Connecticut Comprehensive Drug Laws

May 2025

Prepared by the

CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

Drug Control Division
Commission of Pharmacy

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The following is a reference guide prepared by the Connecticut Department of Consumer Protection's Drug Control Division that is designed to provide pertinent state statutes and regulations related to pharmaceuticals in one place, for easy access and enhanced continuity. These materials are provided for informational purposes only. Please see the Connecticut General Statutes and the Regulations of Connecticut State Agencies as the official authority for the information contained herein. Please direct any questions about the law or this document to DCP.DrugControl@ct.gov. The Department is not authorized to provide conclusions tantamount to preclearance, or provide legal advice, but encourages you to seek legal counsel should you require.

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CHAPTER 400j PHARMACY

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. Definitions: As used in this chapter, unless the context otherwise requires: (1) "Administer" or "Administration" 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)"Advanced pharmacy technician" means a pharmacy technician who: (A) Receives from the department a designation (i) under section 2 of this act, and (ii) which permits delegation of certain pharmacist responsibilities to the pharmacy technician; and (B) is qualified in accordance with section 2 of this act;

(3) "Automated prescription dispensing machine" means a device and associated software operated by a pharmacy or a pharmacy that is registered as a nonresident pharmacy pursuant to section 20-627, in a nursing home or skilled nursing facility licensed pursuant to sections 19a-490 and 19a-491, that packages and labels patient-specific medication or multiple medications for the purposes of administration by a registered nurse or a licensed practical nurse based on a prescription that has completed final verification by a licensed pharmacist;

(4) "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;

(5) "Clerk" means an individual who is: (A) Registered with the department, in accordance with section 3 of this act, to work in the area of a pharmacy or institutional pharmacy where controlled substances or other legend drugs are dispensed by, or under the supervision of, a pharmacist; (B) not employed or contracted by a pharmacy or institutional pharmacy solely to deliver dispensed drugs to patients off the premises of the pharmacy or institutional pharmacy; and (C) not involved in order entry, the dispensing process or preparing a prescription for final verification;

(6) "Commission" means the Commission of Pharmacy appointed under the provisions of section 20-572;

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

(8) "Compatible drugs" means multiple drugs that are not adversely impacted, whether chemically or physically, in constitution or quality by one another;

(9) "Compliance packaging" means packaging that: (A) Is prepared at a pharmacy to assist a patient in administering solid oral dosage forms of one or more drugs that have been prescribed for the patient; (B) divides the patient's drugs into a series of compartments or containers within one package according to (i) the directions for use, and (ii) the day and time such drugs are to be administered; and (C) is reusable or nonreusable;

(10) "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;

(11) “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;

(12) “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;

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

(14) “Deprescribing” means the systematic process of identifying and discontinuing drugs in instances in which existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values and preferences;

(15) "Direct supervision" means the supervision of pharmacy personnel, including, but not limited to, pharmacy interns, pharmacy technicians and advanced pharmacy technicians, by a pharmacist who:

(A) Is physically present on the premises of the pharmacy or institutional pharmacy while (i) routine drug dispensing functions are being performed on such premises, and (ii) the pharmacy personnel who are under such pharmacist's supervision are physically present on such premises; and

(B) conducts in-process and final performance checks;

(16) “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;

(17) “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;

(18) “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;

(19) "Final verification" means the last review that: (A) Is conducted to complete the dispensing process by verifying that the product to be dispensed conforms to the product ordered or prescribed by the prescribing practitioner; and (B) includes, at a minimum, comparing, for accuracy, the original prescription, the contents of the prescription label and the contents of the prescription container;

(20) "Health care institution" means institution, as defined in section 19a-490;

(21) "Health care institutional pharmacy" means an institutional pharmacy located within a health care institution;

(22) “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;

(23) “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.”;

(24) “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.”;

(25) “Medical device and oxygen provider” means a person who distributes devices or oxygen pursuant to a medical order or prescription, except if such person already maintains an active pharmacy license;

(26) “Medication reconciliation” means a process of comparing the medications a patient is taking and should be taking with newly ordered medications (A) for the purpose of addressing duplications, omissions and interactions and the need to continue current medications, and (B) by looking at information such as the medication name, dose, frequency, route of administration and purpose;

(27) “Nonlegend device” means a device that is not a legend device;

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

(29) "Nonresident pharmacy" has the same meaning as provided in section 20-627;

(30) "Order entry" means the process by which prescription data is entered into an electronic data processing system used by a pharmacy to record dispensed products, which prescription data shall include, but need not be limited to: (A) Patient demographic data; (B) drug name and strength; (C) drug quantity; (D) directions for use; and (E) the number of authorized refills, including, but not limited to, any use of "PRN" or "ad lib" in lieu of a specific number of authorized refills;

(31) "Patient" means a human or other animal who receives any health care service provided by a health care provider, including, but not limited to, a pharmacist, for: (A) The purpose of curing, diagnosing, mitigating, palliating, preventing, screening for or treating a past, current or future medical condition; or

(B) any research-related purpose;

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

(33) “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;

(34) “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;

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

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

(37) “Polypharmacy” means the use of multiple drugs by a patient, including any medication that is inappropriate or not medically necessary, such as those not indicated, not effective or constituting a therapeutic duplication;

(38) “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;

(39) “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;

(40) “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;

(41) "Redispense" means to reprocess any drug: (A) That is prescribed to a patient, was previously dispensed in compliance packaging and has been returned to the dispensing pharmacy due to a change in the patient's prescription or prescriptions; (B) by comparing the directions on the prescription label with the directions on the prescription to ensure accuracy; (C) by selecting such drug from the returned compliance packaging or from stock to fill a current prescription for such drug; (D) by counting such drug and placing such drug in the proper container or compliance packaging compartment for return to the patient; and (E) by affixing to the container or compliance packaging a label containing (i) the prescription information set forth in section 20-617 and required under section 4 of this act, and (ii) any additional notations required due to the prescribing practitioner's directions;

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

(43) “Substitute” means to dispense without the prescribing practitioner's express authorization a different drug product than the drug product prescribed;

(44) “Third-party logistics provider” means a person who distributes drugs, devices or cosmetics while taking possession of the drugs, devices or cosmetics but who does not take title of the drugs, devices or cosmetics;

(45) “Virtual manufacturer” means a person who engages in the manufacture of drugs, devices or cosmetics for which such person: (A) Owns the new drug application or abbreviated new drug application number, if a prescription drug; (B) owns the unique device identification number, as available, for a prescription device; (C) contracts with a contract manufacturing organization for the physical manufacture of the drugs, devices or cosmetics; (D) is not involved in the physical manufacture of the drugs, devices or cosmetics; and (E) at no time takes physical possession of or stores the drugs, devices or cosmetics; and

(46) “Virtual wholesale distributor” means a person who facilitates or brokers the transfer of drugs, devices or cosmetics without taking physical possession of the drugs, devices or cosmetics.

Sec. 20-572. Commission of Pharmacy. Appointment and term of members: There shall be in the department a Commission of Pharmacy that 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. 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. Supervision by Commissioner of Consumer Protection: The commissioner shall exercise 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. 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. 20-576-1. Definitions: For the purpose of sections 20-576-1 through 20-576-53, inclusive, of the Regulations of Connecticut State Agencies, the following terms have the meanings indicated:

(a) “Adulterated” has the same meaning as provided in section 21a-105 of the Connecticut General Statutes;

(b) "Commission" means the Commission of Pharmacy;

(c) “Commissioner” means the Commissioner of Consumer Protection or his or her authorized representative;

(d) “Damaged product” means nonlegend products that have been exposed to conditions that the packaging is intended to prevent, or stored in a manner contrary to the manufacturer’s recommendations;

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

(f) "Legend drug" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(g) “Misbranded” has the same meaning as provided in section 21a-106 of the Connecticut General Statutes;

(h) “Nonlegend device” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(i) “Nonlegend drug” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(j) “Nonlegend drug permittee” means the holder of a permit to sell nonlegend drugs pursuant to section 20-624 of the Connecticut General Statutes;

(k) “Nonlegend product” means a nonlegend drug or a nonlegend device;

(l) "Prescribing practitioner" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(m) "Prescription department" means that area within a pharmacy where drugs are compounded and dispensed pursuant to the order of a prescribing practitioner;

(n) “Service” means nonlegend product handling within a vending machine and the maintenance, mechanical services or repairs made to vending machines that allow a person to access the interior of the vending machine containing nonlegend drugs;

(o) “Vending machine” means any automated mechanical device operated by a vending machine registrant from which nonlegend products are dispensed to a consumer;

(p) “Vending machine registrant” means a nonlegend drug permittee that holds an active vending machine registration pursuant to section 20-623 of the Connecticut General Statutes; and

(q) “Wholesaler” means a person issued a certificate of registration in accordance with section 21a-70 (b) of the Connecticut General Statutes.

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 twenty-four 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:

(1) "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

(2) "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. 20-576-30a. Sale of Nonlegend Drugs:

(a) A nonlegend drug permittee shall only purchase nonlegend drugs from a wholesaler or another nonlegend drug permittee.

(b) A nonlegend drug permittee shall ensure all nonlegend products purchased from a wholesaler or other nonlegend drug permittee are labeled for individual sale in accordance with the requirements of the federal Food and Drug Administration or successor agency.

(c) A nonlegend product, the sale of which is subject to quantity limitation, proof of identification, age verification, or other restriction pursuant to federal or state law, shall be stored and maintained by a nonlegend drug permittee in a manner accessible only to employees of the nonlegend drug permittee prior to purchase.

(d) It is the sole responsibility of each nonlegend drug permittee to ensure that all nonlegend products are not expired, and to take reasonable steps to ensure expired nonlegend products are promptly removed from retail display upon expiration.

(e) A nonlegend drug permittee shall, upon receiving a nonlegend product from a wholesaler or another nonlegend drug permittee, and prior to offering any nonlegend products for sale, inspect the expiration date of each nonlegend product offered for sale by authorized employees of such nonlegend drug permittee to ensure such product is not expired.

(f) A nonlegend drug permittee shall not sell or dispense at retail a recalled nonlegend product.

(g) It is the responsibility of each nonlegend drug permittee to prevent the retail sale of any nonlegend product that has been subject to a recall for any reason by the manufacturer, the federal government or the state of Connecticut.

(h) A nonlegend drug permittee shall have a written policy that sets forth a process to respond to recalls, which shall include, but not be limited to, a review of nonlegend products to identify if any nonlegend products offered for retail sale are subject to any such recall and a protocol to remove, return, destroy or sequester nonlegend products as applicable for each recall. The policy shall be electronically submitted to the department not later than forty-eight hours after a request from the department.

(i) Each nonlegend drug permittee shall maintain a record of all nonlegend products purchased from a wholesaler and other nonlegend drug permittees for individual retail sale.

(j) Each nonlegend drug permittee shall maintain a record of each received recall notice.

(k) Each nonlegend drug permittee shall maintain a record of each nonlegend product that was returned by a consumer, and denote on such record the reason for each return, including returns due to recall, damage, or other reason.

(l) All records required to be maintained under this section and section 20-576-31 of the Regulations of Connecticut State Agencies shall be maintained for a minimum of three years.

(m) The retail sale of any nonlegend products without a permit to sell nonlegend drugs pursuant to section 20-624 of the Connecticut General Statutes is prohibited.

(n) The retail sale of any nonlegend product that is commercially known or visually evident to be damaged, adulterated, misbranded, or expired is prohibited.

(o) Neither a nonlegend drug permit, nor a vending machine registration, shall be transferable from one place to another, or from one vending machine to another, without notice to the department, in a form and manner prescribed by the commissioner, at least thirty days prior to such transfer. Neither a nonlegend drug permit, nor a vending machine registration, shall be transferable to another person.

Sec. 20-576-31. Storage, Sale and Acquisition of Nonlegend Drugs in Vending Machines:

(a) A vending machine registrant shall only purchase nonlegend drugs from a wholesaler or another nonlegend drug permittee.

(b) A vending machine registrant shall ensure all nonlegend products purchased from a wholesaler or other nonlegend drug permittee are labeled for individual sale in accordance with the requirements of the federal Food and Drug Administration or successor agency.

(c) All nonlegend products sold in a vending machine shall be:

(1) Stored in accordance with manufacturer recommendations, including, but not limited to, temperature conditions; and

(2) Sold only in the manufacturer's clearly labeled, original, unbroken, tamperproof and expiration-dated packaging.

(d) A nonlegend product subject to any sale restriction pursuant to state or federal law shall not be contained in a vending machine. Such restricted products shall include, but not be limited to, products requiring age verification or proof of identity or subject to a quantity limitation.

(e) No expired nonlegend products shall be sold from a vending machine. Such products shall be removed by the vending machine registrant from the vending machine on or before the manufacturer's expiration date.

(f) A nonlegend drug permittee shall have a written policy to review expiration dates of nonlegend products contained in the vending machine at least monthly. The policy shall be made available to the department not later than forty-eight hours after a request from the department.

(g) Vending machines shall be in good working order. Should a machine become inoperable, the vending machine registrant shall, not later than twenty-four hours after being made aware of the vending machine's inoperability, affix a sign indicating to consumers that the vending machine is not in working order. The vending machine registrant shall arrange for the vending machine to be serviced so that it can return to operation as soon as is commercially reasonable. If the vending machine does not return to operation on or before the seventh calendar day after the vending machine registrant is made aware of the vending machine's inoperability, the vending machine registrant shall notify the department, in a form and manner prescribed by the commissioner, that the vending machine is inoperable and include the following information:

(1) Vending machine registration number;

(2) Serial number of the vending machine;

(3) Vending machine location;

(4) Date vending machine became inoperable;

(5) Date vending machine registrant was made aware that the vending machine became inoperable;

(6) Contents of the vending machine;

(7) A description of why the vending machine is inoperable;

(8) Whether any contents of the vending machine have been damaged or compromised as a result of the vending machine's inoperability;

(9) Whether and when the vending machine is expected to return to operation; and

(10) A contact name and the phone number for the company servicing the vending machine.

(h) Each vending machine registrant shall maintain a record of each service. Such record shall include the date the vending machine was serviced, the company servicing the vending machine and the purpose of the service, and shall be either:

(1) Affixed to the interior of the vending machine, in a manner visible from the exterior of the vending machine; or

(2) Maintained electronically in a manner that the vending machine registrant can provide the records required pursuant to this subsection not later than one business day after a request for such information from the department.

(i) The vending machine shall be securely constructed and either weigh a minimum of seven hundred and fifty pounds or be physically affixed to the building.

(j) Vending machines shall be serviced at least once per year to ensure proper operation.

(k) Any vending machine containing a nonlegend product shall be protected from the

elements through internal systems or an external enclosure, which shall be:

(1) Weather-tight;

(2) Well-ventilated;

(3) Moisture-controlled;

(4) Well-lit;

(5) Protected from direct sunlight; and

(6) Capable of maintaining storage conditions consistent with the manufacturer's recommendations for each nonlegend product at all times.

(l) When a vending machine is relocated inside the authorized premises of a vending machine registrant, the vending machine registrant shall notify the department in writing not later than five calendar days after such relocation. When a vending machine is relocated to the exterior of an authorized premises or another location on such premises where the climate or other elements may impact the vending machine or nonlegend products therein, the vending machine registrant shall request authorization from the department prior to such relocation. Such a request for authorization shall be submitted to the department, in a form and manner prescribed by the commissioner, at least thirty days prior to such proposed relocation and shall describe the reason for the request and provide a description of quality controls to ensure the protection of the vending machine and the nonlegend products contained therein.

(m) In the event that a vending machine has been tampered with or otherwise damaged, or the vending machine's contents have been forcibly removed, stolen or otherwise compromised, the vending machine registrant shall notify the department not later than twenty-four hours after discovering the event. Not later than five days after discovering the event, the vending machine registrant shall submit a written description of the event, including, but not limited to, steps taken by the vending machine registrant to resolve the event and prevent such occurrences from happening again. During such five-day period, the vending machine registrant shall evaluate nonlegend products remaining within the vending machine to determine if the nonlegend products are adulterated or are damaged products. If any such nonlegend

product is adulterated or is a damaged product, the vending machine registrant shall not offer such product for sale and such product shall be immediately removed from the vending machine.

(n) The department may inspect vending machines and the contents thereof. The department's inspection may include, but is not limited to, the following:

(1) Verifying that the owner of the vending machine has the required registration and permit pursuant to section 20-623 of the Connecticut General Statutes; and

(2) Verifying that the vending machine:

(A) Is located where indicated on the registration;

(B) Is in good working order;

(C) Contains required notices and signage;

(D) Has been serviced in accordance with subsection (j) of this section;

(E) Is protected from the elements in accordance with subsection (k) of this section; and

(F) Contains products that are not (i) expired, (ii) subject to a recall, (iii) showing evidence of being tampered with, (iv) damaged, or (v) prohibited for sale within a vending machine.

(o) If the vending machine registrant decides to permanently cease offering nonlegend products at a vending machine, the vending machine registrant shall notify the department in writing not less than five calendar days before nonlegend products will permanently cease to be offered at the vending machine. A sign shall be affixed to the vending machine informing customers of the last date of offering nonlegend products at the vending machine not less than five calendar days before the vending machine will cease offering nonlegend products. All nonlegend products shall be removed from the vending machine by 11:59 p.m. of the last day of offering such products at the vending machine. If such vending machine exclusively offered nonlegend products, the vending machine registrant shall ensure a sign remains affixed to the vending machine, at all times when such machine is accessible to consumers, indicating that the machine is no longer operational.

Pharmacy Technicians in Institutional Pharmacies

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 care-giving institution.

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 non-controlled 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 on-line 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 on-line 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 radio-pharmaceutical 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.

Non-Sterile Compounding

Sec. 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 the Commission of Pharmacy;

(2) ‘‘Non-sterile compounding pharmacy’’ means a pharmacy licensed pursuant to section 20-594 of the General Statues that dispenses non-sterile compounded pharmaceutical products, but does not include a pharmacy that is part of a 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.

Sec. 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.

Sec. 20-576-71. Standards: (a) Sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies shall apply to all non-sterile compounded pharmaceutical products, notwithstanding the location of the patient, including, 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-patient specific 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.

Sec. 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.

Sec. 20-576-73. Hours: A non-sterile compounding pharmacy shall be open at least 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.

Shared Pharmacy Services

Sec. 20-576-74. Definitions: As used in this section and sections 20-576-75 to 20-576-79, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Central dispensing pharmacy" means a licensed pharmacy that acts as an agent of or under contract with an originating pharmacy to dispense a prescription;

(2) "Delivery" means the process of transferring a dispensed prescription that has been through final prescription verification to a patient or patient's representative;

(3) "Direct supervision" has the same meaning as provided in section 20-598a(b) of the Connecticut General Statutes;

(4) "Dispense" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(5) "Drug utilization review" or "DUR" or "Drug utilization review program" means an authorized and structured review of prescribing, dispensing, and utilization of drugs by a licensed pharmacist before, during, and after dispensing a prescription to ensure appropriate drug decision-making and positive

patient outcomes. Such review includes, but is not limited to, the prospective and retrospective utilization reviews mandated by the Omnibus Budget Reconciliation Act (OBRA) of 1990, as amended from time to time;

(6) "Final prescription verification" means the last review of a prescription by a licensed pharmacist prior to approving such prescription for delivery to a patient or patient's representative, after such review and approval the prescription is considered dispensed. Such review includes, but is not limited to, the original prescription, the contents of the prescription label, and the contents of the prescription container to ensure accuracy of a prescription;

(7) "Licensed pharmacy" means a pharmacy that is either licensed pursuant to section 20-594 of the Connecticut General Statutes or a nonresident pharmacy as defined in and operated in accordance with section 20-627 of the Connecticut General Statutes;

(8) "Licensed pharmacist" means a pharmacist either licensed pursuant to section 20-593 of the Connecticut General Statutes or licensed as a 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;

(9) "Order entry" means the process by which pharmacy personnel enter prescription data into a licensed pharmacy's software system. Such data includes, but is not limited to, patient demographics, drug name and strength, drug quantity, the directions for use, 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, and any required cautionary statements;

(10) "Order entry verification" means the process by which a licensed pharmacist verifies prescription data entered in a licensed pharmacy's software system after order entry has been completed and prior to final prescription verification;

(11) "Originating pharmacy" means a licensed pharmacy that accepts a prescription for dispensing to a patient or patient's representative, either on its own or through the use of a central dispensing pharmacy;

(12) "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;

(13) "Pharmacy personnel" means either a licensed pharmacist, a registered pharmacy intern, or a registered pharmacy technician;

(14) "Registered pharmacy intern" means a pharmacy intern registered pursuant to section 20-598 of the Connecticut General Statutes or registered as a pharmacy intern 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;

(15) "Registered pharmacy technician" means a pharmacy technician registered pursuant to section 20-598a of the Connecticut General Statutes or registered as a pharmacy technician 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;

(16) "Remote order entry" means order entry that is conducted from a location other than the physical premises of an originating pharmacy;

(17) “Remote order entry verification” means order entry verification that is conducted from a location other than the physical premises of an originating pharmacy;

(18) “Shared pharmacy services” means a system by which two or more licensed pharmacies process or dispense a prescription; and

(19) “Shipping record” means a record that contains all shipping information for a specific shipment. Such information includes, but is not limited to, each item contained in a shipment

Sec. 20-576-75. Minimum Requirements: (a) Each pharmacy performing shared pharmacy services shall be a licensed pharmacy;

(b) A licensed pharmacy may dispense a prescription at the request of an originating pharmacy and return the dispensed prescription to the originating pharmacy for delivery to a patient or patient’s representative, or if requested by the originating pharmacy, direct delivery to a patient or patient’s representative;

(c) Each licensed pharmacy shall have a dispensing process in which order entry verification is separate and distinguishable from final prescription verification;

(d) Each licensed pharmacy shall have a secure and confidential mechanism with a licensed pharmacy or other authorized user, including pharmacy personnel, for the provision of patient demographics, prescription images, drug utilization reviews, and any other information necessary to appropriately perform order entry, order entry verification, and final prescription verification;

(e) Each licensed pharmacy shall have the ability to scan, with a minimum of a 1:1 ratio and a minimum of 200 pixels per inch, any prescription that is not electronically-transmitted to such pharmacy. Any licensed pharmacy that lacks the ability to scan with a minimum of a 1:1 ratio and a minimum of 200 pixels per inch shall only utilize shared pharmacy services for electronically-transmitted prescriptions and prescription refills pursuant to subsection (c) of this section; and

(f) Each licensed pharmacy that performs shared pharmacy services shall have prescription processing software that is capable of maintaining an audit trail that identifies, at a minimum, each pharmacy personnel or any other pharmacy staff who entered, modified, or verified a prescription during the dispensing process; approved or rejected a drug utilization review; or modified or verified a prescription after final prescription verification.

Sec. 20-576-76. Originating Pharmacy: (a) If an originating pharmacy accepts a prescription for dispensing to a patient or patient’s representative through the use of a central dispensing pharmacy, at least one of such pharmacies shall be located in Connecticut;

(b) An originating pharmacy shall notify a patient or patient’s representative when a prescription may be processed or dispensed via shared pharmacy services;

(c) An originating pharmacy shall provide a patient or patient’s representative with the name of the licensed pharmacy processing or dispensing their prescription. If an originating pharmacy utilizes a pharmacy network under common ownership to process and dispense prescriptions, the patient or patient’s representative shall be notified that any of the network pharmacies may process or dispense their prescription. Such notification may be provided to a patient or patient’s representative via a one-time written notice or signage in the originating pharmacy;

(d) Each licensed pharmacy that participates in shared pharmacy services shall have the same owner or have a written contract or agreement with a participating licensed pharmacy outlining the specific services provided by each licensed pharmacist and licensed pharmacy along with the responsibilities shared by each licensed pharmacist and licensed pharmacy with respect to complying with applicable federal and state pharmacy statutes and regulations;

(e) An originating pharmacy shall maintain each original prescription in a readily retrievable manner at such pharmacy;

(f) An originating pharmacy shall implement and maintain a quality assurance program as described in section 20-635 of the Connecticut General Statutes that documents each prescription error reported to such originating pharmacy by a patient or patient's representative or by a licensed pharmacist or licensed pharmacy participating in shared pharmacy services regardless of where such reported prescription error occurred;

(g) An originating pharmacy shall provide access to all records required by this section, section 20-576-75, and sections 20-576-78 and 20-576-79 of the Regulations of Connecticut State Agencies to the Department of Consumer Protection, Drug Control Division, within 48 hours of said department's request;

(h) An originating pharmacy shall verify, at least annually, that each licensed pharmacy utilized by the originating pharmacy for shared pharmacy services is properly licensed, and the originating pharmacy shall maintain a record of such verification on file for review by the Department of Consumer Protection, Drug Control Division;

(i) An originating pharmacy shall require pharmacy personnel to verify that each shipping container received from a central dispensing pharmacy contains each prescription listed on the shipping record. Such shipping record shall be maintained for a period of no less than three years;

(j) An originating pharmacy shall not provide any controlled substance prescriptions in Schedule II, III, IV or V of the federal Controlled Substances Act to a central dispensing pharmacy;

(k) An originating pharmacy shall perform a final prescription verification each time such pharmacy places a new prescription label over an existing prescription label or alters a dispensed prescription ready for delivery to a patient or patient's representative; and

(l) An originating pharmacy shall be responsible for reporting all dispensation data.

Sec. 20-576-77. Central Dispensing Pharmacy: (a) A central dispensing pharmacy shall maintain a mechanism for tracking each step of the dispensing process performed by an originating pharmacy for each prescription;

(b) A central dispensing pharmacy shall label each prescription or include with the dispensed prescription the name, address, and telephone number of the originating pharmacy and the central dispensing pharmacy along with all information required in section 20-617 of the Connecticut General Statutes;

(c) A central dispensing pharmacy shall ensure that each prescription dispensed and returned to an originating pharmacy is shipped in accordance with manufacturer labeling;

(d) A central dispensing pharmacy shall provide security mechanisms that protect the confidentiality and integrity of patient information;

(e) A central dispensing pharmacy shall provide all information required by this section, sections 20-576-75, 20-576-78 and 20-576-79 of the Regulations of Connecticut State Agencies, to the Department of Consumer Protection, Drug Control Division, within 48 hours of said department's request;

(f) A central dispensing pharmacy shall provide a shipping record to an originating pharmacy listing each prescription a central dispensing pharmacy places in each container shipped to an originating pharmacy;

(g) A central dispensing pharmacy shall maintain a list of up-to-date information of all pharmacy personnel including, but not limited to, pharmacy personnel names, contact information, and credential information for the jurisdiction in which a central dispensing pharmacy is primarily licensed;

(h) A central dispensing pharmacy shall maintain and utilize adequate containers and processes to ensure drug stability and potency during storage and shipping of dispensed prescriptions. Such processes shall include, but are not limited to, (1) utilizing appropriate packaging and devices to ensure each dispensed prescription is maintained within an appropriate temperature range throughout the shipping process and (2) utilizing packaging that is tamper-evident; and

(i) Nothing in this section shall prevent a central dispensing pharmacy from shipping or delivering a prescription directly to a patient or patient's representative at a patient's or patient's representative's request after final prescription verification by a central dispensing pharmacist.

Sec. 20-576-78. Remote Order Entry: (a) Remote order entry shall only be performed by pharmacy personnel;

(1) For the purposes of this section, direct supervision by a licensed pharmacist of a registered pharmacy technician or pharmacy intern performing remote order entry, from a location other than the physical premises of an originating pharmacy, is permitted;

(2) A registered pharmacy technician's performance regarding remote order entry, from a location other than the physical premises of an originating pharmacy, shall be evaluated at least quarterly by the pharmacist manager at the licensed pharmacy at which such pharmacy technician is registered, to determine if such remote order entry work is suitable for such pharmacy technician. A pharmacist manager's quarterly evaluation, to determine if remote order entry work is suitable for the registered pharmacy technician, shall be documented in such pharmacy technician's training record as required by section 20-576-37 of the Regulations of Connecticut State Agencies;

(b) Each licensed pharmacist, each registered pharmacy intern, and each registered pharmacy technician that performs remote order entry, from a location other than the physical premises of an originating pharmacy, shall make efforts to prevent disclosure of confidential information in accordance with section 20-626 of the Connecticut General Statutes.

Sec. 20-576-79. Remote Order Entry Verification: (a) Remote order entry verification shall only be performed by a licensed pharmacist;

(b) Each licensed pharmacist who performs remote order entry verification shall have the ability to refuse a prescription for dispensing and the refused prescription shall be returned to the originating pharmacy;

(c) Each licensed pharmacist that performs remote order entry verification, from a location other than the physical premises of an originating pharmacy, shall make efforts to prevent disclosure of confidential information in accordance with section 20-626 of the Connecticut General Statutes; and

(d) Nothing in this section shall prevent a licensed pharmacist from working at a location other than the physical premises of an originating pharmacy.

20-576a-1. Definitions: As used in sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Authorized Collector" means a retail pharmacy authorized to handle controlled substances, currently licensed pursuant to section 20-594 of the Connecticut General Statutes, with an active registration to be a collector of drugs for disposal issued by the United States Drug Enforcement Agency and the department;

(2) "Authorized Employee" means an individual with an active license or registration who is: (A) a minimum of 18 years of age; and (B) employed by an authorized collector as a licensed pharmacist, pharmacist intern, or pharmacist technician pursuant to chapter 400j of the Connecticut General Statutes;

(3) "Collection Receptacle" means a secured receptacle into which unused or expired drugs, including controlled substances and legend and non-legend drugs, can be deposited by ultimate users;

(4) "Commissioner" means the Commissioner of Consumer Protection or the commissioner's representative;

(5) "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 Connecticut General Statutes;

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

(7) "Drug" has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

(8) "Drug Control Division" means the division within the department responsible for overseeing the return of prescription drugs to pharmacies;

(9) "Inner Liner" means the removable liner within a collection receptacle that meets the requirements specified in 21 CFR 1317.60, that is used to collect drugs when placed in a collection receptacle;

(10) "Pharmacy" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(11) "Prescription" has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

(12) "Reverse Distributor" means a wholesaler or distributor, as defined in Connecticut General Statutes section 21a-70, whether within or without the state of Connecticut, who receives and destroys

prescription medications, including controlled substances and legend and non-legend drugs, from an authorized collector;

(13) "Rigid Container" means a container constructed of sturdy material used to hold the inner liner while in the collection receptacle and to transport the inner liner to the reverse distributor for destruction. Rigid containers are removable from the collection receptacle, are not reusable and are destroyed with the inner liner contained therein;

(14) "Third-party logistics provider" has the same meaning as provided in section 20-571 of the Connecticut General Statutes; and

(15) "Ultimate User" has the same meaning as provided in 21 U.S.C. 802, but also includes any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance.

Sec. 20-576a-2. Authorized collector: (a) A pharmacy may operate a collection receptacle if the pharmacy: (1) meets the requirements specified in 21 CFR 1307 and 21 CFR 1317; (2) meets the requirements set forth in sections 20-576a1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies; and (3) registers with the department as an authorized collector.

