensaries

(a) A dispensary, in good faith, may sell and dispense marijuana to any qualifying patient or primary caregiver that is registered with the department. Except as otherwise provided by sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary dispensing the marijuana shall include the date of dispensing and the dispensary's signature or initials on the dispensary facility's dispensing record log.

(b) All dispensaries shall register with the department to access the prescription monitoring program.

(c) A dispensary shall review a qualifying patient's controlled substance history report within the prescription monitoring program before dispensing any marijuana to the qualifying patient or the qualifying patient's primary caregiver.

(d) A dispensary shall exercise professional judgment to determine whether to dispense marijuana to a qualifying patient or primary caregiver if the dispensary suspects that dispensing marijuana to the qualifying patient or primary caregiver may have negative health or safety consequences for the qualifying patient or the public.

(e) A dispensary may dispense a portion of a qualifying patient's one-month supply of marijuana. The dispensary may dispense the remaining portion of the one- month supply of marijuana at any time except that no qualifying patient or primary caregiver shall receive more than a one-month supply of marijuana in a one-month period.

(f) A dispensary, or dispensary technician, shall require the presentation of a registration certificate together with another valid photographic identification issued to a qualifying patient or primary caregiver, prior to selling marijuana to such qualifying patient or primary caregiver.

(g) A dispensary shall document a qualifying patient's self-assessment of the effects of marijuana in treating the qualifying patient's debilitating medical condition or the symptoms thereof. A dispensary facility shall maintain such documentation electronically for at least three years following the date the patient ceases to designate the dispensary facility and such documentation shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-39. Dispensaries to assign serial number and maintain records. Transfer of records to another dispensary facility

(a) A dispensary shall assign and record a sequential serial number to each marijuana product dispensed to a patient and shall keep all dispensing records in numerical order in a suitable file, electronic file or ledger. The records shall indicate:

(1) The date of dispensing;
(2) The name and address of the certifying physician;
(3) The name and address of the qualifying patient, or primary caregiver if applicable;
(4) The initials of the dispensary who dispensed the marijuana; and
(5) Whether a full or partial one-month supply of marijuana was dispensed.

(b) A dispensary facility shall maintain records created under this section and shall make such records available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(c) When a dispensary department closes temporarily or permanently, the dispensary facility shall, in the interest of public health, safety and convenience, make its complete dispensing records immediately available to a nearby dispensary facility and post a notice of this availability on the window or door of the closed dispensary facility. The dispensary facility shall simultaneously provide such notice to the commissioner.

Sec. 21a-408-40. Labeling of marijuana products by dispensary

(a) A dispensary shall not dispense marijuana that does not bear the producer label required pursuant to section 21a-408-56 of the Regulations of Connecticut State Agencies.

(b) A dispensary, or a dispensary technician under the direct supervision of the dispensary, shall completely and properly label all marijuana products dispensed with all required information as follows:

(1) The serial number, as assigned by the dispensary facility;
(2) The date of dispensing the marijuana;
(3) The quantity of marijuana dispensed;
(4) The name and registration certificate number of the qualifying patient and, where applicable, the primary caregiver;
(5) The name of the certifying physician;
(6) Such directions for use as may be included in the physician's written certification or otherwise provided by the physician;

(7) Name of the dispensary;
(8) Name and address of the dispensary facility;
(9) Any cautionary statement as may be required by Connecticut state statute or regulation; and
(10) A prominently printed expiration date based on the producer's recommended conditions of use and storage that can be read and understood by the ordinary individual.

(c) The expiration date required by this section shall be no later than the expiration date determined by the producer.

(d) No person except a dispensary, or a dispensary technician operating under the direct supervision of a dispensary, shall alter, deface or remove any label so affixed.

Sec. 21a-408-41. Responsibilities of dispensary facility manager

(a) A dispensary facility shall employ the dispensary facility manager at the dispensary facility for at least thirty-five hours per week, except as otherwise authorized by the commissioner.

(b) No person shall be a dispensary facility manager for more than one dispensary facility at a time.

(c) The dispensary facility manager shall be responsible for ensuring that:

(1) Dispensary technicians are registered and properly trained;
(2) All record-retention requirements are met;
(3) All requirements for the physical security of marijuana are met;

(4) The dispensary facility has appropriate pharmaceutical reference materials to ensure that marijuana can be properly dispensed;
(5) The following items are conspicuously posted in the dispensary department in a location and in a manner so as to be clearly and readily identifiable to qualifying patients and primary caregivers:
(A) Dispensary facility license;
(B) The name of the dispensary facility manager; and
(C) The price of all marijuana products offered by the dispensary facility as identified by their registered brand name as set forth in section 21a-408-59 of the Regulations of Connecticut State Agencies; and

(6) Any other filings or notifications required to be made on behalf of the dispensary facility as set forth in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, are completed.

Sec. 21a-408-42. Dispensary technicians. Ratio. Supervision and responsibility

(a) The ratio of dispensary technicians to dispensaries on duty in a dispensary department shall not exceed three dispensary technicians to one dispensary.

(b) A dispensary whose license is under suspension or revocation shall not act as a dispensary technician.

(c) The dispensary providing direct supervision of dispensary technicians shall be responsible for the dispensary technicians' actions. Any violations relating to the dispensing of marijuana resulting from the actions of a dispensary technician, or the use of dispensary technicians

in the performance of tasks in a manner not in conformance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the dispensary. As used in this subsection, "direct supervision" means a supervising dispensary who:

(1) Is physically present in the area or location where the dispensary technician is performing routine marijuana dispensing functions; and

(2) Conducts in-process and final checks on the dispensary technician's performance.

Sec. 21a-408-43. Dispensary technician limitations

(a) Dispensary technicians shall not:

(1) Consult with a qualifying patient or the patient's primary caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or re- garding any medical information contained in a patient medication record;

(2) Consult with the physician who certified the qualifying patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;

(3) Interpret the patient’s clinical data or provide medical advice;

(4) Perform professional consultation with physicians, nurses or other health care professionals or their authorized agents; or

(5) Determine whether a different brand or formulation of marijuana should be substituted for the marijuana product or formulation recommended by the physician or requested by the qualifying patient or primary caregiver.

(b) Notwithstanding subsection (a) of this section, a dispensary technician may communicate with a physician who certified a qualifying patient, or the physician's agent, to obtain a clarification on a qualifying patient’s written certification or instructions provided the supervising dispensary is aware that such clarification is being requested.

Sec. 21a-408-44. Dispensary technician training

(a) Dispensary technicians shall complete initial training as determined by the dispensary facility manager of each dispensary facility. Such training shall include, but not be limited to:

(1) On-the-job and other related education, which shall be commensurate with the tasks dispensary technicians are to perform and which shall be completed prior to the regular performance of such tasks;

(2) Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and

(3) Developments in the field of the medical use of marijuana.

(b) The dispensary technician shall be registered as a dispensary technician with the department prior to the start of such training.

(c) The dispensary facility manager shall assure the continued competency of dispensary technicians through continuing in-service

training designed to supplement initial training, which shall include any guidance specified by the department.

(d) The dispensary facility manager shall be responsible for maintaining a written record documenting the initial and continuing training of dispensary technicians, which shall contain:

(1) The name of the person receiving the training;
(2) The dates of the training;
(3) A general description of the topics covered;
(4) The name of the person supervising the training; and
(5) The signatures of the person receiving the training and the dispensary facility manager.

(e) When a change of dispensary facility manager occurs, the new manager shall review the training record and sign it, indicating that the new manager understands its contents.

(f) A dispensary facility shall maintain the record documenting the dispensary technician training and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-45. Dispensary facility employee training. Employee records

(a) A dispensary facility shall provide to each dispensary facility employee, prior to the employee commencing work at the dispensary facility, at a minimum, training in the following:

(1) The proper use of security measures and controls that have been adopted for the prevention of diversion, theft or loss of marijuana;

(2) Procedures and instructions for responding to an emergency; and
(3) State and federal statutes and regulations regarding patient confidentiality. (b) Each dispensary facility shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies, a training record for each dispensary facility employee. Such record shall include, at a minimum, documentation of all required training, including:

(1) The name of the person receiving the training;
(2) The dates of the training;
(3) A general description of the topics covered;
(4) The name of the person supervising the training; and
(5) The signatures of the person receiving the training and the dispensary facility manager.

Sec. 21a-408-46. Dispensary facility manager notifications

(a) A dispensary facility shall immediately notify the department whenever the dispensary facility manager ceases such management and shall immediately designate with the department the name, address and license number of the dispensary who assumes management of the dispensary facility. A dispensary facility shall file the notice of change in management of a dispensary on a form prescribed by the commissioner and shall pay the filing fee required in section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

(b) If a dispensary facility manager is absent from the dispensary facility for any reason for more than sixteen consecutive days, the dispensary facility shall immediately report such absence to the department. The

dispensary facility shall provide the department with the name of the dispensary designated to be the acting dispensary facility manager no later than five days after the sixteenth consecutive day of the original dispensary facility manager's absence.

(c) If the absence of the dispensary facility manager exceeds forty-two consecutive days, such person shall be deemed to have ceased to be the dispensary facility manager for the dispensary facility. In such case, the dispensary facility shall, in accordance with this section, immediately notify the department of the name, address and license number of the dispensary who is assuming management of the dispensary facility. A dispensary facility shall file the notice of change of dispensary facility manager on a form prescribed by the commissioner and shall pay the filing fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

Sec. 21a-408-47. Dispensing error reporting. Quality assurance program

(a) A dispensary facility shall display a sign concerning the reporting of dispensing errors in a conspicuous location visible to qualifying patients and primary caregivers. The sign shall measure a minimum of eight inches in height and ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the dispensary department. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling

(Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)."

(b) A dispensary facility shall include the following printed statement on the receipt or in the bag or other similar packaging in which marijuana is contained: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)." The dispensary facility shall print such statement in a size and style that allows it to be read without difficulty by patients.

(c) A dispensary facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify and prevent dispensing errors. A dispensary facility shall provide to the commissioner a written copy of such quality assurance program, shall distribute it to all dispensary facility employees, and shall make it readily available on the premises of the dispensary facility. Such policies and procedures shall include:

(1) Directions for communicating the details of a dispensing error to the physician who certified a qualifying patient and to the qualifying patient, the patient's primary caregiver or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

(2) A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

(d) A dispensary facility shall use the findings of its quality assurance program to develop dispensary systems and workflow processes designed to prevent dispensing errors.

(e) A dispensary facility manager shall inform dispensary facility employees of changes to dispensary facility policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

Sec. 21a-408-48. Review of dispensing errors

(a) A dispensary facility manager shall notify all dispensary employees that the discovery or reporting of a dispensing error shall be relayed immediately to a dispensary on duty.

(b) A dispensary facility manager shall ensure that a dispensary performs a quality assurance review for each dispensing error. A dispensary shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.

(c) A dispensary facility manager shall create a record of every quality assurance review. This record shall contain at least the following:

(1) The date or dates of the quality assurance review and the names and titles of the persons performing the review;

(2) The pertinent data and other information relating to the dispensing error reviewed;

(3) Documentation of contact with the qualifying patient, primary caregiver where applicable, and the physician who certified the patient as required by the quality assurance program implemented pursuant to section 21a-408-47 of the Regulations of Connecticut State Agencies;

(4) The findings and determinations generated by the quality assurance review; and

(5) Recommended changes to dispensary facility policy, procedure, systems, or processes, if any.

