Agency
Department of Consumer Protection

Subject
The Practice of Pharmacy

Inclusive Sections
§§ 20-576-1—20-576-79

CONTENTS

The Practice of Pharmacy

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.

(Adopted effective January 11, 1999; Amended November 7, 2024)

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.

(Adopted 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.

(Adopted effective January 11, 1999; Amended 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.

(Adopted effective January 11, 1999; Amended 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.

(Adopted 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.

(Adopted 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.

(Adopted effective January 11, 1999; Amended 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. 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.

(Adopted effective January 11, 1999; Amended April 28, 2011)

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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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 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.

(Adopted 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.

(Adopted 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.

(Adopted 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 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.

(Adopted effective January 11, 1999; Amended 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, 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.

(Adopted 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.

(Adopted effective August 2, 2001)

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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted effective January 11, 1999)

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.

(Effective November 7, 2024)

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, tamper-proof 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.

(Adopted effective January 11, 1999; Amended November 7, 2024)

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.

(Adopted effective January 11, 1999; Amended 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.

(Adopted 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.

(Adopted 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.

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

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.

(Adopted effective January 11, 1999; Amended 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.

(Adopted effective January 11, 1999; Amended 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.

(Adopted 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.

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

(Adopted 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.

(Adopted effective January 11, 1999)

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.

(Adopted 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.

(Adopted 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 of refills authorized by the prescribing practitioner.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted effective January 11, 1999)

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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted effective April 5, 2001; Amended 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.

(Adopted effective April 5, 2001; Amended 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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.

(Adopted 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 radiopharmaceutical to be dispensed shall be labeled with:
(1) the name and address of the pharmacy;
(2) the name of the prescribing practitioner;
(3) the date of dispensing;
(4) the prescription number;
(5) if radioactive, the standard radiation symbol and the words "Caution: Radioactive Material";
(6) the name of the procedure;
(7) the radionuclide and chemical form;
(8) the amount of radioactivity and the calibration date and time;
(9) the expiration time;
(10) the appropriate dosage units;
(11) if a solid, the number of items or weight;
(12) if a gas, the number of ampoules or vials; and
(13) the patient name when intended for individual therapeutic use, or the words "For Physician Use" or "For Physician Use Only."

(c) The immediate inner container (containing the dose) of a radiopharmaceutical to be dispensed shall be labeled with:
(1) the name of the radiopharmaceutical;
(2) the serial number assigned to the prescription or medication order of the radiopharmaceutical;
(3) the standard radiation symbol; and
(4) the words "Caution: Radioactive Material."

(Adopted 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.

(Adopted effective November 30, 2006)

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.

(Adopted effective July 12, 2011)

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.

(Adopted effective July 12, 2011)

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.

(Adopted effective July 12, 2011)

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.

(Adopted effective July 12, 2011)

Sec. 20-576-68. Hours

A sterile compounding pharmacy shall be open at least thirty-five (35) hours per week unless granted a waiver by the Commission of Pharmacy pursuant to section 20-576-59 of the Regulations of Connecticut State Agencies.

(Adopted effective July 12, 2011)

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.

(Effective November 2, 2012)

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.

(Effective November 2, 2012)

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.

(Effective November 2, 2012)

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.

(Effective November 2, 2012)

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.

(Effective November 2, 2012)

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.

(Effective February 18, 2022)

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.

(Effective February 18, 2022)

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.

(Effective February 18, 2022)

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.

(Effective February 18, 2022)

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.

(Effective February 18, 2022)

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.

(Effective February 18, 2022)