(b) An authorized collector applicant shall submit an application and all other required documentation on forms prescribed by the commissioner. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant has adequate facilities to properly carry on the business described in the application and that the applicant conforms to and is in compliance with all applicable federal and state requirements. Registrations shall be renewed annually on or before January 31.

(c) Prior to the issuance of a certificate of registration, the commissioner shall perform an initial inspection of the applicant's premises, collection receptacle and written operating procedures prior to the commencement of collection activities from ultimate users.

(d) The commissioner shall have the right to deny an authorized collector a certificate of registration if the commissioner determines that the issuance of such registration is inconsistent with the public interest, or may have a negative impact on public health and safety.

(e) An authorized collector shall not participate in a take back event, as defined in 21 CFR 1317.65, within the interior of the same building in which the authorized collector's collection receptacle is located.

(f) An authorized collector shall not participate in a mail back program as outlined in 21 CFR 1317.70, whereby the authorized collector receives drugs returned to it via mail.

(g) An authorized collector shall not dispose of its inventory or stock of drugs in the collection receptacle.

(h) An authorized collector shall maintain the confidentiality of ultimate users that utilize the collection receptacle.

(i) No employees, including authorized employees, of an authorized collector shall handle, count, sort, or inventory any drugs brought by ultimate users for deposit in the collection receptacle.

(j) Authorized collectors shall permit the commissioner to enter and inspect their premises and collection receptacles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner.

(k) All records required by sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies 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 and copying by the commissioner at reasonable times. The records shall be maintained by the authorized collector for a period of three years.

(l) Any authorized collector that intends to discontinue its use of a collection receptacle shall notify the director of the Drug Control Division in writing 30 days prior to discontinuing collection activities. Upon the termination of operation, the authorized collector shall dispose of the inner liner and rigid container by following the procedure for disposal of inner liners and rigid containers outlined in section 20-576a-5 of the Regulations of Connecticut State Agencies, and remove the collection receptacle from the prescription department area.

Sec. 20-576a-3. Collection receptacles: (a) Collection receptacles shall be lockable, sturdy, and securely fixed within the authorized collector's registered location, and shall have a one-way access point to allow ultimate users to deposit drugs.

(b) The collection receptacle shall have two locking mechanisms for access to the inner liner, and these locking mechanisms shall have different keys for operating the locks for simultaneous use by two different authorized employees. The one-way access point shall have a locking mechanism to prevent the acceptance of drugs when the pharmacy is closed or the inner liner is full. 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 anyone other than specifically authorized employees.

(c) If it is necessary to unlock the collection receptacle and view the contents of the rigid container in order to determine the drug fill level and avoid overfill, two authorized employees shall perform this check, at an interval determined by the authorized collector. One such authorized employee shall be a Connecticut licensed pharmacist. If the drug fill level of the rigid container has reached a point where overfill is imminent, the collection receptacle shall be locked to prevent ultimate users from depositing any drugs. The authorized collector shall commence disposal of the rigid container within forty-eight hours, pursuant to section 20-576a-5 of the Regulations of the Connecticut State Agencies. The date of the rigid container check, the names of the authorized employees performing the check and the approximate drug fill level of the rigid container shall be entered in the record log maintained by the authorized collector.

(d) The collection receptacle shall be located in the immediate proximity of a designated area where controlled substances are stored and at which an authorized employee is present and the collection receptacle is visible to such authorized employee.

(e) The collection receptacle shall accept drugs only when the authorized collector is open for business and an authorized employee is present.

(f) The collection receptacle shall be secured pursuant to section 20-576-18 of the Regulations of Connecticut State Agencies when the pharmacy is closed.

(g) The outside of each collection receptacle shall prominently display a sign indicating: (1) the types of drugs permitted for deposit; (2) the prohibited items; and (3) that no drugs intended for return are to be left in the vicinity of the collection receptacle at any time.

(h) Waste or trash receptacles located in public areas shall not be within five feet of a collection receptacle.

(i) All of the collection receptacle access points and the sealing of inner liners shall be continuously monitored by video camera with a minimum of fourteen days of information storage. All stored video of the collection receptacle shall be made available upon request of the commissioner not later than forty-eight hours after such request. If an authorized collector is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the authorized collector shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the person or entity conducting the investigation or proceeding notifies the authorized collector that it is not necessary to retain the recording.

(j) Requirements for minimum security and safeguard standards for collection receptacles may be determined for each authorized collector by the commissioner after consideration of the protection offered from an overall standpoint in instances wherein other security measures provided exceed those specifically stated. If the authorized collector has provided other safeguards that can be regarded as an adequate substitute for some element of protection required of such authorized collector, such added protection may be taken into account by the commissioner in evaluating overall required security measures. In cases where special hazards exist, such as extremely large stock, exposed handling, or unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards shall be required by the commissioner.

(k) An authorized collector shall maintain collection receptacles to prevent theft and unauthorized access of the collection receptacle or inner liner.

(l) Any loss, theft, serious damage or destruction of a collection receptacle or its contents shall be reported by an authorized collector within seventy-two hours of any such occurrence to the director of the Drug Control Division.

Sec. 20-576a-4. Inner liners and rigid containers: (a) All inner liners shall have a permanent unique identification number, and the authorized collector shall track and maintain a record log to track all inner liners used in the collection receptacle and their unique identification numbers. Such record log shall be the same record log required for use in sections 20-576a-5(a) and (b) of the Regulations of Connecticut State Agencies.

(b) All inner liners shall contain an absorbent material sufficient to prevent leakage of any drugs deposited in a collection receptacle.

(c) All inner liners shall be placed in or a part of a rigid container prior to use and placement inside a collection receptacle. Prior to placement inside a collection receptacle, the permanent unique identification number of the inner liner shall be marked, in a clear and permanent manner, on the rigid container. The inner liner shall remain inside the rigid container from the point of placement in the collection receptacle to the time of destruction. Rigid containers shall be leak resistant, and have sealable openings.

(d) All inner liners used in collection receptacles shall meet the requirements of 21 CFR 1317.60 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 20-576a-5. Disposal: (a) To dispose of inner liners and rigid containers: (1) the reverse distributor shall be present and ready to receive the inner liner; (2) two authorized employees shall be present and performing the removal and replacement of the rigid container and inner liner, and one such authorized employee shall be a Connecticut licensed pharmacist; (3) the rigid container, including the inner liner, shall be removed from the collection receptacle together and the inner liner shall be immediately sealed and replaced with a new rigid container and inner liner; (4) the rigid container shall then be sealed at all openings with tamper evident tape and display the unique identification number of the inner liner contained therein; (5) the rigid container shall not have any outer markings that would indicate the nature of its contents; (6) the authorized employees present during the disposal shall record all required information and perform all actions necessary to record log entries pursuant to this section; (7) the authorized employees shall provide the sealed rigid container that contains the sealed inner liner to a registered reverse distributor for destruction, who shall sign the authorized collector's log book; and (8) the entire process shall be monitored and recorded by video camera, pursuant to section 20-576a-3 of the Regulations of Connecticut State Agencies.

(b) An authorized employee shall record the following information for each transaction in record logs: (1) the date that the new inner liner and rigid container were placed in the collection receptacle; (2) the inner liner unique identification number; (3) the date that the numbered inner liner and rigid container was taken and sealed from the collection receptacle and provided to the reverse distributor; (4) the names and signatures of the two authorized employees who witnessed and performed both the removal and replacement of the inner liner and rigid container; and (5) the name, registration number, and address of the reverse distributor. Inner liner and rigid container record logs shall be maintained by the authorized collector for three years and shall be made available for inspection upon request by the department.

(c) No materials deposited in the collection receptacle and captured in the inner liner shall be removed, counted, sorted or otherwise handled.

(d) Upon placing a new inner liner and rigid container into a collection receptacle, the inner liner is presumed to contain prescription medications, including controlled substances and legend and non-legend drugs and shall be disposed of in accordance with 21 CFR 1317 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies. Inner liners and rigid containers shall not be reused in a collection receptacle.

(e) No on-site destruction of any rigid container, inner liner or its contents shall be permitted by the authorized collector or at such collector's premises.

(f) The reverse distributor may designate a third-party logistics provider to serve as an authorized representative of the reverse distributor.

(g) Law enforcement authorities may, pursuant to an agreement with an authorized collector, accept delivery of the sealed rigid container that contains the sealed inner liner in the same manner as a reverse distributor as set forth in sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies, provided law enforcement authorities shall not be required to register with the department as a reverse distributor. Law enforcement authorities may destroy the sealed inner liner and rigid

container pursuant to their department procedures and policies. Law enforcement authorities shall not be required by this section to participate in the collection and disposal of returned drugs to pharmacies.

Sec. 20-576a-6. Reverse distributors: (a) No reverse distributor shall operate as such until it has registered with the department, which registration shall be renewed annually on or before January 31.

(b) A reverse distributor application for registration shall either be received by the department in conjunction with a new wholesale or distributor registration application, or as an amendment to an existing wholesale or distributor registration held by the reverse distributor applicant pursuant to section 21a-70 of the Connecticut General Statutes.

(c) Upon annual renewal, the reverse distributor shall provide information related to the amount of drugs destroyed and any additional information required by the department.

(d) A reverse distributor applicant shall submit an application and all other documentation required by the commissioner on forms prescribed by the commissioner. No registration shall be approved under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant has adequate facilities and apparatus to properly carry on the business described in their application and that the applicant conforms to and is in compliance with federal and state requirements, including 21 CFR 1317 and sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies.

(e) The commissioner shall have the right to deny a reverse distributor registration if the commissioner determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider, among others, the factors enumerated in section 21a-70(c) of the Connecticut General Statutes and any potential negative impact on public health and safety.

(f) A reverse distributor shall maintain record logs, which contain the following information for each transaction: (1) the name and address of the authorized collector from whom the reverse distributor collected the rigid container; (2) the date of collection of the rigid container from the authorized collector; (3) the date of delivery of the rigid container to the reverse distributor or the date the reverse distributor obtained possession of the rigid container; (4) the inner liner unique identification number marked on the outside of the rigid container; (5) the destruction date of each rigid container and its contents; and (6) the names of the reverse distributor employees or representatives who performed each function.

(g) A reverse distributor shall not open or unseal, or otherwise tamper with a rigid container prior to destruction unless ordered to do so by the commissioner.

(h) Two employees of the reverse distributor shall witness the destruction of the rigid container and its contents, participate in completion of the logs, and each shall enter their names and signatures to the record log. Record logs shall be maintained by the reverse distributor for three years and copies shall be made available to the department for inspection upon request.

(i) Reverse distributors 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.

(j) Reverse distributors shall permit the commissioner to enter and inspect their premises and delivery vehicles and to audit their records and written operating procedures upon request of the Drug Control Division. Upon reasonable suspicion by the department of tampering or adulteration of a rigid container in the possession of a reverse distributor, the department may seize such rigid container.

(k) Any loss, theft, serious damage or destruction of an inner liner or rigid container shall be reported by a reverse distributor, within seventy-two hours of any such occurrence, to the director of the Drug Control Division.

Sec. 20-576a-7. Grounds for discipline: (a) The commissioner may suspend, revoke or refuse to renew a registration of an authorized collector or reverse distributor, place conditions on such registration, issue a letter of reprimand, or take other actions permitted by statute or regulation, including sections 20-579, 21a-8 and 21a-70 of the Connecticut General Statutes. Failure to renew a registration in a timely manner shall not be a violation for purposes of this section. Any of the following shall be sufficient cause for such action:

(1) Furnishing of false or fraudulent information in any application or other document filed with the department;

(2) Any criminal conviction of the authorized collector or reverse distributor under any federal or state statute concerning drugs;

(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;

(4) Failure to maintain effective controls against diversion, theft or loss of controlled substances or other materials placed in the collection receptacles by authorized collectors while the rigid container is in the collection receptacle and by reverse distributors, after receiving the rigid container from the authorized collector;

(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) Failure to keep and maintain accurate records as required by sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies;

(7) 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;

(8) False, misleading or deceptive representations to the public or the commissioner;

(9) Involvement in a fraudulent or deceitful practice or transaction;

(10) Performance of incompetent or negligent work;

(11) Failure to maintain the entire collection receptacle or pharmacy area in which it is located in a clean, orderly and working condition;

(12) 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 by or at an authorized collector or a reverse distributor;

(13) Failure to comply with any provision of sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies; or

(14) A violation of 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.

(b) Before denying, suspending, revoking or refusing to renew a registration, the commissioner shall afford the applicant an opportunity for a hearing in accordance with the provisions of chapter 54 of the Connecticut General Statutes.

(c) No authorized collector or reverse distributor whose registration has been revoked may apply for a registration under sections 20-576a-1 to 20-576a-7, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of such revocation.

(d) A registrant may at any time voluntarily surrender its certificate of registration for any or all of the following reasons: (1) As an indication of its good faith in desiring to remedy any incorrect or unlawful practices or (2) as a voluntary act arising out of such registrant's desire to terminate prescribing or handling of controlled substances in any or all schedules. Any such voluntary surrender shall constitute authority for the commissioner or said commissioner's authorized agent to terminate and revoke any registration without a hearing or any other proceeding.

Sec. 20-577. 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. 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. 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, suspend or place conditions on 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 per violation of any provision of this chapter 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 accepted, for return to general inventory or regular stock, any drug sold or delivered to a patient, unless accepting such drug for return to general inventory or regular stock is otherwise permitted or required by law; (12) 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; (13) 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; (14) has performed or been a party to a fraudulent or deceitful practice or transaction; (15) 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; (16) has performed incompetent or negligent work; (17) 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; (18) 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; (19) has failed to maintain the entire pharmacy premises, its components and contents in a clean, orderly and sanitary condition; (20) has failed to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time; or (21) has failed to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding – Nonsterile Preparations, as amended from time to time.

(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, suspend or place conditions on 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. 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. 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 guilty of a class D felony. For the 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. 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.

PART II - LICENSING OF PHARMACISTS AND PHARMACIES. REGISTRATION OF PHARMACY INTERNS AND PHARMACY TECHNICIANS

Sec. 20-590. 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. 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 annually and may be renewed upon completion of an application on a form approved by the department, payment of one hundred 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. Pharmacy license; application; information required; issuance or renewal of license; expiration. Transfer of pharmacy to new location. Report re administrative or legal action: (a) Except as limited by section 20-596, a pharmacist, health care institution 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 the department's 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.

(f) Each pharmacy licensed pursuant to this section shall report to the department any administrative or legal action commenced against such pharmacy by any state or federal regulatory agency or accreditation entity not later than ten business days after receiving notice of the commencement of such action.

Sec. 20-595. 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. 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. 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. 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. 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. 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 year 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 notice of a change in officers or directors of a corporation holding a nonresident pharmacy certificate of registration 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.

(15) The fee for filing notice of a change in name, ownership or management of a nonresident 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.

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

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

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

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. 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. 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. 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. 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. 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. 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 (f) of section 20-614, as amended by this act, 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. 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. 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) Prior to or simultaneous with the dispensing of a drug pursuant to subsection (b) of this section, a pharmacist or other employee of the pharmacy shall, whenever practicable, offer for the pharmacist to

discuss the drug to be dispensed and to counsel the patient on the usage of the drug, except when the person obtaining the prescription is other than the person named on the prescription form or electronic record 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 patient either in person at the pharmacy or by telephone.

(e) Nothing in this section shall be construed to require a pharmacist to provide counseling to a patient who refuses such counseling. The pharmacist shall keep a record of such counseling, any refusal by or inability of the patient to accept counseling or a refusal by the patient to provide information regarding such counseling. 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) (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. 20-614-1. 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. 20-615. 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. Prescriptions: Refills; transfers: (a) As used in this section:

(1) "Diabetes device" means a device, including, but not limited to, a blood glucose test strip, glucometer, continuous glucometer, lancet, lancing device or insulin syringe, that is (A) a legend device or nonlegend device, and (B) used to cure, diagnose, mitigate, prevent or treat diabetes or low blood sugar;

(2) "Diabetic ketoacidosis device" means a device that is (A) a legend or nonlegend device, and (B) used to screen for or prevent diabetic ketoacidosis;

(3) "Glucagon drug" means a drug that contains glucagon and is (A) a legend drug or nonlegend drug, (B) prescribed for self-administration on an outpatient basis, and (C) approved by the federal Food and Drug Administration to treat low blood sugar;

(4) "Insulin drug" means a drug, including, but not limited to, an insulin pen, that contains insulin and is (A) a legend drug or nonlegend drug, (B) prescribed for self-administration on an outpatient basis, and (C) approved by the federal Food and Drug Administration to treat diabetes; and

(5) "Usual customary charge to the public" means a charge for a particular prescription not covered by Medicaid, excluding charges made to third-party payors and special discounts offered to individuals, including, but not limited to, senior citizens.

(b) Except as provided in subsection (c) or (d) of this section, a prescription may be refilled only upon the written, oral or electronically-transmitted order of a prescribing practitioner.

(c) 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.

(d) (1) (A) Notwithstanding subsection (c) of this section, a pharmacist may immediately prescribe and dispense to a patient not more than a thirty-day supply of a diabetic ketoacidosis device, insulin drug or glucagon drug, and any diabetes devices that are necessary to administer such supply of such insulin drug or glucagon drug, if:

(i) The patient informs the pharmacist that the patient has less than a seven-day supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device;

(ii) The pharmacist determines, in the pharmacist's professional judgment, that the patient will likely suffer significant physical harm within seven days if the patient does not obtain an additional supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device before the expiration of said seven days;

(iii) The pharmacist reviews the electronic prescription drug monitoring program established pursuant to section 21a-254 and determines that no pharmacist prescribed and dispensed a supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device to the patient pursuant to this subsection during the twelve-month period immediately preceding, unless:

(I) The pharmacist determines, by contacting the pharmacy that filled the most recent prescription for such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device, by examining another prescription database or reviewing the most recent prescription for such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device or a prescription label containing the most recent prescription information for such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device, that no pharmacist dispensed a supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device to the patient pursuant to this subsection during said twelve-month period; or

(II) The electronic prescription drug monitoring program established pursuant to section 21a-254 is unavailable; and

(iv) Not later than seventy-two hours after the pharmacist dispenses such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device the pharmacist, or the pharmacist's representative, provides notice to the practitioner who, other than the pharmacist, most recently prescribed such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device to the patient.

(B) A pharmacist shall immediately prescribe and dispense to a patient not more than a thirty-day supply of a diabetic ketoacidosis device, insulin drug or glucagon drug, and any diabetes devices that are necessary to administer such supply of the insulin drug or glucagon drug, if the criteria established in subparagraphs (A)(i) to (A)(iv), inclusive, of this subdivision have been satisfied and the patient pays, or has health insurance coverage, for such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device.

(2) No pharmacist who prescribes and dispenses a supply of a diabetic ketoacidosis device, insulin drug or glucagon drug, and any diabetes devices that are necessary to administer such supply of the insulin drug or glucagon drug, pursuant to subdivision (1) of this subsection shall require the patient to tender payment to the pharmacist for such supply in an amount that exceeds:

(A) The amount of the coinsurance, copayment, deductible or other out-of-pocket expense that the patient's health insurance coverage imposes for such supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device; or

(B) The usual customary charge to the public for such supply of such insulin drug, glucagon drug, diabetes devices or diabetes ketoacidosis device if the patient does not have health insurance coverage for such supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device.

(3) Nothing in subdivision (1) or (2) of this subsection shall be construed to prohibit a pharmacist from requiring a patient to submit to the pharmacist, before the pharmacist prescribes or dispenses a supply of a diabetic ketoacidosis device, insulin drug or glucagon drug, and any diabetes devices necessary to administer such insulin drug or glucagon drug, pursuant to said subdivisions, proof of health insurance coverage for the patient, personal identification for the patient, contact information for a health care provider providing treatment to the patient, information concerning previous prescriptions issued to the patient for the insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device, a sworn statement by the patient stating that the patient is unable to timely obtain the insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device that the patient is seeking pursuant to this subsection without suffering significant physical harm, and any amount required by the pharmacist under subdivision (2) of this subsection.

(4) Each pharmacist shall refer a patient who requests a supply of an insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device pursuant to this subsection to a federally-qualified health center

if:

(A) The pharmacist determines that the patient does not have health insurance coverage for such supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device; or

(B) The patient informs the pharmacist that the patient is concerned that the net cost to the patient for such supply of such insulin drug, glucagon drug, diabetes devices or diabetic ketoacidosis device is unaffordable.

(e) 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 (b) 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. 20-616a. Prescription refills for quantity of drug greater than initial quantity prescribed. Conditions: A pharmacist may exercise his or her professional judgment in refilling a prescription for a quantity of a drug greater than the initial quantity of a drug prescribed by the prescribing practitioner, provided (1) such refill is made after the patient's initial prescription is dispensed, (2) such refill does not exceed a ninety-day supply of such drug and does not exceed the total quantity of such drug authorized by the prescribing practitioner, (3) the prescribing practitioner has not indicated that the initial quantity or refill quantity of the prescribed drug shall not be changed, (4) such drug is not a controlled drug, as defined in section 21a-240, (5) the pharmacist informs the prescribing practitioner of such refill at the earliest reasonable time, but not later than forty-eight hours after such refill is made, and (6) the patient's health insurance policy or health benefit plan, if any, will cover the refill quantity dispensed, without additional coinsurance, deductible or other out-of-pocket expense required from the patient.

Sec. 20-617. Prescriptions: Notation of drug quantity, expiration date, generic name and drug manufacturer and MedWatch program information. Label information for generic drug substitutions: (a) 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 subsection shall be no later than the expiration date determined by the manufacturer.

(b) In addition to the information required to be included on the label of each prescription container pursuant to subsections (a) and (c) of this section, each pharmacist shall include on the label of each prescription container or on the receipt or other similar packaging in which the prescription is contained for a drug sold only by generic name, as defined in section 20-14a, and not by brand name, as defined in said section: (1) The name of the manufacturer of the generic drug placed in the container, and (2) the Internet web site address and toll-free telephone number for the United States Food and Drug Administration's safety information and adverse event reporting program (MedWatch).

(c) In addition to the information required to be included on the label of each prescription container pursuant to subsections (a) and (b) of this section, if a pharmacist substitutes a generic name drug for a brand name drug, such pharmacist shall include on the label of the prescription container: (1) The name of the generic drug placed in the container, and (2) the brand name of the drug that the generic drug was substituted for.

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.

(c) The addition of a flavoring agent in accordance with subsections (a) and (b) of this section shall be exempt from the requirements established in subsections (a) to (m), inclusive, of section 20-633b, any regulations adopted pursuant to subsection (o) of section 20-633b and United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding - Nonsterile Preparations, and Chapter 800, Hazardous Drugs, as both may be amended from time to time.

Sec. 20-618. 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. 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 specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product is “brand medically necessary” or “no substitution”, (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify “brand medically necessary” or “no substitution” on the prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to “brand medically necessary” or “no substitution”.

(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) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or biological product 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.

(k) 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 (g) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

(l) 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 or biological product, unless the pharmacist (1) provides prior notice of the use of a different drug or biological product 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 or biological product 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 (c) 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.

(m) Not later than forty-eight hours following the dispensing of an interchangeable biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer of the product. The entry shall be made in a manner that provides notice to the prescriber and may be made through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. If the entry is not made by any of the means specified in subdivision (1), (2), (3) or (4) of this subsection, the pharmacist shall communicate the product dispensed to the prescriber using either facsimile, telephone or electronic transmission, provided such communication shall not be required when a refill prescription is not changed from the product dispensed on the prior filling of the prescription. The provisions of this subsection shall not apply to interchangeable biological products dispensed by a pharmacy operated by a hospital licensed in accordance with the provisions of chapter 368v.

(n) 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. 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. 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. 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, at a store or in a vending machine that is owned and operated by a business that has obtained from the commission or the department a permit to sell nonlegend drugs pursuant to section 20-624. Nonlegend drugs may be sold in a vending machine, which vending machine shall be owned and operated by a business that has obtained from the department a permit for each vending machine in which such business offers nonlegend drugs for sale. If an applicant seeks to locate two or more vending machines selling nonlegend drugs at a single premises, only one permit to sell nonlegend drugs shall be required. Any person who is not licensed as a pharmacy and wishes to sell nonlegend drugs in a vending machine shall apply to the department, in a form and manner prescribed by the commissioner, in order to obtain a permit to sell nonlegend drugs. Nonlegend drugs shall be labeled and packaged in accordance with state and federal law.

(b) (1) A vending machine offering nonlegend drugs may also offer nonlegend devices or test strips intended for use by an individual to test for a particular substance prior to injection, inhalation or ingestion of the substance to prevent accidental overdose by injection, inhalation or ingestion of such substance. Each vending machine offering nonlegend drugs or nonlegend devices shall be individually registered with the department, and each application to register a vending machine offering nonlegend drugs or nonlegend devices shall designate an individual who shall be responsible for properly maintaining such vending machine.

(2) Each person who registers a vending machine pursuant to subdivision (1) of this subsection, and the individual designated as the individual responsible for properly maintaining the registered vending machine, shall ensure that such vending machine (A) maintains the proper temperature and humidity for each nonlegend drug offered in such vending machine as required by the original manufacturer of such nonlegend drug, (B) only contains nonlegend drugs and nonlegend devices that remain in the original containers provided by the manufacturers of such nonlegend drugs or nonlegend devices, (C) only offers nonlegend drugs and nonlegend devices that are unexpired and unadulterated, (D) only offers nonlegend drugs and nonlegend devices that are not subject to a recall, provided any nonlegend drug or nonlegend device that is the subject of a recall shall be promptly removed from such vending machine, (E) only contains nonlegend drugs and nonlegend devices, sundries and other nonperishable items, (F) has a clear and conspicuous written statement attached to such vending machine disclosing the name, address and toll-free telephone number of the owner and operator of such vending machine, (G) has a clear and conspicuous written statement attached to such vending machine advising a consumer to check the expiration date of a nonlegend drug or nonlegend device contained in such vending machine before the consumer uses such nonlegend drug or nonlegend device, (H) has attached to such vending machine, in a size and prominent location visible to consumers, a written notice stating "Drug tampering or expired product? Notify the Department of Consumer Protection, Drug Control Division, by calling (telephone number of the toll-free telephone line established by the department pursuant to section 21a-2)", (I) does not offer any nonlegend drug or nonlegend device that requires age verification, is subject to any quantity limit or is subject to any sales restriction under state or federal law, and (J) does not contain any package

of a nonlegend drug that contains more than a five-day supply of the nonlegend drug as determined according to the usage directions provided by the manufacturer of such nonlegend drug.

(c) Any person who violates any provision of this section shall be fined not more than one thousand dollars per violation.

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 that ships, mails or delivers, in any manner, legend devices or legend drugs into this state pursuant to a prescription order.

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

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

(2) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as comply with all requests for information made by the commission or department pursuant to this section;

(3) Disclose to the department whether the nonresident pharmacy is dispensing sterile pharmaceuticals, as defined in section 20-633b, within this state. If any such dispensed sterile pharmaceutical is not patient-specific, the nonresident pharmacy shall submit a copy of the manufacturing license or registration issued by the regulatory or licensing agency of the state in which it is licensed, and a copy of any registration issued by the federal Food and Drug Administration to the department;

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

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

(6) A nonresident pharmacy shall provide a toll-free telephone number to facilitate communication between patients in this state and a pharmacist at such nonresident pharmacy who has access to the patient's records at all times. Such toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state;

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

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

Sec. 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 out the purpose of this section.

Sec. 20-629. Denial, revocation or suspension of nonresident pharmacy certificate of registration. Referral by commission: (a) The commission may deny, revoke or suspend any certificate of registration as a nonresident pharmacy for:

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

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

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

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

(b) The commission may, in addition to any action authorized under subsection (a) of this section, refer the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

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 care plans, management agreements and policies. Scope. Care-giving institutions, devices and qualified pharmacists. Regulations: (a) For the purposes of this section:

(1) "Care-giving institution" has the same meaning as provided in section 20-571;

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

(3) "Collaborative drug therapy care plan" means a written document memorializing the outcome of the process through which one or more qualified pharmacists and one or more prescribing practitioners discuss, review and agree on an approach to achieve a patient's desired health outcome;

(4) "Collaborative drug therapy management agreement" means an agreement between one or more qualified pharmacists and one or more prescribing practitioners to manage the drug therapy of, and devices prescribed to, individual patients, or a patient population, based on a written protocol or a collaborative drug therapy care plan;

(5) "Collaborative drug therapy management policy" means a written policy adopted by a care-giving institution under which one or more qualified pharmacists manage the drug therapy of, and devices prescribed to, individual patients, or a patient population, based on a written protocol or a collaborative drug therapy care plan;

(6) "Device" has the same meaning as provided in section 20-571;

(7) "Pharmacist" has the same meaning as provided in section 20-571;

(8) “Prescribing practitioner” has the same meaning as provided in section 20-571;

(9) “Provider-patient relationship” means a relationship between a prescribing practitioner and a patient in which (A) the patient has made a medical complaint, (B) the patient has provided such patient's medical history, (C) the patient has received a physical examination, and (D) there exists a logical connection between such medical complaint, medical history and physical examination and any drug or device prescribed for such patient; and

(10) “Qualified pharmacist” means a pharmacist who (A) is deemed competent under regulations adopted by the commissioner pursuant to subsection (e) of this section, and (B) has reviewed the latest edition of the “Pharmacists' Patient Care Process” published by the Joint Commission of Pharmacy Practitioners.

(b) Except as provided in section 20-631b, one or more qualified pharmacists may enter into a collaborative drug therapy management agreement or manage the drug therapy of, and devices prescribed to, individual patients, or a patient population, under a collaborative drug therapy management policy. In order to enter into a collaborative drug therapy management agreement or collaborative drug therapy care plan, or operate under a collaborative drug therapy management policy, a prescribing practitioner shall first establish a provider-patient relationship with the patient or patients who will receive collaborative drug therapy or devices. Each patient's collaborative drug therapy or device management shall be based on a diagnosis made by such patient's prescribing practitioner or a specific test set forth in a collaborative drug therapy management agreement or collaborative drug therapy management policy.