(d) A dispensary facility shall maintain quality assurance review records in an orderly manner and filed by date.

(e) A dispensary facility shall maintain a copy of the dispensary facility's quality assurance program and records of all reported dispensing errors and quality assurance reviews and make such documents available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-49. Electronic system record-keeping safeguards

(a) If a dispensary facility uses an electronic system for the storage and retrieval of patient information or other marijuana records, the dispensary facility shall use a system that:

(1) Guarantees the confidentiality of the information contained therein;

(2) Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the dispensary; and

(3) Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Sec. 21a-408-50. Dispensary reporting into the prescription monitoring program

(a) At least once per day, a dispensary shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy, a copy of which may be purchased from the American Society for Automation in Pharmacy on their Internet web site: www.asapnet.org.

(b) A dispensary shall transmit to the department, in a format approved by the department, the fields listed in this subsection, including, but not limited to, the following:
(1) Drug Enforcement Administration Pharmacy number, which shall be populated by a number provided by the department;
(2) Birth date;
(3) Sex code;
(4) Date order filled, which shall be the date marijuana is dispensed;
(5) Order number, which shall be the serial number assigned to each marijuana product dispensed to a patient; (6) New-refill code;
(7) Quantity;
(8) Days supply;
(9) National Drug Code number, which shall be provided by the department; (10) Drug Enforcement Administration Prescriber identification number;
(11) Date order written, which shall be the date the written certification

was issued; (12) Number of refills authorized;
(13) Order origin code, which shall be provided by the department;
(14) Patient last name;
(15) Patient first name;
(16) Patient street address;
(17) State;
(18) Payment code for either cash or third-party provider; and
(19) Drug name, which shall be the brand name of the marijuana product.

(c) A dispensary shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and Connecticut state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

Sec. 21a-408-51. Security requirements for dispensary facilities

(a) A dispensary facility shall:

(1) Not maintain marijuana in excess of the quantity required for normal, efficient operation;

(2) Store all marijuana in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;

(3) Maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

(4) Keep all approved safes and approved vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;

(8) Keep the dispensary department securely locked and protected from entry by unauthorized employees; and

(9) Post a sign at all entry ways into any area of the dispensary facility containing marijuana, including a room with an approved safe or approved vault, which sign shall be a minimum of twelve inches in height and twelve inches in width which shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(b) If a dispensary facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards, including, but not limited to, a supervised watchman service.

(c) If diversion, theft or loss of marijuana has occurred from a dispensary facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such dispensary

facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408- 70, inclusive, of the Regulations of Connecticut State Agencies, or stored at a location other than that for which the dispensary facility license was issued, shall be subject to embargo or seizure by the department in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any dispensary facility whose license is revoked or not renewed shall dispose of its entire stock of marijuana in accordance with sections 21a-408-64 of the Regulations of Connecticut State Agencies.

(f) If a dispensary facility has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of such facility, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

Sec. 21a-408-52. Operation of production facility

(a) Only a producer shall own and operate a production facility.
(b) A producer shall not:
(1) Produce or manufacture marijuana in any place except its approved production facility;
(2) Sell, deliver, transport or distribute marijuana from any place except its approved production facility;
(3) Produce or manufacture marijuana for use outside of Connecticut;
(4) Sell, deliver, transport or distribute marijuana to any place except a

dispensary facility located in Connecticut;
(5) Enter into an exclusive agreement with any dispensary facility;
(6) Refuse to deal with any dispensary facility that is willing to deal with such producer on the same terms and conditions as other dispensary facilities with whom the producer is dealing; or

(7) Either directly or indirectly discriminate in price between different dispensary facilities that are purchasing a like, grade, strain, brand, and quality of marijuana or marijuana product, provided nothing herein shall prevent differentials which only make due allowance for differences in the cost of manufacture, sale or delivery resulting from the differing methods or quantities in which such marijuana or marijuana products are sold or delivered to such dispensary facilities.

(c) A producer license shall permit the licensee to operate at a single production facility location. Prior to operating a production facility at a different location, a producer shall obtain an additional producer license in accordance with the producer license selection and application process set forth in sections 21a-408-20 to 21a-408-21 of the Regulations of Connecticut State Agencies, except that if the maximum number of producer licenses allowed under the Act have been issued, the commissioner may permit additional production facilities to be operated by a currently licensed producer.

(d) A producer shall establish and maintain an escrow account in a financial institution in Connecticut, obtain a letter of credit from a financial institution in Connecticut, or obtain a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, upon terms approved by the commissioner, in the amount of two million dollars. The money secured by the escrow account, letter of credit or

surety bond shall be payable to the state of Connecticut in the event the producer fails to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides an uninterrupted supply of marijuana or marijuana products to its usual dispensary facility customers during the term of the license. The commissioner may reduce or eliminate the escrow account, letter of credit or surety bond in accordance with the terms set forth in section 21a-408-29 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-53. Minimum requirements for the storage and handling of marijuana by producers

(a) All production facilities shall:
(1) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for the production and manufacture of marijuana;
(2) Separate for storage, in a quarantined area, marijuana that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such marijuana is destroyed;
(3) Be maintained in a clean and orderly condition; and
(4) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Any area within the production facility where marijuana will be manufactured into an edible form shall comply with the Connecticut Food, Drug and Cosmetic Act, Connecticut General Statutes, sections 21a-91 to 21a-120, inclusive, and, Connecticut General Statutes,

sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.
(c) A producer shall compartmentalize all areas in the production facility based on function and shall restrict access between compartments. The producer shall establish, maintain and comply with written policies and procedures, approved by the commissioner, regarding best practices for the secure and proper production and manufacturing of marijuana. These shall include, but not be limited to, policies and procedures that:
(1) Restrict movement between production compartments;
(2) Provide for different colored identification cards for production facility employees based on the production compartment to which they are assigned at a given time so as to ensure that only employees necessary for a production function have access to that compartment of the production facility;
(3) Require pocketless clothing for all production facility employees working in an area containing marijuana; and
(4) Document the chain of custody of all marijuana and marijuana products.

(d) Producers shall establish, maintain, and comply with written policies and procedures, approved by the commissioner, for the manufacture, security, storage, inventory, and distribution of marijuana. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft or loss, and for correcting all errors and inaccuracies in inventories. Producers shall include in their written policies and procedures, a process for the following:

(1) Handling mandatory and voluntary recalls of marijuana products. Such process shall be adequate to deal with recalls due to any action initiated at the request of the commissioner and any voluntary action by the producer to remove defective or potentially defective marijuana

products from the market or any action undertaken to promote public health and safety by replacing existing marijuana products with improved products or packaging;

(2) Preparing for, protecting against, and handling any crises that affects the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(3) Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated marijuana is segregated from all other marijuana and destroyed. This procedure shall provide for written documentation of the marijuana disposition; and

(4) Ensuring the oldest stock of a marijuana product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(e) A producer shall store all marijuana in the process of manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion, theft or loss, shall make marijuana accessible only to the minimum number of specifically authorized employees essential for efficient operation, and shall return marijuana to its secure location immediately after completion of the process or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the producer shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing marijuana inside an area or building that affords adequate security.

(f) No person, except production facility employees, local law enforcement, the commissioner or commissioner's authorized representative or other federal, state of Connecticut or local government

officials, where necessary to perform their governmental duties, shall be allowed on the premises of a production facility, except that:
(1) Laboratory staff may enter a production facility for the sole purpose of identifying and collecting marijuana samples for purposes of conducting laboratory tests; and
(2) Upon prior written request, the commissioner or the commissioner's authorized representative may permit other persons to enter a production facility.

(g)(1) All persons who are not production facility employees, but who are permitted on the premises of a production facility pursuant to subsection (f)(1) or (2) of this section, shall obtain a visitor identification badge from a production facility employee, prior to entering the production facility. A production facility employee shall escort and monitor visitors at all times. A visitor shall visibly display the visitor identification badge at all times the visitor is in the production facility. A visitor shall return the visitor identification badge to a production facility employee upon exiting the production facility.

(2) The producer shall log all visitors in and out, and shall maintain a log that includes the date, time and purpose of the visit. A producer shall maintain such log and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(3) If an emergency requires the presence of a visitor and makes it impractical to obtain permission pursuant to subsection (f)(2) of this section, the producer shall provide written notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A producer shall monitor the visitor and maintain a log of such visit as required by this subsection.

Sec. 21a-408-54. Producer record keeping

Producers shall keep records of all marijuana produced or manufactured and of all marijuana disposed of by them. Such records shall be maintained and made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies and, in each case shall show:

(1) The brand name, kind and quantity of marijuana involved;
(2) The date of such production or removal from production;
(3) A record of all marijuana sold, transported or otherwise disposed of;
(4) The date and time of selling, transporting or disposing of the marijuana;
(5) The name and address of the dispensary facility to which the marijuana was sold;
(6) The name of the dispensary who took custody of the marijuana; and
(7) The name of the production facility employee responsible for transporting the marijuana.

Sec. 21a-408-55. Manufacturing of marijuana products

(a) A producer shall only manufacture or sell marijuana products in the following forms:

1. (1) Raw material;
2. (2) Cigarettes;
3. (3) Extracts, sprays, tinctures or oils;
4. (4) Topical applications, oils or lotions;
5. (5) Transdermal patches;

6. (6) Baked goods; and
7. (7) Capsules or pills.

(b) No marijuana product shall:
(1) Include alcoholic liquor, dietary supplements or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than one-half of one percent of alcohol by volume or ethanol-based tinctures with an alcohol level approved by the commissioner;
(2) Be manufactured or sold as a beverage or confectionary;
(3) Be manufactured or sold in a form or with a design that:
(A) Is obscene or indecent;
(B) May encourage the use of marijuana for recreational purposes;
(C) May encourage the use of marijuana for a condition other than a debilitating medical condition; or
(D) Is customarily associated with persons under the age of eighteen;

(4) Have had pesticide chemicals or organic solvents used during the production or manufacturing process, except that the commissioner may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of marijuana crops.

(c) Any marijuana product not in compliance with this section shall be deemed adulterated.

Sec. 21a-408-56. Packaging and labeling by producer

(a) A producer shall individually package, label and seal marijuana products in unit sizes such that no single unit contains more than a one-month supply of marijuana.

