

THE PRACTICE OF PHARMACY

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Sec. 20-576-1. Definitions

For the purpose of sections 20-576-1 through 20-576-53 of the Regulations of Connecticut State Agencies, the following terms shall have the meanings indicated:

- (a) "Commission" means the Commission of Pharmacy;
- (b) "Department" means the Department of Consumer Protection;
- (c) "Legend drug" has the meaning given to this term by Section 20-571 of the General Statutes;
- (d) "Prescribing practitioner" has the meaning given to this term by Section 20-571 of the General Statutes; and
- (e) "Prescription department" means that area within a pharmacy where drugs are compounded and dispensed pursuant to the order of a prescribing practitioner.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective Jan. 11, 1999; Amended effective August 1, 2007.)

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.

(Added effective January 11, 1999; Amended effective November 30, 2006.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999; Amended effective August 10, 2000.)

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. No more than 40 clock hours may be obtained in any one week. The professional experience may be obtained by completing any combination of the following:

(1) work in a Connecticut pharmacy or an institutional pharmacy approved by the commission;

(2) an educational experiential program established and monitored by a school or college of pharmacy accredited by the American Council on Pharmaceutical Education 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 American Council on Pharmaceutical Education 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 working in a Connecticut pharmacy or institutional pharmacy approved by the commission:

(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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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 area 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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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 applicants 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 of 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.

(Added effective January 11, 1999; Amended effective August 2, 2001.)

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, prescriptions containers to be refilled or written request 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.

(Added effective January 11, 1999.)

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.

(Added effective August 2, 2001.)

Sec. 20-576-19. Disclosure of times of operations 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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

Sec. 20-576-27. Substitution of drugs. Definitions

As used in sections 20-576-27 through 20-576-30, inclusive, of the Regulations of Connecticut State Agencies, "Purchaser" means the patient for whom the drug product is prescribed, or the patient's authorized agent, or, in the case of a minor or incompetent person, the patient's parent or guardian except that for subsection (e) of section 20-619 of the General Statutes the word "Purchaser" means the Payor of a prescription drug; and "Substitution" means the dispensing of a different drug, biological, medicinal substance, device or brand of the same in place of the drug, biological, medicinal substance, device or brand of the same prescribed without the express permission of the prescribing practitioner, except as provided in section 20-619 of the General Statutes, or in hospitals without the express approval of the medical staff pharmacy committee.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

Sec. 20-576-31. Sale of nonlegend drugs in vending machines

No nonlegend drug shall be sold or offered or exposed for sale or dispensed by any means in any type of vending machines.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999; Amended effective June 28, 2004.)

PHARMACY TECHNICIANS IN INSTITUTIONAL PHARMACIES

Sec. 20-576-33. Ratio

The ratio of pharmacy technicians to pharmacists in an institutional pharmacy shall be as follows:

(1) In an outpatient pharmacy, the ratio shall not exceed two pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed three pharmacy technicians to one supervising pharmacist;

(2) In an inpatient pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist; and

(3) In a satellite pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999; Amended effective February 22, 2000.)

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.

(Added effective January 11, 1999; Amended effective June 28, 2004.)

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.

(Added effective January 11, 1999; Amended effective June 28, 2004.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999; Amended effective March 6, 2000; June 28, 2004.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

PHARMACY TECHNICIANS IN PHARMACIES

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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 or refills authorized by the prescribing practitioner.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

Sec. 20-576-50. Notice to commission upon commencement of use or change

Any pharmacy institution 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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective January 11, 1999.)

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.

(Added effective April 5, 2001; Amended effective February 1, 2006.)

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.

(Added effective April 5, 2001; Amended effective February 1, 2006.)

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.

(Added effective April 5, 2001.)

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.

(Added effective April 5, 2001.)

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.

(Added effective April 5, 2001.)

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.

(Added effective April 5, 2001.)

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.

(Added effective November 30, 2006.)

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.

(Added effective November 30, 2006.)

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."

(Added effective November 30, 2006.)

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.

(Added effective November 30, 2006.)