(c) A collaborative drug therapy management agreement or collaborative drug therapy management policy may authorize a qualified pharmacist or qualified pharmacists to initiate, modify, continue, discontinue or deprescribe a drug therapy, or initiate, continue or discontinue use of, or deprescribe, a device, that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific or patient population-specific written protocol or collaborative drug therapy care plan, but shall not authorize a qualified pharmacist or qualified pharmacists to establish a port to administer parenteral drugs. A collaborative drug therapy management agreement or collaborative drug therapy management policy may specifically address issues that may arise during a medication reconciliation and concerns related to polypharmacy that enable an authorized qualified pharmacist or qualified pharmacists to initiate, modify, continue, discontinue or deprescribe drug therapy. In instances where drug therapy is discontinued or deprescribed, the qualified pharmacist or qualified pharmacists shall notify the prescribing practitioner of such discontinuance or deprescribing not later than twenty-four hours after such drug therapy is discontinued or deprescribed. Each written protocol or collaborative drug therapy care plan developed, pursuant to a collaborative drug therapy management agreement or collaborative drug therapy management policy, shall contain detailed direction concerning the actions that the qualified pharmacist or qualified pharmacists may perform for the patient or patient population. Such written protocol or collaborative drug therapy care plan shall include, but need not be limited to, (1) the specific drug or drugs, therapeutic class of drug or classes of drugs, or devices to be managed by the qualified pharmacist or qualified pharmacists, (2) the terms and conditions under which drug therapy may be initiated, modified, continued, discontinued or deprescribed, or use of a device may be initiated, continued or discontinued, or a device may be deprescribed, (3) the conditions and events upon which the qualified pharmacist is, or qualified pharmacists are, required to notify the prescribing practitioner, (4) the laboratory tests that may be ordered, and (5) a definition of the patient population included in such written protocol or collaborative drug therapy care plan. All activities performed by the qualified

pharmacist or qualified pharmacists in conjunction with the protocol or collaborative drug therapy care plan shall be documented in the patient's medical record in accordance with the prescribing practitioner's policies or, in the case of a care-giving institution, all applicable care-giving institution policies. Each collaborative drug therapy management agreement, collaborative drug therapy management policy, written protocol and collaborative drug therapy care plan shall be available for inspection by the Department of Consumer Protection and the Department of Public Health. A copy of the protocol shall be filed in the patient's medical record.

(d) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection (e) of this section, the competence necessary for the pharmacist to participate in each collaborative drug therapy management agreement, collaborative drug therapy management policy and collaborative drug therapy care plan in which such pharmacist seeks to participate by, among other things, demonstrating that such pharmacist has reviewed the latest edition of the "Pharmacists' Patient Care Process" published by the Joint Commission of Pharmacy Practitioners.

(e) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall (1) adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a collaborative drug therapy management agreement, the minimum content of the collaborative drug therapy management agreement and such other matters said commissioners deem necessary to carry out the purpose of this section, and (2) on or after July 1, 2022, amend such regulations to include competency requirements for participation in a collaborative drug therapy management policy or collaborative drug therapy care plan and the minimum content of collaborative drug therapy management policies, collaborative drug therapy care plans and written protocols governing collaborative drug therapy and device management.

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.

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 and epinephrine cartridge injectors by pharmacists and pharmacy technicians. Disclosures. Training. Recordkeeping. Regulations: (a) (1) Any person licensed as a pharmacist under part II of this chapter may order, prescribe and administer: (A) Any vaccine, approved or authorized by the United States Food and Drug Administration that is listed on the National Centers for Disease Control and Prevention's age-appropriate immunization schedule, to any patient who is: (i) Eighteen years of age or older; or (ii) at least twelve years of age but younger than eighteen years of age with (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor; (B) Any vaccine not included on the National Centers for Disease Control and Prevention's Adult Immunization Schedule to any patient who is eighteen years of age or older, provided the vaccine administration instructions for such vaccine are available on the National Centers for Disease Control and Prevention's Internet web site; and (C) Any vaccine pursuant to a verbal or written prescription of a prescribing practitioner for a specific patient. (2) A pharmacist shall make a reasonable effort to review a patient's vaccination history to prevent any inappropriate use of a requested vaccine. (3) All vaccines administered pursuant to this section shall be administered in accordance with the: (A) Vaccine manufacturer's package insert or the orders of a prescribing practitioner; and (B) regulations adopted pursuant to subsection (d) of this section. (4) A pharmacist may delegate to an advanced pharmacy technician the pharmacist's authority to administer a vaccine described in subparagraph (A) of subdivision (1) of this subsection to a patient described in said subparagraph, provided the advanced pharmacy technician administers the vaccine: (A) Under the direct supervision of such pharmacist; and (B) in accordance with the provisions of this section and the regulations adopted pursuant to subsection (d) of this section.

(b) A pharmacist who has completed the training required in regulations adopted pursuant to subsection (d) of this section may administer an epinephrine cartridge injector, as defined in section 19a-909, to a patient whom the pharmacist reasonably believes, based on such pharmacist's knowledge and training, is experiencing anaphylaxis, regardless of whether such patient has a prescription for an epinephrine cartridge injector. Such pharmacist, or such pharmacist's designee, shall call the 9-1-1 emergency telephone number either before or immediately after such pharmacist administers the epinephrine cartridge injector to such patient. Such pharmacist shall document the date, time and circumstances in which such pharmacist administered such epinephrine cartridge injector, and maintain such documentation for at least three years.

(c) (1) A certified and registered pharmacy technician may administer a vaccine to a patient at a pharmacy if: (A) The managing pharmacist of such pharmacy is authorized to administer vaccines under this section; and (B) such pharmacy technician (i) has successfully completed a course of hands-on training, certified by the American Council for Pharmacy Education, concerning the administration of vaccines, (ii) has been trained at such pharmacy regarding the process for administering vaccines to patients at such pharmacy, (iii) successfully completes at least one hour of annual continuing education concerning immunization, (iv) has been evaluated by the managing pharmacist of such pharmacy, and (v) administers such vaccine at the direction of the pharmacist on duty at such pharmacy. (2) During the period beginning on September first and ending on March thirty-first of the succeeding calendar year, a certified and registered pharmacy technician shall not count toward the pharmacist-to-technician ratio set forth in section 20-576-33 of the regulations of Connecticut state agencies if such pharmacy technician: (A) Is authorized to administer vaccines under this section; and (B) exclusively performs duties related to the administration of vaccines during such period.

(d) (1) 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: (A) Require any pharmacist who administers a vaccine pursuant to this section to successfully complete an immunization training program for pharmacists; (B) 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; (C) identify qualifying training programs, which are accredited by the National Centers for Disease Control Prevention, the Accreditation Council for Pharmacy Education or another appropriate national accrediting body; and (D) establish a system of control and reporting. (2) The Commissioner of Consumer Protection may amend the regulations adopted pursuant to subdivision (1) of this subsection, in accordance with the provisions of chapter 54, to: (A) Establish additional requirements concerning delegations by pharmacists to advanced pharmacy technicians under this section; and (B) the administration of vaccines by advanced pharmacy technicians under this section.

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 authorized by 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 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 Department of Health and Human Services Centers for Disease Control and Prevention for vaccination of adult patients 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.

Sec. 20-633a. Pharmacy rewards program. Plain language summary. Violation: (a) For purposes of this section:

(1) "Pharmacy rewards program" means a promotional arrangement under which a retailer provides a consumer with store credits, discounts or other tangible benefits in exchange for the consumer filling drug prescriptions through such retailer or its affiliate;

(2) "HIPAA authorization" means an authorization to disclose medical records that meets the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) (HIPAA), as amended from time to time, or regulations adopted thereunder;

(3) "Protected health information" has the meaning assigned to it in 45 CFR 160.103, as amended from time to time; and

(4) "Marketing" has the meaning assigned to it in 45 CFR 164.501, as amended from time to time.

(b) Prior to enrolling a consumer in a pharmacy rewards program, a retailer shall provide the consumer with a written plain language summary of the terms and conditions of such program. If the consumer is required to sign a HIPAA authorization form to participate in the program, the retailer shall include information on the form, adjacent to the point where the HIPAA authorization form is to be signed, that states: (1) The specific uses or disclosures of protected health information the HIPAA authorization allows, (2) whether protected health information obtained by the retailer will be disclosed to third parties and, if so disclosed, that such information will not be protected by federal or state privacy laws, (3) which, if any, third parties will have access to the consumer's protected health information, (4) how the consumer may revoke the HIPAA authorization, and (5) that the consumer is entitled to a copy of the HIPAA authorization form once signed.

(c) The terms “HIPAA”, “Health Insurance Portability and Accountability Act of 1996”, “HIPAA authorization”, “protected health information” and “marketing” shall be defined in promotional materials, in the plain language summary required pursuant to subsection (b) of this section, and on the HIPAA authorization form adjacent to the point where the HIPAA authorization form is to be signed, if such terms are used in such materials, summary or enrollment form.

(d) A violation of subsection (b) or (c) of this section shall be deemed an unfair or deceptive act or practice in the conduct of trade or commerce under subsection (a) of section 42-110b.

Sec. 20-633b. Sterile compounding pharmacies. Sterile compounding by health care institutions. Requirements. Exemption. Regulations: (a) As used in this section:

(1) "Medical order" means a written, oral or electronic order by a prescribing practitioner for a drug to be dispensed by a pharmacy for administration to a patient;

(2) "Prescribing practitioner" has the same meaning as provided in section 20-14c;

(3) "Sterile compounding pharmacy" means a pharmacy or nonresident pharmacy that dispenses or compounds sterile pharmaceuticals;

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

(5) "USP chapters" means chapters 797, 800 and 825 of the United States Pharmacopeia that pertain to compounding sterile pharmaceuticals and their referenced companion documents, as amended from time to time.

(b) (1) (A) If an applicant for a new pharmacy license under section 20-594 intends to compound sterile pharmaceuticals, the applicant shall file an addendum to the pharmacy license application such applicant files pursuant to section 20-594 to include sterile pharmaceutical compounding. The department shall inspect the proposed pharmacy premises of such applicant and such applicant shall not compound sterile pharmaceuticals until such applicant receives notice that the addendum to such applicant's application has been approved by the department and the commission. Nothing in this section shall be construed to affect a licensed hospital's ability to compound sterile pharmaceuticals for such hospital's patients consistent with federal law.

(B) If an existing pharmacy licensed pursuant to section 20-594 intends to compound sterile pharmaceuticals for the first time on or after July 1, 2014, such pharmacy shall apply for an addendum to such pharmacy's application on file with the department to include sterile pharmaceutical

compounding. The department shall inspect the pharmacy premises of such pharmacy and such pharmacy shall not compound sterile pharmaceuticals until such pharmacy receives written notice that such addendum application has been approved by the department and the commission.

(C) If an existing health care institutional pharmacy licensed pursuant to section 20-594 intends to compound sterile pharmaceuticals for the first time on or after July 1, 2023, such health care institutional pharmacy shall apply for an addendum to such health care institutional pharmacy's application on file with the department to include sterile pharmaceutical compounding. The department shall inspect the pharmacy premises of such health care institutional pharmacy, and such health care institutional pharmacy shall not compound sterile pharmaceuticals until such health care institutional pharmacy receives written notice that such health care institutional pharmacy's addendum application has been approved by the department and the commission.

(2) (A) If an applicant for a new nonresident pharmacy registration intends to compound sterile pharmaceuticals for sale or delivery in this state, the applicant shall file an addendum to the registration application such applicant files pursuant to section 20-627 to include sterile pharmaceutical compounding. Such applicant shall provide to the department written proof that such applicant has passed inspection by the appropriate state agency in the state where such applicant is located. Such applicant shall not compound sterile pharmaceuticals for sale or delivery in this state until such applicant receives written notice that such addendum has been approved by the department and the commission.

(B) If an existing nonresident pharmacy intends to compound sterile pharmaceuticals for sale or delivery in this state for the first time on or after July 1, 2014, such nonresident pharmacy shall apply for an addendum to such nonresident pharmacy's application on file with the department to include sterile pharmaceutical compounding. Such nonresident pharmacy shall provide to the department written proof that such nonresident pharmacy has passed inspection by the appropriate state agency in the state where such nonresident pharmacy is located. Such nonresident pharmacy shall not compound sterile pharmaceuticals until such nonresident pharmacy receives written notice that such addendum application has been approved by the department and the commission.

(c) A sterile compounding pharmacy shall comply with the USP chapters. A sterile compounding pharmacy shall also comply with all applicable federal and state statutes and regulations.

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

(2) If a sterile compounding pharmacy provides sterile pharmaceuticals without a patient-specific prescription or medical order, the sterile compounding pharmacy shall also obtain a certificate of registration from the Department of Consumer Protection pursuant to section 21a-70 and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site inventory of sterile pharmaceuticals no greater than a thirty-day supply, calculated from the completion of compounding, which thirty-day period shall include the period required for third-party analytical testing, to be performed in accordance with the USP chapters.

(e) (1) If a sterile compounding pharmacy plans to remodel any area utilized for the compounding of sterile pharmaceuticals or adjacent space, relocate any space utilized for the compounding of sterile pharmaceuticals or upgrade or conduct a nonemergency repair to the heating, ventilation, air conditioning

or primary or secondary engineering controls for any space utilized for the compounding of sterile pharmaceuticals, the sterile compounding pharmacy shall notify the Department of Consumer Protection, in writing, not later than forty-five days prior to commencing such remodel, relocation, upgrade or repair. Such written notification shall include a plan for such remodel, relocation, upgrade or repair and such plan shall be subject to department review and approval. If a sterile compounding pharmacy makes an emergency repair, the sterile compounding pharmacy shall notify the department of such emergency repair, in writing, not later than twenty-four hours after such repair is commenced.

(2) If the USP chapters require sterile recertification after such remodel, relocation, upgrade or repair, the sterile compounding pharmacy shall provide a copy of such sterile compounding pharmacy's sterile recertification to the Department of Consumer Protection not later than five days after the sterile recertification approval. The recertification shall only be performed by an independent licensed environmental monitoring entity.

(f) A sterile compounding pharmacy shall report, in writing, to the Department of Consumer Protection any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined in the USP chapters, not later than the end of the next business day after discovering such violation or noncompliance.

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

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

(h) Each sterile compounding pharmacy shall prepare and maintain a policy and procedure manual. The policy and procedure manual shall comply with the USP chapters.

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

(j) Notwithstanding the provisions of subdivision (2) of subsection (b) of this section, a sterile compounding pharmacy that is a nonresident pharmacy shall provide to the Department of Consumer Protection proof that such nonresident pharmacy has passed an inspection in such nonresident pharmacy's home state, based on the USP chapters. Such nonresident pharmacy shall submit to the Department of Consumer Protection a copy of the most recent inspection report with such nonresident pharmacy's initial nonresident pharmacy application and shall submit to the department a copy of such nonresident pharmacy's most recent inspection report every two years thereafter. If the state in which such nonresident pharmacy is located does not conduct inspections based on standards required in the USP

chapters, such nonresident pharmacy shall provide satisfactory proof to the department that such nonresident pharmacy is in compliance with the standards required in the USP chapters.

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

(l) (1) For purposes of this subsection, a "designated pharmacist" means a pharmacist responsible for overseeing the compounding of sterile pharmaceuticals and the application of the USP chapters, as said chapters pertain to sterile compounding.

(2) Any pharmacy licensed pursuant to section 20-594 that provides sterile pharmaceuticals shall notify the department of such pharmacy's designated pharmacist.

(3) The designated pharmacist shall be responsible for providing proof such designated pharmacist has completed a program approved by the commissioner that demonstrates the competence necessary for the compounding of sterile pharmaceuticals, in compliance with all applicable federal and state statutes and regulations.

(4) The designated pharmacist shall immediately notify the department whenever such designated pharmacist ceases such designation.

(5) Nothing in this section shall prevent a designated pharmacist from being the pharmacy manager.

(m) Notwithstanding the provisions of this section, the addition of a flavoring agent in accordance with subsections (a) and (b) of section 20-617a shall be exempt from the requirements of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding - Nonsterile Preparations, and Chapter 800, Hazardous Drugs, as both may be amended from time to time.

(n) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, to implement the provisions of subsections (a) to (m), inclusive, of this section.

Sec. 20-633c. Prescribing of opioid antagonists by licensed pharmacists. Regulations: (a) A person who is licensed as a pharmacist under part II of this chapter and is certified in accordance with subsection (b) of this section may prescribe, in good faith, an opioid antagonist, as defined in section 17a-714a. Such pharmacist shall (1) provide appropriate training regarding the administration of such opioid antagonist to the person to whom the opioid antagonist is dispensed, and (2) maintain a record of such dispensing and the training required pursuant to this chapter.

(b) A pharmacist may only prescribe an opioid antagonist pursuant to this section if the pharmacist has been trained and certified by a program approved by the Commissioner of Consumer Protection.

(c) A pharmacist who prescribes an opioid antagonist in compliance with this section shall be deemed not to have violated any standard of care for a pharmacist.

(d) The provisions of this section shall apply only to a pharmacist certified in accordance with subsection (b) of this section. No pharmacist may delegate or direct any other person to prescribe an opioid antagonist or train any person in the administration of such opioid antagonist pursuant to the provisions of subsection (a) of this section.

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

Sec. 20-633d. Medical protocol standing order for dispensing of opioid antagonists by licensed pharmacists. Regulations: (a) A prescribing practitioner, as defined in section 20-14c, who is authorized to prescribe an opioid antagonist, as defined in section 17a-714a, and a pharmacy may enter into an agreement for a medical protocol standing order at such pharmacy allowing a pharmacist licensed under part II of this chapter to dispense an opioid antagonist that is (1) administered by an intranasal application delivery system or an auto-injection delivery system, (2) approved by the federal Food and Drug Administration, and (3) dispensed to any person at risk of experiencing an overdose of an opioid drug, as defined in 42 CFR 8.2, or to a family member, friend or other person in a position to assist a person at risk of experiencing an overdose of an opioid drug.

(b) Any such medical protocol standing order shall be deemed issued for a legitimate medical purpose in the usual course of the prescribing practitioner's professional practice. The pharmacy shall provide the Department of Consumer Protection with a copy of every medical protocol standing order agreement entered into with a prescribing practitioner under this section.

(c) A pharmacist may only dispense an opioid antagonist pursuant to a medical protocol standing order if the pharmacist has been trained and certified as part of a program approved by the Commissioner of Consumer Protection.

(d) A pharmacist who dispenses an opioid antagonist pursuant to a medical protocol standing order shall (1) provide appropriate training regarding the administration of such opioid antagonist to the person to whom the opioid antagonist is dispensed, (2) maintain a record of such dispensing and the training required pursuant to this chapter, and (3) send a copy of the record of such dispensing to the prescribing practitioner who entered into an agreement for a medical protocol standing order with the pharmacy.

(e) A pharmacist who dispenses an opioid antagonist in accordance with the provisions of this section shall be deemed not to have violated any standard of care for a pharmacist.

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

Sec. 20-633e. Pharmacy and institutional pharmacy perpetual inventory of Schedule II controlled substances. Regulations: (a) As used in this section, “pharmacy” and “institutional pharmacy” have the same meanings as provided in section 20-571.

(b) Each pharmacy and institutional pharmacy shall maintain a perpetual inventory of each Schedule II controlled substance, designated as such in regulations adopted pursuant to section 21a-243.

(c) The perpetual inventory required pursuant to subsection (b) of this section shall be reconciled on a monthly basis. Any loss, theft or unauthorized destruction of a controlled substance discovered during the reconciliation shall be reported by a pharmacy or institutional pharmacy not later than seventy-two hours after discovery of any such occurrence to the Commissioner of Consumer Protection pursuant to section 21a-262 and section 21a-262-3 of the regulations of Connecticut state agencies.

(d) Schedule II controlled substance perpetual inventory records shall be (1) kept on the premises of the pharmacy or institutional pharmacy, (2) maintained in an orderly manner separate from all other records, (3) filed by date, and (4) retained for a period of not less than three years. Such records shall be

made immediately available for inspection and copying by the Commissioner of Consumer Protection, the commissioner's authorized representative or other persons authorized to review such records pursuant to section 21a-265.

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

Sec. 20-633f. Ordering and administration of COVID-19-related, HIV-related and influenza-related tests, and prescribing of HIV-related prophylaxes, by licensed pharmacists. Recordkeeping. Confidentiality. Disclosure. Regulations:(a) For the purposes of this section:

(1) "COVID-19" means the respiratory disease designated by the World Health Organization on February 11, 2020, as coronavirus 2019, and any related mutation thereof recognized by said organization;

(2) "COVID-19-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, COVID-19;

(3) "HIV-related prophylaxis" means any drug approved by the federal Food and Drug Administration or any successor agency as a pre-exposure or post-exposure prophylaxis for the human immunodeficiency virus;

(4) "HIV-related test" has the same meaning as provided in section 19a-70; and

(5) "Influenza-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, influenza disease.

(b) (1) Any pharmacist licensed under this chapter may order, and administer to a patient, a COVID-19-related test or influenza-related test if: (A) Such pharmacist (i) is employed by a pharmacy that has submitted to the Department of Public Health a complete clinical laboratory improvement amendment application for certification for the COVID-19-related test or influenza-related test and the Department of Public Health has approved such application, and (ii) has completed any training required by the Department of Consumer Protection; and

(B) the patient is (i) eighteen years of age or older, or (ii) at least twelve years of age but younger than eighteen years of age with (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor.

(2) Any pharmacist licensed under this chapter may order, and administer to a patient, a COVID-19-related test or influenza-related test if: (A) Such pharmacist is employed by a hospital; and (B) the patient is (i) eighteen years of age or older, or (ii) at least twelve years of age but younger than eighteen years of age with (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor.

(3) Any pharmacist licensed under this chapter may delegate to an advanced pharmacy technician the pharmacist's authority to administer to a patient a COVID-19-related test or influenza-related test under this subsection if: (A) The advanced pharmacy technician has completed any training required by the Department of Consumer Protection concerning the proper administration of the COVID-19-related test or influenza-related test; and

(B) the advanced pharmacy technician administers the COVID-19-related test or influenza-related test (i) under the direct supervision of such pharmacist, and (ii) in accordance with the provisions of this section and the regulations adopted pursuant to subsection (g) of this section.

(c) (1) On or after the adoption of regulations pursuant to subsection (g) of this section, any pharmacist licensed under this chapter may order, and administer to a patient, an HIV-related test if: (A) Such pharmacist (i) is employed by a pharmacy that has submitted to the Department of Public Health a complete clinical laboratory improvement amendment application for certification for the HIV-related test and the Department of Public Health has approved such application, and (ii) has completed the training required under regulations adopted pursuant to subsection (g) of this section; and

(B) the patient is (i) eighteen years of age or older, or (ii) at least twelve years of age but younger than eighteen years of age with (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor.

(2) On or after the adoption of regulations pursuant to subsection (g) of this section, any pharmacist licensed under this chapter may order, and administer to a patient, an HIV-related test if: (A) Such pharmacist is employed by a hospital; and

(B) the patient is (i) eighteen years of age or older, or (ii) at least twelve years of age but younger than eighteen years of age and such pharmacist has obtained (I) the consent of such patient's parent, legal guardian or other person having legal custody of such patient, or (II) proof that such patient is an emancipated minor.

(3) Any pharmacist licensed under this chapter may delegate to an advanced pharmacy technician the pharmacist's authority to administer to a patient an HIV-related test under this subsection and the regulations adopted pursuant to subsection (g) of this section if: (A) The advanced pharmacy technician has completed any training required by the Department of Consumer Protection concerning the proper administration of the HIV-related test; and

(B) the advanced pharmacy technician administers the HIV-related test (i) under the direct supervision of such pharmacist, and (ii) in accordance with the provisions of this section and the regulations adopted pursuant to subsection (g) of this section.

(d) (1) If a pharmacist orders and administers, or if a pharmacist orders and an advanced pharmacy technician working under the pharmacist's direct supervision administers, a COVID-19-related test or influenza-related test under subsection (b) of this section, or an HIV-related test under subsection (c) of this section, the pharmacist shall: (A) Provide the results of such test to (i) the patient, in writing, (ii) the patient's primary care provider, if the patient identifies any such primary care provider, and (iii) the Commissioner of Consumer Protection or said commissioner's designee, upon request by said commissioner or such designee;

(B) report the results of such test to the director of health of the town, city or borough in which such case resides and to the Department of Public Health in the manner set forth in section 19a-215 and applicable regulations; and

(C)maintain a record of the results of such test for three years.

(2) No pharmacist shall delegate to an advanced pharmacy technician the pharmacist's duty to provide to the patient the results of: (A) A COVID-19-related test or influenza-related test ordered and administered under subsection (b) of this section; or

(B) an HIV-related test ordered and administered under subsection (c) of this section.

(e) (1) If a pharmacist orders and administers, or if a pharmacist orders and an advanced pharmacy technician working under the pharmacist's direct supervision administers, an HIV-related test under subsection (c) of this section and the result of such test is negative, the pharmacist may prescribe and dispense to the patient any HIV-related prophylaxis according to the manufacturer's package insert, provided: (A) Such pharmacist has completed the training required under the regulations adopted pursuant to subsection (g) of this section;

(B) such patient satisfies the criteria established in such package insert; and

(C) such HIV-related prophylaxis is prescribed and dispensed in accordance with all applicable requirements established in (i) this section, (ii) this chapter, or (iii) any regulations adopted pursuant to subsection (g) of this section or this chapter.

(2) If a pharmacist prescribes any HIV-related prophylaxis under subdivision (1) of this subsection, the pharmacist shall provide to the Commissioner of Consumer Protection or the commissioner's designee, upon request by said commissioner or such designee: (A) A copy of the results of the HIV-related test described in subdivision (1) of this subsection;

(B) prescription information maintained pursuant to this chapter; and (C) any other documentation the commissioner may require in regulations adopted pursuant to subsection (g) of this section.

(f) Notwithstanding the provisions of section 1-210, all information a pharmacist submits to the Department of Consumer Protection pursuant to this section, or any regulation adopted pursuant to subsection (g) of this section, shall be confidential. The department shall use such information to perform the department's duties concerning pharmacy, to ensure compliance with and enforce provisions of the general statutes and regulations of Connecticut state agencies concerning pharmacy and for no other purpose. If the department brings an enforcement action and uses any such information as part of such action, the department may disclose such information to the parties to such action only if such disclosure is required by applicable law. No such party shall further disclose such information except to a tribunal, the Commission of Pharmacy, an administrative agency or a court with jurisdiction over such action. Such tribunal, commission, agency or court shall ensure that such information is subject to a qualified protective order, as defined in 45 CFR 164.512(e), as amended from time to time.

(g) (1) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, the Commission of Pharmacy, a state-wide professional society representing the interests of physicians practicing medicine in this state and a state-wide organization representing the interests of health care professionals and scientists specializing in the control and prevention of infectious diseases, shall adopt regulations, in accordance with the provisions of chapter 54, to implement the provisions of this section. Such regulations shall, at a minimum: (A) Ensure compliance with all applicable guidance issued by the federal Centers for Disease Control and Prevention;

(B) ensure that each HIV-related prophylaxis prescribed and dispensed under subsection (e) of this section is prescribed and dispensed in accordance with the approval the federal Food and Drug Administration has granted for such HIV-related prophylaxis;

(C) establish permissible routes of administration;

(D) establish prescription duration limits not to exceed (i)sixty days for any pre-exposure HIV-related prophylaxis, or (ii) thirty days for any post-exposure HIV-related prophylaxis;

(E) specify (i)how frequently a pharmacist shall provide treatment to a patient under this section, (ii) when a pharmacist providing treatment to a patient under this section shall refer such patient to such patient's primary care provider or any other health care provider identified by such patient, and (iii) the circumstances in which a pharmacist shall recommend that a patient undergo screenings for sexually transmitted infections other than the human immunodeficiency virus;

(F) establish requirements concerning private areas for consultations between pharmacists and patients;

(G) establish training requirements concerning (i) methods to obtain a patient's complete sexual history, (ii)delivering a positive HIV-related test result to a patient, (iii) referring a patient who has tested positive for the human immunodeficiency virus to the services that are available to such patient, and

(iv)using HIV-related prophylaxes for patients who have tested negative for the human immunodeficiency virus;

(H) identify qualifying training programs, which are accredited by the National Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education or another appropriate national accrediting body; and

(I) establish a system of control and reporting.

(2) The Commissioner of Consumer Protection may amend the regulations adopted pursuant to subdivision (1) of this subsection, in accordance with the provisions of chapter 54, to: (A) Establish additional requirements concerning delegations by pharmacists to advanced pharmacy technicians under this section; and

(B) the administration of COVID-19-related tests, influenza-related tests and HIV-related tests by advanced pharmacy technicians under this section.

Sec. 20-633g. Operation of mobile pharmacies by licensed pharmacies. Application. Recordkeeping. Operations. Regulations: (a) (1) A pharmacy may apply to the department, in a form and manner prescribed by the commissioner, to operate a mobile pharmacy in a temporary location for the purpose of: (A) Conducting (i) a temporary pharmacy operation, (ii) a vaccination event, or (iii) an opioid antagonist training and prescribing event; or (B) serving a community that may not have adequate access to pharmacy services.

(2) No pharmacy may operate a mobile pharmacy without prior written approval from the department. Each mobile pharmacy shall be supervised by a pharmacist. The department may inspect a mobile pharmacy before pharmacy services are provided in the mobile pharmacy, and at any time during usual business hours or while such mobile pharmacy is in operation. The department may issue an order closing a mobile pharmacy if the department determines that: (A) The mobile pharmacy has failed to comply with (i) any provision of this section or this chapter, (ii) any regulation adopted pursuant to subsection (d) of this section or this chapter, or (iii) any applicable law or regulation of any jurisdiction concerning drugs, devices or the practice of pharmacy;

(B) conditions are unsafe to store or dispense drugs; or (C) there is insufficient security at such mobile pharmacy.

(b) A pharmacy that operates a mobile pharmacy under this section shall: (1) Maintain a record of all drugs that are removed from the pharmacy premises for the purpose of operating such mobile pharmacy;

(2) maintain a record of each drug that is dispensed at such mobile pharmacy and include such record in such pharmacy's records not later than twenty-four hours after such drug is dispensed;

(3) except as provided in subsection (c) of this section, inventory and return all unused drugs to the pharmacy premises by the close of business each day;

(4) while operating such mobile pharmacy, store all drugs in such mobile pharmacy in a manner that (A) prevents any drug diversion, and (B) is consistent with the storage conditions specified by the manufacturers of such drugs;

(5) establish and maintain a patient communication plan to ensure that patients can obtain prescription refills if such mobile pharmacy is unavailable; and

(6) if permitted by the federal Drug Enforcement Administration or a successor agency, store controlled substances in the mobile pharmacy in accordance with regulations adopted by the commissioner pursuant to section 21a-262.

(c) No pharmacy shall, without prior approval from the department: (1) Operate a mobile pharmacy for more than (A) seven consecutive days in a single location, or (B) fourteen days within a five-mile radius of the prior mobile pharmacy location; or (2) store drugs overnight in a mobile pharmacy or outside of the pharmacy premises.

(d) The commissioner may, with the advice and consent of the commission, adopt regulations in accordance with chapter 54 to implement the provisions of this section.

Sec. 20-633h. Unscheduled closings by licensed pharmacies. Plan. Disclosures. Prescription transfers. Regulations: (a) For the purposes of this section, "pharmacy district manager" means an individual who (1) supervises at least three pharmacies within this state, and (2) is responsible for the activities within such pharmacies, including, but not limited to, staffing, payroll and hiring.