(b) A producer shall place any product containing marijuana in a child-resistant and light-resistant package. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

(c) A producer shall label each marijuana product prior to sale to a dispensary and shall securely affix to the package a label that states in legible English:
(1) The name and address of the producer;
(2) The brand name of the marijuana product that was registered with the department pursuant to section 21a-408-59 of the Regulations of Connecticut State Agencies;
(3) A unique serial number that will match the product with a producer batch and lot number so as to facilitate any warnings or recalls the department or producer deem appropriate;
(4) The date of final testing and packaging;
(5) The expiration date;
(6) The quantity of marijuana contained therein;
(7) A terpenes profile and a list of all active ingredients, including:
(A) tetrahydrocannabinol (THC);
(B) tetrahydrocannabinol acid (THCA);
(C) cannabidiol (CBD);
(D) cannabidiolic acid (CBDA); and
(E) any other active ingredient that constitute at least 1% of the marijuana batch used in the product.
(8) A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals and chemical residue analysis; and
(9) Such other information necessary to comply with state of Connecticut labeling requirements for similar products not containing marijuana, including but not limited to the Connecticut Food, Drug and

Cosmetic Act, Connecticut General Statutes, sections 21a-91 to 21a-120, inclusive, and Connecticut General Statutes, sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.
(d) A producer shall not label marijuana products as "organic" unless the marijuana plants have been organically grown as defined in section 21a-92 of the Connecticut General Statutes and the marijuana products have been produced, processed, manufactured and certified to be consistent with organic standards in compliance with section 21a-92a of the Connecticut General Statutes.

Sec. 21a-408-57. Laboratory requirements

No laboratory shall handle, test or analyze marijuana unless such laboratory:

(1) Is registered with the department as a controlled substance laboratory;
(2) Is independent from all other persons involved in the marijuana industry in Connecticut, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, certifying physician or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of marijuana; and

(3) Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master's level degree in chemical or biological sciences and a minimum

of two years of post-degree laboratory experience or a bachelor's degree in biological sciences and a minimum of four years of post-degree laboratory experience.

Sec. 21a-408-58. Laboratory testing

(a) Immediately prior to manufacturing any marijuana product or packaging raw marijuana for sale to a dispensary, a producer shall segregate all harvested marijuana into homogenized batches.

(b) A producer shall make available each such batch at the production facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

(c) From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a dispensary facility, until the laboratory provides the results from its tests and analysis, the producer shall segregate and withhold from use the entire batch of marijuana, except the samples that have been removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a dispensary facility prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any marijuana upon the completion of any testing, use, or research. If a laboratory disposes of marijuana, the laboratory shall comply with 21a-408-64 of the Regulations of Connecticut State Agencies.

(e) If a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the producer shall dispose of the entire batch from which the sample was taken in accordance with section 21a-408-64 of the Regulations of Connecticut State Agencies.

(1) For purposes of the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia, which can be obtained at http://www.usp.org.

(2) For purposes of the mycotoxin test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Test

Alfatoxin B1 Alfatoxin B2 Alfatoxin O1 Alfatoxin O2 Ochratoxin A

Specification

<20 uG/KG of Substance <20 uG/KG of Substance <20 uG/KG of Substance <20 uG/KG of Substance <20 uG/KG of Substance

(3) For purposes of the heavy metal test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Metal Natural Health Products Acceptable limits uG/KG BW/Day

Arsenic <0.14 Cadmium <0.09 Lead <0.29 Mercury <0.29

(4) For purposes of the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.

(f) If a sample of marijuana passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a dispensary facility.

(g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(h) A producer shall provide to a dispensary facility the laboratory test results for each batch of marijuana used in a product purchased by the dispensary facility. Each dispensary facility shall have such laboratory results available upon request to qualifying patients, primary caregivers and physicians who have certified qualifying patients.

Sec. 21a-408-59. Brand name

(a) A producer shall assign a brand name to each marijuana product. A producer shall register each brand name with the department, on a form

prescribed by the commissioner, prior to any sale to a dispensary facility and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

(1) Tetrahydrocannabinol (THC);
(2) Tetrahydrocannabinol acid (THCA);
(3) Cannabidiols (CBD);
(4) Cannabidiolic acid (CBDA); and
(5) Any other active ingredient that constitutes at least 1% of the marijuana batch used in the product.
(b) A producer shall not label two marijuana products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within subsection (a)(1) to (4), inclusive, of this section within a range of 97% to 103%.

(c) The department shall not register any brand name that:

(1) Is identical to, or confusingly similar to, the name of an existing non-marijuana product;

(2) Is identical to, or confusingly similar to, the name of an unlawful product or substance;

(3) Is confusingly similar to the name of a previously approved marijuana product brand name;

(4) Is obscene or indecent;

(5) May encourage the use of marijuana for recreational purposes;

(6) May encourage the use of marijuana for a condition other than a debilitating medical condition;

(7) Is customarily associated with persons under the age of 18; or

(8) Is related to the benefits, safety or efficacy of the marijuana product unless supported by substantial evidence or substantial clinical data.

Sec. 21a-408-60. Transportation of marijuana

(a) Prior to transporting any marijuana or marijuana product, a producer shall:

(1) Complete a shipping manifest using a form prescribed by the commissioner; and

(2) Securely transmit a copy of the manifest to the dispensary facility that will receive the products and to the department at least twenty-four hours prior to transport.

(b) The producer and dispensary facility shall maintain all shipping manifests and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(c) A producer shall only transport marijuana products:

(1) In a locked, safe and secure storage compartment that is part of the vehicle transporting the marijuana; and

(2) In a storage compartment that is not visible from outside the vehicle.

(d) A production facility employee, when transporting marijuana, shall travel directly from the producer facility to the dispensary facility and shall not make any stops in between, except to other dispensary facilities.

(e) A producer shall ensure that all delivery times and routes are randomized.

(f) A producer shall staff all transport vehicles with a minimum of two employees. At least one delivery team member shall remain with the vehicle at all times that the vehicle contains marijuana.

(g) A delivery team member shall have access to a secure form of communication with employees at the production facility at all times that the vehicle contains marijuana.

(h) A delivery team member shall possess a department-issued identification card at all times when transporting or delivering marijuana and shall produce it to the commissioner, the commissioner's authorized representative or law enforcement official upon request.

Sec. 21a-408-61. Security requirements for producers

(a) A producer shall:

(1) Not produce, manufacture or maintain marijuana in excess of the quantity required for normal, efficient operation;

(2) Store all marijuana products in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;

(3) Maintain all marijuana that is not part of a finished product in a secure area or location within the production facility accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

(4) Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing or storage of marijuana, securely locked or protected from entry, except for the actual time required to remove or replace marijuana;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees; and

(8) Keep the production facility securely locked and protected from entry at all times.

(b) If a production facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards such as a supervised watchman service.

(c) If a loss, theft, or diversion of marijuana has occurred from a production facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such production facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408- 70, inclusive, of the Regulations of Connecticut State Agencies, or at a location other than that for which the producer license

was issued, shall be subject to seizure in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any producer whose license is revoked or not renewed shall dispose of its entire stock of marijuana under conditions approved by the department.

(f) If a producer has provided other safeguards, which can be regarded in total as an adequate substitute for some element of protection required of such producer, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

(g) No person shall be allowed access to any area within a production facility containing marijuana except laboratory employees and production facility employees whose responsibilities necessitate access to the area of the production facility containing marijuana and then for only as long as necessary to perform the person's job duties.

(h) Any area of a production facility containing marijuana, including a room with an approved safe or approved vault, shall have a sign posted at all entry ways, which shall be a minimum of twelve inches in height and twelve inches in width and shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(i) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a production facility if necessary to perform their governmental duties.

Sec. 21a-408-62. Security alarm systems; minimum requirements for dispensary facilities and production facilities

(a) All dispensary facilities and production facilities shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade equipment, which shall, at a minimum, include:

(1) A perimeter alarm;
(2) Motion detector;
(3) Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The dispensary facility or production facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being produced, harvested, manufactured, stored or handled. At entry and exit points, the dispensary facility or production facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(4) Twenty-four hour recordings from all video cameras, which the dispensary facility or production facility shall make available for immediate viewing by the commissioner or the commissioner's authorized representative upon request and shall retain for at least thirty days. If a dispensary facility or producer is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the dispensary facility or producer shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the dispensary facility manager or producer that it is not necessary to retain the recording;

(5) Duress alarm, which for purposes of this subsection means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

(6) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(7) Holdup alarm, which for purposes of this subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

(8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

(9) A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensary facility or producer within five minutes of the failure, either by telephone, email, or text message;

(10) The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(11) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(12) The ability to remain operational during a power outage.

(b) A dispensary facility or a production facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subsection (a) of this section, each production facility shall have a back-up alarm system approved by the commissioner that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(d) A dispensary facility or a production facility shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the commissioner or the commissioner's authorized representative, and others when approved by the commissioner. A dispensary facility and producer shall make available a current list of authorized employees and service employees that have access to the surveillance room to the commissioner or the commissioner's authorized representative upon request. A dispensary facility and producer shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(e) A dispensary facility and producer shall keep the outside perimeter of the dispensary facility and production facility premises well-lit.

(f) All video recording shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A dispensary facility and producer shall erase all recordings prior to disposal or sale of the facility.

(g) A dispensary facility and producer shall keep all security equipment in good- working order and shall test such equipment no less than two times per year.

Sec. 21a-408-63. Dispensary and producer reportable events

(a) Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana or of any loss or unauthorized alteration of records related to marijuana or qualifying patients, a dispensary or producer shall immediately notify:

(1) Appropriate law enforcement authorities; and
(2) The Drug Control Division of the department.
(b) A dispensary or producer shall provide the notice required by subsection (a) of this section to the department by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of marijuana diverted, stolen, lost, destroyed or damaged and confirmation that the local law enforcement authorities were notified. A dispensary or producer shall make such notice no later than twenty-four hours after discovery of the event.

(c) A dispensary or producer shall notify the Drug Control Division of the department no later than the next business day, followed by written notification no later than ten business days, of any of the following:

(1) An alarm activation or other event that requires response by public safety personnel;

(2) A breach of security;

(3) The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

(4) Corrective measures taken, if any.

(d) A dispensary and producer shall maintain and shall make available all documentation related to an occurrence that is reportable pursuant to subsections (a) through (c), inclusive, of this section in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-64. Disposal of marijuana

(a) A dispensary, producer, laboratory, law enforcement or court official or the commissioner or the commissioner's authorized representative shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated marijuana in the following manner:

(1) By surrender without compensation of such marijuana to the commissioner or the commissioner's authorized representative; or

(2) By disposal in the presence of an authorized representative of the commissioner in such a manner as to render the marijuana non-recoverable.

(b) The person disposing of the marijuana shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies a separate record of each such disposal indicating:

(1) The date and time of disposal;
(2) The manner of disposal;
(3) The brand name and quantity of marijuana disposed of; and
(4) The signatures of the persons disposing of the marijuana, the authorized representative of the commissioner and any other persons present during the disposal.

Sec. 21a-408-65. Inventory

(a) Each dispensary facility and production facility, prior to commencing business, shall:

(1) Conduct an initial comprehensive inventory of all marijuana at the facility. If a facility commences business with no marijuana on hand, the dispensary or producer shall record this fact as the initial inventory; and

(2) Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of marijuana, which

shall enable the facility to detect any diversion, theft or loss in a timely manner.

(b) Upon commencing business, each dispensary facility and production facility shall conduct a weekly inventory of marijuana stock, which shall include, at a minimum, the date of the inventory, a summary of the inventory findings, the name, signature and title of the individuals who conducted the inventory, the date of receipt of marijuana, the name and address of the producer from whom received, where applicable, and the kind and quantity of marijuana received. The record of all marijuana sold, dispensed or otherwise disposed of shall show the date of sale, the name of the dispensary facility, qualifying patient or primary caregiver to whom the marijuana was sold, the address of such person and the brand and quantity of marijuana sold.