(b) Each pharmacy shall maintain a plan to manage unscheduled closings. Such plan shall be reviewed and updated, if necessary, on an annual basis, and be provided to, and reviewed with, all pharmacy personnel on an annual basis. Such plan shall include:

(1) The name of the individual who is responsible for notifying the Commission of Pharmacy of an unscheduled closing;

(2) The name of the individual who is responsible for updating the hours of operation in the pharmacy's electronic record system to prevent acceptance of electronically transmitted prescriptions during an unscheduled closing;

(3) The name of the individual who is responsible for updating the pharmacy's telephone system during an unscheduled closing to (A) prevent the acceptance of orally transmitted prescriptions during the unscheduled closing, and (B) provide a message that alerts patients that such pharmacy will be closed and their prescriptions may be obtained from a nearby pharmacy;

(4) A list of all pharmacies that are located within a two-mile radius of the pharmacy that is experiencing an unscheduled closing, or the next closest pharmacy if there is no pharmacy within such two-mile radius; and

(5) The name of the individual who is responsible for posting, at the entrance to such pharmacy and at each entrance of the structure if such pharmacy is located within another structure, signage stating the duration of an unscheduled closing.

(c) If a pharmacy experiences an unscheduled closing, the pharmacist manager of the pharmacy or, if the pharmacy operates more than five pharmacy locations in this state, the pharmacy district manager shall:

(1) Modify such pharmacy's hours of operation in such pharmacy's electronic record system to prevent the acceptance of electronically transmitted prescriptions during the unscheduled closing;

(2) Adjust such pharmacy's telephone system to prevent the acceptance of orally transmitted prescriptions during the unscheduled closing;

(3) Provide a telephone system message alert to patients notifying patients that (A) such pharmacy is not open, and (B) patients may obtain medications from a nearby pharmacy;

(4) Post signage at the entrance to such pharmacy, and at each entrance of the structure if such pharmacy is located within another structure, (A) stating that such pharmacy is closed, (B) disclosing the duration of the unscheduled closing, and (C) providing (i) a list of all pharmacies that are located within a two-mile radius of such pharmacy, or (ii) the next closest pharmacy if there is no pharmacy within such two-mile radius; and

(5) Upon request by another pharmacy to transfer a prescription to such other pharmacy, transfer any prescription dispensed by the pharmacy experiencing the unscheduled closing and reverse any third-party payor claims associated with such prescription.

(d) Any pharmacy that verifies that another pharmacy is experiencing an unscheduled closing may, upon a patient's request, dispense a prescription that is dispensed and waiting at the pharmacy experiencing the unscheduled closing by using information obtained from the closed pharmacy, the electronic prescription drug monitoring program or another source that the pharmacist dispensing such prescription believes provides a reasonable assurance of accurate information necessary to dispense such prescription. In the event that a pharmacy dispenses a prescription during an unscheduled closing of another pharmacy:

(1) The pharmacy dispensing such prescription shall contact the pharmacy experiencing the unscheduled closing not later than twenty-four hours after such closed pharmacy reopens to transfer such prescription, in accordance with section 20-616;

(2) The pharmacy that experienced the unscheduled closing shall provide to the pharmacy that dispensed such prescription during such unscheduled closing all information necessary for the transfer of such prescription; and

(3) The pharmacy that experienced the unscheduled closing shall reverse any third-party payor claims associated with such transferred prescription not later than twenty-four hours after such pharmacy reopens.

(e) The Department of Consumer Protection shall adopt regulations, in accordance with chapter 54, to implement the provisions of this section. Such regulations shall include, but need not be limited to, provisions for the placement of a secured container at a pharmacy that allows patients to, during the hours in which the pharmacy may be open or closed, obtain prescriptions that were dispensed by such pharmacy. Prior to the effective date of such regulations, the department may temporarily permit the use and placement of a secured container at a pharmacy, provided the pharmacy submits to the department, for the department's approval, written protocols prior to placing, providing access to or using the secured container and such pharmacy receives written approval from the department for such placement, access or use. To obtain temporary approval under this subsection, a secure container shall:

(1) Weigh more than seven hundred fifty pounds or be affixed to the physical structure of the building where the pharmacy is located, and be located immediately adjacent to the portion of such building where such pharmacy is located;

(2) Only permit access to authorized pharmacy personnel or individuals retrieving the prescriptions with a unique identification system;

(3) Be under video surveillance at all times;

(4) Be capable of maintaining a record of all products that are placed inside of the secure container, and the date and time each individual prescription is accessed; and

(5) Comply with any other protocol required by the department to ensure patient confidentiality, ensure public health and safety and prevent diversion.

Sec. 20-633j. Authorization, refilling and dispensing of legend devices by licensed pharmacists. Notice to prescribing practitioner: (a) For the purposes of this section, "drug", "legend device", "pharmacist" and "prescribing practitioner" have the same meanings as provided in section 20-571.

(b) A pharmacist may authorize or refill a prescription for a legend device if such legend device is approved by the federal Food and Drug Administration for use in combination with a drug prescribed by a prescribing practitioner.

(c) A pharmacist who dispenses a legend device as described in subsection (b) of this section shall identify the prescribing practitioner who prescribed the drug that is associated with such legend device, and shall send written notice to such prescribing practitioner, not later than seventy-two hours after the pharmacist dispenses such legend device to the patient, disclosing that such pharmacist dispensed such legend device to such patient.

Sec. 20-633k. Prescribing of emergency and hormonal contraceptives by licensed pharmacists. Training. Patient screening. Disclosures and notices. Assistance by pharmacy technicians. Recordkeeping. Regulations: (a) For the purposes of this section:

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

(2) “Emergency contraceptive” means a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure;

(3) “Hormonal contraceptive” means a drug, including, but not limited to, a hormonal contraceptive patch, an intravaginal hormonal contraceptive or an oral hormonal contraceptive, composed of a hormone, or a combination of hormones, approved by the federal Food and Drug Administration to prevent pregnancy;

(4) “Legend drug” has the same meaning as provided in section 20-571;

(5) “Pharmacist” has the same meaning as provided in section 20-571;

(6) “Pharmacy” has the same meaning as provided in section 20-571;

(7) “Pharmacy technician” has the same meaning as provided in section 20-571; and

(8) “Prescribe” means to order, or designate a remedy or any preparation of, a legend drug for a specific patient.

(b) A pharmacist who satisfies the requirements established in this section, and any regulations adopted pursuant to subsection (e) of this section, may prescribe, in good faith, an emergency contraceptive or hormonal contraceptive to a patient subject to the following conditions:

(1) The pharmacist has completed an educational training program that (A) concerns prescribing emergency contraceptives and hormonal contraceptives by a pharmacist, (B) addresses appropriate medical screening of patients, contraindications, drug interactions, treatment strategies and modifications and when to refer patients to medical providers, and (C) is accredited by the Accreditation Council for Pharmacy Education;

(2) The pharmacist has reviewed the most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention, or any successor document thereto, prior to prescribing any emergency contraceptive or hormonal contraceptive and, if the pharmacist deviates from the guidance provided in such document, documents the pharmacist's rationale in deviating from such guidance in writing;

(3) Prior to dispensing an emergency contraceptive or hormonal contraceptive and at least once per calendar year thereafter for any returning patient, the pharmacist completes a screening document, which the department shall make available on the department's Internet web site, and the pharmacist, or the pharmacy that employs such pharmacist, retains such document for at least three years, except nothing in this subdivision shall be construed to prevent a pharmacist, in the pharmacist's professional discretion, from issuing a prescription for a hormonal contraceptive for a period not to exceed twelve months or from requiring more frequent screenings;

(4) If the pharmacist determines that prescribing an emergency contraceptive or hormonal contraceptive to a patient is clinically appropriate, the pharmacist shall (A) counsel the patient about what the patient should monitor and when the patient should seek additional medical attention, and (B) send notice to any health care provider that the patient identifies as the patient's primary care provider or, if the patient does not disclose the identity of the patient's primary care provider, provide to the patient any relevant documentation; and

(5) The pharmacist provides to the patient a document outlining age-appropriate health screenings that are consistent with recommendations made by the Centers for Disease Control and Prevention.

(c) A pharmacy technician may, at a pharmacist's request, assist the pharmacist in prescribing an emergency contraceptive or hormonal contraceptive to a patient by providing screening documentation to the patient, taking and recording the patient's blood pressure and documenting the patient's medical history, provided the pharmacy technician has completed an educational training program that satisfies the requirements established in subdivision (1) of subsection (b) of this section.

(d) Each pharmacy shall maintain copies of all documents concerning any screening performed

under this section for at least three years, and each pharmacy shall, upon request by the department, make such screening documents available to the department for inspection.

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

Sec. 20-633k-1. Definitions: For purposes of sections 20-633k-1 to 20-633k-10, inclusive, of the Regulations of Connecticut State Agencies, the following terms have the following meanings unless otherwise expressly stated:

(1) "Care Facility" means a freestanding emergency department, as defined in section 19a-493d of the Connecticut General Statutes, or an emergency department located within a hospital, licensed pursuant to chapter 368v of the Connecticut General Statutes;

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

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

(4) "Emergency contraceptive" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;

(5) "Hormonal contraceptive" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;

(6) "Patient" means an individual seeking a prescription for hormonal or emergency contraceptives from a prescribing pharmacist;

(7) "Pharmacy technician" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;

(8) "Practitioner" means an individual, other than a prescribing pharmacist, licensed by a state, commonwealth or territory of the United States, who is authorized to issue a prescription within the scope of the individual's practice;

(9) "Prescribing pharmacist" means a person who (A) is licensed as a pharmacist under part II of chapter 400j of the Connecticut General Statutes; (B) has completed the training requirements set forth in section 20-633k-2 of the Regulations of Connecticut State Agencies, (C) has a valid training certificate evidencing completion; and (D) is legally authorized to prescribe a hormonal contraceptive or an emergency contraceptive;

(10) "Prescribe" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;

(11) "Screening document for an emergency contraceptive" means the document prescribed by the commissioner and posted on the department's internet website which includes: (A) questions to determine whether an emergency contraceptive is clinically appropriate for a patient; (B) age-appropriate health screening information; and (C) a treatment algorithm for emergency contraceptives;

(12) "Screening document for a hormonal contraceptive" means the document prescribed by the commissioner and posted on the department's internet website which includes: (A) questions to

determine whether a hormonal contraceptive is clinically appropriate for a patient; (B) age-appropriate health screening information; and (C) a treatment algorithm for hormonal contraceptives;

(13) "Treatment algorithm for emergency contraceptives" means a document, included in the screening document for an emergency contraceptive, that sets forth the steps of a treatment pathway for emergency contraceptives and when a referral to a practitioner is recommended; and

(14) "Treatment algorithm for hormonal contraceptives" means a document, included in the screening document for a hormonal contraceptive, that sets forth the steps of a treatment pathway for hormonal contraceptives and when a referral to a practitioner is recommended.

Sec. 20-633k-2. Training Requirements for Prescribing of Hormonal Contraceptives and Emergency Contraceptives: (a) The department shall compile a list of educational training programs that satisfy the criteria set forth in section 20-633k of the Connecticut General Statutes and subsection (b) of this section. Such programs shall be submitted to the department in a form and manner prescribed by the commissioner. The department shall post on its internet website educational training programs deemed by the department to satisfy such criteria.

(b) Educational training programs that prescribing pharmacists and pharmacist technicians are required to complete prior to prescribing hormonal contraceptives and emergency contraceptives shall be accredited by the Accreditation Council for Pharmacy Education and shall include the following topics:

(1) The types of hormonal and emergency contraceptives that are available to patients;

(2) Interviewing techniques for use with patients seeking hormonal and emergency contraceptives;

(3) The information contained in the screening document for an emergency contraceptive, and the screening document for a hormonal contraceptive, and how to use such documents;

(4) The most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention on its internet web site, or any successor document thereto and how to use such information;

(5) The provision of patient counseling and education regarding any emergency contraceptive and hormonal contraceptive mechanism, effectiveness, benefits, risks, and instructions for use of any contraceptive selected;

(6) Contraindications to emergency contraceptive and hormonal contraceptive use and when patient referrals to a practitioner are appropriate;

(7) Guidelines for assisting patients in the selection of an emergency contraceptive and a hormonal contraceptive;

(8) Guidelines for management of side effects and when those side effects require referral to a healthcare provider or care facility;

(9) Record keeping required pursuant to section 20-633k-6 of the Regulations of Connecticut State Agencies; and

(10) Prohibited acts set forth in section 20-633k-10 of the Regulations of Connecticut State Agencies.

(c) Prior to a prescribing pharmacist and any pharmacy technician assisting a patient in accordance with section 20-633k-3(b) of the Regulations of Connecticut State Agencies, a prescribing pharmacist and any assisting pharmacy technician shall successfully complete an educational training program approved by the department and shall obtain a certificate of completion from such program.

(d) Such certificate of completion shall be valid for thirty-six months from the date of completion recorded on the certificate. Upon expiration of such certificate, a pharmacist or pharmacy technician shall successfully complete a subsequent educational training program approved by the department and obtain a new certificate of completion in order to continue to prescribe hormonal and emergency contraceptives or assist with prescribing such contraceptives as permitted pursuant to section 20-633k of the Connecticut General Statutes. The pharmacist and pharmacy technician shall maintain a valid certificate of completion at all times and produce a copy of such certificate of completion to the department upon request.

Sec. 20-633k-3. Screening: (a) Except as provided in subsection (b) of this section, each prescribing pharmacist shall assist the patient in completing the screening document for an emergency contraceptive or the screening document for a hormonal contraceptive, as applicable.

(b) A pharmacy technician who has obtained a certificate of completion from an educational training program approved by the department may, at the prescribing pharmacist's request, assist the prescribing pharmacist in prescribing an emergency contraceptive or hormonal contraceptive by:

(1) Providing the applicable screening document for an emergency contraceptive or screening document for a hormonal contraceptive to a patient and assisting a patient in completing the documents;

(2) Taking and recording the patient's blood pressure; and

(3) Documenting the patient's medical history.

(c) The completed screening document for an emergency contraceptive or screening document for a hormonal contraceptive, as applicable, shall be reviewed by a prescribing pharmacist.

(d) Nothing in this section shall prevent a prescribing pharmacist from requesting that any screening document for a hormonal contraceptive be completed more frequently than every twelve months by the patient in order to obtain a prescription for a hormonal contraceptive.

(e) Each prescribing pharmacist shall use the screening document for an emergency contraceptive and screening document for a hormonal contraceptive, as applicable. Any additional information provided by the prescribing pharmacist to the patient related to the prescription of an emergency or hormonal contraceptive shall be provided as a separate document.

Sec. 20-633k-4. Prescribing of Hormonal Contraception: (a) In order to prescribe hormonal contraception to a patient, a prescribing pharmacist shall:

(1) Administer the screening document for a hormonal contraceptive; and

(2) Conduct an interview of the patient.

(b) If a prescribing pharmacist determines that the prescribing of hormonal contraception is not clinically appropriate based on the treatment algorithm for hormonal contraceptives for any reason, such prescribing pharmacist shall (1) refer the patient to a practitioner, (2) not prescribe the hormonal contraceptive, and (3) document the reasons for such determination and referral on the screening document for a hormonal contraceptive.

(c) The prescription written by the prescribing pharmacist, including the time period for the initial filling of the prescription, along with any refills, shall not exceed a total of twelve months.

(d) Any pharmacist may dispense a prescription written by a prescribing pharmacist or practitioner.

(e) Upon meeting with the patient, the prescribing pharmacist shall discuss and subsequently provide a copy of the completed screening document for a hormonal contraceptive to the patient, which shall include any documented reasons such pharmacist determined such contraceptive was not clinically appropriate pursuant to subsection (b) of this section.

(f) The prescribing pharmacist shall ensure that such pharmacist is using the most current version of the screening document for a hormonal contraceptive.

Sec. 20-633k-5. Prescribing of Emergency Contraception: (a) In order to prescribe an emergency contraceptive to a patient, a prescribing pharmacist shall:

(1) administer the screening document for an emergency contraceptive; and

(2) conduct an interview of the patient.

(b) If a prescribing pharmacist determines that the prescribing of an emergency contraceptive is not clinically appropriate based on the screening document for an emergency contraceptive for any reason, including, but not limited to, the treatment algorithm for emergency contraceptives, such prescribing pharmacist shall (1) refer the patient to a practitioner, (2) not prescribe the emergency contraceptive, and (3) document the reasons for such determination and referral on the completed screening document.

(c) A prescription for an emergency contraceptive shall not have any refills.

(d) Any pharmacist may dispense a prescription written by a prescribing pharmacist or practitioner.

(e) Upon meeting with the patient, the prescribing pharmacist shall discuss and subsequently provide the completed screening document for an emergency contraceptive, which shall include any reasons documented pursuant to subsection (b) of this section, which explains the potential side effects of the emergency contraceptive and when to seek care from a healthcare provider, practitioner or care facility regardless of whether the patient was prescribed an emergency contraceptive.

(f) The prescribing pharmacist shall ensure that such pharmacist is using the most current version of the screening document for emergency contraceptive.

Sec. 20-633k-6. Record Keeping: (a) Completed screening documents for an emergency contraceptive and completed screening documents for a hormonal contraceptive shall be maintained in the same manner as the prescription on file at the pharmacy that dispensed the applicable contraceptive to the patient prescribed such contraceptive not less than three years after the date of such prescription.

(b) All records created as part of any pharmacist prescribing a hormonal or an emergency contraceptive shall be maintained for not less than three years after the date of such prescription.

(c) All records created as part of any pharmacist prescribing hormonal or emergency contraceptives shall be readily retrievable and provided to the department, upon request, by such pharmacist not later than forty-eight hours after such request.

Sec. 20-633k-7. Transfers: (a) A pharmacy is not required to have a prescribing pharmacist to accept a transfer of a prescription for a hormonal contraceptive and such prescription, including a prescription written by a prescribing pharmacist, may be transferred to any pharmacy.

(b) All transferred prescriptions shall comply with the requirements set forth in section 20-616 of the Connecticut General Statutes.

Sec. 20-633k-8. Communication to a Primary Care Provider: (a) Except as provided in subsection (b) of this section, each prescribing pharmacist who prescribes a hormonal or an emergency contraceptive shall provide notice to the patient's primary care provider of the prescription not later than twenty-four hours after prescribing such hormonal or emergency contraceptive.

(b) In the event the patient does not disclose the identity of the patient's primary care provider, the prescribing pharmacist shall provide the patient with any relevant documentation.

Sec. 20-633k-9. Confidentiality: (a) The prescribing pharmacist shall take reasonable precautions to ensure that the patient is able to provide the required health information, including, but not limited to, responses to the screening document and any interview questions, in a confidential manner.

(b) No pharmacist or pharmacy shall reveal any records or information concerning the nature of pharmaceutical services rendered to a patient in contravention of state or federal law.

Sec. 20-633k-10. Prohibited Acts: (a) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive in an instance where the screening document for a hormonal contraceptive or screening document for an emergency contraceptive indicates that referral to a practitioner is clinically appropriate.

(b) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive without a completed screening document for such contraceptive.

(c) A prescribing pharmacist shall not issue a prescription for a total supply period greater than twelve months based on the directions for use provided on the prescription.

(d) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive outside of the approved use stated in the product's package insert approved by the Federal Food and Drug Administration or successor agency.

(e) A prescribing pharmacist shall not prescribe a medical device, with or without hormonal contraceptives, that is implanted by a practitioner for the purpose of preventing pregnancy, including intrauterine and implantable devices.

Sec. 20-633l. Disclosure of information by licensed pharmacists regarding drugs used for termination of pregnancy. Prohibition concerning automatic reciprocal jurisdiction: (a) For the purposes of this section, "drug", "pharmacist" and "pharmacy" have the same meanings as provided in section 20-571.

(b) A pharmacist who is employed by a pharmacy that has been approved to dispense drugs for the termination of a pregnancy shall provide to any patient who is seeking any such drug a list of the pharmacies nearest to such patient that dispense such drug if the pharmacy does not have a supply of such drug.

(c) A pharmacist who is, or has been, licensed in another state or jurisdiction shall not be subject to automatic reciprocal discipline in this state for any disciplinary action taken in such other state or jurisdiction, provided such disciplinary action was based solely on the termination of a pregnancy under conditions which would not violate the laws of this state.

Sec. 20-634. Dispensing group practices and dispensing assistants. Registration. Fees. Exemptions. Prohibitions. Penalties: (a) For the purposes of this section:

(1) "Centralized dispensing practitioner" means a prescribing practitioner (A) who is employed by, or affiliated with, a dispensing group practice, and (B) whom the dispensing group practice designates as the prescribing practitioner who is authorized to dispense legend drugs and legend devices on behalf of other prescribing practitioners who are employed by, or affiliated with, such dispensing group practice;

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

(3) "Dispense" has the same meaning as provided in section 20-571;

(4) "Dispensing assistant" means an individual who is (A) registered with the department under subdivision (1) of subsection (d) of this section, (B) employed by a dispensing group practice, and (C) supervised by (i) the centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice;

(5) "Dispensing group practice" means a group practice that (A) centralizes the dispensing of legend drugs or legend devices prescribed by prescribing practitioners who are employed by, or affiliated with, the group practice through (i) a centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice, and (B) is registered with the department pursuant to subsection (b) of this section;

(6) "Group practice" has the same meaning as provided in section 19a-486i;

(7) "Legend device" has the same meaning as provided in section 20-571;

(8) "Legend drug" has the same meaning as provided in section 20-571;

(9) "Pharmacist" has the same meaning as provided in section 20-571;

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

(11) "Prescribing practitioner" has the same meaning as provided in section 20-571;

(12) "Prescription" has the same meaning as provided in section 20-635;

(13) "Professional samples" has the same meaning as provided in section 20-14c; and

(14) "Seventy-two-hour supply" means a quantity of a legend drug or legend device that does not exceed the dosage amount necessary for seventy-two hours according to the directions for use of the legend drug or legend device.

(b) (1) No group practice may dispense legend drugs or legend devices as a dispensing group practice unless such group practice submits an application to, and receives a registration from, the department under this subdivision. Each application submitted to the department under this subdivision shall be submitted on a form, and in a manner, prescribed by the department and designate a centralized dispensing practitioner or a pharmacist who is employed by the group practice and shall serve as the primary contact for the department, and shall be accompanied by a registration fee in the amount of two hundred dollars. Each registration issued pursuant to this subdivision shall be valid for a period of two years, and the department may renew such registration for additional two-year periods upon its receipt of a complete renewal application submitted on a form, and in a manner, prescribed by the department and a renewal fee of two hundred dollars.

(2) Except as provided in subdivision (3) of this subsection, each dispensing group practice that dispenses, or proposes to dispense, in this state more than a seventy-two-hour supply of any legend drug or legend device shall (A) register for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254, and (B) comply with all reporting and usage requirements for the electronic prescription drug monitoring program as set forth in subsection (j) of section 21a-254.

(3) No dispensing group practice that dispenses, or proposes to dispense, less than a seventy-two-hour supply of legend drugs or legend devices shall be subject to the provisions of subdivision (2) of this subsection if such dispensing group practice exclusively dispenses such supply of legend drugs or legend devices as professional samples.

(c) A dispensing group practice that employs a pharmacist for the purpose of dispensing legend drugs or legend devices shall not be required to obtain a pharmacy license for the dispensing group practice's premises under section 20-594. The pharmacist shall report directly to a prescribing practitioner who is employed by, or affiliated with, the dispensing group practice, and may supervise dispensing assistants employed by such dispensing group practice, perform in-process and final checks without obtaining any additional verification from the prescribing practitioner to whom such pharmacist reports and perform any component of the practice of pharmacy.

(d) (1) No individual may act as a dispensing assistant unless such individual submits an application to, and receives a registration from, the department under this subdivision. Each application submitted to the department under this subdivision shall be submitted on a form, and in a manner, prescribed by the department, and shall be accompanied by a registration fee in the amount of one hundred dollars. Each registration issued pursuant to this subdivision shall be valid for a period of two years, and the department may renew such registration for additional two-year periods upon its receipt of a complete renewal application submitted on a form, and in a manner, prescribed by the department and a renewal fee of one hundred dollars.

(2) A dispensing assistant who is registered with the department under subdivision (1) of this subsection may perform the duties of a pharmacy technician, provided the dispensing assistant performs such duties under the supervision of a prescribing practitioner who is employed by or affiliated with, or a pharmacist who is employed by, the dispensing group practice that employs such dispensing assistant. Each dispensing assistant shall be subject to the same responsibilities and liabilities set forth in this chapter, and any regulations adopted pursuant to this chapter, concerning pharmacy technicians.

(e) A prescribing practitioner who is employed by, or affiliated with, a dispensing group practice may dispense legend drugs or legend devices to the prescribing practitioner's patients without engaging the services of the centralized dispensing practitioner or a pharmacist who is employed by the dispensing group practice.

(f) (1) No centralized dispensing practitioner or pharmacist employed by a dispensing group practice shall dispense a legend drug, legend device or controlled substance for, or order that a legend drug, legend device or controlled substance be dispensed to, any individual who is not being treated by a prescribing practitioner who is employed by, or affiliated with, the dispensing group practice.

(2) No dispensing group practice shall accept or dispense any prescription from a prescribing practitioner who is not employed by, or affiliated with, the dispensing group practice.

(3) No dispensing group practice shall exhibit within or upon the outside of the premises occupied by such dispensing group practice, or include in any advertisement for such dispensing group practice, (A) the words "drug store", "pharmacy", "apothecary" or "medicine shop" or any combination thereof, or (B) any other display, symbol or word indicating that such dispensing group practice or premises is a pharmacy.

(g) The department may refuse to issue or renew a dispensing group practice registration under subsection (b) of this section or a dispensing assistant registration under subsection (d) of this section, revoke, suspend or place conditions on a dispensing group practice's registration issued under subsection (b) of this section or a dispensing assistant's registration under subsection (d) of this section, and assess a civil penalty not to exceed one thousand dollars per violation if the dispensing group practice or a centralized dispensing practitioner, dispensing assistant or pharmacist employed by, or acting as an agent on behalf of, such dispensing group practice violates any provision of (1) subsections (a) to (f), inclusive, of this section, or (2) this chapter, or any regulations adopted pursuant to this chapter, concerning dispensing legend drugs or legend devices.

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.

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.

Sec. 20-636. Sign re storage and disposal of prescription drugs. Sticker or label on container or packaging:

(a) Each pharmacy, as defined in section 20-635, shall post a sign in a conspicuous place on the premises of such pharmacy, notifying consumers that they may visit the Internet web site of the Department of Consumer Protection for information concerning the safe storage of prescription drugs and disposal of unused and expired prescription drugs.

(b) On and after January 1, 2024, each pharmacy shall affix a fluorescent orange sticker or label to each container or packaging in which an opioid drug, as defined in section 20-14o, or controlled substance in schedule II, III, IV or V, is sold or dispensed, containing the following statement in black ink:

"DANGER TO CHILDREN

KEEP OUT OF REACH".

(c) Not later than July 1, 2024, the Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to provide guidance for pharmacies concerning the optimal size of and font size used on the stickers or labels required pursuant to subsection (b) of this section. Not later than September 1, 2023, the commissioner shall implement policies and procedures necessary to implement such guidance while in the process of adopting such policies and procedures as regulations. Policies and procedures implemented pursuant to this section shall be valid until the time final regulations are adopted.

Sec. 20-636-1. Definitions: In addition to the defined terms set forth in section 20-571 of the Connecticut General Statutes, as used in this section and sections 20-636-2 to 20-636-4, inclusive, of the Regulations of Connecticut State Agencies:

(1) “Container” means the receptacle that holds the legend drug, labeled with information required by federal and state law for dispensing;

(2) “Controlled substance” means an opioid drug, as defined in section 20-14o of the Connecticut General Statutes, or a controlled substance in schedule II, III, IV or V;

(3) “Fluorescent orange” means the hexadecimal color #ff6700 with RGB values of R:255, G:103, B:0, and CMYK values of C:0, M:60, Y:100, K:0;

(4) “Packaging” means the bag, box, wrapping, or other material used to contain or enclose the container for delivery to a patient; and

(5) “Label or sticker” means symbols, graphics or other information about the controlled substance, either directly on the container or packaging, or affixed to the container or packaging on separate material such as paper or film.

Sec. 20-636-2. Dimensions: (a) The label or sticker shall be round and no less than one and one-quarter inch in diameter.

(b) The label or sticker shall be fluorescent orange in color with black text.

Sec. 20-636-3. Warning Statement: (a) Each label or sticker shall have a single black graphic of an equilateral triangle of no less than 0.67 inches per side, containing an exclamation point, of no less than 0.3 inches in height, inside the triangle.

(b) Each label or sticker shall contain the following warning statement in black ink: "DANGER TO CHILDREN KEEP OUT OF REACH" in flat regular Arial or Calibri typeface and no less than eight-point font in size.

(c) The text and the graphic on the label or sticker shall be clearly legible and unobscured.

(d) A label or sticker exemplar shall be published on the Department’s internet website for use by pharmacies on all applicable packaging and containers and any pharmacy’s use of such exact exemplar on applicable packaging and containers shall constitute compliance with the requirements set forth in this section and section 20-636-2 of the Regulations of Connecticut State Agencies.

Sec. 20-636-4. Placement: A pharmacy shall ensure a label or sticker (1) is directly on, or firmly affixed to, the outer surface of the container or packaging, (2) is legible, unobscured, prominently placed and conspicuous so that it is readily visible to the patient; and (3) does not: (A) obstruct the opening of the container or packaging; (B) impede the delivery of the controlled substance; or (C) obscure any information on the prescription label affixed to the container or packaging that is required by federal and state law.

Sec. 20-638. Definitions: As used in this section and sections 20-638a to 20-638c, inclusive:

(1) "Assistance program" has the same meaning as provided in subsection (a) of section 19a-12a;

(2) "Chemical dependency" has the same meaning as provided in subsection (a) of section 19a-12a;

(3) "Health care professionals" has the same meaning as provided in subsection (a) of section 19a-12a;

(4) "Hospital" has the same meaning as provided in section 19a-490;

(5) "Medical review committee" has the same meaning as provided in subsection (a) of section 19a-12a;

(6) "Pharmacist" has the same meaning as provided in section 20-571;

(7) "Pharmacy" has the same meaning as provided in section 20-571; and

(8) "Pharmacy intern" has the same meaning as provided in section 20-571.

Sec. 20-638a. Admission of pharmacists and pharmacy interns. Referral to department. Notification of disciplinary action against program participants. Recordkeeping and confidentiality. Annual reports and audit: (a) Any pharmacist or pharmacy intern may access the assistance program, provided the assistance program:

(1) Satisfies the requirements established in this section; and

(2) includes at least one medical review committee that satisfies the requirements established in subsections (b) to (h), inclusive, of this section.

(b) (1) Prior to admitting any pharmacist or pharmacy intern into the assistance program, a medical review committee shall:

(A) Determine whether such pharmacist or pharmacy intern is an appropriate candidate for rehabilitation and participation in such program; and

(B) establish the terms and conditions for such pharmacist's or pharmacy intern's participation in such program.