(c) A complete and accurate record of all stocks or brands of marijuana on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the dispensary facility manager or producer may choose, so long as it is not more than one year following the prior year's inventory.

(d) All inventories, procedures and other documents required by this section shall be maintained on the premises and made available in accordance with section 21a-408- 70 of the Regulations of Connecticut State Agencies.

(e) Whenever any sample or record is removed by a person authorized to enforce the provisions of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or the provisions of the state of Connecticut food, drug and cosmetic statutes and regulations for the purpose of investigation or as evidence, such person shall tender a

receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

Sec. 21a-408-66. Marketing: prohibited conduct, statements and illustrations; commissioner review of advertisements

(a) A producer, production facility employee, producer backer, dispensary facility employee, dispensary facility backer or physician, in any combination, shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a physician, dispensary or marijuana product.

(b) An advertisement for marijuana or any marijuana product shall not contain: (1) Any statement that is false or misleading in any material particular or is otherwise in violation of the Connecticut Unfair Trade Practices Act, sections 42-110a to 42-110q, inclusive, of the Connecticut General Statutes;

(2) Any statement that falsely disparages a competitor's products;

(3) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) Any statement, design, representation, picture or illustration that encourages or represents the use of marijuana for a condition other than a debilitating medical condition;

(5) Any statement, design, representation, picture or illustration that encourages or represents the recreational use of marijuana;

(6) Any statement, design, representation, picture or illustration related to the safety or efficacy of marijuana, unless supported by substantial evidence or substantial clinical data;

(7) Any statement, design, representation, picture or illustration portraying anyone under the age of eighteen, objects suggestive of the presence of anyone under the age of eighteen, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of eighteen;

(8) Any offer of a prize, award or inducement to a qualifying patient, primary caregiver or physician related to the purchase of marijuana or a certification for the use of marijuana; or

(9) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, the state of Connecticut or any person or entity associated with the state of Connecticut.

(c) Any advertisement for marijuana or a marijuana product shall be submitted to the commissioner at the same time as, or prior to, the dissemination of the advertisement.

(d) The submitter of the advertisement shall provide the following information in addition to the advertisement itself:

(1) A cover letter that:

(A) Provides the following subject line: Medical marijuana advertisement review package for a proposed advertisement for (Brand Name);

(B) Provides a brief description of the format and expected distribution of the proposed advertisement; and

(C) Provides the submitter's name, title, address, telephone number, fax number, and email address;

(2) An annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) Verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) Verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) Verification that an official translation of a foreign language advertisement is accurate;

(6) Annotated references to support disease or epidemiology information, cross- referenced to the advertisement summary; and

(7) A final copy of the advertisement, including a video where applicable, in a format acceptable to the commissioner.

(e) Advertising packages that are missing any of the elements in subsection (d) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the department receives an incomplete package, it shall so notify the submitter.

(f) The commissioner may:

(1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the commissioner determines that the advertisement would be false or misleading without such a disclosure; or

(2) Make recommendations with respect to changes that are:
(A) Necessary to protect the public health, safety and welfare; or
(B) Consistent with dispensing information for the product under review.
(3) If appropriate and if information exists, recommend statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific disease states, disease symptoms and population groups.

Sec. 21a-408-67. Marijuana advertising; requirements for true statements and fair balance

(a) All advertisements for marijuana or marijuana products that make a statement relating to side effects, consequences, contraindications and effectiveness shall present a true statement of such information. When applicable, advertisements broadcast through media such as radio, television, or other electronic media shall include such information in the audio or audio and visual parts of the presentation.

(b) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(c) An advertisement does not satisfy the requirement that it present a "true statement" of information relating to side effects, consequences, contraindications, and effectiveness if it fails to present a fair balance

between information relating to side effects, consequences, contraindications and effectiveness in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(d) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

(1) Contains a representation or suggestion that a marijuana strain, brand or product is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marijuana strains or products, unless such a claim has been demonstrated by substantial evidence or substantial clinical experience;

(2) Contains favorable information or opinions about a marijuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

(3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(4) Uses a study on individuals without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;

(5) Uses data favorable to a marijuana product derived from patients treated with a different product or dosages different from those approved

in the state of Connecticut; (6) Contains favorable information or conclusions from a study that is inadequate

in design, scope, or conduct to furnish significant support for such information or conclusions; or

(7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(e) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of the marijuana product or strain may cause fatalities or serious damage to a patient.

Sec. 21a-408-68. Marijuana marketing; advertising at a dispensary facility; producer advertising of prices

(a) A dispensary facility shall:

(1) Except as otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, restrict external signage to a single sign no larger than sixteen inches in height by eighteen inches in width;

(2) Not illuminate a dispensary facility sign advertising a marijuana product at any time;

(3) Not advertise marijuana brand names or utilize graphics related to marijuana or paraphernalia on the exterior of the dispensary facility or the building in which the dispensary facility is located; and

(4) Not display marijuana and paraphernalia so as to be clearly visible from the exterior of a dispensary facility.

(b) A producer shall not advertise the price of its marijuana, except that it may make a price list available to a dispensary facility.

Sec. 21a-408-69. Dispensary facility and producer records; furnishing of information; audits

(a) Each dispensary facility and producer shall maintain a complete set of all records necessary to fully show the business transactions related to marijuana for a period of the current tax year and the three immediately prior tax years, all of which shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(b) The commissioner may require any licensee or registrant to furnish such information as the commissioner considers necessary for the proper administration of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, and may require an audit of the business of any dispensary facility or producer and the expense thereof shall be paid by such dispensary facility or producer.

Sec. 21a-408-70. Inspection of records; entry on premises

(a) Every person required by sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents, shall maintain such documents in an auditable format for no less than three years. Upon request, such person shall make such documents immediately available for inspection and copying by the commissioner, the commissioner's authorized representative or others authorized by the Act or sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to review the documents. In complying with this section, no person shall use a foreign language, codes or symbols to designate marijuana types or persons in the keeping of any required document.

(b) For purposes of the supervision and enforcement of the medical marijuana program established pursuant to chapter 420f of the Connecticut General Statutes, the commissioner or the commissioner's authorized representative, is authorized:

(1) To enter, at reasonable times, any place, including a vehicle, in which marijuana is held, dispensed, sold, produced, delivered, transported, manufactured or otherwise disposed of;

(2) To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and

(3) To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

S E C T I O N IV

Statutes within other state agencies

Statutes outside chapters 400j, 417, 418, 420b, 420c which may have an impact on the areas of practice within the said chapters

1-277 and section 1 of this act, sections 1-266 to 1-286, inclusive, do not require a governmental agency in this state to use or permit the use of electronic records or electronic signatures.

Sec. 1-272. Legal recognition of electronic records, electronic signatures and electronic contracts. (a) A record or signature may not be denied legal effect or enforceability solely because the record or signature is in electronic form.(b) A contract may not be denied legal effect or enforceability solely because an electronic record was used in the formation of the contract. (c) If a law requires a record to be in writing, an electronic record satisfies the law. (d) If a law requires a signature, an electronic signature satisfies the law.

(P.A. 02-68, S. 7.)

Sec. 17b-363a. Return of unused prescription drugs dispensed in long-term care facilities to vendor pharmacies. Requirements. Regulations. Fines. Annual list of drugs in program. (a) Each long-term care facility shall return to the vendor pharmacy which shall accept, for repackaging and reimbursement to the Department of Social Services, drug products that were dispensed to a patient and not used if such drug products are (1) prescription drug products that are not controlled substances, (2) sealed in individually packaged units, (3) returned to the vendor pharmacy within the recommended period of shelf life for the purpose of redispensing such drug products, (4) determined to be of acceptable integrity by a licensed pharmacist, and (5) oral and parenteral medication in single-dose sealed containers approved by the federal Food and Drug Administration, topical or inhalant drug products in units of use containers approved by the federal Food and Drug Administration or parenteral medications in multiple-

dose sealed containers approved by the federal Food and Drug Administration from which no doses have been withdrawn.

(b) Notwithstanding the provisions of subsection (a) of this section:

(1) If such drug products are packaged in manufacturer's unit-dose packages, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Social Services if such drugs may be redispensed for use before the expiration date, if any, indicated on the package.

(2) If such drug products are repackaged in manufacturer's unit-dose or multiple-dose blister packs, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Social Services if (A) the date on which such drug product was repackaged, such drug product's lot number and expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.

(c) Each long-term care facility shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.

(d) The Department of Social Services (1) shall reimburse to the vendor pharmacy the reasonable cost of services incurred in the

operation of this section, as determined by the commissioner, and (2) may establish procedures, if feasible, for reimbursement to non Medicaid payors for drug products returned pursuant to this section.

(e) The Department of Consumer Protection, in consultation with the Department of Social Services, shall adopt regulations, in accordance with the provisions of chapter 54, which shall govern the repackaging and labeling of drug products returned pursuant to subsections (a) and (b) of this section. The Department of Consumer Protection shall implement the policies and procedures necessary to carry out the provisions of this section until January 1, 2002, while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal within twenty days after implementation.

Sec. 18-81q. Return of unused prescription drugs dispensed in correctional facilities to vendor pharmacies. Requirements. Regulations. (a) Each correctional institution shall return to the vendor pharmacy which shall accept, for repackaging and reimbursement to the Department of Correction, drug products that were dispensed to a patient and not used if such drug products are (1) prescription drug products that are not controlled substances, (2) sealed in individually packaged units, (3) returned to the vendor pharmacy within the recommended period of shelf life for the purpose of redispensing such drug products, (4) determined to be of acceptable integrity by a licensed pharmacist, and (5) oral and parenteral medication in single-dose sealed containers approved by the federal Food and Drug Administration, topical or inhalant drug products in units of use containers approved by the federal

Food and Drug Administration or parenteral medications in multiple-dose sealed containers approved by the federal Food and Drug Administration from which no doses have been withdrawn.

(b) Notwithstanding the provisions of subsection (a) of this section:

(1) If such drug products are packaged in manufacturer's unit-dose packages, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Correction if such drugs may be redispensed for use before the expiration date, if any, indicated on the package.

(2) If such drug products are repackaged in manufacturer's unit-dose or multiple-dose blister packs, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Correction if (A) the date on which such drug product was repackaged, such drug product's lot number and expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.

(c) The Department of Correction shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.

(d) The Department of Correction shall reimburse to the vendor

pharmacy the reasonable cost of services incurred in the operation of this section, as determined by the Commissioner of Correction.

(e) The Department of Consumer Protection, in consultation with the Department of Correction, shall adopt regulations, in accordance with the provisions of chapter 54, which shall govern the repackaging and labeling of drug products returned pursuant to subsections (a) and (b) of this section. The Department of Consumer Protection shall implement the policies and procedures necessary to carry out the provisions of this section until January 1, 2003, while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal within twenty days after implementation.