(2) No action taken by a medical review committee pursuant to subdivision (1) of this subsection shall be construed as the practice of medicine or mental health care.

(c) (1) Except as provided in subsection (f) of this section, a medical review committee shall not admit into the assistance program any pharmacist or pharmacy intern who:

(A) Has any pending disciplinary charges, prior history of disciplinary action or consent order issued by any professional licensing, registering or disciplinary body;

(B) has been charged with, or convicted of, (i) any felony under the laws of this state, or (ii) any offense committed outside of this state that, if committed within this state, would constitute a felony under the laws of this state; or

(C) is alleged to have harmed a patient.

(2) A medical review committee shall refer any pharmacist or pharmacy intern who satisfies the criteria established in subdivision (1) of this subsection to the Department of Consumer Protection, and shall submit to the department all records and files maintained by such committee concerning such pharmacist or pharmacy intern. Such referral may include the medical review committee's recommendations concerning which intervention, referral assistance, rehabilitation or support services are appropriate for such pharmacist or pharmacy intern.

(d) (1) The assistance program shall regularly review the sources of information available to such program to determine whether, and a pharmacist or pharmacy intern participating in such program shall immediately send notice to such program if:

(A) Any disciplinary charges are filed against such pharmacist or pharmacy intern;

(B) any professional licensing, registering or disciplinary body takes any disciplinary action against such pharmacist or pharmacy intern; or

(C) such pharmacist or pharmacy intern is charged with, or convicted of, (i) any felony under the laws of this state, or (ii) any offense committed outside of this state that, if committed within this state, would constitute a felony under the laws of this state.

(2) Upon determining that a pharmacist or pharmacy intern satisfies the criteria established in, or receiving any notice sent by a pharmacist or pharmacy intern pursuant to, subdivision (1) of this subsection, the assistance program shall refer the pharmacist or pharmacy intern to the Department of Consumer Protection and submit to the department all records and files maintained by the assistance program concerning such pharmacist or pharmacy intern.

(e) The assistance program shall refer a pharmacist or pharmacy intern to the Department of Consumer Protection, and shall submit to the department all records and files maintained by such program concerning the pharmacist or pharmacy intern, if:

(1) The assistance program determines that such pharmacist or pharmacy intern (A) is unable to practice such pharmacist's or pharmacy intern's profession with skill and safety or poses a threat to the health and safety of any person or patient in the health care or pharmacy setting, and (B) does not refrain from practicing such pharmacist's or pharmacy intern's profession or fails to participate in a recommended program of rehabilitation; or

(2) such pharmacist or pharmacy intern fails to comply with the terms or conditions of, or refuses to participate in, the assistance program.

(f) Upon receiving a referral under subdivision (2) of subsection (c) of this section, subdivision (2) of subsection (d) of this section, subsection (e) of this section or subparagraph (A) of subdivision (3) of subsection (e) of section 19a-12b, the Department of Consumer Protection shall determine if the pharmacist or pharmacy intern is eligible to participate in, or continue participating in, the assistance program and whether such participation shall be treated as confidential as set forth in subsection (h) of

this section. The Department of Consumer Protection may seek the advice of the assistance program and professional health care societies or organizations in determining which intervention, referral assistance, rehabilitation or support services are appropriate for the pharmacist or pharmacy intern. If the Department of Consumer Protection determines that the pharmacist or pharmacy intern is an appropriate candidate for confidential participation in the assistance program, and such pharmacist or pharmacy intern participates in such program in accordance with the terms agreed upon by such program, the department and such pharmacist or pharmacy intern, the entire record of the referral and investigation of such pharmacist or pharmacy intern shall be confidential and shall not be disclosed, except at the request of such pharmacist or pharmacy intern, for the duration of such pharmacist's or pharmacy intern's participation in, and following successful completion of, such assistance program.

(g) Upon written notice to the Department of Consumer Protection by the oversight committee that the assistance program is in compliance with a corrective action plan developed pursuant to subdivision (2) of subsection (e) of section 19a-12b, the department may refer pharmacists and pharmacy interns to the assistance program for continued intervention, rehabilitation, referral assistance or support services and shall submit to the assistance program all records and files concerning such pharmacists and pharmacy interns.

(h) (1) All information given or received in connection with any intervention, rehabilitation, referral assistance or support services provided by the assistance program pursuant to this section, including, but not limited to, the identity of any pharmacist or pharmacy intern seeking or receiving such intervention, rehabilitation, referral assistance or support services, shall be confidential and shall not be disclosed:

(A) To any third person or entity, unless such disclosure is reasonably necessary for the purposes of (i) such intervention, rehabilitation, referral assistance or support services, or (ii) an audit conducted in accordance with subsection (j) of this section; or

(B) in any civil or criminal case or proceeding or in any administrative or other legal proceeding unless (i) the pharmacist or pharmacy intern seeking or obtaining such intervention, rehabilitation, referral assistance or support services waives such confidentiality, or (ii) such disclosure is otherwise required by law.

(2) Except as provided in subdivision (1) of this subsection, no person shall request or require in any civil or criminal case or proceeding, or in any administrative or other legal proceeding, disclosure of any information given or received in connection with the intervention, rehabilitation, referral assistance or support services provided pursuant to this section.

(3) The proceedings of a medical review committee shall not be subject to discovery or introduced into evidence in any civil action for or against a pharmacist or pharmacy intern arising out of matters that are subject to evaluation and review by such committee, and no person who was in attendance at such proceedings shall be permitted or required to testify in any such civil action as to the content of such proceedings. Nothing in this subdivision shall be construed to preclude in any civil action:

(A) The use of any writing recorded independently of such proceedings;

(B) the testimony of any person concerning such person's knowledge, acquired independently of such proceedings, about the facts that form the basis for instituting such civil action;

(C) arising out of allegations of patient harm caused by health care or pharmacy services rendered by a pharmacist or pharmacy intern who, at the time such services were rendered, had been requested to refrain from practicing such pharmacist's or pharmacy intern's profession or whose practice of such profession was restricted, the disclosure of such request to refrain from practicing or such restriction; or

(D) against a pharmacist or pharmacy intern, disclosure of the fact that the pharmacist or pharmacy intern participated in the assistance program, the dates of participation, the reason for participation and confirmation of successful completion of the assistance program, provided a court of competent jurisdiction has determined that good cause exists for such disclosure after (i) notification to such pharmacist or pharmacy intern of the request for such disclosure, and (ii) a hearing concerning such disclosure at the request of any party, and provided further, the court imposes appropriate safeguards against unauthorized disclosure or publication of such information.

(4) Nothing in this subsection shall be construed to prevent the assistance program from disclosing any information in connection with any administrative proceeding related to the imposition of any disciplinary action against any pharmacist or pharmacy intern whom the assistance program refers to the Department of Consumer Protection pursuant to subdivision (2) of subsection (c) of this section, subdivision (2) of subsection (d) of this section, subsection (e) of this section or subparagraph (A) of subdivision (3) of subsection (e) of section 19a-12b.

(i) (1) The assistance program shall report annually to the appropriate professional licensing or registering board or commission or, in the absence of such board or commission, to the Department of Consumer Protection:

(A) On the number of pharmacists and pharmacy interns participating in the assistance program who are under the jurisdiction of such board or commission or, in the absence of such board or commission, the Department of Consumer Protection;

(B) the purposes for participating in the assistance program; and

(C) whether participants are practicing their profession with skill and safety, and without posing a threat to the health and safety of any person or patient, in the health care or pharmacy setting.

(2) On or before December thirty-first, annually, the assistance program shall report the information described in subdivision (1) of this subsection 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.

(j) (1) If the Department of Public Health notifies the Department of Consumer Protection that the Department of Public Health has waived the annual audit requirement established in subsection (l) of section 19a-12a, the Department of Consumer Protection may require an audit of the assistance program for the year that is the subject of such waiver for the purposes of examining the quality control of such program and ensuring compliance with the requirements established in this section. Each audit conducted pursuant to this subsection shall:

(A) Be conducted on the premises of the assistance program by an auditor (i) who has been selected by the assistance program, and (ii) whom the assistance program and the Department of Consumer Protection have jointly determined is qualified to conduct such audit; and

(B) consist of a random sampling of at least twenty per cent of the assistance program's files for pharmacists and pharmacy interns or ten such files, whichever is greater.

(2) Prior to conducting an audit pursuant to this subsection, the auditor shall agree, in writing:

(A) Not to copy any of the assistance program's files or records;

(B) not to remove any of the assistance program's files or records from the premises of such program;

(C) to destroy all personally identifying information about pharmacists and pharmacy interns participating in the assistance program upon completion of the audit;

(D) not to disclose any personally identifying information about any pharmacist or pharmacy intern participating in the assistance program to any person or entity other than a person employed by the assistance program who is authorized by such program to receive such disclosure; and

(E) not to disclose in any audit report any personally identifying information about any pharmacist or pharmacy intern participating in the assistance program.

(3) Upon completion of an audit conducted pursuant to this subsection, the auditor shall submit a written audit report to the assistance program, the Department of Consumer Protection, the Professional Assistance Oversight Committee established under section 19a-12b, and 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.

Sec. 20-638b. Petition re inability of pharmacist or pharmacy intern to practice with reasonable skill or safety. Report re arrest or disciplinary action. Investigation. Disclosure. Procedure:

(a) (1) Any health care professional, hospital, pharmacy, pharmacist or pharmacy intern shall, and any other person may, file a petition with the Department of Consumer Protection when such health care professional, hospital, pharmacy, pharmacist, pharmacy intern or other person has any information that appears to show that a pharmacist or pharmacy intern is, or may be, unable to practice such pharmacist's or pharmacy intern's profession with reasonable skill or safety for any of the following reasons:

(A) Physical illness or loss of motor skill, including, but not limited to, deterioration through the aging process;

(B) emotional disorder or mental illness;

(C) abuse or excessive use of drugs, including, but not limited to, alcohol, narcotics or other chemicals;

(D) illegal, incompetent or negligent conduct in the practice of such pharmacist's or pharmacy intern's profession;

(E) possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other medically proper purposes;

(F) misrepresentation or concealment of a material fact in obtaining or reinstating a license or registration to practice such pharmacist's or pharmacy intern's profession; or

(G) violation of any provision of this chapter or any regulation adopted under this chapter.

(2) A health care professional, hospital, pharmacy, pharmacist or pharmacy intern shall, and any other person may, file a petition described in subdivision (1) of this subsection not later than thirty days after

obtaining the information to support such petition. Each petition shall be filed with the Department of Consumer Protection in a form and manner prescribed by the Commissioner of Consumer Protection.

(b) Any health care professional, hospital, pharmacy, pharmacist or pharmacy intern that refers a pharmacist or pharmacy intern to the assistance program for intervention shall be deemed to have satisfied the obligations imposed on such health care professional, hospital, pharmacy, pharmacist or pharmacy intern under subsection (a) of this section with respect to the pharmacist's or pharmacy intern's inability to practice such pharmacist's or pharmacy intern's profession with reasonable skill or safety due to chemical dependency, emotional or behavioral disorder or physical or mental illness.

(c) Any pharmacist or pharmacy intern who has been the subject of an arrest arising out of an allegation of the possession, use, prescription for use or distribution of alcohol, a controlled substance or a legend drug shall, not later than thirty days after such arrest, send notice to the Department of Consumer Protection, in a form and manner prescribed by the Commissioner of Consumer Protection, disclosing such arrest. Such pharmacist or pharmacy intern shall be deemed to have satisfied such notice requirement if such pharmacist or pharmacy intern seeks intervention with the assistance program during such thirty-day period.

(d) If a duly authorized professional disciplinary agency of any state, the District of Columbia, a United States possession or territory or a foreign jurisdiction takes any disciplinary action against a pharmacist or pharmacy intern that is similar in nature to any action specified in section 20-579, the pharmacist or pharmacy intern shall report such disciplinary action to the Department of Consumer Protection not later than thirty days after such agency takes such action. Any failure to report in accordance with the provisions of this subsection may constitute grounds for disciplinary action under this chapter.

(e) No health care professional, hospital, pharmacy, pharmacist, pharmacy intern or other person who files a petition pursuant to subsection (a) of this section, or provides any information to the Department of Consumer Protection or the assistance program, shall, without a showing of malice, be liable for damage or injury to the pharmacist or pharmacy intern for filing such petition or providing such information. The assistance program shall not be liable for damage or injury to the pharmacist or pharmacy intern without a showing of malice.

(f) The Department of Consumer Protection shall investigate each petition filed pursuant to subsection (a) of this section, in accordance with the provisions of section 21a-11, to determine if probable cause exists to issue a statement of charges and institute proceedings against the pharmacist or pharmacy intern under subsection (i) of this section.

(g) As part of an investigation of a petition filed pursuant to subsection (a) of this section, the Department of Consumer Protection may order the pharmacist or pharmacy intern to submit to a physical or mental examination to be performed by a physician or an advanced practice registered nurse chosen from a list approved by the department. The Department of Consumer Protection may seek the advice of established medical organizations or health care professionals in determining the nature and scope of any diagnostic examinations to be used as part of any such physical or mental examination. The chosen physician or advanced practice registered nurse shall make a written statement of such physician's or advanced practice registered nurse's findings.

(h) If the pharmacist or pharmacy intern fails to obey the Department of Consumer Protection's order to submit to an examination or attend a hearing, the department may petition the superior court for the judicial district of Hartford to order such examination or attendance and said court, or any judge assigned to said court, shall have jurisdiction to issue such order.

(i) Subject to the provisions of section 4-182, the Department of Consumer Protection shall not restrict, suspend or revoke any license or registration, or limit a pharmacist's or pharmacy intern's right to practice the pharmacist's or pharmacy intern's profession, until the pharmacist or pharmacy intern has been given notice and opportunity for hearing in accordance with said section.

Sec. 20-638c. Pharmacy professional assistance program account: There is established an account to be known as the "pharmacy professional assistance program account" which shall be a separate, nonlapsing account within the General Fund. The account shall contain any moneys required by law to be deposited in the account. Moneys in the account shall be paid by the Commissioner of Consumer Protection to the assistance program for the provision of education, prevention, intervention, referral assistance, rehabilitation and support services to pharmacists and pharmacy interns who have a chemical dependency, an emotional or behavioral disorder or a physical or mental illness.

CHAPTER 416 - DEPARTMENT OF CONSUMER PROTECTION

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. 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. Refund of fees for unused permits. Fine for payment by check returned as uncollectible. Fine for late renewal of license, certificate or registration. Reinstatement of lapsed license: (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. In addition, the commissioner may require the applicant to pay to the department any fees charged by a financial institution to the department as a result of such returned check.

(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.

(d) Notwithstanding any other provision of the general statutes, each applicant whose license has lapsed for a period longer than the length of time allowing automatic reinstatement may apply for reinstatement to the appropriate board. Upon receipt of such application and payment of the fee, the board may, at its discretion, reinstate a lapsed license without examination, provided such application for reinstatement is accompanied by a notarized letter and supporting documentation attesting to the applicant's related work experience in their occupation or profession from the time he or she had let such license lapse. Such applicant, upon approval by the board, shall pay all back license and late fees in order for such license to be reinstated.

Sec. 21a-5. 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. 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 glass work and flat glass work, established under chapter 393;

(4) Repealed by P.A. 99-73, S. 10;

(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;

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

(16) The State Board of Accountancy established under section 20-280.

Sec. 21a-7. Powers and duties of boards and commissions within Department of Consumer Protection: (a) Each board or commission within 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. Any exercise of such functions by such a board or commission that is adverse to a party shall be a proposed decision and subject to approval, modification or rejection by the commissioner.

(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 or the Commissioner of Consumer Protection deems necessary. 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 or the Commissioner 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 (A) thirty days after the date of submission for such application or completed renewal application, as applicable, or (B) a period of time deemed appropriate by the Commissioner of Consumer Protection, but not to exceed sixty days after such date of submission.

(b) Each board or commission within the Department of Consumer Protection under section 21a-6 that makes a proposed final decision that is adverse to a party as described in subdivision (1) of subsection (a) of this section, shall submit such proposed decision to the Commissioner of Consumer Protection. Not later than thirty calendar days after receipt of any such proposed decision, the Commissioner of Consumer Protection shall notify such board or commission that the commissioner shall render the final decision concerning such matter. Not later than thirty days after receipt of any such proposed decision, the commissioner shall approve, modify or reject the proposed decision or remand the proposed decision for further review or for the taking of additional evidence. The commissioner shall notify the board or commission in writing of the commissioner's decision and include in such notification the rationale for such decision. The decision of the commissioner shall be the final decision in accordance with section 4-180 for purposes of reconsideration in accordance with section 4-181a or appeal to the Superior Court in accordance with section 4-183.

Sec. 21a-8. 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.

(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 quarterly a list of all complaints received within the previous quarter 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. 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.

(9) The department may contract with a third party, if the commissioner deems it necessary, 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) Not later than January 15, 2015, and annually thereafter, the commissioner, in accordance with section 11-4a, shall report the following to the joint standing committee of the General Assembly having cognizance of matters relating to consumer protection and occupational licensing: (1) The total number of complaints received by the department in the previous calendar year concerning the work and practice of persons licensed, registered or certified by the boards or commissions specified in subdivisions (1) and (3) of section 21a-6, (2) the nature of each complaint, (3) the department's resolution of each complaint, including, if applicable, whether the complaint (A) was dismissed because the allegation, if substantiated, would not constitute a violation of any statute or regulation, (B) was investigated, (C) was dismissed, following an investigation, for lack of probable cause, (D) was resolved by a settlement, and whether a penalty was imposed pursuant to such settlement, or (E) was brought for formal hearing, and whether a violation was found and a penalty imposed.

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

(1) The commissioner shall, in consultation with each board or commission, exercise the functions of licensing, certification, registration, accreditation of schools and the rendering of findings, orders and adjudications.

(2) 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.

(3) 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 adopted 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.

(4) 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; or (D) impose a fine not exceeding one thousand dollars per violation. The commissioner may discontinue, suspend or rescind any action taken under this subdivision. If a license, registration or certificate is voluntarily surrendered or is not renewed, the commissioner shall not be prohibited from suspending, revoking or imposing other penalties permitted by law on any such license, registration or certificate.

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. Uniform rules of procedure. Regulations re subjects within jurisdiction of boards and commissions within Department of Consumer Protection. Prohibited acts by practitioners. Rejection of decisions with anticompetitive effect. 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 (4) 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, commission or commissioner or to aid another in obtaining a license, registration or certificate issued by the board, commission or commissioner; (2) performs work beyond the scope of the license, registration or certificate issued by the board, commission or commissioner; (3) illegally uses or transfers a license, registration or certificate issued by the board, commission or commissioner; (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 (4) 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) In order to ensure compliance with the provisions of the Sherman Act, 15 USC 1 et seq., as amended from time to time, the Commissioner of Consumer Protection shall reject any proposed final decision of a board or commission submitted for the commissioner's approval pursuant to section 21a-7 if the commissioner finds such decision will have an anticompetitive effect.

(e) 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-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 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 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 recommendations 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 proceedings 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 proceedings;

(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) If any party of record desires a copy of the transcript, it will be made available 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 Connecticut 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.

Sec. 21a-10. 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-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 following 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:

(1) home improvement contractor; and

(2) home improvement salesman.

Sec. 21a-11. Powers and duties of commissioner: (a) 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.

(b) 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.

Sec. 21a-12f. Program for collection and disposal of unwanted pharmaceuticals. Public awareness campaign. Regulations: (a) The Department of Consumer Protection shall, in consultation with the Connecticut Pharmacists Association and the Connecticut Police Chiefs Association, develop and implement a program for the collection and disposal of unwanted pharmaceuticals. Such program shall provide for (1) a secure locked box that is accessible to the public on a twenty-four-hour daily basis

for the anonymous drop-off of unwanted pharmaceuticals at each municipal police station, and (2) the transport of such pharmaceuticals to an appropriate facility for witnessed incineration.

(b) The Department of Consumer Protection shall, within available appropriations, organize a public awareness campaign to educate the public concerning the dangers of unsafe disposal of pharmaceuticals and of the availability of the pharmaceutical collection and disposal program at municipal police stations.

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

Sec. 21a-63. 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-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 a representative 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 Connecticut permit.

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 thermometer 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, retention 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 manufacturer'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.

Sec. 21a-64. 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. 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 (3) of section 20- 571, as amended by this act, 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 syringe services 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 (24) 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 syringe services 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) A registered syringe service program established pursuant to section 19a-124 may apply to the Department of Consumer Protection for approval to provide access to not more than ten hypodermic needles and syringes per transaction to program participants authorized by said department, through a secured machine with the use of a patient specific access number, personalized magnetic strip card or any technology that identifies an individual for the purpose of providing access to hypodermic needles and syringes. The secured machine shall prevent unauthorized access and be immobile. Any products provided by the secured machine shall provide information on access to treatment services to assist individuals obtaining products from the secured machine. The machine shall only be placed in an area where contents can be stored in accordance with the manufacturer's recommendation, unless the secured machine can provide adequate environmental controls independent of the external environment. A locked syringe disposal container to accept hypodermic needles and syringes that have already been used shall

be available as part of the secured machine or in the area around the secured machine. Only authorized personnel of such program may collect the used syringes for proper disposal.

(d) Except as provided in subsection (c) of this section, 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.

(e) 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. 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-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 Connecticut 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 resheathing may occur when technical procedure involved requires resheathing 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 nonreuseable;

(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 Consumer 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 Connecticut 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-67. 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. 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. "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. Registration of manufacturers and wholesalers of drugs. Sale of drugs limited. (a) Definitions: As used in this section:

(1) "Drugs", "devices" and "cosmetics" have the same meanings as defined in section 21a-92, "wholesaler" or "distributor" means a person, including, but not limited to, a medical device and oxygen provider, a third-party logistics provider, a virtual manufacturer or a virtual wholesale distributor, as such terms are defined in section 20-571, whether within or without the boundaries of the state of Connecticut, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in subdivision (24) 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 that supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule II, III, IV or V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a licensed hospital that supplies drugs to another hospital or an authorized practitioner for research purposes, (C) a retail pharmacy that supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, of a rest home with nursing supervision or of a state correctional institution, and (D) a pharmacy within a licensed hospital that contains another hospital wholly within its physical structure that supplies to such contained hospital a quantity of a noncontrolled drug or a schedule II, III, IV, or V controlled substance normally stocked by such hospitals to provide for the needs of a patient, pursuant to a prescription or medication order of an authorized practitioner, receiving inpatient care on a unit that is operated by the contained hospital shall not be deemed a wholesaler under this section;

(2) "manufacturer" means (A) a person, whether within or without the boundaries of the state of Connecticut, who produces, prepares, cultivates, grows, propagates, compounds, converts or processes, directly or indirectly, by extraction from substances of natural origin or by means of chemical synthesis or by a combination of extraction and chemical synthesis, or who packages, repackages, labels or relabels a container under such manufacturer's own or any other trademark or label any drug, device or cosmetic for the purpose of selling such items, or (B) a sterile compounding pharmacy, as defined in section 20-

633b, as amended by this act, that dispenses sterile pharmaceuticals without a prescription or a patient specific medical order;

(3) "drug", "device" and "cosmetic" have the same meanings as provided in section 21a-92; and

(4) "commissioner" means the Commissioner of Consumer Protection or his or her designee.

(b) **Registration of wholesalers and manufacturers of drugs required. Exceptions. 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, except a sterile compounding pharmacy, as defined in subsection (a) of section 20-633b, whose principal place of business is located outside the state, who is registered with the federal Food and Drug Administration or any successor agency and who files a copy of such registration with the commissioner. A fee of one hundred ninety dollars shall be charged for each wholesaler's certificate and renewal thereof. A separate certificate and corresponding fee is required for each location existing in this state and for each location existing outside of this state that distributes products into this state. The fee for a manufacturer's certificate and renewal thereof shall be two hundred eighty-five dollars for manufacturers employing not more than five licensed pharmacists or qualified chemists or both; three hundred seventy-five dollars for manufacturers employing not more than ten licensed pharmacists or qualified chemists or both; and nine hundred forty dollars for manufacturers employing more than ten licensed pharmacists or qualified chemists or both. No such certificate shall be issued to a manufacturer unless such drugs, medical devices or cosmetics are manufactured or compounded under the direct supervision of a licensed pharmacist or a qualified chemist. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant is equipped as to facilities and apparatus to properly carry on the business described in his application and that the applicant conforms to chapter 418 and regulations adopted thereunder.

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

(f) **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 wholesaler or manufacturer shall sell any drugs except to the state or any political subdivision thereof, to another manufacturer or wholesaler, to any hospital recognized by the state as a general or specialty hospital, to any institution having a full-time pharmacist who is actively engaged in the practice of pharmacy in such institution not less than thirty-five hours a week, to a chronic and convalescent nursing home having a pharmacist actively engaged in the practice of pharmacy based upon the ratio of one-tenth of one hour per patient per week but not less than twelve hours per week, to a practicing physician, podiatrist, dentist, optometrist or veterinarian or to a licensed pharmacy or a store to which a permit to sell nonlegend drugs has been issued as provided in section 20-624. The commissioner may adopt such regulations as are necessary to administer and enforce the provisions of this section.

(i) Each registered manufacturer or wholesaler of drugs shall operate a system to identify suspicious orders of controlled substances and shall immediately inform the Director of the Drug Control Division of suspicious orders. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. Each registered manufacturer or wholesaler of drugs shall also send the Drug Control Division a copy of any suspicious activity reporting submitted to the federal Drug Enforcement Administration pursuant to 21CFR 1301.74.

(j) 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. 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-70f. Report of payment or transfer of value by manufacturer to advanced practice registered nurse who is practicing not in collaboration with a physician. Penalty: (a) For purposes of this section:

(1) "Advanced practice registered nurse" means a person licensed pursuant to chapter 378;

(2) "Applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply that is operating in the United States, or in a territory, possession, or commonwealth of the United States;

(3) "Payment or other transfer of value" means a transfer of anything of value, except (A) a transfer of anything of value that is made indirectly to an advanced practice registered nurse through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the advanced practice registered nurse, or (B) a transfer of anything of value that meets the requirements for exclusion under 42 USC 1320a-7h(e)(10), as amended from time to time;

(4) "Covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under subchapter XVIII of chapter 7 of Title 42 of the United States Code or the state Medicaid plan under subchapter XIX or XXI of said chapter or a waiver of such a plan; and

(5) "Covered device" means any device for which payment is available under subchapter XVIII of chapter 7 of Title 42 of the United States Code or the state Medicaid plan under subchapter XIX or XXI of said chapter or a waiver of such a plan.

(b) (1) Not later than July 1, 2017, and annually thereafter, an applicable manufacturer that provides a payment or other transfer of value to an advanced practice registered nurse, who is practicing not in collaboration with a physician in the state, in accordance with subsection (b) of section 20-87a, shall

submit to the Commissioner of Consumer Protection, in the form and manner prescribed by the commissioner, the information described in 42 USC 1320a-7h, as amended from time to time, for the preceding calendar year.

(2) In determining whether an applicable manufacturer is required to submit information concerning a payment or other transfer of value to an advanced practice registered nurse in accordance with the provisions of this subsection, the applicable manufacturer shall refer to the list of advanced practice registered nurses who are authorized to practice not in collaboration with a physician published by the Commissioner of Public Health on the Department of Public Health's Internet web site in accordance with subsection (b) of section 20-87a.

(3) The commissioner may publish such information on the Department of Consumer Protection's Internet web site.

(c) An applicable manufacturer that fails to report in accordance with this section shall be assessed a civil penalty in an amount not less than one thousand dollars or more than four thousand dollars for each payment or other transfer of value not reported.

Sec. 21a-70g. Investigational drug, biological product or device for patients with terminal illnesses. Liability of manufacturer: (a) A manufacturer of an investigational drug, biological product or device, as defined in section 20-14q, may make available the manufacturer's investigational drug, biological product or device to a patient who is eligible under subsection (b) of section 20-14q and may (1) provide the investigational drug, biological product or device to such patient without receiving compensation, or (2) require such patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product or device.

(b) Nothing in this section shall create a cause of action against a manufacturer of an investigational drug, biological product or device that makes available such investigational drug, biological product or device to an eligible patient for any harm done to such patient resulting from the investigational drug, biological product or device.

Sec. 21a-70h: Registration as pharmaceutical marketing firm. Definitions: For the purposes of this section and sections 21a-70i to 21a-70k:

(1) "Commissioner" means the Commissioner of Consumer Protection or the commissioner's authorized representative;

(2) "Contact" means any communication transmitted in person or by telephone, electronic mail, text message or other electronic means between a pharmaceutical representative and a prescribing practitioner or pharmacist, to promote or provide information relating to a legend drug;

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

(4) "Legend drug" has the same meaning as provided in section 20-571;

(5) "Pharmaceutical manufacturer" (A) means a (i) person, whether within or without the boundaries of the state of Connecticut, that (I) produces, prepares, cultivates, grows, propagates, compounds, converts or processes a drug, directly or indirectly, by extraction from substances of natural origin, by

means of chemical synthesis or by a combination of extraction and chemical synthesis, or (II) packages, repackages, labels or relabels a drug container under such manufacturer's own trademark or label, or any other trademark or label, for the purpose of selling the drug, or (ii) sterile compounding pharmacy, as defined in section 20-633b that dispenses sterile pharmaceuticals without a prescription or a patient-specific medical order intended for use in humans, and (B) includes, but is not limited to, a virtual manufacturer, as defined in section 20-571 ;

(6) "Pharmaceutical marketing firm" means a pharmaceutical manufacturer that employs or compensates pharmaceutical representatives;

(7) "Pharmaceutical representative" means any person, including, but not limited to, a sales representative, who markets, promotes or provides information regarding a legend drug for human use to a prescribing practitioner and is employed or compensated by a pharmaceutical manufacturer;

(8) "Pharmacist" has the same meaning as provided in section 20-571; and

(9) "Prescribing practitioner" has the same meaning as provided in section 20-571.

Sec. 21a-70i. Registration of pharmaceutical manufacturer as pharmaceutical marketing firm. Fees. List of employees. Reports: (a) On and after October 1, 2023, a pharmaceutical manufacturer that employs a pharmaceutical representative shall register annually with the department as a pharmaceutical marketing firm, in a form and manner prescribed by the commissioner. No pharmaceutical manufacturer shall authorize an individual to perform the duties of a pharmaceutical representative on such manufacturer's behalf unless such manufacturer has obtained a pharmaceutical marketing firm registration from the department pursuant to this section. Registrations issued pursuant to this section shall expire annually on June thirtieth.

(b) The nonrefundable fee for registration as a pharmaceutical marketing firm and for annual renewal of such registration shall be one hundred fifty dollars. Any pharmaceutical marketing firm that fails to renew its registration on or before June thirtieth shall pay a late fee of one hundred dollars for each year that such firm did not renew, in addition to the annual renewal fee required under this section.