(June Sp. Sess. P.A. 01-9, S. 27, 131; June 30 Sp. Sess. P.A. 03-6, S. 146(d); P.A. 04-169, S. 17; 04-189, S. 1.)

History: June Sp. Sess. P.A. 01-9 effective July 1, 2001; June 30 Sp. Sess. P.A. 03-6 and P.A. 04-169 replaced Department of Consumer Protection with Department of Agriculture and Consumer Protection, effective July 1, 2004; P.A. 04-189 repealed Sec. 146 of June 30 Sp. Sess. P.A. 03-6, thereby reversing the merger of the Departments of Agriculture and Consumer Protection, effective June 1, 2004.

TREATMENT FOR A DRUG OVERDOSE.

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

Section 1. Section 17a-714a of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective October 1, 2012*):

A licensed health care professional who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe, dispense or administer an opioid antagonist to treat or prevent a drug overdose without being liable for damages in a civil action or subject to criminal prosecution for prescribing, dispensing or administering such opioid antagonist or for any subsequent use of such opioid antagonist. For purposes of this section, "opioid antagonist" means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of drug overdose.

Sec. 2. (*Effective October 1, 2012*) Not later than January 15, 2013, the Commissioner of Mental Health and Addiction Services shall report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health concerning the number of opioid antagonist prescriptions issued under programs administered by the Department of Mental Health and Addiction Services to persons other than drug users for self-administration of the opioid antagonist, in accordance with section 17a-714a of the general statutes, as amended by this act.

Approved June 15, 2012

Sec. 17b-363a. Return of unused prescription drugs dispensed in long-term care facilities to vendor pharmacies. Requirements.

Regulations. Fines. Annual list of drugs in program. (a) Each long-term care facility shall return to the vendor pharmacy which shall accept, for repackaging and reimbursement to the Department of Social Services, drug products that were dispensed to a patient and not used if such drug products are (1) prescription drug products that are not controlled substances, (2) sealed in individually packaged units, (3) returned to the vendor pharmacy within the recommended period of shelf life for the purpose of redispensing such drug products, (4) determined to be of acceptable integrity by a licensed pharmacist, and (5) oral and parenteral medication in single-dose sealed containers approved by the federal Food and Drug Administration, topical or inhalant drug products in units of use containers approved by the federal Food and Drug Administration or parenteral medications in multiple-dose sealed containers approved by the federal Food and Drug Administration from which no doses have been withdrawn.

(b) Notwithstanding the provisions of subsection (a) of this section:

(1) If such drug products are packaged in manufacturer's unit-dose packages, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Social Services if such drugs may be redispensed for use before the expiration date, if any, indicated on the package.

(2) If such drug products are repackaged in manufacturer's unit-dose or multiple-dose blister packs, such drug products shall be returned to the vendor pharmacy for redispensing and reimbursement to the Department of Social Services if (A) the date on which such drug product was repackaged, such drug product's lot number and expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such

drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.

(c) Each long-term care facility shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.

(d) The Department of Social Services (1) shall reimburse to the vendor pharmacy the reasonable cost of services incurred in the operation of this section, as determined by the commissioner, and (2) may establish procedures, if feasible, for reimbursement to non Medicaid payors for drug products returned pursuant to this section.

(e) The Department of Consumer Protection, in consultation with the Department of Social Services, shall adopt regulations, in accordance with the provisions of chapter 54, which shall govern the repackaging and labeling of drug products returned pursuant to subsections (a) and (b) of this section. The Department of Consumer Protection shall implement the policies and procedures necessary to carry out the provisions of this section until January 1, 2002, while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal within twenty days after implementation.

(f) Any long-term care facility that violates or fails to comply with the provisions of this section shall be fined not more than thirty thousand dollars for each incidence of noncompliance. The Commissioner of Social Services may offset payments due a facility to collect the penalty. Prior to imposing any penalty pursuant to this subsection, the

commissioner shall notify the long-term care facility of the alleged violation and the accompanying penalty and shall permit such facility to request that the department review its findings. A facility shall request such review not later than fifteen days after receipt of the notice of violation from the department. The department shall stay the imposition of any penalty pending the outcome of the review. The commissioner may impose a penalty upon a facility pursuant to this subsection regardless of whether a change in ownership of the facility has taken place since the time of the violation, provided the department issued notice of the alleged violation and the accompanying penalty prior to the effective date of the change in ownership and record of such notice is readily available in a central registry maintained by the department. Payments of fines received pursuant to this subsection shall be deposited in the General Fund and credited to the Medicaid account.

(g) The Commissioner of Social Services, in consultation with the pharmacy review panel established in section 17b-362a, shall update and expand by June 30, 2003, and annually thereafter, the list of drugs that are included in the drug return program. Such list shall include the fifty drugs with the highest average wholesale price that meet the requirements for the program, as established in subsection (a) of this section.

(June Sp. Sess. P.A. 00-2, S. 37, 53; May 9 Sp. Sess. P.A. 02-1, S. 119; P.A. 03-116, S. 1; June 30 Sp. Sess. P.A. 03-6, S. 146(d); P.A. 04-169, S. 17; 04-189, S. 1; 04-258, S. 28.)

History: June Sp. Sess. P.A. 00-2 effective July 1, 2000; May 9 Sp. Sess. P.A. 02-1 added new Subsec. (f) re imposition of fine for violation or failure to comply with section, effective July 1, 2002; P.A. 03-116 added Subsec. (g) re annual list of drugs included in program, effective

June 18, 2003; June 30 Sp. Sess. P.A. 03-6 and P.A. 04-169 replaced Department of Consumer Protection with Department of Agriculture and Consumer Protection, effective July 1, 2004; P.A. 04-189 repealed Sec. 146 of June 30 Sp. Sess. P.A. 03-6, thereby reversing the merger of the Departments of Agriculture and Consumer Protection, effective June 1, 2004; P.A. 04-258 amended Subsec. (f) by changing amount of fine from "thirty thousand dollars" to "not more than thirty thousand dollars" and making technical changes, effective July 1, 2004.

Sec. 19a-25b Each health care provider licensed in this state with prescriptive authority may generate prescriptions in this state utilizing an electronic prescribing system. The Department of Consumer Protection may, within available appropriations, advise and assist health care providers in such utilization.

Sec. 19a-25c A health care institution licensed by the Department of Public Health pursuant to chapter 368v of the general statutes may create, maintain or utilize medical records or a medical records system in electronic format, paper format or both, provided such records or system are designed to store medical records or patient health information in a medium that is reproducible and secure.

Sec. 19a-509c. Prescription orders in health care facilities. In a facility licensed pursuant to this chapter, a physician assistant, advanced practice registered nurse, registered nurse or licensed practical nurse may, except with respect to an order for schedule II controlled substances, reduce to writing the oral or written order of a prescribing practitioner, as defined in section 20-571, and transmit the order to a pharmacy licensed under sections 20-570 to 20-625, inclusive. Such transmitted order shall contain the name of the prescribing practitioner

and shall be treated as a written prescription for purposes of sections 20-570 to 20-625, inclusive.

(P.A. 91-27, S. 1; P.A. 95-264, S. 48.)

History: P.A. 95-264 made technical changes.

Sec. 19a-509d. Transcription and execution of verbal medication orders. When a physician or other authorized prescriber conveys a medication order to a licensed pharmacist by verbal means for a patient in a health care facility licensed pursuant to this chapter, or for a client in a facility operated or licensed by the Department of Mental Retardation, such order shall be received and immediately committed to writing in the patient's or client's chart by the pharmacist. Any order so written may be acted upon by the facility's nurses and physician assistants with the same authority as if the order were received directly from the prescriber. Any order conveyed in this manner shall be countersigned by the prescriber within twenty-four hours unless otherwise provided by state or federal law or regulations.

(P.A. 91-75; P.A. 94-124, S. 2.)

History: P.A. 94-124 made section applicable to facilities of the department of mental retardation.

Sec. 19a-639a (c) The Office of Health Care Access shall, in its discretion, exempt from certificate of need review pursuant to sections 19a-638 and 19a-639 any health care facility or institution that proposes

to purchase or operate an electronic medical records system on or after October 1, 2005.

Sec. 20-87a. Definitions. Scope of practice. (a) The practice of nursing by a registered nurse is defined as the process of diagnosing human responses to actual or potential health problems, providing supportive and restorative care, health counseling and teaching, case finding and referral, collaborating in the implementation of the total health care regimen, and executing the medical regimen under the direction of a licensed physician, dentist or advanced practice registered nurse.

(b) Advanced nursing practice is defined as the performance of advanced level nursing practice activities that, by virtue of post basic specialized education and experience, are appropriate to and may be performed by an advanced practice registered nurse. The advanced practice registered nurse performs acts of diagnosis and treatment of alterations in health status, as described in subsection (a) of this section, and shall collaborate with a physician licensed to practice medicine in this state. If practicing in (1) an institution licensed pursuant to subsection (a) of section 19a-491 as a hospital, residential care home, health care facility for the handicapped, nursing home, rest home, mental health facility, substance abuse treatment facility, infirmary operated by an educational institution for the care of students enrolled in, and faculty and staff of, such institution, or facility operated and maintained by any state agency and providing services for the prevention, diagnosis and treatment or care of human health conditions, or (2) an industrial health facility licensed pursuant to subsection (h) of section 31-374 which serves at least two thousand employees, or (3) a clinic operated by a state agency, municipality, or private nonprofit corporation, or (4) a clinic operated by any educational institution prescribed by regulations adopted pursuant to section 20-99a, the advanced practice registered

nurse may, in collaboration with a physician licensed to practice medicine in this state, prescribe, dispense, and administer medical therapeutics and corrective measures. In all other settings, the advanced practice registered nurse may, in collaboration with a physician licensed to practice medicine in the state, prescribe and administer medical therapeutics and corrective measures and may request, sign for, receive and dispense drugs in the form of professional samples in accordance with sections 20-14c to 20-14e, inclusive, except that an advanced practice registered nurse licensed pursuant to section 20-94a and maintaining current certification from the American Association of Nurse Anesthetists who is prescribing and administrating medical therapeutics during surgery may only do so if the physician who is medically directing the prescriptive activity is physically present in the institution, clinic or other setting where the surgery is being performed. For purposes of this subsection, "collaboration" means a mutually agreed upon relationship between an advanced practice registered nurse and a physician who is educated, trained or has relevant experience that is related to the work of such advanced practice registered nurse. The collaboration shall address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the advanced practice registered nurse, a method to review patient outcomes and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between an advanced practice registered nurse and a physician shall be in writing and shall address the level of schedule II and III controlled substances that the advanced practice registered nurse may prescribe and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, laboratory tests and other diagnostic procedures that the advanced practice registered nurse may prescribe, dispense and administer. An advanced practice registered

nurse licensed under the provisions of this chapter may make the determination and pronouncement of death of a patient, provided the advanced practice registered nurse attests to such pronouncement on the certificate of death and signs the certificate of death no later than twenty-four hours after the pronouncement.

(c) The practice of nursing by a licensed practical nurse is defined as the performing of selected tasks and sharing of responsibility under the direction of a registered nurse or an advanced practice registered nurse and within the framework of supportive and restorative care, health counseling and teaching, case finding and referral, collaborating in the implementation of the total health care regimen and executing the medical regimen under the direction of a licensed physician or dentist.

(d) In the case of a registered or licensed practical nurse employed by a home health care agency, the practice of nursing includes, but is not limited to, executing the medical regimen under the direction of a physician licensed in a state that borders Connecticut.

(P.A. 75-166, S. 1, 6; P.A. 89-107, S. 1; 89-389, S. 1, 22; P.A. 94-213, S. 4; P.A. 97-112, S. 2; P.A. 99-168, S. 1; P.A. 03-8, S. 1; P.A. 04-221, S. 34; 04-255, S. 22; May Sp. Sess. P.A. 04-2, S. 108.)

Sec. 20-14d. Dispensing of drugs by licensed practitioners to be in accordance with sections 20-14c to 20-14g, inclusive. Notwithstanding any provision of the general statutes, no drug may be dispensed by a prescribing practitioner except in accordance with the provisions of this section and sections 20-14c, 20-14f and 20-14g.

(P.A. 85-545, S. 2, 6; P.A. 95-264, S. 65; P.A. 99-175, S. 2.)

History: P.A. 95-264 changed "licensed" practitioner to "prescribing" practitioner and made technical changes; P.A. 99-175 made technical changes.

See Sec. 20-631 re collaborative drug therapy management agreements between pharmacists and physicians.

Sec. 20-8a et seq. cited. 207 C. 346, 347.

Sec. 20-14e. Dispensing of drugs. (a) A drug dispensed by a prescribing practitioner shall be personally dispensed by the prescribing practitioner and the dispensing of such drug shall not be delegated except that, in emergency departments of acute care hospitals licensed under chapter 368v, the tasks related to dispensing such drug may be carried out by a nurse licensed pursuant to chapter 378 under the supervision of the prescribing practitioner.

(b) A patient's medical record shall include a complete record of any drug dispensed by the prescribing practitioner.

(c) A prescribing practitioner dispensing a drug shall package the drug in containers approved by the federal Consumer Product Safety Commission, unless requested otherwise by the patient, and shall label the container with the following information: (1) The full name of the patient; (2) the prescribing practitioner's full name and address; (3) the date of dispensing; (4) instructions for use; and (5) any cautionary statements as may be required by law.

(d) Professional samples dispensed by a prescribing practitioner shall be exempt from the requirements of subsection (c) of this section.

(P.A. 85-545, S. 3, 6; P.A. 95-264, S. 50; P.A. 99-80, S. 2; 99-175, S. 3.)

History: P.A. 95-264 changed "licensed" practitioner to "prescribing" practitioner throughout section and deleted Subsec. (e) which had required compliance with Sec. 20-175a consumer information requirements when dispensing drugs other than professional samples; P.A. 99-80 amended Subsec. (a) by adding exception for nurses in emergency departments; P.A. 99-175 amended Subsec. (c) to make technical changes and add numerical Subdiv. indicators.

Sec. 20-8a et seq. cited. 207 C. 346, 347.

Sec. 20-14g. Regulations. The Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy, may adopt regulations, in accordance with chapter 54, to carry out the provisions of sections 20-14c to 20-14f, inclusive.

(P.A. 85-545, S. 5, 6; P.A. 99-175, S. 4; June 30 Sp. Sess. P.A. 03-6, S. 146(c); P.A. 04-189, S. 1.)

History: P.A. 99-175 made technical changes; June 30 Sp. Sess. P.A. 03-6 replaced Commissioner of Consumer Protection with Commissioner of Agriculture and Consumer Protection, effective July 1, 2004; P.A. 04-189 repealed Sec. 146 of June 30 Sp. Sess. P.A. 03-6, thereby reversing the merger of the Departments of Agriculture and Consumer Protection, effective June 1, 2004.

Sec. 20-8a et seq. cited. 207 C. 346, 347.

Sec. 20-12d. Medical functions performed by physician assistants. Prescriptive authority. (a) A physician assistant who has complied with the provisions of sections 20-12b and 20-12c may perform medical functions delegated by a supervising physician when: (1) The supervising physician is satisfied as to the ability and competency of the physician assistant; (2) such delegation is consistent with the health and welfare of the patient and in keeping with sound medical practice; and (3) such functions are performed under the oversight, control and direction of the supervising physician. The functions that may be performed under such delegation are those that are within the scope of the supervising physician's license, within the scope of such physician's competence as evidenced by such physician's postgraduate education, training and experience and within the normal scope of such physician's actual practice. Delegated functions shall be implemented in accordance with written protocols established by the supervising physician. All orders written by physician assistants shall be followed by the signature of the physician assistant and the printed name of the supervising physician. A physician assistant may, as delegated by the supervising physician within the scope of such physician's license, (A) prescribe and administer drugs, including controlled substances in schedule IV or V in all settings, (B) renew prescriptions for controlled substances in schedule II, III, IV or V in all settings, (C) prescribe and administer controlled substances in schedule II or III in all settings, provided in all cases where the physician assistant prescribes a controlled substance in schedule II or III, the physician under whose supervision the physician assistant is prescribing shall document such physician's approval of the order in the patient's medical record not later than one calendar day thereafter, and (D) prescribe and approve the use of durable medical equipment. The physician assistant may, as delegated by the supervising physician within the scope of such physician's license, request, sign for,

receive and dispense drugs to patients, in the form of professional samples, as defined in section 20-14c, or when dispensing in an outpatient clinic as defined in the regulations of Connecticut state agencies and licensed pursuant to subsection (a) of section 19a-491 that operates on a not-for-profit basis, or when dispensing in a clinic operated by a state agency or municipality. Nothing in this subsection shall be construed to allow the physician assistant to request, sign for, receive or dispense any drug the physician assistant is not authorized under this subsection to prescribe.

(b) All prescription forms used by physician assistants shall contain the printed name, license number, address and telephone number of the physician under whose supervision the physician assistant is prescribing, in addition to the signature, name, address and license number of the physician assistant.

(c) No physician assistant may: (1) Engage in the independent practice of medicine; (2) claim to be or allow being represented as a physician licensed pursuant to this chapter; (3) use the title of doctor; or (4) associate by name or allow association by name with any term that would suggest qualification to engage in the independent practice of medicine. The physician assistant shall be clearly identified by appropriate identification as a physician assistant to ensure that the physician assistant is not mistaken for a physician licensed pursuant to this chapter.

(d) A physician assistant licensed under this chapter may make the actual determination and pronouncement of death of a patient, provided: (1) The death is an anticipated death; (2) the physician assistant attests to such pronouncement on the certificate of death; and (3) the physician

assistant or a physician licensed by the state of Connecticut certifies the death and signs the certificate of death no later than twenty-four hours after the pronouncement.

(P.A. 90-211, S. 6, 23; P.A. 95-271, S. 4, 40; P.A. 96-12, S. 1; P.A. 99-102, S. 9; P.A. 00-205, S. 2; P.A. 04-221, S. 21; 04-255, S. 21; P.A. 05-219, S. 1; P.A. 06-196, S. 247; P.A. 08-184, S. 13.)

History: P.A. 95-271 added references to osteopathic physicians, effective July 6, 1995; P.A. 96-12 added Subsec. (d) re pronouncement of death by physician assistants; P.A. 99-102 deleted obsolete references to osteopathy and osteopathic physicians and made technical changes; P.A. 00-205 amended Subsec. (a) by revising prescriptive authority of physician assistants; P.A. 04-221 amended Subsec. (a) by authorizing physician assistant to request, sign for and receive drugs for dispensing to patients; P.A. 04-255 amended Subsec. (d)(3) by allowing physician assistant to sign certificate of death and by making technical changes; P.A. 05-219 amended Subsec. (a) by expanding physician assistants' authority to renew prescriptions for controlled substances to schedules II to V, inclusive, in all settings and expanding their authority to prescribe and administer controlled substances in schedules II or III in all settings, provided for the latter, physician approval is documented in the patient's medical record not later than the next calendar day; P.A. 06-196 made technical changes in Subsec. (a), effective June 7, 2006; P.A. 08-184 added Subsec. (a)(3)(D) authorizing physician assistant to prescribe and approve use of durable medical equipment..

Sec. 20-14c. Dispensing and labeling of drugs. Definitions. As used in this section and sections 20-14d to 20-14g, inclusive, and section 20-12d:

(1) "Dispense" has the same meaning as provided in section 20-571.

(2) "Drug" means a legend drug, as defined in section 20-571, or a controlled drug, as defined in section 21a-240.

(3) "Prescribing practitioner" means a physician, dentist, podiatrist, optometrist, physician assistant, advanced practice registered nurse, nurse-midwife or veterinarian licensed by the state of Connecticut and authorized to prescribe medication within the scope of such person's practice.

(4) "Professional samples" means complimentary starter dose drugs packaged in accordance with federal and state statutes and regulations that are provided to a prescribing practitioner free of charge by a manufacturer or distributor and distributed free of charge by the prescribing practitioner to such prescribing practitioner's patients.

(P.A. 85-545, S. 1, 6; P.A. 89-389, S. 13, 22; P.A. 90-211, S. 12, 23; P.A. 92-88, S. 2; P.A. 95-264, S. 49; P.A. 99-102, S. 20; 99-175, S. 1.)

History: P.A. 89-389 redefined "licensed practitioner" to include advanced practice registered nurses and nurse-midwives; P.A. 90-211 added the reference to Sec. 20-12d in introductory language and redefined "licensed practitioner" to include physician assistants; P.A. 92-88 redefined "licensed practitioner" to include optometrists; P.A. 95-264 substituted definition of "prescribing practitioner" for "licensed practitioner" and included veterinarians and made technical changes; (Revisor's note: In 1999 the Revisors editorially corrected the statutory reference in Subdiv. (1), changing "subdivision (8)" to "subdivision (9)"); P.A. 99-102 deleted obsolete reference to osteopathy and made

technical changes; P.A. 99-175 made technical and gender neutral changes.

Sec. 20-14d. Dispensing of drugs by licensed practitioners to be in accordance with sections 20-14c, 20-14f and 20-14g. Notwithstanding any provision of the general statutes, no drug may be dispensed by a prescribing practitioner except in accordance with the provisions of this section and sections 20-14c, 20-14f and 20-14g.

(P.A. 85-545, S. 2, 6; P.A. 95-264, S. 65; P.A. 99-175, S. 2.)

History: P.A. 95-264 changed "licensed" practitioner to "prescribing" practitioner and made technical changes; P.A. 99-175 made technical changes.

See Sec. 20-631 re collaborative drug therapy management agreements between pharmacists and physicians.

Sec. 20-8a et seq. cited. 207 C. 346.

Sec. 20-14e. Dispensing of drugs. Dispensing of contact lenses containing a drug or ocular agents-T. (a) A drug dispensed by a prescribing practitioner shall be personally dispensed by the prescribing practitioner and the dispensing of such drug shall not be delegated except that, in emergency departments of acute care hospitals licensed under chapter 368v, the tasks related to dispensing such drug may be carried out by a nurse licensed pursuant to chapter 378 under the supervision of the prescribing practitioner.

(b) A patient's medical record shall include a complete record of any drug dispensed by the prescribing practitioner.