(c) On the date of its initial registration, and annually thereafter, each pharmaceutical marketing firm shall provide to the department a list of all pharmaceutical representatives employed or compensated by such firm. Each pharmaceutical marketing firm shall notify the department, in a form and manner prescribed by the commissioner, of each individual who is no longer employed or compensated as a pharmaceutical representative or who was hired or compensated as a pharmaceutical representative after the date on which such firm provided such annual list, not later than two weeks after such individual leaves employment or was hired or otherwise compensated.

(d) The department shall prominently post on its Internet web site the most recent list provided by each pharmaceutical marketing firm pursuant to subsection (c) of this section.

(e) Any person who is not identified to the department pursuant to subsection (c) of this section shall not perform the duties of a pharmaceutical representative on behalf of the pharmaceutical marketing firm.

(f) Not later than July 1, 2024, and annually thereafter, each pharmaceutical marketing firm shall provide the commissioner with the following information regarding the performance for the previous

calendar year of each of its pharmaceutical representatives identified to the department pursuant to subsection (c) of this section at any time during the previous calendar year, in a form and manner prescribed by the commissioner:

(1) The aggregate number of contacts such pharmaceutical representative had with prescribing practitioners and pharmacists;

(2) The specialty of such prescribing practitioner and each pharmacist with whom such pharmaceutical representative made contact;

(3) Whether product samples, materials or gifts of any value were provided to a prescribing practitioner or such practitioner's staff in a prescribing practitioner's office or to a pharmacist; and

(4) An aggregate report of all free samples, by drug name and strength, in a form and manner prescribed by the commissioner.

(g) The department shall annually compile a report on the activities of pharmaceutical marketing firms in the state. Not later than December 31, 2024, and annually thereafter, the department shall post such report on its Internet web site and submit such report to the Secretary of the Office of Policy and Management.

Sec. 21a-70j. Disclosure by pharmaceutical sales representative engaged in legend drug marketing to prescribing practitioner or pharmacist: Each pharmaceutical marketing firm that employs or compensates a pharmaceutical representative who is engaged in marketing, promoting or providing information regarding a legend drug for human use in this state shall ensure that such pharmaceutical representative discloses, in writing, to a prescribing practitioner or pharmacist, each time such pharmaceutical representative makes contact with the prescribing practitioner or pharmacist:

(1) The list price of a legend drug when such pharmaceutical representative provides information concerning the legend drug to such prescribing practitioner or pharmacist based on the dose and quantity of such legend drug as described in the medication package insert; and

(2) Information on the variation efficacy of the legend drug marketed to different racial and ethnic groups, if such information is available.

Sec. 21a-70k. Authority of commissioner re pharmaceutical marketing firms. Regulations:

(a) The commissioner may (1) refuse to authorize the issuance or renewal of a registration to operate as a pharmaceutical marketing firm, (2) revoke, suspend or place conditions on a registration to operate as a pharmaceutical marketing firm, and (3) assess a penalty of up to one thousand dollars for each violation of any provision of section 21a-70i , or 21a-70j, or take other action permitted by section 21a-11 , if the applicant or holder of the registration fails to comply with the requirements set forth in section 21a-70i , or 21a-70j.

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

Sec. 21a-71. 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-75. Regulations. Hearings. Civil penalties for noncompliance: (a) The commissioner shall adopt regulations necessary to carry out the purposes of sections 21a-73 to 21a-77, inclusive, for the best interests of consumers and, in addition, shall by regulation: (1) Designate those consumer commodities as to which display of the unit price shall be required, upon a determination that such display will be in the best interests of consumers; (2) designate the unit of weight, measure, or count in terms of which the unit price of each consumer commodity designated under subdivision (1) shall be expressed, provided that no designated unit shall be such as to require persons subject to the provisions of subsection (a) of section 21a-74 to measure any consumer commodity solely for the purpose of complying with said section; (3) designate whether the unit price of each consumer commodity designated under subdivision (1) shall be expressed to the nearest whole cent or fraction thereof; (4) prescribe the means for the disclosure of price information upon determination that such means would be more effective than those prescribed in subdivision (1) or (2) of subsection (b) of said section 21a-74.

(b) The commissioner shall adopt regulations pursuant to the provisions of chapter 54.

(c) The commissioner shall hold a hearing in accordance with the provisions of chapter 54 whenever he has probable cause to believe, or whenever twenty-five or more citizens state in writing to him their belief, that a person has violated any of the provisions of sections 21a-73 to 21a-76, inclusive.

(d) Upon a finding that a person has violated any of the provisions of sections 21a-73 to 21a-76, inclusive, the commissioner may issue a warning citation or may impose a civil penalty of not more than one hundred dollars for the first offense and not more than five hundred dollars for each subsequent offense. Each violation with respect to all units of a particular consumer commodity on any single day shall be deemed a single offense.

Sec. 21a-76. Exceptions: The provisions of sections 21a-73 to 21a-77, inclusive, shall not apply to any owner-operated single retail store or to any store occupying a total retail sales area of not more than three thousand five hundred square feet.

Sec. 21a-77. Criminal penalty: Any person who violates any provision of sections 21a-73 to 21a-77, inclusive, shall be fined not more than two hundred dollars for the first offense and not more than one thousand dollars for each subsequent offense. Each violation with respect to all units of a particular consumer commodity on any single day shall be deemed a single offense.

Sec. 21a-78b. Suspension of application. Monitoring by department: Section 21a-78b is repealed, effective October 1, 1999.

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-90. Counterfeit drug or device. Prohibition. Investigation. Hearings. Violations. Regulations. Fine: (a) For the purposes of this section:

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

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

(b) No person shall knowingly import or reimport into the state, purchase for resale, sell, offer for sale, dispense, as defined in section 20-571, or deliver in any manner a counterfeit drug or device.

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

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

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

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

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

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

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

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

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

CHAPTER 418 UNIFORM FOOD, DRUG AND COSMETIC ACT

Sec. 21a-91. Short title and legislative intent: This chapter may be cited as the "Connecticut Food, Drug and Cosmetic Act", and is intended to enact state legislation: (1) Which will safeguard the public health and promote the public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandising deceit, arising from intrastate commerce in food, drugs, devices and cosmetics; (2) which shall be uniform, as provided in this chapter, with the federal Food, Drug and Cosmetic Act and with the Federal Trade Commission Act, to the extent to which it outlaws the false advertisement of food, drugs, devices and cosmetics; and (3) which will promote uniformity of such legislation and its administration and enforcement in and throughout the United States.

Sec. 21a-92. Definitions: For the purposes of this chapter and sections 21a-65 and 21a-90, the following terms shall have the meanings hereinafter specified:

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

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

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

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

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

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

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

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

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

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

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

(12) “Immediate container” shall not include package liners;

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

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

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

(16) “Labeling” means all labels and other written, printed or graphic matter (A) upon any article or any of its containers or wrappers, or (B) accompanying such article, provided, if an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be

taken into account, among other things, not only representations made or suggested by statement, word, design, device or sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual, and provided the representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or for such other use as involves prolonged contact with the body;

(17) "Natural food" means food (A) that has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring; and (B) that has not been processed in a manner that makes such food significantly less nutritive; and (C) on and after the Commissioner of Consumer Protection recognizes the occurrence of the events described in subdivisions (1) and (2) of subsection (a) of section 21a-92c, that has not been genetically engineered, as defined in section 21a-92b, provided this subparagraph shall apply only to food that is intended for human consumption. Processing of food by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not, of itself, prevent the designation of such food as "natural food";

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

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

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

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

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

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

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

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

Sec. 21a-93. Prohibited acts: The following acts and the causing thereof shall be prohibited: (1) The sale in intrastate commerce of any food, drug, device or cosmetic that is adulterated or misbranded;

(2) the adulteration or misbranding of any food, drug, device or cosmetic in intrastate commerce;

(3) the receipt in intrastate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise;

(4) the introduction or delivery for introduction into intrastate commerce of (A) any food in violation of section 21a-103 or (B) any new drug in violation of section 21a-110;

(5) the dissemination within this state, in any manner or by any means or through any medium, of any false advertisement;

(6) the refusal to permit (A) entry and the taking of a sample or specimen or the making of an investigation as authorized by section 21a-116, or (B) access to or copying of any record as authorized by section 21a-117;

(7) the refusal to permit entry or inspection as authorized by section 21a-118;

(8) the giving of a guaranty or undertaking in intrastate commerce, referred to in subsection (c) of section 21a-95, that is false;

(9) the forging, counterfeiting, simulating or falsely representing, or, without proper authority, using, any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act;

(10) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a food, drug, device or cosmetic, or the doing of any other act with respect to a food, drug, device or cosmetic, or the labeling or advertisement thereof, which results in a violation of this chapter;

(11) the using in interstate commerce, in the labeling or advertisement of any drug, of any representation or suggestion that an application with respect to such drug is effective under Section 355 of the federal act or under section 21a-110, or that such drug complies with the provisions of either such section;

(12) the violation of any provision of section 21a-108;

(13) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable state law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package

in which that drug is distributed or sold, or such other printed matter as is approved by the commissioner or under the federal act. Nothing in this subdivision shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter unless specifically exempted under the federal act, as effective on April 26, 1974;

(14) the using by any person to his own advantage, or revealing, other than to the commissioner or his duly authorized agents or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under authority of this chapter concerning any method, process, substance or any other subject which as a trade secret is entitled to protection;

(15) (A) placing or causing to be placed upon any drug or device or upon the container of any drug or device, with intent to defraud, the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof; or

(B) selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof transported, received or held for transportation in commerce, with knowledge that the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof has been placed thereon in a manner prohibited by subparagraph (A) of this subdivision; or

(C) making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof upon any drug, device or container thereof;

(16) failing to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding - Sterile Preparations, as amended from time to time, concerning compounding or preparation of sterile drugs; or

(17) failing to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 795, Pharmaceutical Compounding - Nonsterile Preparations, as amended from time to time, concerning compounding or preparation of nonsterile drugs.

Sec. 21a-95. Penalties: (a) Any person who violates any provision of section 21a-93 shall, on conviction thereof, be imprisoned not more than six months or fined not more than five hundred dollars or both; but, if the violation is committed after a conviction of such person under this subsection has become final, such person shall be imprisoned not more than one year or fined not more than one thousand dollars or both.

(b) Notwithstanding the provisions of subsection (a) of this section, any person who violates any provision of section 21a-93, with intent to defraud or mislead, shall be imprisoned not more than one year or fined not more than one thousand dollars or both.

(c) No person shall be subject to the penalties of subsection (a) of this section for having violated subsection (a) or (c) of section 21a-93 if he establishes a guaranty or undertaking signed by and containing the name and address of the person residing in this state from whom he received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of this chapter. In such guaranty this chapter shall be designated by title.

(d) No publisher, radiobroadcast licensee, advertising agency or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor or seller of the article to which the advertisement relates, shall be subject to the penalties of subsection (a) of this section by reason of his dissemination of any false advertisement, unless he has refused, on the request of the commissioner, to furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency in the United States, who caused him to disseminate such false advertisement.

Sec. 21a-96. Seizures: (a) Whenever the commissioner or his authorized agent finds, or has probable cause to believe, that any food, drug, device or cosmetic is offered or exposed for sale, or held in possession with intent to distribute or sell, or is intended for distribution or sale in violation of any provision of this chapter, whether it is in the custody of a common carrier or any other person, he may affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, in violation of this chapter and has been embargoed. Within twenty-one days after an embargo has been placed upon any article, the embargo shall be removed by the commissioner or a summary proceeding for the confiscation of the article shall be instituted by the commissioner. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the commissioner or his agent, or, after summary proceedings have been instituted, without permission from the court. If the embargo is removed by the commissioner or by the court, neither the commissioner nor the state shall be held liable for damages because of such embargo if the court finds that there was probable cause for the embargo.

(b) Proceedings before the Superior Court brought in accordance with this section shall be by complaint, verified by affidavit, which may be made on information and belief in the name of the commissioner against the article to be confiscated.

(c) The complaint shall contain: (1) A particular description of the article, (2) the name of the place where the article is located, (3) the name of the person in whose possession or custody the article was found, if such name is known to the person making the complaint or can be ascertained by reasonable effort, and (4) a statement as to the manner in which the article is adulterated or misbranded or the characteristics which render its distribution or sale illegal.

(d) Upon the filing of the verified complaint, the court shall issue a warrant directed to the proper officer to seize and take in his possession the article described in the complaint and bring the same before the court which issued the warrant and to summon the person named in the warrant, and any other person found in possession of the article, to appear at the time and place therein specified.

(e) Any such person shall be summoned by service of a copy of the warrant in the same manner as a summons issuing out of the court in which the warrant has been issued.

(f) The hearing upon the complaint shall be at the time and place specified in the warrant, which time shall not be less than five days or more than fifteen days from the date of issuing the warrant, but, if the execution and service of the warrant has been less than three days before the return of the warrant, either party shall be entitled to a reasonable continuance. Upon the hearing the complaint may be amended.

(g) Any person who appears and claims the food, drug, device or cosmetic seized under the warrant shall be required to file a claim in writing.

(h) If, upon the hearing, it appears that the article was offered or exposed for sale, or had in possession with intent to distribute or sell, or was intended for distribution or sale, in violation of any provision of

this chapter, it shall be confiscated and disposed of by destruction or sale as the court may direct, but no such article shall be sold contrary to any provision of this chapter. The proceeds of any sale, less the legal costs and charges, shall be paid into the State Treasury.

(i) If the article seized is not injurious to health and is of such character that, when properly packed, marked, branded or otherwise brought into compliance with the provisions of this chapter, its sale would not be prohibited, the court may order such article delivered to the owner upon the payment of the costs of the proceedings and the execution and delivery to the state department instituting the proceedings, as obligee, of a good and sufficient bond to the effect that such article will be brought into compliance with the provisions of this chapter under the supervision of said department, and the expenses of such supervision shall be paid by the owner obtaining release of the article under bond.

(j) Whenever the commissioner or any of his authorized agents finds in any room, building, vehicle of transportation, or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable article which is unsound, or contains any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the commissioner, or his authorized agent, shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as a human food.

(k) The commissioner may, after notice and hearing, impose a civil penalty of not more than five hundred dollars for each separate offense on any person who removes any tag or other appropriate marking affixed to an article which has been embargoed or condemned in accordance with the provisions of this section, without the permission of the commissioner or his agent.

Sec. 21a-105. 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. 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 (16) of section 20-571, as amended by this act, 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-108. 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. 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. 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. 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. 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. 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. 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 sexually transmitted 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-115-1. Application of regulations. Definitions: (a) The provisions of regulations promulgated under the Connecticut Food, Drug and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 21a-92 of the general statutes shall be applicable also to such terms when used in regulations promulgated under the act.

Sec. 21a-115-2. Labeling: (a) Labeling includes all written, printed or graphic matter accompanying an article at any time while such article is in intrastate commerce or held for sale after shipment or delivery in intrastate commerce.

(b) The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Sec. 21a-115-5. Hearings: (a) Presentation of views under subsection (b) of section 21a-97 of the general statutes shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceedings. Such views may be presented in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 21a-95 (c) of the general statutes applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request seasonably made by the person to whom a notice appointing a time and place for the presentation of views under subsection (b) of section 21a-97 of the general statutes has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the commissioner of consumer protection.

Sec. 21a-115-6. Examination of samples: (a) For the purpose of this section the term "examination," as applied to samples collected, includes analyses or tests or other examinations.

(b) When an officer or employee of the commissioner of consumer protection collects a sample of a food, drug or cosmetic for examination under the act, he shall collect at least twice the quantity estimated by him to be sufficient for examination, unless (1) the amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated; (2) the cost of twice the quantity so estimated exceeds five dollars; (3) the article is perishable; (4) the examination consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory.

(c) The Connecticut Agricultural Experiment Station or the state department of health is authorized to destroy (1) any sample when they determine that no examination of such sample will be made; (2) any sample or part thereof when the commissioner determines that no notice under subsection (b) of section 21a-97 of the general statutes, and no case under the act, is or will be based on such sample; (3) any sample or part thereof when the sample was the basis of a notice under said subsection (b) of section 21a-

97 and when, after opportunity for presentation of views following such notice, the commissioner determines that no other such notice, and no case under the act, is or will be based on such sample; (4) any sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when the commissioner determines that no other such case is or will be based on such sample; (5) any sample or part thereof if the article is perishable; (6) any sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for examination.

Sec. 21a-115-9. Inadequate labels; use of label space; language of labels and labeling: (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-102 (f) 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 promit 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) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 21a-102 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-102 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-115-15. 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 representations: (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.

(See 1963 Supp. § 21a-106.)

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 specified in said subsection (f) (for example, 1¼ pounds may be expressed as "1 pound 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, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 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 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) 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, capsule, 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 preparation 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 condition 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, stramonium, 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 cosmetic 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 in expressing 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 specified in subsection (f) (for example, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "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 example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" 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 sudivision (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 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-115-28. Definitions: 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 accordance 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 registration 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 experience to assume responsibility for positions related to compliance with registration 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, marketed, 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 container 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 procedures 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 whereby 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 documentation 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.

Sec. 21a-116. 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. 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. 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. 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. 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.

CHAPTER 419 - RETAIL DRUG CONTROL ACT

Sec. 21a-126. 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. 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. 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.

CHAPTER 420b - DEPENDENCY-PRODUCING DRUGS

PART I - GENERAL PROVISIONS

Sec. 21a-240. 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, dispenser or prescribing practitioner. 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, the sterilized seed of such plant which is incapable of germination, or industrial hemp, as defined in 7 USC 5940, as amended from time to time. 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. Marijuana 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, the sterilized seed of such plant which is incapable of germination, or industrial hemp, as defined in 7 USC 5940, as amended from time to time. 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 a substance of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (A) Morphine-type: (i) Opium or opiate, or any salt, compound, derivative, or preparation of opium or opiate which is similar to any such substance in chemical structure or which is similar to any such substance in physiological effect and which shows a like potential for abuse, which is a controlled substance under this chapter unless modified; (ii) any salt,

compound, isomer, derivative, or preparation of any such substance which is chemically equivalent or identical to any substance referred to in clause (i) of this subdivision, but not including the isoquinoline alkaloids of opium; (iii) opium poppy or poppy straw; or (iv) (I) fentanyl or any salt, compound, derivative or preparation of fentanyl which is similar to any such substance in chemical structure or which is similar to any such substance in physiological effect and which shows a like potential for abuse, which is a controlled substance under this chapter unless modified, or (II) any salt, compound, isomer, derivative or preparation of any such substance which is chemically equivalent or identical to any substance referred to in subclause (I) of this clause; or (B) cocainetype; coca leaves or any salt, compound, derivative or preparation of coca leaves, or any salt, compound, isomer, derivatives or preparation of any such substance which is chemically equivalent or identical to any such substance or which is similar to any such substance in physiological effect and which shows 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.

(59) “THC” means tetrahydrocannabinol, including, but not limited to, delta-7, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol and delta-10-tetrahydrocannabinol, and any material, compound, mixture or preparation which contain their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, regardless of the source, except: (A) Dronabinol substituted in sesame oil and encapsulated in a soft gelatin capsule in a federal Food and Drug Administration or successor agency approved product, or (B) any tetrahydrocannabinol product that has been approved by the federal Food and Drug Administration or successor agency to have a medical use and reclassified in any schedule of controlled substances or unscheduled by the federal Drug Enforcement Administration or successor agency.

(60) “Total THC” means the sum of the percentage by weight of tetrahydrocannabinolic acid, multiplied by eight hundred seventy-seven-thousandths, plus the percentage of weight of tetrahydrocannabinol.

(61) “Manufactured cannabinoid” means cannabinoids naturally occurring from a source other than marijuana that are similar in chemical structure or physiological effect to cannabinoids derived from marijuana, as defined in section 21a-243, but are derived by a chemical or biological process.

(62) “Synthetic cannabinoid” means 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 that is produced artificially and not derived from an organic source naturally containing cannabinoids, unless listed in another schedule pursuant to section 21a-243.

Sec. 21a-241. 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. Schedules of controlled substances. Exceptions: Section 21a-242 is repealed.

Sec. 21a-243. 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 (cannabicyclohex-anol; 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).

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, depressant 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; cyclohexanone; 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 substances.

(c) To the extent that it is possible, medical treatment rather than criminal sanctions 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 purposes 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 existence of these isomers, esters, ethers and salts is possible within the specific chemical 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 chemical 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, hydromorhone, metopon, morphine, oripavine, oxycodone, oxymorphone and thebaine;

(2) any salt, compound,isomer, derivative or preparation thereof which is chemically 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 Levopropoxyphene 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 nervous 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 substances:

(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, (1) including any material, compound, mixture or 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, and (2) excepting any marijuana product that has been approved by the federal Food and Drug Administration or successor agency to have a medical use and reclassified in any schedule of controlled substances or unscheduled by the federal Drug Enforcement Administration or successor agency. Any marijuana product described in subdivision (2) of this subsection shall be included in the same schedule designated by the federal Drug Enforcement Administration or successor agency.

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 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) 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, Pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration 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 psychoactive 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 ingredients 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]-dihydroxyestr-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) Methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3-one);

(39) Methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-one);

(40) Methyltesterone;

(41) Mibolerone;

(42) 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-testosterone');

(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:

(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 whenever 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 following 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 transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile 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 verification 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.

Sec. 21a-244. 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-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 requirements 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 experiences 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 Protection 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 automated 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

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-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;

(2) "Hospital" means "hospital" as defined in section 19a-490 of the Connecticut General Statutes; and

(3) "Licensed practitioner" means "licensed practitioner" as defined in section 21a-244a of the Connecticut General Statutes.

Sec. 21a-244a-2. Hospitals and licensed practitioners 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. Hospitals and licensed practitioners 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. 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. Any hospital or licensed practitioner, 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 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 patient populations and physical locations for which the electronic 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 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 used to identify 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 or the licensed practitioner;

(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 responsible for issuing, maintaining 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.

Sec. 21a-245. 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. 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, advanced practice registered nurses 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 or an advanced practice registered nurse licensed pursuant to chapter 378, the Commissioner of Consumer Protection shall without unnecessary delay, (1) license such physician to possess and supply marijuana for the treatment of glaucoma or the side effects of chemotherapy, or (2) license such advanced practice registered nurse to possess and supply marijuana for the treatment of 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 each location existing in this state and for each location existing outside of this state that distributes products into this state; 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 drugs, medical devices or cosmetics.

(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. 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. 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. 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) A licensed practitioner shall not be required to electronically transmit a prescription when:

(1) Electronic transmission is not available due to a temporary technological or electrical failure. In the event of a temporary technological or electrical failure, the practitioner shall, without undue delay, reasonably attempt to correct any cause for the failure that is within his or her control. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record as soon as practicable, but in no instance more than seventy-two hours following the end of the temporary technological or electrical failure that prevented the electronic transmittal of the prescription. For purposes of this subdivision, "temporary technological or electrical failure" means failure of a computer system, application or device or the loss of electrical power to such system, application or device, or any other service interruption to such system, application or device that reasonably prevents the practitioner from utilizing his or her certified application to electronically transmit the prescription in accordance with subsection (b) of this section;

(2) The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronically transmitted prescription in a timely manner and that such delay would adversely impact the patient's medical condition, provided if such prescription is for a controlled substance, the quantity of such controlled substance does not exceed a five-day supply for the patient, if the controlled substance was used in accordance with the directions for use. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(3) The prescription is to be dispensed by a pharmacy located outside this state. A practitioner who issues a prescription, but fails to electronically transmit the prescription, as permitted by this subsection, shall document the reason for the practitioner's failure to electronically transmit the prescription in the patient's medical record;

(4) Use of an electronically transmitted prescription may negatively impact patient care, such as a prescription containing two or more products to be compounded by a pharmacist, a prescription for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, a prescription that contains long or complicated directions, a prescription that requires certain elements to be included by the federal Food and Drug and Administration, or an oral prescription communicated to a pharmacist by a health care practitioner for a patient in a chronic and convalescent nursing home, licensed pursuant to chapter 368v; or

(5) The practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the technological capacity to issue electronically transmitted prescriptions. For the purposes of this subsection, "technological capacity" means possession of a computer system, hardware or device that can be used to electronically transmit controlled substance prescriptions consistent with the requirements of the federal Controlled Substances Act, 21 USC 801, as amended from time to time. The provisions of this subdivision shall not apply to a practitioner when such practitioner is prescribing as a telehealth provider, as defined in section 19a-906, section 1 of public act 20-2 of the July special session or section 1 of this act, as applicable, pursuant to subsection (c) of section 19a-906, subsection (c) of section 1 of public act 20-2 of the July special session or subsection (c) of section 1 of this act, as applicable.

(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 20-619(24) 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. 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. 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. 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.

(j) (1) A prescribing practitioner, as defined in section 20-14c, shall not, except in an emergency, prescribe, dispense or administer controlled substances in schedules II to IV, inclusive, to a member of his or her immediate family. For purposes of this section, "immediate family member" means a spouse, parent, child, sibling, parent-in-law, son or daughter-in-law, brother or sister-in-law, step-parent, stepchild, step-sibling or other relative residing in the same residence as the prescribing practitioner and shall not include an animal in the residence. In an emergency, a prescribing practitioner may prescribe, dispense or administer not more than a seventy-two-hour supply of such controlled substances to an immediate family member only when there is no other qualified prescribing practitioner available.

(2) A prescribing practitioner who prescribes, dispenses or administers any controlled substance to a member of his or her immediate family pursuant to subdivision (1) of this subsection shall perform an assessment for the care and treatment of the patient, medically evaluate the patient's need for such controlled substance and document such assessment and need in the normal course of his or her business. The prescribing practitioner shall document the emergency that gave rise to the prescription, dispensing or administering of such controlled substance to the immediate family member.

(k) A prescribing practitioner, as defined in section 20-14c, shall not, except in an emergency, prescribe, dispense or administer controlled substances in schedules II to IV, inclusive, for his or her own use. In an emergency, a prescribing practitioner may prescribe, dispense or administer not more than a seventy-two-hour emergency supply of such controlled substances for self-use only when there is no other qualified prescribing practitioner available.

Sec. 21a-253. Possession of marijuana pursuant to a prescription: 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 (1) 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, or (2) an advanced practice registered nurse licensed under the provisions of chapter 378 and further authorized by subsection (a) of section 21a-246 by said commissioner to possess and supply marijuana for the treatment of the side effects of chemotherapy.

Sec. 21a-254. Designation of restricted drugs or substances by regulations. Records required by chapter. Electronic prescription drug monitoring program: (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, freestanding 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 freestanding 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 annually 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 annual inventory date, and kept on file for three years; and 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 that are dispensed by pharmacies, nonresident pharmacies, as defined in section 20-627, outpatient pharmacies in hospitals or institutions or by any other dispenser. 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) Prior to July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20-627, outpatient pharmacy in a hospital or institution and dispenser 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) (A) Except as provided in this subdivision, on and after July 1, 2016, each pharmacy, nonresident pharmacy, as defined in section 20- 627, outpatient pharmacy in a hospital or institution, and dispenser shall report to the commissioner by electronic means, in a format approved by the commissioner, the

following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy immediately upon, but in no event later than the next business day after, dispensing such prescriptions: (i) Dispenser identification number; (ii) the date the prescription for the controlled substance was filled; (iii) the prescription number; (iv) whether the prescription for the controlled substance is new or a refill; (v) the national drug code number for the drug dispensed; (vi) the amount of the controlled substance dispensed and the number of days' supply of the controlled substance; (vii) a patient identification number; (viii) the patient's first name, last name and street address, including postal code; (ix) the date of birth of the patient; (x) 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 (xi) the type of payment.

(B) If the electronic prescription drug monitoring program is not operational, such pharmacy or dispenser shall report the information described in this subdivision not later than the next business day after regaining access to such program. For purposes of this subdivision, "business day" means any day during which the pharmacy is open to the public.

(C) Each veterinarian, licensed pursuant to chapter 384, who dispenses a controlled substance prescription shall report to the commissioner the information described in subparagraph (A) of this subdivision, at least weekly, by electronic means or, if the veterinarian does not maintain records electronically, in a format approved by the commissioner.

(5) 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.

(6) The commissioner and any such vendor shall not disclose controlled substance prescription information reported pursuant to subdivisions (3) and (4) 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 (5) of this subsection shall be guilty of a class D felony.

(7) The commissioner shall provide, upon request, controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to the following: (A) The prescribing practitioner or such practitioner's authorized agent, 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 or such practitioner's authorized agent, 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, or such pharmacist's authorized pharmacy technician, 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, such practitioner's authorized agent, the pharmacist or such pharmacist's authorized pharmacy technician shall submit a written and signed request to the commissioner for controlled substance prescription information. Such prescribing practitioner, pharmacist or pharmacist's authorized pharmacy technician 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.

(8) No person or employer shall prohibit, discourage or impede a prescribing practitioner, pharmacist or pharmacist's authorized pharmacy technician from requesting controlled substance prescription information pursuant to this subsection.

(9) Prior to prescribing greater than a seventy-two-hour supply of any controlled substance to any patient, the prescribing practitioner or such practitioner's authorized agent shall review the patient's records in the electronic prescription drug monitoring program established pursuant to this subsection. Whenever a prescribing practitioner prescribes a controlled substance, other than a schedule V nonnarcotic controlled substance, for the continuous or prolonged treatment of any patient, such prescriber, or such prescriber's authorized agent, shall review, not less than once every ninety days, the patient's records in such prescription drug monitoring program. Whenever a prescribing practitioner prescribes a schedule V nonnarcotic controlled substance, for the continuous or prolonged treatment of any patient, such prescribing practitioner, or such prescribing practitioner's authorized agent, shall review, not less than annually, the patient's records in such prescription drug monitoring program. If such electronic prescription drug monitoring program is not operational, such prescribing practitioner may prescribe greater than a seventy-two-hour supply of a controlled substance to a patient during the time of such program's inoperability, provided such prescribing practitioner or such authorized agent reviews the records of such patient in such program not more than twenty-four hours after regaining access to such program.

(10) (A) A prescribing practitioner may designate an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the prescribing practitioner. The prescribing practitioner shall ensure that any authorized agent's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The prescribing practitioner and any authorized agent shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A prescribing practitioner may be subject to disciplinary action for acts of the authorized agent as provided in section 21a-322.

(B) Notwithstanding the provisions of subparagraph (A) of this subdivision, a prescribing practitioner who is employed by or provides professional services to a hospital shall, prior to designating an authorized agent to review the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the prescribing practitioner, (i) submit a request to designate one or more authorized agents for such purposes and a written protocol for oversight of the authorized agent or agents to the commissioner, in the form and manner prescribed by the commissioner, and (ii) receive the commissioner's approval to designate such authorized agent or agents and of such written protocol. Such written protocol shall designate either the hospital's medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner as the person responsible for ensuring that the authorized agent's or agents' access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A hospital medical director, a hospital department head, who is a prescribing practitioner, or another prescribing practitioner designated as the person responsible for overseeing an authorized agent's or agents' access to such program and information in the written protocol approved by the commissioner may be subject to disciplinary action for acts of the authorized agent or agents as provided in section

21a-322. The commissioner may inspect hospital records to determine compliance with written protocols approved in accordance with this section.