(c) A prescribing practitioner dispensing a drug shall package the drug in

containers approved by the federal Consumer Product Safety Commission, unless requested otherwise by the patient, and shall label the container with the following information: (1) The full name of the patient; (2) the prescribing practitioner's full name and address; (3) the date of dispensing; (4) instructions for use; and (5) any cautionary statements as may be required by law.

(d) Professional samples dispensed by a prescribing practitioner shall be exempt from the requirements of subsection (c) of this section.

(e) A prescribing physician or surgeon may dispense and sell contact lenses that contain a drug, as defined in section 20-571, and such physician or surgeon shall be exempt from the requirements of subsection (c) of this section when dispensing or selling contact lenses. As used in this subsection, "physician" means a person holding a license issued pursuant to this chapter, except a homeopathic physician.

(f) A licensed optometrist, authorized to practice advanced optometric care pursuant to section 20-127, who dispenses contact lenses that contain ocular agents-T, as defined in subdivision (5) of subsection (a) of section 20-127, shall be exempt from the requirements of subsection (c) of this section when dispensing or selling contact lenses.

(P.A. 85-545, S. 3, 6; P.A. 95-264, S. 50; P.A. 99-80, S. 2; 99-175, S. 3; P.A. 09-58, S. 2.)

History: P.A. 95-264 changed "licensed" practitioner to "prescribing" practitioner throughout section and deleted Subsec. (e) which had required compliance with Sec. 20-175a consumer information requirements when dispensing drugs other than professional samples; P.A. 99-80 amended Subsec. (a) by adding exception for nurses in emergency departments; P.A. 99-175 amended Subsec. (c) to make technical changes and add numerical Subdiv. indicators; P.A. 09-58 added Subsecs. (e) and (f) exempting physicians, surgeons and optometrists, who dispense and sell contact lenses that contain a drug or

ocular agents-T, from requirements of Subsec. (c).

Sec. 20-8a et seq. cited. 207 C. 346.

COVERAGE OF TELEMEDICINE SERVICES UNDER MEDICAID.

Section 1. 17b-245c (*Effective January 1, 2013*) (a) (1) As used in this section, "telemedicine" means the use of interactive audio, interactive video or interactive data communication in the delivery of medical advice, diagnosis, care or treatment, and includes the types of services described in subsection (d) of section 20-9 of the general statutes and 42 CFR 410. 78(a)(3). "Telemedicine" does not include the use of facsimile or audio-only telephone.

(2) "Clinically appropriate" means care that is (A) provided in a timely manner and meets professionally recognized standards of acceptable medical care; (B) delivered in the appropriate medical setting; and (C) the least costly of multiple, equally-effective alternative treatments or diagnostic modalities.

(b) The Commissioner of Social Services may establish a demonstration project to offer telemedicine as a Medicaid-covered service at federally-qualified community health centers. Under the demonstration project, in-person contact between a health care provider and a patient shall not be required for health care services delivered by telemedicine that otherwise would be eligible for reimbursement under the state Medicaid plan program, to the extent permitted by federal law and where deemed clinically appropriate.

(c) The Commissioner of Social Services may establish rates for cost reimbursement for telemedicine services provided to Medicaid recipients under the demonstration project. The commissioner shall consider, to the extent applicable, reductions in travel costs by health care providers and patients to deliver or to access health care services and such other factors as the Commissioner of Social Services deems relevant.

(d) The Commissioner of Social Services may apply, if necessary, to the federal government for an amendment to the state Medicaid plan to establish the demonstration project.

(e) The transmission, storage and dissemination of data and records related to telemedicine services provided under the demonstration project shall be in accordance with federal and state law and regulations concerning the privacy, security, confidentiality and safeguarding of individually identifiable information.

(f) The commissioner shall submit a report, in accordance with section 11-4a of the general statutes, on any demonstration project established pursuant to this section to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and human services. The report shall concern the services offered and the cost-effectiveness of the program.

PRESCRIPTION DRUG ADMINISTRATION IN NURSING HOME FACILITIES.

Section 1. 19a-521d*(Effective October 1, 2012)* A medical director of a nursing home facility, as defined in section 19a-521 of the general

statutes, may establish protocols for a prescription drug formulary system in accordance with guidelines established by the American Society of Health-System Pharmacists and any applicable collaborative drug therapy management agreement, as described in section 20-631 of the general statutes. The medical director of a nursing home facility that implements a prescription drug formulary system may make a substitution for a drug prescribed to a patient of the facility in accordance with the provisions of this section. Prior to making any substitution for a drug prescribed to a patient of the facility in accordance with the facility's protocols, the medical director, or the medical director's designee, shall notify the prescribing practitioner of the medical director's intention to make such substitution. If the prescribing practitioner does not authorize the medical director or the medical director's designee to make such substitution or objects to such substitution, the medical director, or the medical director's designee, shall not make the substitution. Notwithstanding the provisions of this section, a facility, when administering prescription drugs to a patient who receives benefits under a medical assistance program administered by the Department of Social Services, shall consider and administer prescription drugs to such patient in accordance with (1) the department's preferred drug lists, developed in accordance with section 17b-274d of the general statutes, (2) prescription drug formularies under Medicare Part D, or (3) the patient's health insurance policy, as the medical director of the nursing home facility deems appropriate.

Approved May 14, 2012

Sec. 20-14f. Report to commissioner of intent to continue to dispense drugs other than professional samples. A prescribing practitioner who, as part of his practice, dispenses any drug other than professional

samples shall notify the Commissioner of Consumer Protection that he is engaged in the dispensing of drugs and shall, biennially, upon the date of renewal of the controlled substance registration required by section 21a-317, inform the commissioner of his intent to continue to dispense drugs to his patients.

(P.A. 85-545, S. 4; P.A. 95-264, S. 66; June 30 Sp. Sess. P.A. 03-6, S. 146(c); P.A. 04-189, S. 1.)

History: P.A. 95-264 changed "licensed" practitioner to "prescribing" practitioner; June 30 Sp. Sess. P.A. 03-6 replaced Commissioner of Consumer Protection with Commissioner of Agriculture and Consumer Protection, effective July 1, 2004; P.A. 04-189 repealed Sec. 146 of June 30 Sp. Sess. P.A. 03-6, thereby reversing the merger of the Departments of Agriculture and Consumer Protection, effective June 1, 2004.

Sec. 20-8a et seq. cited. 207 C. 346.

Sec. 20-8a et seq. cited. 207 C. 346.

28-32 Sec. 49. (NEW) (*Effective from passage*) (a) For purposes of this section and section 50 of this act:

(1) "Drugs" means (A) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of said publications; (B) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (C) substances, other than food, intended to affect the structure or any function of the body of man or animals; and (D) substances intended for use as a component of any article specified in subparagraph (A), (B) or (C) of this subdivision. "Drugs" does not include devices or their components, parts or accessories;

(2) "Controlled drugs" means those drugs which contain any quantity of a substance which has been designated as subject to the federal Controlled Substances Act, or which has been designated as a depressant or stimulant drug pursuant to federal food and drug laws, or which has been designated by the Commissioner of Consumer Protection pursuant to section 21a-243 of the general statutes, as having a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and as having a tendency to promote abuse or psychological or physiological dependence, or both. Such controlled drugs are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant drugs. "Controlled drugs" does not include alcohol, nicotine or caffeine;

(3) "Controlled substance" means a drug, substance or immediate precursor in schedules I to V, inclusive, of the Connecticut controlled substance scheduling regulations adopted pursuant to section 21a-243 of the general statutes. "Controlled substance" does not include alcohol, nicotine or caffeine.

(b) Upon declaration of an emergency by the Governor or the Governor's authorized representative having authority to declare emergencies, a hospital pharmacy, pharmacy or registrant authorized by state or federal law to be in possession of controlled substances may, in accordance with applicable federal regulations, policies and guidelines and with prior approval of the Commissioner of Consumer Protection, transfer or distribute drugs or controlled drugs to a licensed pharmacy, a registrant authorized by state or federal law to be in possession of controlled substances, or a location authorized by the commissioner. Such registrant shall record the transfer accurately and in compliance with all state and federal statutes and regulations and shall report the transfer, in writing, to the commissioner.

28-32a Sec. 50. (NEW) (*Effective from passage*) (a) Each licensed wholesaler that distributes prescription drugs, including licensed

repackagers of the finished form of controlled drugs or noncontrolled prescription drug products, shall provide the Commissioner of Consumer Protection an inventory report regarding such wholesaler's on-hand inventory of specifically identified prescription drugs, in all forms and strengths.

(b) (1) The Commissioner of Consumer Protection shall establish a list of strategic prescription drugs for which reporting is required pursuant to subsection (a) of this section. The list shall include, but not be limited to, selected vaccines and antibiotic products. The list shall be based on priorities established by the commissioner after consultation with the Commissioner of Public Health. The list shall be based upon anticipated medication requirements for public health preparedness, pharmacological-terrorism prevention or response, and medication and economic integrity and shall be issued biannually, indicating any additions, substitutions or deletions that have been made to such list since it was last issued.

(2) An inventory report made pursuant to subsection (a) of this section shall include, but not be limited to, (A) the name, address, town and state of the wholesaler and manufacturer, (B) the name of the prescription drug, (C) the quantity of the drug on hand, including the size of each container and number of containers, and (D) the date of the report. Such information shall be reported at such time and in a manner prescribed by the Commissioner of Consumer Protection.

(c) Information provided by licensed wholesalers pursuant to this section shall not be subject to disclosure under the Freedom of Information Act, as defined in section 1-200 of the general statutes, and shall be available only to the Department of Consumer Protection, the Department of Public Health, the Office of Emergency Management and such other agencies or entities as the Commissioner of Consumer Protection determines, after request by such agency or entity and demonstration of a need for the information for purposes of public health preparedness,

pharmacological-terrorism prevention or response, medication integrity or such other purpose deemed appropriate by the commissioner.

(d) The Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy, may adopt regulations, in accordance with chapter 54 of the general statutes, to carry out the provisions of this section.

(e) Any person who violates the provisions of subsection (a) of this section shall be fined not more than ten thousand dollars or imprisoned not more than one year, or both.

Sec. 38a-510 (a) No health insurance policy issued on an individual basis, whether issued by an insurance company, a hospital service corporation, a medical service corporation or a health care center, which provides coverage for prescription drugs may require any person covered under such policy to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs.

(b) The provisions of this section shall apply to any such policy delivered, issued for delivery, renewed, amended or continued in this state on or after July 1, 2005.

THE PRESCRIPTIVE AUTHORITY OF ADVANCED PRACTICE REGISTERED NURSES.

Section 1. Subsection (b) of section 20-87a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2006*):

(b) Advanced nursing practice is defined as the performance of advanced level nursing practice activities that, by virtue of postbasic specialized education and experience, are appropriate to and may be performed by an advanced practice registered nurse. The advanced practice registered nurse performs acts of diagnosis and treatment of alterations in health status, as described in subsection (a) of this section, and shall collaborate with a physician licensed to practice medicine in this state. In all settings, the advanced practice registered nurse may, in collaboration with a physician licensed to practice medicine in this state, prescribe, dispense and administer medical therapeutics and corrective measures and may request, sign for, receive and dispense drugs in the form of professional samples in accordance with sections 20-14c to 20-14e, inclusive, except that an advanced practice registered nurse licensed pursuant to section 20-94a and maintaining current certification from the American Association of Nurse Anesthetists who is prescribing and administrating medical therapeutics during surgery may only do so if the physician who is medically directing the prescriptive activity is physically present in the institution, clinic or other setting where the surgery is being performed. For purposes of this subsection, "collaboration" means a mutually agreed upon relationship between an advanced practice registered nurse and a physician who is educated, trained or has relevant experience that is related to the work of such advanced

practice registered nurse. The collaboration shall address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the advanced practice registered nurse, a method to review patient outcomes and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between an advanced practice registered nurse and a physician shall be in writing and shall address the level of schedule II and III controlled substances that the advanced practice registered nurse may prescribe and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, laboratory tests and other diagnostic procedures that the advanced practice registered nurse may prescribe, dispense and administer. An advanced practice registered nurse licensed under the provisions of this chapter may make the determination and pronouncement of death of a patient, provided the advanced practice registered nurse attests to such pronouncement on the certificate of death and signs the certificate of death no later than twenty-four hours after the pronouncement.

Approved June 6, 2006

Public Act No. 11-44

AN ACT CONCERNING THE BUREAU OF REHABILITATIVE SERVICES AND IMPLEMENTATION OF PROVISIONS OF THE BUDGET CONCERNING HUMAN SERVICES AND PUBLIC HEALTH.

Section 17b-493 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2011*):

A pharmacist shall, except as limited by **[**subsection (c)**]** subsections (c), (e) and (i) of section 20-619, as amended by this act, and section 17b-274, as amended by this act, substitute a therapeutically and chemically equivalent generic drug product for a prescribed drug product when filling a prescription for an eligible person under the program.

Substitute House Bill No. 6791

Public Act No. 05-212

AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY REGULATION.

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

Section 1. (NEW) (*Effective from passage*) Not later than January 1, 2006, the Department of Consumer Protection shall submit to the joint standing committee of the General Assembly having cognizance of matters relating to general law, in accordance with the provisions of section 11-4a of the general statutes, a report that summarizes the activities of the department related to the regulation of the Pharmacy Practice Act, the federal Food, Drug and Cosmetic Act and the state controlled substance act. Such report shall include, but not be limited to, information on the number and type of pharmacy inspections and investigations conducted by the Department of Consumer Protection concerning: (1) The number of investigations conducted, (2) the

reason for each investigation, (3) the subject matter of each investigation, (4) the outcome of each investigation, (5) any action taken by any board of the Department of Public Health or the Commission of Pharmacy, (6) any action taken by the Commissioner of Consumer Protection on a practitioner's controlled substance registration, and (7) the timeline for such investigation beginning with the opening of such case investigation and ending with the final board or commission action. Such report shall be updated and resubmitted to the said joint standing committee on January 1, 2007, and on January 1, 2008.

Sec. 2. (NEW) (*Effective from passage*) Not later than January 1, 2006, in accordance with the provisions of section 11-4a of the general statutes, The University of Connecticut Health Center shall submit a report to the Legislative Program Review and Investigations Committee that identifies deficiencies in the administration of drugs in correctional facilities found within the previous calendar year. Such report shall be updated on January 1, 2007, and on January 1, 2008.

Department of Public Health Public Health Code 19a-14-40. Medical records, definition, purpose *Current with materials published in Connecticut Law Journal through 12/31/2008* 529

Medical Records

19a-14-40. Medical records, definition, purpose

The purpose of a medical record is to provide a vehicle for: documenting actions taken in patient management; documenting patient progress; providing meaningful medical information to other practitioners should the patient transfer to a new provider or should the provider be unavailable for some reason. A medical record shall include, but not be

limited to, information sufficient to justify any diagnosis and treatment rendered, dates of treatment, actions taken by non-licensed persons when ordered or authorized by the provider; doctors' orders, nurses notes and charts, birth certificate work-sheets, and any other diagnostic data or documents specified in the rules and regulations. All entries must be signed by the person responsible for them.
(Effective August 29, 1984.)

Public Act No. 09-136

AN ACT CONCERNING PRESCRIPTION EYE DROP REFILLS.

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

Section 1. (NEW) (*Effective January 1, 2010*) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, amended, renewed or continued in this state on or after January 1, 2010, that provides coverage for prescription eye drops, shall not deny coverage for a renewal of prescription eye drops when (1) the renewal is requested by the insured less than thirty days from the later of (A) the date the original prescription was distributed to the insured, or (B) the date the last renewal of such prescription was distributed to the insured, and (2) the prescribing physician indicates on the original prescription that additional quantities are needed and the renewal requested by the insured does not exceed the number of additional quantities needed.

Sec. 2. (NEW) (*Effective January 1, 2010*) Each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the

general statutes delivered, issued for delivery, amended, renewed or continued in this state on or after January 1, 2010, that provides coverage for prescription eye drops, shall not deny coverage for a renewal of prescription eye drops when (1) the renewal is requested by the insured less than thirty days from the later of (A) the date the original prescription was distributed to the insured, or (B) the date the last renewal of such prescription was distributed to the insured, and (2) the prescribing physician indicates on the original prescription that additional quantities are needed and the renewal requested by the insured does not exceed the number of additional quantities needed.

Approved June 18, 2009

Federal Requirements

Section 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in **§1301.28** of this chapter. blue

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974]

Federal Requirements

Section 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in **paragraph (d)** of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph **(e)**, **(f)**, or **(g)** of this section. The original prescription shall be maintained in accordance with **Sec. 1304.04(h)** of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to **Sec. 1306.07**.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in Sec. 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in **Sec. 1306.05**, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of **Sec. 1306.05**, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written

prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with **Sec. 1306.05** written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this **paragraph (e)** and it shall be maintained in accordance with **Sec. 1304.04(h)** of this chapter.

(f) A prescription prepared in accordance with **Sec. 1306.05** written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this **paragraph (f)** and it shall be maintained in accordance with **Sec. 1304.04(h)**.

(g) A prescription prepared in accordance with **Sec. 1306.05** written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a

hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with **§ 1304.04(h)** of this chapter.

Federal Requirements

Section 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a

terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Sec. 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by Sec. 1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

(21 U.S.C. 801, et seq.)

SECTION V - Index

APRN info	Sec 20-87a	Page
Authority of DCP Agents	Sec 21a-261	Page

Biennial Inventory	Sec 21a-254 (h)	Page
Brand Medically Necessary	Sec 20-619 (b,c)	Page
Causes for Suspension, Revocation	Sec 20-579	Page
Change of Employment	Sec 20-576-10	Page
Change of Shift Responsibility	Sec 21a-262-9(b)	Page
Closing of Pharmacy Dept	Sec 20-576-17	Page
Collaborative Practice	Sec 20-631	Page
Confidentiality/HIPPA	Sec 20-626	Page
Continuing Education	Sec 20-600	Page
Definitions (General) C/S	Sec 21a-240	Page
Definitions of MD, Osteo etc	Sec 21a-252	Page
Doctor Shopping	Sec 21a-266(a,c,h)	Page
Drug Destruction ECF	Sec 21a-262 (b)	Page
Drug Destructions	Sec 21a-262	Page and
Drug in original Container	Sec 21a-257	Page
E-Box Drugs by Retail Pharmacy	Sec 21a-250 (2)	Page

Emergency C-2 Prescription	Sec 21a-249(e)	Page
Emergency Room Dispensing	Sec 20-622	Page
Entry on premises	Sec 21a-261	Page
Ethics/Not to fill RX	Sec 20-571 (21)	Page
Exempt Narcotics	Sec 21a-272	Page
Expiration Date on label	Sec 20-617 (2)	Page
Faxed requirements	Sec 20-576-40	Page
Generic Substitution Sign	Sec 20-619 (d)	Page
Grounds for Suspension of CSP	Sec 21a-322	Page
Hospice Patients faxed Rx's	CFR: 1306.11	Page
Hospital Units from Ext. Hospitals	Sec 21a-70 (D)	Page
Influenza	Sec. 20-633	Page
Influenza (regulations)	Sec. 20-633-1	Page
Inspection of Records	Sec 21a-261	Page
Labeling of Package of CS	Sec 21a-256	Page
Loss/Theft of CS in Pharmacy	Sec 21a-262-5(c)	Page
Manufacturer Registration	Sec 21a-70	Page

MAR's elec/paper	Sec 19a-25c	Page
Misbranded Drugs and Devices	Sec 21a-106	Page
Needle and Syringe Sale	Sec 21a-65	Page
Non Resident Pharmacy	Sec 20-627	Page
Partial filling of C-2's	CFR: 1306.13	Page
Penalty to keep or furnish Records	Sec 21a-255	Page
Pharmacy Hours of Operation	Sec 20-576-13	Page
Pharmacy Manager Absence	Sec 20-576-22	Page
Pharmacy Manager Hours	Sec 20-597 (b)	Page
Pharmacy Manager Posting	Sec 20-576-21	Page
Pharmacy Tech Definitions	Sec 20-576-32	Page
Pharmacy Tech Ratio (Institutions)	Sec 20-576-33	Page
Pharmacy Tech Ratio (Retail)	Sec 20-576-36	Page
Pharmacy Tech Training	Sec 20-576-37	Page
Practitioner Dispensing		
DPH Public Health	Sec 20-14d, e, f	

Code		
Practitioner/Patient Relationship	Sec 21a-326-1-(c)	Page
and DPH Health Code	19a-14-40	
Prescription Error Reporting	Sec 20-635	Page
Prescription Monitoring	Sec	
Prescription Monitoring (Regulations)	Sec 21a-254-2	Page
Prescription Requirements (CS)	Sec 21a-249	Page
Proof of ID	Sec 21a-254 Sec 3	Page
Records Required (CS)	Sec 21a-254	Page
Refusal of RPH to fill Rx	Sec 20-570 (21)	Page
Regulations Concerning CSP Regs	Sec 21a-326-1	Page
Registration of Pharmacy Interns	Sec 20-576-8	Page
Registration of Pharmacy Techs	Sec 20-598a	Page
Reporting of CS Loss	Sec 21a-262	Page

Rx transfer for Cont Subs	Sec 21a-249 (l)	Page
Rx transfer for legend drugs	Sec 20-616 (c)	Page
Sample for Examination or Invest	Sec 21a-116	Page
Scope of Practice (Practitioner)	Sec 20-571 (22)	Page
	Sec 20-613 (d)	Page
	Sec 21a-252(a)	Page
	Sec 21a-316	Page
	Sec 21a-326-1 {Reg}	Page
and DPH Statute	20-14c (3)	Page
and DPH Statute	20-87a	Page
Seizures	Sec 21a-96	Page
Subst of Generic - Pt notification	Sec 20-576-28	Page
Substitution of Generics	Sec 20-619 (b)	Page
Theft of Controlled Substances	Sec21a-262-5 (c)	Page
Unscheduled Closing of Pharmacy	Sec 20-576-18a	Page

Warrants	Sec 21a-261	Page
Wholesaler Registration	Sec 21a-70	Page