(C) A pharmacist may designate a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist only for the purposes of facilitating the pharmacist's review of such patient information. The pharmacist shall ensure that any such pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. The pharmacist and any authorized pharmacy technician shall be subject to the provisions of 45 CFR 164.308, as amended from time to time, concerning administrative safeguards for the protection of electronic protected health information. A pharmacist may be subject to disciplinary action for acts of the authorized pharmacy technician.

(D) Prior to designating a pharmacy technician to access the electronic prescription drug monitoring program and patient controlled substance prescription information on behalf of the pharmacist, the supervising pharmacist shall provide training for the authorized pharmacy technicians. Such training shall designate a pharmacist as the person responsible for ensuring that the authorized pharmacy technician's access to such program and patient controlled substance prescription information is limited to the purposes described in this section and occurs in a manner that protects the confidentiality of information that is accessed through such program. A pharmacist designated as the person responsible for overseeing the pharmacy technician's access to such program may be subject to disciplinary action for acts of the authorized pharmacy technician. The commissioner may inspect records to document pharmacy technician training, that pharmacy technicians have access to the program and that patient controlled substance prescription information has been limited in accordance with the provisions of this section.

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

(12) The provisions of this section shall not apply to (A) samples of controlled substances dispensed by a physician to a patient, or (B) any controlled substances dispensed to hospital inpatients.

(13) The provisions of this section shall not apply to any institutional pharmacy or pharmacist's drug room operated by a facility, licensed under section 19a-495 and regulations adopted pursuant to said section 19a-495, that dispenses or administers directly to a patient an opioid agonist for treatment of a substance use disorder.

(14) The commissioner may provide controlled substance prescription information obtained in accordance with subdivisions (3) and (4) of this subsection to other state agencies, pursuant to an agreement between the commissioner and the head of such agency, provided the information is obtained for a study of disease prevention and control related to opioid abuse or the study of morbidity and mortality caused by overdoses of controlled substances. The provision of such information shall be in accordance with all applicable state and federal confidentiality requirements.

(15) Nothing in this section shall prohibit a prescribing practitioner or such prescribing practitioner's authorized agent from disclosing controlled substance prescription information submitted pursuant to

subdivisions (3) and (4) of this subsection to the Department of Social Services for the purposes of administering any of said department's medical assistance programs.

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 dispensed 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. Such records and any unused drugs or portions thereof shall be promptly returned to the hospital pharmacy when no longer required by the patient.

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 Connecticut 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 outpatients 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:

(A) The 20th day of the month for all prescriptions dispensed on and between the 1st and the 15th days of the month; and

(B) The 5th day of the following month for all prescriptions dispensed on and between the 16th day and the last day of the month.

(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 department 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.

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. 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 three thousand five hundred dollars or be imprisoned for not more than two years or be both fined and imprisoned; and for the second and each subsequent offense shall be guilty of a class C felony.

Sec. 21a-256. 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. 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. 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. 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. 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. 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. 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 or her 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 or her 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" have the same meanings as provided 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.

(d) A registered nurse licensed by the Department of Public Health and employed by a home health care agency, as defined in section 19a-490, may, with the permission of a designated representative of the patient, oversee the destruction and disposal of the patient's controlled substances, using the recommendations for the proper disposal of prescription drugs on the Internet web site of the Department of Consumer Protection. Such registered nurse shall maintain written or electronic documentation for a period of three years of any such destruction and disposal on a form prescribed by the Commissioner of Consumer Protection. Such written or electronic documentation shall be maintained with the patient's medical record. Nothing in this subsection shall prevent the registered nurse and patient's designated representative from depositing the patient's controlled substances in a statutorily authorized prescription drug drop box.

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

⅛ ounce of a powder, crystal, flake, or granule—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 package 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 least ½ inch. (The GSA Class 5 rated steel door meets all the qualifications for 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 equivalent. 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 Substances 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 controlled 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 Substances 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) nonrecoverable.

(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. If No. 250 or more controlled substance units all schedule II controlled substances shall be stored in an approved vault.

(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) containers stocked.

(c) All controlled substances in the process of manufacture, 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 immediately 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 substances must be securely locked inside an area or building which affords adequate security.

Sec. 21a-262-5. Licensed pharmacies: (a) Schedule II Stock, if less than No. 150 controlled substance units a substantially 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 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 in such pharmacy, and shall require additional safeguards to ensure the security of the controlled substances.

(d) The Commissioner of Consumer Protection may require any licensed pharmacy(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.

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 speciically 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, educational 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 laboratories: (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 Substance 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 completely 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 specifically referred to in section 21a-262-1 through section 21a-262-10 inclusive: (a) Schedule II 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 responsibility 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 substantially 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 subsection 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 substance 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 infirmaries, clinics, summer camps, and other institutions or establishments providing health care services including those which are group, private, state, and/or municipally operated: (a) Schedule II 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 compliance 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 pharmacist, 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.

Sec. 21a-263. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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 care center, as defined in section 19a-77, that is identified as a child 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 care center, as defined in section 19a-77, that is identified as a child 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. Penalty for illegal possession. Alternative sentences. Immunity: (a)(1) Any person who possesses or has under such person's control any quantity of any controlled substance, except less than one-half ounce of a cannabis-type substance and except as authorized in this chapter, shall be guilty of a class A misdemeanor.

(2) For a second offense of subdivision (1) of this subsection, the court shall evaluate such person and, if the court determines such person is a drug-dependent person, the court may suspend prosecution of such person and order such person to undergo a substance abuse treatment program.

(3) For any subsequent offense of subdivision (1) of this subsection, the court may find such person to be a persistent offender for possession of a controlled substance in accordance with section 53a-40.

(b) Any person who violates subsection (a) 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 care center, as defined in section 19a-77, that is identified as a child care center by a sign posted in a conspicuous place shall be guilty of a class A misdemeanor and shall be sentenced to a term of imprisonment and a period of probation during which

such person shall perform community service as a condition of such probation, in a manner ordered by the court.

(c) 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 described in subdivision (49) of section 21a-240.

(d) 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 possession or control of a controlled substance in violation of subsection (a) 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.

(e) No provision of this section shall be construed to alter or modify the meaning of the provisions of section 21a-278.

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-279b. Construction of public act 15-2 of the June special session re violations of section 21a-279: The provisions of public act 15-2 of the June special session concerning a person who is convicted of a violation of section 21a-279 shall not be construed in a manner that changes such person's eligibility to hold a certificate under sections 7-294d, 29-36f and 29-37p or a permit under section 29-28 or such person's ability to possess a firearm, ammunition or an electronic weapon under sections 53a-217 and 53a-217c.

Sec. 21a-280. 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. 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. 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. 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. 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.

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.

CHAPTER 420c - CONTROLLED SUBSTANCE REGISTRATION

Sec. 21a-316. "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. Registration required. Notification of transportation of a controlled substance to treat a patient at an alternate location required. Report of dispensation of a controlled substance at an alternate location 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 (1) obtain a certificate of registration issued by the Commissioner of Consumer Protection in accordance with the provisions of this chapter, (2) if the practitioner is engaged in prescribing a controlled substance, register for access to the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254 in a manner prescribed by the commissioner, and (3) if the practitioner is engaged in transporting a controlled substance for the purpose of treating a patient in a location that is different than the address that the practitioner provided to the Department of Consumer Protection as a registrant, as defined in section 21a-240, notify the department, in a manner prescribed by the commissioner, of the intent to transport such controlled substance and, after dispensing such controlled substance, return any remaining amount of such controlled substance to a secure location at the address provided to the department. If the practitioner cannot return any remaining amount of such controlled substance to such address, the commissioner may approve an alternate location, provided such location is also approved by the federal Drug Enforcement Agency, or any successor agency. The practitioner shall report any dispensation by the practitioner of a controlled substance that occurs at a location other than the address provided to the department to the prescription drug monitoring program pursuant to subsection (j) of section 21a-254 upon returning to such address.

Sec. 21a-318. 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. Professional or institutional approval to precede registration: (a) 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.

(b) The Commissioner of Consumer Protection may change the status of a controlled substance registration to inactive for any practitioner who fails to maintain a license, registration or approval of a

license to practice his or her medical profession for a period longer than ninety days. Such change in license status shall not be considered disciplinary and the registration shall be reinstated without additional fee, if the practitioner restores his or her license, registration or approval to practice his or her profession with the Department of Public Health or associated board or commission, and the reinstatement occurs prior to the expiration of the controlled substance registration.

Sec. 21a-320. 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. 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. 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; (10) failure to keep records of medical evaluations of patients and all controlled substances dispensed, administered or prescribed to patients by a practitioner; (11) failure to establish and implement administrative safeguards for the protection of electronic protected health information pursuant to 45 CFR 164.308, as amended from time to time; and (12) breach of any such safeguards by a prescribing practitioner's authorized agent.

Sec. 21a-323. 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. 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. 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. 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-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 subtances 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.

Sec. 21a-327. 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. 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

DEPARTMENT OF PUBLIC HEALTH

Sec. 19a-12a. Professional assistance program for regulated professions. Definitions. Program requirements. Referrals to Department of Public Health. Notification of disciplinary action against program participants. Annual reporting requirements. Confidentiality. Annual audit: (a) As used in this section and section 19a-12b:

(1) "Assistance program" means the program established pursuant to subsection (b) of this section to provide education, prevention, intervention, referral assistance, rehabilitation or support services to health care professionals, pharmacists and pharmacy interns who have a chemical dependency, emotional or behavioral disorder or physical or mental illness;

(2) "Chemical dependency" means abusive or excessive use of drugs, including alcohol, narcotics or chemicals, that results in physical or psychological dependence;

(3) "Health care professionals" includes any person licensed or who holds a permit pursuant to chapter 370, 372, 373, 375, 375a, 376, 376a, 376b, 376c, 377, 378, 379, 379a, 380, 381, 381a, 382a, 383, 383a, 383b, 383c, 384, 384a, 384b, 384c, 384d, 385, 398 or 399;

(4) "Medical review committee" means any committee that reviews and monitors participation by health care professionals, pharmacists or pharmacy interns in the assistance program, including a medical review committee described in section 19a-17b;

(5) "Pharmacist" has the same meaning as provided in section 20-571; and

(6) "Pharmacy intern" has the same meaning as provided in section 20-571.

(b) State or local professional societies or membership organizations of health care professionals, pharmacists and pharmacy interns, or any combination thereof, may establish a single assistance program to serve all health care professionals, pharmacists and pharmacy interns, provided the assistance program (1) operates in compliance with the provisions of this section and sections 20-638 to 20-638b, inclusive, and (2) includes one or more medical review committees that comply with the applicable provisions of (A) subsections (c) to (f), inclusive, of this section, and (B) subsections (b) to (h), inclusive, of section 20-638a. The program shall (i) be an alternative, voluntary and confidential opportunity for the rehabilitation of health care professionals, persons who have applied to become health care professionals, pharmacists and pharmacy interns, and (ii) include mandatory, periodic evaluations of each participant's ability to practice with skill and safety and without posing a threat to the health and safety of any person or patient in the health care or pharmacy setting.

(c) Prior to admitting a health care professional into the assistance program, a medical review committee shall (1) determine if the health care professional is an appropriate candidate for rehabilitation and participation in the program, and (2) establish the participant's terms and conditions for participating in the program. No action taken by the medical review committee pursuant to this subsection shall be construed as the practice of medicine or mental health care.

(d) A medical review committee shall not admit into the assistance program any health care professional who has pending disciplinary charges, prior history of disciplinary action or a consent order by any professional licensing or disciplinary body or has been charged with or convicted of a felony under the laws of this state, or of an offense that, if committed within this state, would constitute a felony. A medical review committee shall refer such health care professional to the Department of Public Health and shall submit to the department all records and files maintained by the assistance program concerning such health care professional. Upon such referral, the Department of Public Health shall determine if the health care professional is eligible to participate in the assistance program and whether such participation should be treated as confidential pursuant to subsection (h) of this section. The Department of Public Health may seek the advice of professional health care societies or organizations and the assistance program in determining what intervention, referral assistance, rehabilitation or support services are appropriate for such health care professional. If the Department of Public Health determines that the health care professional is an appropriate candidate for confidential participation in the assistance program, the entire record of the referral and investigation of the health care professional shall be confidential and shall not be disclosed, except at the request of the health care professional, for the duration of the health care professional's participation in and upon successful completion of the program, provided such participation is in accordance with terms agreed upon by the department, the health care professional and the assistance program.

(e) Any health care professional participating in the assistance program shall immediately notify the assistance program upon (1) being made aware of the filing of any disciplinary charges or the taking of any disciplinary action against such health care professional by a professional licensing or disciplinary body, or (2) being charged with or convicted of a felony under the laws of this state, or of an offense that, if committed within this state, would constitute a felony. The assistance program shall regularly review available sources to determine if disciplinary charges have been filed, or disciplinary action has been taken, or felony charges have been filed or substantiated against any health care professional who has been admitted to the assistance program. Upon such notification, the assistance program shall refer such health care professional to the Department of Public Health and shall submit to the department all records and files maintained by the assistance program concerning such health care professional. Upon such referral, the Department of Public Health shall determine if the health care professional is eligible to continue participating in the assistance program and whether such participation should be treated as confidential in accordance with subsection (h) of this section. The Department of Public Health may seek the advice of professional health care societies or organizations and the assistance program in determining what intervention, referral assistance, rehabilitation or support services are appropriate for such health care professional. If the Department of Public Health determines that the health care professional is an appropriate candidate for confidential participation in the assistance program, the entire record of the referral and investigation of the health care professional shall be confidential and shall not be disclosed, except at the request of the health care professional, for the duration of the health care professional's participation in and upon successful completion of the program, provided such

participation is in accordance with terms agreed upon by the department, the health care professional and the assistance program.

(f) A medical review committee shall not admit into the assistance program any health care professional who is alleged to have harmed a patient. Upon being made aware of such allegation of harm a medical review committee and the assistance program shall refer such health care professional to the Department of Public Health and shall submit to the department all records and files maintained by the assistance program concerning such health care professional. Such referral may include recommendations as to what intervention, referral assistance, rehabilitation or support services are appropriate for such health care professional. Upon such referral, the Department of Public Health shall determine if the health care professional is eligible to participate in the assistance program and whether such participation should be provided in a confidential manner in accordance with the provisions of subsection (h) of this section. The Department of Public Health may seek the advice of professional health care societies or organizations and the assistance program in determining what intervention, referral assistance, rehabilitation or support services are appropriate for such health care professional. If the Department of Public Health determines that the health care professional is an appropriate candidate for confidential participation in the assistance program, the entire record of the referral and investigation of the health care professional shall be confidential and shall not be disclosed, except at the request of the health care professional, for the duration of the health care professional's participation in and upon successful completion of the program, provided such participation is in accordance with terms agreed upon by the department, the health care professional and the assistance program.

(g) The assistance program shall report annually to the appropriate professional licensing board or commission or, in the absence of such board or commission, to the Department of Public Health on the number of health care professionals participating in the assistance program who are under the jurisdiction of such board or commission or in the absence of such board or commission, the Department of Public Health, the purposes for participating in the assistance program and whether participants are practicing health care with skill and safety and without posing a threat to the health and safety of any person or patient in the health care setting. Annually, on or before December thirty-first, the assistance program shall report such information to the joint standing committee of the General Assembly having cognizance of matters relating to public health, in accordance with the provisions of section 11-4a.

(h) (1) All information given or received in connection with any intervention, rehabilitation, referral assistance or support services provided by the assistance program pursuant to this section, including the identity of any health care professional seeking or receiving such intervention, rehabilitation, referral assistance or support services shall be confidential and shall not be disclosed (A) to any third person or entity, unless disclosure is reasonably necessary for the accomplishment of the purposes of such intervention, rehabilitation, referral assistance or support services or for the accomplishment of an audit in accordance with subsection (l) of this section, or (B) in any civil or criminal case or proceeding or in any legal or administrative proceeding, unless the health care professional seeking or obtaining intervention, rehabilitation, referral assistance or support services waives the confidentiality privilege under this subsection or unless disclosure is otherwise required by law. Unless a health care professional waives the confidentiality privilege under this subsection or disclosure is otherwise required by law, no person in any civil or criminal case or proceeding or in any legal or administrative proceeding may request or require any information given or received in connection with the intervention, rehabilitation, referral assistance or support services provided pursuant to this section.

(2) The proceedings of a medical review committee shall not be subject to discovery or introduced into evidence in any civil action for or against a health care professional arising out of matters that are subject to evaluation and review by such committee, and no person who was in attendance at such proceedings shall be permitted or required to testify in any such civil action as to the content of such proceedings. Nothing in this subdivision shall be construed to preclude (A) in any civil action, the use of any writing recorded independently of such proceedings; (B) in any civil action, the testimony of any person concerning such person's knowledge, acquired independently of such proceedings, about the facts that form the basis for the instituting of such civil action; (C) in any civil action arising out of allegations of patient harm caused by health care services rendered by a health care professional who, at the time such services were rendered, had been requested to refrain from practicing or whose practice of medicine or health care was restricted, the disclosure of such request to refrain from practicing or such restriction; or (D) in any civil action against a health care professional, disclosure of the fact that a health care professional participated in the assistance program, the dates of participation, the reason for participation and confirmation of successful completion of the program, provided a court of competent jurisdiction has determined that good cause exists for such disclosure after (i) notification to the health care professional of the request for such disclosure, and (ii) a hearing concerning such disclosure at the request of any party, and provided further, the court imposes appropriate safeguards against unauthorized disclosure or publication of such information.

(3) Nothing in this subsection shall be construed to prevent the assistance program from disclosing information in connection with administrative proceedings related to the imposition of disciplinary action against any health care professional referred to the Department of Public Health by the assistance program pursuant to subsection (d), (e), (f) or (i) of this section or by the Professional Assistance Oversight Committee pursuant to subsection (e) of section 19a-12b.

(i) If at any time, (1) the assistance program determines that a health care professional is not able to practice with skill and safety or poses a threat to the health and safety of any person or patient in the health care setting and the health care professional does not refrain from practicing health care or fails to participate in a recommended program of rehabilitation, or (2) a health care professional who has been referred to the assistance program fails to comply with terms or conditions of the program or refuses to participate in the program, the assistance program shall refer the health care professional to the Department of Public Health and shall submit to the department all records and files maintained by the assistance program concerning such health care professional. Upon such referral, the Department of Public Health shall determine if the health care professional is eligible to participate in the assistance program and whether such participation should be provided in a confidential manner in accordance with the provisions of subsection (h) of this section. The Department of Public Health may seek the advice of professional health care societies or organizations and the assistance program in determining what intervention, rehabilitation, referral assistance or support services are appropriate for such health care professional. If the Department of Public Health determines that the health care professional is an appropriate candidate for confidential participation in the assistance program, the entire record of the referral and investigation of the health care professional shall be confidential and shall not be disclosed, except at the request of the health care professional, for the duration of the health care professional's participation in and upon successful completion of the program, provided such participation is in accordance with terms agreed upon by the department, the health care professional and the assistance program.

(j) (1) Any physician, hospital or state or local professional society or organization of health care professionals that refers a physician for intervention to the assistance program shall be deemed to have satisfied the obligations imposed on the person or organization pursuant to subsection (a) of section 20-13d, with respect to a physician's inability to practice medicine with reasonable skill or safety due to chemical dependency, emotional or behavioral disorder or physical or mental illness.

(2) Any physician, physician assistant, hospital or state or local professional society or organization of health care professionals that refers a physician assistant for intervention to the assistance program shall be deemed to have satisfied the obligations imposed on the person or organization pursuant to subsection (a) of section 20-12e, with respect to a physician assistant's inability to practice with reasonable skill or safety due to chemical dependency, emotional or behavioral disorder or physical or mental illness.

(k) The assistance program established pursuant to subsection (b) of this section shall meet with the Professional Assistance Oversight Committee established under section 19a-12b on a regular basis, but not less than four times each year.

(l) (1) On or before November first, annually, the assistance program shall select a person determined to be qualified by the assistance program and the Department of Public Health to conduct an audit on the premises of the assistance program for the purpose of examining quality control of the program and compliance with all requirements of this section. The Department of Public Health may waive the audit requirement, provided (A) the Professional Assistance Oversight Committee established under section 19a-12b has agreed to such waiver, in writing, and (B) the Department of Public Health has notified the Department of Consumer Protection of such waiver, in writing.

(2) Any audit conducted pursuant to this subsection shall consist of a random sampling of at least twenty per cent of the assistance program's files or ten files, whichever is greater. Prior to conducting the audit, the auditor shall agree in writing (A) not to copy any program files or records, (B) not to remove any program files or records from the premises, (C) to destroy all personally identifying information about health care professionals participating in the assistance program upon the completion of the audit, (D) not to disclose personally identifying information about health care professionals participating in the program to any person or entity other than a person employed by the assistance program who is authorized by such program to receive such disclosure, and (E) not to disclose in any audit report any personally identifying information about health care professionals participating in the assistance program.

(3) Upon completion of the audit conducted pursuant to this subsection, the auditor shall submit a written audit report to the assistance program, the Department of Public Health, the Professional Assistance Oversight Committee established under section 19a-12b and the joint standing committee of the General Assembly having cognizance of matters relating to public health, in accordance with the provisions of section 11-4a.

Sec. 19a-12b. Professional Assistance Oversight Committee. Duties. Access to professional assistance program records. Corrective action plans. Confidentiality of records and proceedings: (a) The Department of Public Health shall establish a Professional Assistance Oversight Committee for the assistance program. Such committee's duties shall include, but not be limited to, overseeing quality assurance. The oversight committee shall consist of the following members:

(1) Three members selected by the Department of Public Health, who are health care professionals with training and experience in mental health or addiction services,

(2) three members selected by the assistance program, who are not employees, board or committee members of the assistance program and who are health care professionals with training and experience in mental health or addiction services, and

(3) one member selected by the Department of Mental Health and Addiction Services who is a health care professional.

(b) The assistance program shall provide administrative support to the oversight committee.

(c) Beginning January 1, 2008, the oversight committee shall meet with the assistance program on a regular basis, but not fewer than four times each year.

(d) The oversight committee may request and shall be entitled to receive copies of files or such other assistance program records it deems necessary, provided all information pertaining to the identity of any health care professional shall first be redacted by the assistance program. No member of the oversight committee may copy, retain or maintain any such redacted records. If the oversight committee determines that a health care professional is not able to practice with skill and safety or poses a threat to the health and safety of any person or patient in the health care setting, and the health care professional has not refrained from practicing health care or has failed to comply with terms or conditions of participation in the assistance program, the oversight committee shall notify the assistance program to refer the health care professional to the Department of Public Health. Upon such notification, the assistance program shall refer the health care professional to the Department of Public Health, in accordance with the provisions of subsection (i) of section 19a-12a.

(e) (1) If, at any time, the oversight committee determines that the assistance program (A) has not acted in accordance with the provisions of this section, section 19a-12a or sections 20-638 and 20-638a, or (B) requires remedial action based upon the audit performed under subsection (l) of section 19a-12a or subsection (j) of section 20-638a, the oversight committee shall notify the assistance program of such determination, in writing, not later than thirty days after such determination.

(2) The assistance program shall develop and submit to the oversight committee a corrective action plan addressing such determination not later than thirty days after the date of such notification. The assistance program may seek the advice and assistance of the oversight committee in developing the corrective action plan. Upon approval of the corrective action plan by the oversight committee, the oversight committee shall provide a copy of the approved plan to the assistance program, the Department of Public Health and, if the approved plan addresses pharmacists or pharmacy interns, the Department of Consumer Protection.

(3) (A) If the assistance program fails to comply with the corrective action plan, the oversight committee may (i) amend the plan, or (ii) direct the assistance program to refer some or all of the records of (I) the health care professionals in the assistance program to the Department of Public Health for a determination under subparagraph (B) of this subdivision, or (II) the pharmacists and pharmacy interns in the assistance program to the Department of Consumer Protection for a determination under subsection (f) of section 20-638a.

(B) Upon such referral, the Department of Public Health shall determine if each referred health care professional is eligible for continued intervention, rehabilitation, referral assistance or support services and whether participation in such intervention, rehabilitation, referral assistance or support services should be treated as confidential in accordance with subsection (h) of section 19a-12a. If the Department of Public Health determines that a health care professional is an appropriate candidate for confidential participation in continued intervention, referral assistance, rehabilitation or support services, the entire record of the referral and investigation of the health care professional shall be confidential and shall not be disclosed, except at the request of the health care professional, for the duration of the health care professional's participation in and upon successful completion of the program, provided such participation is in accordance with terms agreed upon by the department and the health care professional.

(4) Upon written notice to the Department of Public Health by the oversight committee that the assistance program is in compliance with a corrective action plan developed pursuant to subdivision (2) of this subsection, the department may refer health care professionals to the assistance program for continued intervention, rehabilitation, referral assistance or support services and shall submit to the assistance program all records and files concerning such health care professionals.

(f) Records created for, by or on behalf of the oversight committee shall not be deemed public records and shall not be subject to the provisions of section 1-210. Such records shall be treated as confidential in accordance with the provisions of subsection (h) of section 19a-12a and subsection (h) of section 20-638a.

(g) The proceedings of the oversight committee shall not be subject to discovery or introduced into evidence in any civil action for or against a health care professional, pharmacist or pharmacy intern arising out of matters that are subject to evaluation and review by such committee, and no person who was in attendance at such proceedings shall be permitted or required to testify in any such civil action as to the content of such proceedings. Nothing in this subdivision shall be construed to preclude (1) in any civil action, the use of any writing recorded independently of such proceedings; (2) in any civil action, the testimony of any person concerning such person's knowledge, acquired independently of such proceedings, about the facts that form the basis for the instituting of such civil action; (3) in any civil action arising out of allegations of patient harm caused by health care or pharmacy services rendered by a health care professional, pharmacist or pharmacy intern who, at the time such services were rendered, had been requested to refrain from practicing or whose practice of medicine, health care or pharmacy was restricted, the disclosure of such request to refrain from practicing or such restriction; or (4) in any civil action against a health care professional, pharmacist or pharmacy intern, disclosure of the fact that a health care professional, pharmacist or pharmacy intern participated in the assistance program, the dates of participation, the reason for participation and confirmation of successful completion of the program, provided a court of competent jurisdiction has determined that good cause exists for such disclosure after (A) notification to the health care professional, pharmacist or pharmacy intern of the request for such disclosure, and (B) a hearing concerning such disclosure at the request of any party, and provided further, the court imposes appropriate safeguards against unauthorized disclosure or publication of such information.

Sec. 19a-521d. Prescription drug formulary systems in nursing home facilities: A medical director of a nursing home facility, as defined in section 19a-521, 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 or collaborative drug

therapy management policy, as defined in section 20-631. 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 list, developed in accordance with section 17b-274d, (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.

Sec. 19a-906. Telehealth services: (a) As used in this section:

(1) "Asynchronous" has the same meaning as provided in section 19a906 of the general statutes.

(2) "Connecticut medical assistance program" means the state's Medicaid program and the Children's Health Insurance program administered by the Department of Social Services.

(3) "Facility fee" has the same meaning as provided in section 19a508c of the general statutes.

(4) "Health record" has the same meaning as provided in section 19a906 of the general statutes.

(5) "Medical history" has the same meaning as provided in section 19a-906 of the general statutes.

(6) "Medication-assisted treatment" has the same meaning as provided in section 19a-906 of the general statutes.

(7) "Originating site" has the same meaning as provided in section

(8) "Peripheral devices" has the same meaning as provided in section 19a-906 of the general statutes.

(9) "Remote patient monitoring" has the same meaning as provided in section 19a-906 of the general statutes.

(10) "Store and forward transfer" has the same meaning as provided in section 19a-906 of the general statutes.

(11) "Synchronous" has the same meaning as provided in section 19a906 of the general statutes.

(12) "Telehealth" means the mode of delivering health care or other health services via information and communication technologies to facilitate the diagnosis, consultation and treatment, education, care management and self-management of a patient's physical, oral and mental health, and includes interaction between the patient at the originating site and the telehealth provider at a distant site, synchronous interactions, asynchronous store and forward transfers or remote patient monitoring, but does not include interaction through (A) facsimile, texting or electronic mail, or (B) audio-only telephone unless the telehealth provider is (i) in-network, or (ii) a provider enrolled in the Connecticut medical assistance

program providing such health care or other health services to a Connecticut medical assistance program recipient.

(13) "Telehealth provider" means any person who is (A) an in-network provider or a provider enrolled in the Connecticut medical assistance program providing health care or other health services to a Connecticut medical assistance program recipient through the use of telehealth within such person's scope of practice and in accordance with the standard of care applicable to such person's profession, and (B) (i) a physician or physician assistant licensed under chapter 370 of the general statutes, physical therapist or physical therapist assistant licensed under chapter 376 of the general statutes, chiropractor licensed under chapter 372 of the general statutes, naturopath licensed under chapter 373 of the general statutes, podiatrist licensed under chapter 375 of the general statutes, occupational therapist or occupational therapy assistant licensed under chapter 376a of the general statutes, optometrist licensed under chapter 380 of the general statutes, registered nurse or advanced practice registered nurse licensed under chapter 378 of the general statutes, psychologist licensed under chapter 383 of the general statutes, marital and family therapist licensed under chapter 383a of the general statutes, clinical social worker or master social worker licensed under chapter 383b of the general statutes, alcohol and drug counselor licensed under chapter 376b of the general statutes, professional counselor licensed under chapter 383c of the general statutes, dietitian-nutritionist certified under chapter 384b of the general statutes, speech and language pathologist licensed under chapter 399 of the general statutes, respiratory care practitioner licensed under chapter 381a of the general statutes, audiologist licensed under chapter 397a of the general statutes, pharmacist licensed under chapter 400j of the general statutes, paramedic licensed pursuant to chapter 384d of the general statutes, nurse-midwife licensed under chapter 377 of the general statutes, dentist licensed under chapter 379 of the general statutes, behavior analyst licensed under chapter 382a of the general statutes, genetic counselor licensed under chapter 383d of the general statutes, music therapist certified in the manner described in chapter 383f of the general statutes, art therapist certified in the manner described in chapter 383g of the general statutes or athletic trainer licensed under chapter 375a of the general statutes, or (ii) an appropriately licensed, certified or registered physician, physician assistant, physical therapist, physical therapist assistant, chiropractor, naturopath, podiatrist, occupational therapist, occupational therapy assistant, optometrist, registered nurse, advanced practice registered nurse, psychologist, marital and family therapist, clinical social worker, master social worker, alcohol and drug counselor, professional counselor, dietitian-nutritionist, speech and language pathologist, respiratory care practitioner, audiologist, pharmacist, paramedic, nurse-midwife, dentist, behavior analyst, genetic counselor, music therapist, art therapist or athletic trainer, in another state or territory of the United States or the District of Columbia, that provides telehealth services pursuant to his or her authority under any relevant order issued by the Commissioner of Public Health and maintains professional liability insurance or other indemnity against liability for professional malpractice in an amount that is equal to or greater than that required for similarly licensed, certified or registered Connecticut health care providers.

(b) (1) Notwithstanding the provisions of section 19a-906 of the general statutes, during the period beginning on the effective date of this section and ending on June 30, 2023, a telehealth provider may only provide a telehealth service to a patient when the telehealth provider:

(A) Is communicating through real-time, interactive, two-way communication technology or store and forward transfer technology;

(B) Has determined whether the patient has health coverage that is fully insured, not fully insured or provided through Medicaid or the Children's Health Insurance Program, and whether the patient's health coverage, if any, provides coverage for the telehealth service;

(C) Has access to, or knowledge of, the patient's medical history, as provided by the patient, and the patient's health record, including the name and address of the patient's primary care provider, if any;

(D) Conforms to the standard of care applicable to the telehealth provider's profession and expected for in-person care as appropriate to the patient's age and presenting condition, except when the standard of care requires the use of diagnostic testing and performance of a physical examination, such testing or examination may be carried out through the use of peripheral devices appropriate to the patient's condition; and

(E) Provides the patient with the telehealth provider's license number, if any, and contact information.

(2) Notwithstanding the provisions of section 19a-906 of the general statutes, if a telehealth provider provides a telehealth service to a patient during the period beginning on the effective date of this section and ending on June 30, 2023, the telehealth provider shall, at the time of the telehealth provider's first telehealth interaction with a patient, inform the patient concerning the treatment methods and limitations of treatment using a telehealth platform, including, but not limited to, the limited duration of the relevant provisions of this section and sections 3 to 7, inclusive, of this act, and, after providing the patient with such information, obtain the patient's consent to provide telehealth services. The telehealth provider shall document such notice and consent in the patient's health record. If a patient later revokes such consent, the telehealth provider shall document the revocation in the patient's health record.

(c) Notwithstanding the provisions of this section or title 20 of the general statutes, no telehealth provider shall, during the period beginning on the effective date of this section and ending on June 30, 2023, prescribe any schedule I, II or III controlled substance through the use of telehealth, except a schedule II or III controlled substance other than an opioid drug, as defined in section 20-14o of the general statutes, in a manner fully consistent with the Ryan Haight Online Pharmacy Consumer Protection Act, 21 USC 829(e), as amended from time to time, for the treatment of a person with a psychiatric disability or substance use disorder, as defined in section 17a-458 of the general statutes, including, but not limited to, medication-assisted treatment. A telehealth provider using telehealth to prescribe a schedule II or III controlled substance pursuant to this subsection shall electronically submit the prescription pursuant to section 21a-249 of the general statutes, as amended by this act.

(d) During the period beginning on the effective date of this section and ending on June 30, 2023, each telehealth provider shall, at the time of the initial telehealth interaction, ask the patient whether the patient consents to the telehealth provider's disclosure of records concerning the telehealth interaction to the patient's primary care provider. If the patient consents to such disclosure, the telehealth provider shall provide records of all telehealth interactions during such period to the patient's primary care provider, in a timely manner, in accordance with the provisions of sections 20-7b to 20-7e, inclusive, of the general statutes.

(e) During the period beginning on the effective date of this section and ending on June 30, 2023, any consent or revocation of consent under this section shall be obtained from or communicated by the patient, or the patient's legal guardian, conservator or other authorized representative, as applicable.

(f) (1) The provision of telehealth services and health records maintained and disclosed as part of a telehealth interaction shall comply with all provisions of the Health Insurance Portability and Accountability Act of 1996 P.L. 104-191, as amended from time to time, and the rules and regulations adopted thereunder, that are applicable to such provision, maintenance or disclosure.

(2) Notwithstanding the provisions of section 19a-906 of the general statutes and subdivision (1) of this subsection, a telehealth provider that is an in-network provider or a provider enrolled in the Connecticut medical assistance program that provides telehealth services to a Connecticut medical assistance program recipient, may, during the period beginning on the effective date of this section and ending on June 30, 2023, use any information or communication technology in accordance with the directions, modifications or revisions, if any, made by the Office for Civil Rights of the United States Department of Health and Human Services to the provisions of the Health Insurance Portability and Accountability Act of 1996 P.L. 104-191, as amended from time to time, or the rules and regulations adopted thereunder.

(g) Notwithstanding any provision of the general statutes, nothing in this section shall, during the period beginning on the effective date of this section and ending on June 30, 2023, prohibit a health care provider from: (1) Providing on-call coverage pursuant to an agreement with another health care provider or such health care provider's professional entity or employer; (2) consulting with another health care provider concerning a patient's care; (3) ordering care for hospital outpatients or inpatients; or (4) using telehealth for a hospital inpatient, including for the purpose of ordering medication or treatment for such patient in accordance with the Ryan Haight Online Pharmacy Consumer Protection Act, 21 USC 829(e), as amended from time to time. As used in this subsection, "health care provider" means a person or entity licensed or certified pursuant to chapter 370, 372, 373, 375, 376 to 376b, inclusive, 378, 379, 380, 381a, 383 to 383c, inclusive, 384b, 397a, 399 or 400j of the general statutes or licensed or certified pursuant to chapter 368d or 384d of the general statutes.

(h) Notwithstanding any provision of the general statutes, no telehealth provider shall charge a facility fee for a telehealth service provided during the period beginning on the effective date of this section and ending on June 30, 2023.

(i) (1) Notwithstanding any provision of the general statutes, no telehealth provider shall provide health care or health services to a patient through telehealth during the period beginning on the effective date of this section and ending on June 30, 2023, unless the telehealth provider has determined whether or not the patient has health coverage for such health care or health services.

(2) Notwithstanding any provision of the general statutes, a telehealth provider who provides health care or health services to a patient through telehealth during the period beginning on the effective date of this section and ending on June 30, 2023, shall:

(A) Accept as full payment for such health care or health services:

(i) An amount that is equal to the amount that Medicare reimburses for such health care or health services if the telehealth provider determines that the patient does not have health coverage for such health care or health services; or

(ii) The amount that the patient's health coverage reimburses, and any coinsurance, copayment, deductible or other out-of-pocket expense imposed by the patient's health coverage, for such health care

or health services if the telehealth provider determines that the patient has health coverage for such health care or health services.

(3) If a telehealth provider determines that a patient is unable to pay for any health care or health services described in subdivisions (1) and (2) of this subsection, the provider shall offer to the patient financial assistance, if such provider is otherwise required to offer to the patient such financial assistance, under any applicable state or federal law.

(j) Notwithstanding any provision of the general statutes or any regulation adopted thereunder, a telehealth provider may provide telehealth services pursuant to the provisions of this section from any location.

(k) Notwithstanding the provisions of section 19a-906 of the general statutes, during the period beginning on the effective date of this section and ending on June 30, 2023, any Connecticut entity, institution or health care provider that engages or contracts with a telehealth provider that is licensed, certified or registered in another state or territory of the United States or the District of Columbia to provide health care or other health services shall verify the credentials of such provider in the state in which he or she is licensed, certified or registered, ensure that such a provider is in good standing in such state, and confirm that such provider maintains professional liability insurance or other indemnity against liability for professional malpractice in an amount that is equal to or greater than that required for similarly licensed, certified or registered Connecticut health care providers.

(l) Notwithstanding sections 4-168 to 4-174, inclusive, of the general statutes, from the period beginning on the effective date of this section and ending on June 30, 2023, the Commissioner of Public Health may temporarily waive, modify or suspend any regulatory requirements adopted by the Commissioner of Public Health or any boards or commissions under chapters 368a, 368d, 368v, 369 to 381a, inclusive, 382a, 383 to 388, inclusive, 397a, 398, 399, 400a, 400c, 400j and 474 of the general statutes as the Commissioner of Public Health deems necessary to reduce the spread of COVID-19 and to protect the public health for the purpose of providing residents of this state with telehealth services from out-of-state practitioners.

Sec. 3.: (Effective from passage) (a) For the purposes of this section:

(1) "Asynchronous" has the same meaning as provided in section 19a906 of the general statutes;

(2) "Originating site" has the same meaning as provided in section 19a-906 of the general statutes;

(3) "Remote patient monitoring" has the same meaning as provided in section 19a-906 of the general statutes;

(4) "Store and forward transfer" has the same meaning as provided in section 19a-906 of the general statutes;

(5) "Synchronous" has the same meaning as provided in section 19a906 of the general statutes;

(6) "Telehealth" means the mode of delivering health care or other health services via information and communication technologies to facilitate the diagnosis, consultation and treatment, education, care management and self-management of an insured's physical, oral and mental health, and includes interaction between the insured at the originating site and the telehealth provider at a distant site, synchronous interactions, asynchronous store and forward transfers or remote patient monitoring, but

does not include interaction through (A) facsimile, texting or electronic mail, or (B) audio-only telephone if the telehealth provider is out-of-network; and

(7) "Telehealth provider" means any person who (A) provides health care or other health services through the use of telehealth within such person's scope of practice and in accordance with the standard of care applicable to such person's profession, and (B) is (i) a physician or physician assistant licensed under chapter 370 of the general statutes, physical therapist or physical therapist assistant licensed under chapter 376 of the general statutes, chiropractor licensed under chapter 372 of the general statutes, naturopath licensed under chapter 373 of the general statutes, podiatrist licensed under chapter 375 of the general statutes, occupational therapist or occupational therapy assistant licensed under chapter 376a of the general statutes, optometrist licensed under chapter 380 of the general statutes, registered nurse or advanced practice registered nurse licensed under chapter 378 of the general statutes, psychologist licensed under chapter 383 of the general statutes, marital and family therapist licensed under chapter 383a of the general statutes, clinical social worker or master social worker licensed under chapter 383b of the general statutes, alcohol and drug counselor licensed under chapter 376b of the general statutes, professional counselor licensed under chapter 383c of the general statutes, dietitian-nutritionist certified under chapter 384b of the general statutes, speech and language pathologist licensed under chapter 399 of the general statutes, respiratory care practitioner licensed under chapter 381a of the general statutes, audiologist licensed under chapter 397a of the general statutes, pharmacist licensed under chapter 400j of the general statutes, paramedic licensed pursuant to chapter 384d of the general statutes, nurse-midwife licensed under chapter 377 of the general statutes, dentist licensed under chapter 379 of the general statutes, behavior analyst licensed under chapter 382a of the general statutes, genetic counselor licensed under chapter 383d of the general statutes, music therapist certified in the manner described in chapter 383f of the general statutes, art therapist certified in the manner described in chapter 383g of the general statutes or athletic trainer licensed under chapter 375a of the general statutes, or (ii) an in-network and appropriately licensed, certified or registered physician, physician assistant, physical therapist, physical therapist assistant, chiropractor, naturopath, podiatrist, occupational therapist, occupational therapy assistant, optometrist, registered nurse, advanced practice registered nurse, psychologist, marital and family therapist, clinical social worker, master social worker, alcohol and drug counselor, professional counselor, dietitian nutritionist, speech and language pathologist, respiratory care practitioner, audiologist, pharmacist, paramedic, nurse-midwife, dentist, behavior analyst, genetic counselor, music therapist, art therapist or athletic trainer, in another state or territory of the United States or the District of Columbia, that provides telehealth services pursuant to his or her authority under any relevant order issued by the Commissioner of Public Health and maintains professional liability insurance or other indemnity against liability for professional malpractice in an amount that is equal to or greater than that required for similarly licensed, certified or registered Connecticut health care providers.

(b) Notwithstanding any provision of the general statutes, each individual health insurance policy that provides coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes that is effective at any time during the period beginning on the effective date of this section and ending on June 30, 2023, shall, at all times that the policy remains in effect during such period, provide coverage for medical advice, diagnosis, care or treatment provided through telehealth, to the same extent coverage is provided for such advice, diagnosis, care or treatment when provided to the insured in person. The policy shall not, at any time during such period, exclude coverage for a service

that is appropriately provided through telehealth because such service is provided through telehealth or a telehealth platform selected by an in-network telehealth provider.

(c) Notwithstanding any provision of the general statutes, no telehealth provider who receives a reimbursement for a covered service provided through telehealth in accordance with subsection (b) of this section shall seek any payment for such service from the insured who received such service, except for any coinsurance, copayment, deductible or other out-of-pocket expense set forth in the insured's policy. Such amount shall be deemed by the telehealth provider to be payment in full.

(d) Nothing in this section shall prohibit or limit a health insurer, health care center, hospital service corporation, medical service corporation or other entity from conducting utilization review for telehealth services, provided such utilization review is conducted in the same manner and uses the same clinical review criteria as a utilization review for an in-person consultation for the same service. Except as provided in subsection (b) or (c) of this section, the coverage required under subsection (b) of this section shall be subject to the same terms and conditions applicable to all other benefits under the policy providing such coverage.

Sec. 4.: (Effective from passage) (a) For the purposes of this section:

(1) "Asynchronous" has the same meaning as provided in section 19a906 of the general statutes;

(2) "Originating site" has the same meaning as provided in section 19a-906 of the general statutes;

(3) "Remote patient monitoring" has the same meaning as provided in section 19a-906 of the general statutes;

(4) "Store and forward transfer" has the same meaning as provided in section 19a-906 of the general statutes;

(5) "Synchronous" has the same meaning as provided in section 19a906 of the general statutes;

(6) "Telehealth" means the mode of delivering health care or other health services via information and communication technologies to facilitate the diagnosis, consultation and treatment, education, care management and self-management of an insured's physical, oral and mental health, and includes interaction between the insured at the originating site and the telehealth provider at a distant site, synchronous interactions, asynchronous store and forward transfers or remote patient monitoring, but does not include interaction through (A) facsimile, texting or electronic mail, or (B) audio-only telephone if the telehealth provider is out-of-network; and

(7) "Telehealth provider" means any person who (A) provides health care or other health services through the use of telehealth within such person's scope of practice and in accordance with the standard of care applicable to such person's profession, and (B) is (i) a physician or physician assistant licensed under chapter 370 of the general statutes, physical therapist or physical therapist assistant licensed under chapter 376 of the general statutes, chiropractor licensed under chapter 372 of the general statutes, naturopath licensed under chapter 373 of the general statutes, podiatrist licensed under chapter 375 of the general statutes, occupational therapist or occupational therapy assistant licensed under chapter 376a of the general statutes, optometrist licensed under chapter 380 of the general statutes, registered nurse or advanced practice registered nurse licensed under chapter 378 of the general statutes, psychologist licensed under chapter 383 of the general statutes, marital and family therapist licensed under chapter 383a of the general statutes, clinical social worker or master social worker licensed under chapter 383b

of the general statutes, alcohol and drug counselor licensed under chapter 376b of the general statutes, professional counselor licensed under chapter 383c of the general statutes, dietitian-nutritionist certified under chapter 384b of the general statutes, speech and language pathologist licensed under chapter 399 of the general statutes, respiratory care practitioner licensed under chapter 381a of the general statutes, audiologist licensed under chapter 397a of the general statutes, pharmacist licensed under chapter 400j of the general statutes, paramedic licensed pursuant to chapter 384d of the general statutes, nurse-midwife licensed under chapter 377 of the general statutes, dentist licensed under chapter 379 of the general statutes, behavior analyst licensed under chapter 382a of the general statutes, genetic counselor licensed under chapter 383d of the general statutes, music therapist certified in the manner described in chapter 383f of the general statutes, art therapist certified in the manner described in chapter 383g of the general statutes or athletic trainer licensed under chapter 375a of the general statutes, or (ii) an in-network and appropriately licensed, certified or registered physician, physician assistant, physical therapist, physical therapist assistant, chiropractor, naturopath, podiatrist, occupational therapist, occupational therapy assistant, optometrist, registered nurse, advanced practice registered nurse, psychologist, marital and family therapist, clinical social worker, master social worker, alcohol and drug counselor, professional counselor, dietitian nutritionist, speech and language pathologist, respiratory care practitioner, audiologist, pharmacist, paramedic, nurse-midwife, dentist, behavior analyst, genetic counselor, music therapist, art therapist or athletic trainer, in another state or territory of the United States or the District of Columbia, that provides telehealth services pursuant to his or her authority under any relevant order issued by the Commissioner of Public Health and maintains professional liability insurance or other indemnity against liability for professional malpractice in an amount that is equal to or greater than that required for similarly licensed, certified or registered Connecticut health care providers.

(b) Notwithstanding any provision of the general statutes, each group health insurance policy that provides coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes that is effective at any time during the period beginning on the effective date of this section and ending on June 30, 2023, shall, at all times that the policy remains in effect during such period, provide coverage for medical advice, diagnosis, care or treatment provided through telehealth, to the same extent coverage is provided for such advice, diagnosis, care or treatment when provided to the insured in person. The policy shall not, at any time during such period, exclude coverage for a service that is appropriately provided through telehealth because such service is provided through telehealth, or a telehealth platform selected by an in-network telehealth provider.

(c) Notwithstanding any provision of the general statutes, no telehealth provider who receives a reimbursement for a covered service provided through telehealth in accordance with subsection (b) of this section shall seek any payment for such service from the insured who received such service, except for any coinsurance, copayment, deductible or other out-of-pocket expense set forth in the insured's policy. Such amount shall be deemed by the telehealth provider to be payment in full.

(d) Nothing in this section shall prohibit or limit a health insurer, health care center, hospital service corporation, medical service corporation or other entity from conducting utilization review for telehealth services, provided such utilization review is conducted in the same manner and uses the same clinical review criteria as a utilization review for an in-person consultation for the same service. Except as provided in subsection (b) or (c) of this section, the coverage required under subsection (b) of this section

shall be subject to the same terms and conditions applicable to all other benefits under the policy providing such coverage.

Sec. 5.: (Effective from passage) (a) As used in this section:

(1) "Health carrier" has the same meaning as provided in section 38a1080 of the general statutes;

(2) "Insured" has the same meaning as provided in section 38a-1 of the general statutes;

(3) "Telehealth" has the same meaning as provided in sections 3 and 4 of this act; and

(4) "Telehealth provider" has the same meaning as provided in sections 3 and 4 of this act.

(b) Notwithstanding any provision of the general statutes, no health carrier shall reduce the amount of a reimbursement paid to a telehealth provider for covered health care or health services that the telehealth provider appropriately provided to an insured through telehealth during the period beginning on the effective date of this section and ending on June 30, 2023, because the telehealth provider provided such health care or health services to the patient through telehealth and not in person.

Sec. 6.: (Effective from passage) (a) As used in this section:

(1) "Telehealth" means the mode of delivering health care or other health services via information and communication technologies to facilitate the diagnosis, consultation and treatment, education, care management and self-management of a patient's physical, oral and mental health, and includes (A) interaction between the patient at the originating site and the telehealth provider at a distant site, and (B) synchronous interactions, asynchronous store and forward transfers or remote patient monitoring. "Telehealth" does not include the use of facsimile, texting or electronic mail.

(2) "Connecticut medical assistance program" means the state's Medicaid program and the Children's Health Insurance Program under Title XXI of the Social Security Act, as amended from time to time.

(b) Notwithstanding the provisions of section 17b-245c, 17b-245e or 19a-906 of the general statutes, or any other section, regulation, rule, policy or procedure governing the Connecticut medical assistance program, the Commissioner of Social Services may, in the commissioner's discretion and to the extent permissible under federal law, provide coverage under the Connecticut medical assistance program for audio-only telehealth services for the period beginning on the effective date of this section and ending on June 30, 2023.

Sec. 7.: (Effective from passage) (a) As used in this section:

(1) "Advanced practice registered nurse" means an advanced practice registered nurse licensed pursuant to chapter 378 of the general statutes;

(2) "Physician" has the same meaning as provided in section 21a-408 of the general statutes;

(3) "Qualifying patient" has the same meaning as provided in section 21a-408 of the general statutes; and

(4) "Written certification" has the same meaning as provided in section 21a-408 of the general statutes.

(b) Notwithstanding the provisions of sections 21a-408 to 21a-408n, inclusive, of the general statutes, or any other section, regulation, rule, policy or procedure concerning the certification of medical marijuana patients, a physician or advanced practice registered nurse may issue a written certification to

a qualifying patient and provide any follow-up care using telehealth services during the period beginning on the effective date of this section and ending on June 30, 2023, provided all other requirements for issuing the written certification to the qualifying patient and all recordkeeping requirements are satisfied.

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.

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.

Sec. 20-14e. Dispensing of drugs. Prescribing and dispensing of oral antibiotic drugs for chlamydia or gonorrhea. 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) Notwithstanding the provisions of this section or chapter 400j, a prescribing practitioner who diagnoses a chlamydia or gonorrhea infection in a patient may prescribe and dispense oral antibiotic drugs to such patient and the patient's partner or partners in order to prevent further infection without a physical examination of such partner or partners. A prescribing practitioner who prescribes or dispenses

oral antibiotic drugs to the partner or partners of a patient diagnosed with a chlamydia or gonorrhea infection shall, in accordance with the provisions of this subsection, not be deemed to have violated the prescribing practitioner's standard of care for such prescribing or dispensing drugs. The Commissioner of Public Health, in consultation with the Commissioner of Consumer Protection, may adopt regulations, in accordance with chapter 54, to implement the provisions of this subsection.

(f) 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.

(g) 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.

Sec. 20-14i. Administration of medication by trained persons: Any provisions to the contrary notwithstanding, chapter 378 shall not prohibit the administration of medication to persons (1) attending day programs, residing in residential facilities or receiving individual and family support, under the jurisdiction of the Departments of Children and Families, Correction, Developmental Services and Mental Health and Addiction Services, (2) being detained in juvenile detention centers or residing in residential facilities dually licensed by the Department of Children and Families and the Department of Public Health, or (3) residing in substance abuse treatment facilities licensed by the Department of Children and Families pursuant to section 17a-145 when such medication is administered by trained persons, pursuant to the written order of a physician licensed under this chapter, a dentist licensed under chapter 379, an advanced practice registered nurse licensed to prescribe in accordance with section 20-94a or a physician assistant licensed to prescribe in accordance with section 20-12d, authorized to prescribe such medication. The provisions of this section shall not apply to institutions, facilities or programs licensed pursuant to chapter 368v.

Sec. 20-14n. Disciplinary action for purchasing for resale, selling, offering for sale or delivering in any manner a counterfeit drug or device: Any prescribing practitioner, as defined in section 20-14c, who violates the provisions of subsection (b) of section 21a-90 shall be subject to disciplinary action pursuant to section 19a-17.

Sec. 20-14o. Prescriptions for opioid drugs: (a) As used in this section:

(1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2, as amended from time to time;

(2) "Adult" means a person who is at least eighteen years of age;

(3) "Prescribing practitioner" has the same meaning as provided in section 20-14c;

(4) "Minor" means a person who is under eighteen years of age;

(5) "Opioid agonist" means a medication that binds to the opiate receptors and provides relief to individuals in treatment for abuse of or dependence on an opioid drug;

(6) “Opiate receptor” means a specific site on a cell surface that interacts in a highly selective fashion with an opioid drug;

(7) “Palliative care” means specialized medical care to improve the quality of life of patients and their families facing the problems associated with a life-threatening illness; and

(8) “Opioid antagonist” has the same meaning as provided in section 17a-714a.

(b) When issuing a prescription for an opioid drug to an adult patient for the first time for outpatient use, a prescribing practitioner who is authorized to prescribe an opioid drug shall not issue a prescription for more than a seven-day supply of such drug, as recommended in the National Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain.

(c) A prescribing practitioner shall not issue a prescription for an opioid drug to a minor for more than a five-day supply of such drug.

(d) Notwithstanding the provisions of subsections (b) and (c) of this section, if, in the professional medical judgment of a prescribing practitioner, more than a seven-day supply of an opioid drug is required to treat an adult patient's acute medical condition, or more than a five-day supply of an opioid drug is required to treat a minor patient's acute medical condition, as determined by the prescribing practitioner, or is necessary for the treatment of chronic pain, pain associated with a cancer diagnosis or for palliative care, then the prescribing practitioner may issue a prescription for the quantity needed to treat the acute medical condition, chronic pain, pain associated with a cancer diagnosis or pain experienced while the patient is in palliative care. The condition triggering the prescription of an opioid drug for more than a seven-day supply for an adult patient or more than a five-day supply for a minor patient shall be documented in the patient's medical record and the practitioner shall indicate that an alternative to the opioid drug was not appropriate to address the medical condition.

(e) The provisions of subsections (b), (c) and (d) of this section shall not apply to medications designed for the treatment of abuse of or dependence on an opioid drug, including, but not limited to, opioid agonists and opioid antagonists.

(f) When issuing a prescription for an opioid drug to an adult or minor patient, the prescribing practitioner shall discuss with the patient the risks associated with the use of such opioid drug, including, but not limited to, the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and the reasons the prescription is necessary, and, if applicable, with the custodial parent, guardian or other person having legal custody of the minor if such parent, guardian or other person is present at the time of issuance of the prescription.

Sec. 20-14r. Voluntary nonopioid directive form. Establishment and publication. Immunity from liability: (a) As used in this section:

(1) “Opioid drug” has the same meaning as provided in 42 CFR 8.2, as amended from time to time;

(2) “Prescribing practitioner” has the same meaning as provided in section 20-14c; and

(3) “Voluntary nonopioid directive form” means a form that is voluntarily filed by a patient with a prescribing practitioner that indicates such patient's request to not be issued a prescription or medication order for an opioid drug.

(b) The Department of Public Health, in consultation with the Departments of Consumer Protection and Mental Health and Addiction Services, shall establish a voluntary nonopioid directive form and publish such form on its Internet web site for public use. Any person who does not wish to be issued a prescription or medication order for an opioid drug may file such form with a prescribing practitioner. Upon receipt of a voluntary nonopioid directive form, a prescribing practitioner shall document such receipt in the patient's medical record.

(c) The voluntary nonopioid directive form established by the Department of Public Health shall allow a patient to appoint a duly authorized guardian or health care proxy to override a previously recorded voluntary nonopioid directive form. Such patient, duly authorized guardian or health care proxy may revoke the directive, orally or in writing, for any reason, at any time.

(d) An electronically transmitted prescription to a pharmacy shall be presumed to be valid for the purposes of this section and a pharmacist shall not be held in violation of this section for dispensing a controlled substance in contradiction to a voluntary nonopioid directive form.

(e) No prescribing practitioner acting with reasonable care shall be liable for damages in a civil action, subject to criminal prosecution or deemed to have violated the standard of care for such prescribing practitioner for refusing to issue a prescription or medication order for an opioid pursuant to a voluntary nonopioid directive form.

(f) No person acting in good faith as a duly authorized guardian or health care proxy shall be liable for damages in a civil action or subject to criminal prosecution for revoking or overriding a voluntary nonopioid directive form.

(g) A prescribing practitioner who wilfully fails to comply with a patient's voluntary nonopioid directive form may be subject to disciplinary action pursuant to section 19a-17.

(h) No emergency department prescribing practitioner, acting either as the patient's practitioner or as the medical control officer for emergency medical services personnel, and acting with reasonable care shall be liable for damages in a civil action, subject to criminal prosecution or deemed to have violated the standard of care for a prescribing practitioner for issuing a prescription for or administering a controlled substance containing an opioid to a person who has a voluntary nonopioid directive form, when, in such prescribing practitioner's professional medical judgment, a controlled substance containing an opioid is necessary and such prescribing practitioner had no knowledge of the patient's voluntary nonopioid directive form at the time of issuance or administration.

Sec. 20-14s. Treatment agreement required for prescription of opioid drugs for duration greater than twelve weeks: A prescribing practitioner, as defined in section 20-14c of the general statutes, who prescribes an opioid drug, as defined in section 20-14o of the general statutes, for the treatment of pain for a patient for a duration greater than twelve weeks shall establish a treatment agreement with the patient or discuss a care plan for the chronic use of opioids with the patient. The treatment agreement or care plan shall, at a minimum, include treatment goals, risks of using opioids, urine drug screens and expectations regarding the continuing treatment of pain with opioids, such as situations requiring discontinuation of opioid treatment and, to the extent possible, nonopioid treatment options, including, but not limited to manipulation, massage therapy, acupuncture, physical therapy and other treatment regimens or modalities. A record of the treatment agreement or care plan shall be recorded in the patient's medical record.

ADMINISTRATION OF MEDICATIONS: RESIDENTIAL FACILITIES, RESPITE CENTERS, DAY PROGRAMS, COMMUNITY TRAINING HOMES, AND INDIVIDUAL AND FAMILY SUPPORTS

Sec. 17a-210-5. Storage and disposal of medications in residential facilities, respite centers and day programs: (a) All medications, except for controlled medications, shall be kept in a locked container, cabinet or closet used exclusively for the purpose of storage of medications. Medications for internal use shall be stored separately from substances that are for external administration. All controlled medications shall be stored in accordance with section 21a-262-9 of the Regulations of Connecticut State Agencies. Each residential facility, respite center and day program shall have counting procedures in place to ensure the correct disposition of controlled medications.

(b) Medications requiring refrigeration shall be stored separately from food. If a separate, locked refrigerator is not available, these medications may be placed in a locked container in the same refrigerator in which food is stored. The temperature of the refrigerator shall be maintained between 36-46 degrees Fahrenheit.

(c) Access to medications shall be limited to persons authorized to administer medications. Each residential facility, respite center and day program in which certified non-licensed personnel may administer medication shall maintain a copy of each person's current certificate to administer medications at each site where such administration occurs.

(d) Medications for consumers who are permitted to self-administer medication in accordance with subsection (ee) of section 17a-210-1 and section 17a-210-4 of the Regulations of Connecticut State Agencies shall be stored in such a way as to make them inaccessible to other consumers. Such medications shall be stored in a locked container or locked area unless the supervising nurse makes a determination that unlocked storage of the medication poses no threat to the health or safety of the consumer or other consumers.

(e) All medications shall be stored in labeled containers from a pharmacy.

(f) Unused, outdated or unlabeled non-controlled medications shall be destroyed in a non-recoverable manner by licensed or certified non-licensed personnel in the presence of at least one (1) witness. Non-controlled medication destruction shall be documented by program or facility staff in the records maintained by the program or the residential facility.

(g) In community-based residential facilities, unused, outdated or unlabeled controlled medications shall be destroyed in a non-recoverable manner by licensed personnel in the presence of at least one (1) witness. In non-community-based residential facilities, the Department of Consumer Protection shall be notified in order to destroy in a non-recoverable manner unused, outdated or unlabeled controlled medications. The destruction of controlled medications shall be recorded on the appropriate documentation forms and on the receipt and disposition forms by program or facility staff in the records maintained by the residential facility.

(h) Trained non-licensed personnel shall not dispose of any medications.

(i) Licensed personnel, certified non-licensed personnel and trained non-licensed personnel shall follow applicable state and federal statutes and regulations regarding the handling and administration of controlled medications.