Sec. 19-13-D8v. Pharmaceutical services in chronic and convalescent nursing homes and rest homes with nursing supervision

(a) **Definitions**

For the purposes of these regulations:

(1) "Administering" means an act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with Federal and State laws and regulations governing such act. The complete act of administration includes removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the physician's order, giving the individual dose to the proper patient, and promptly recording the time and dose given.

(2) "Community Pharmacy" means a pharmacy licensed pursuant to Section 20-168 of the Connecticut General Statutes. An exception may be made for those cases where a specific patient has a third party prescription drug plan which requires the patient to obtain medications from a specific pharmacy located outside the State of Connecticut, provided such pharmacy complies with the requirements of the State of Connecticut regulations and the policy of the facility regarding labeling and packaging.

(3) "Compounding" means the act of selecting, mixing, combining, measuring, counting or otherwise preparing a drug or medicine.

(4) "Dispensing" means those acts of processing a drug for delivery or for administration to a patient pursuant to the order of a practitioner consisting of: The checking of the directions on the label with the directions on the prescription or order to determine accuracy, the selection of the drug from stock to fill the order, the counting, measuring, compounding, or preparation of the drug, the placing of the drug in the proper container, the affixing of the label to the container, and the addition to a written prescription of any required notations. For purposes of this part, it does not include the acts of delivery of a drug to a patient or of administration of the drug to the patient.

(5) "Distributing" means the movement of a legend drug from a community pharmacy or institutional pharmacy to a nursing service area, while in the originally labeled manufacturer's container or in a prepackaged container labeled according to Federal and State statutes and regulations.

(6) "Dose" means the amount of drug to be administered at one time.

(7) "Facility" means a chronic and convalescent nursing home or rest home with nursing supervision.

(8) "Institutional Pharmacy" means that area within a chronic and convalescent nursing home commonly known as the pharmacy, which is under the direct charge of a full-time pharmacist and wherein drugs are stored and regularly compounded or dispensed and the records of such compounding or dispensing maintained, by such pharmacist.

(9) "Legend Drugs" means any article, substance, preparation or device which bears the legend: Federal law prohibits dispensing without a prescription.

(10) "Pharmaceutical Services" means the functions and activities encompassing the procurement, dispensing, distribution, storage and control of all pharmaceuticals used within the facility, and the monitoring of patient drug therapy.

(11) "Pharmacist" means a person duly licensed by the Connecticut Commission of Pharmacy to engage in the practice of pharmacy pursuant to Section 20-170 of the

Connecticut General Statutes.

(12) " 'PRN' Drug" means a drug which a physician has ordered to be administered only when needed under certain circumstances.

(13) "Practitioner" means a physician, dentist or other person authorized to prescribe drugs in the course of professional service in the State of Connecticut.

(14) "Single Unit" means one, discrete pharmaceutical dosage form (e.g., one tablet or one capsule) of a drug. A single unit becomes a unit dose, if the physician orders that particular amount of a drug.

(15) "Unit Dose" means the ordered amount of a drug in a prepackaged dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(b) **Pharmaceutical services.**

(1) Each facility shall assure the availability of pharmaceutical services to meet the needs of the patients. All such pharmaceutical services shall be provided in accordance with all applicable federal and state laws and regulations.

Drug distribution and dispensing functions shall be conducted through:

(A) a community pharmacy; or

(B) an institutional pharmacy.

(2) The pharmaceutical services obtained by each facility shall be provided under the supervision of a pharmacist as follows:

(A) If the facility operates an institutional pharmacy, the facility shall employ a pharmacist who shall supervise the provision of pharmaceutical services at least thirty-five (35) hours per week.

(B) When pharmaceutical services are obtained through a community pharmacy, the facility shall have a written agreement with a pharmacist to serve as a consultant on pharmaceutical services, as follows:

(i) The consultant pharmacist shall visit the facility at least monthly, to review the pharmaceutical services provided, make recommendations for improvements thereto and monitor the service to assure the ongoing provision of accurate, efficient and appropriate services.

(ii) Signed dated reports of the pharmacist's monthly reviews, findings and recommendations shall be forwarded to the facility's Administrator, Medical Director and Director of Nursing and kept on file in the facility for a minimum of three (3) years.

(C) Whether pharmaceutical services are obtained through a community pharmacy or an institutional pharmacy, the facility shall ensure that a pharmacist is responsible for the following functions:

(i) compounding, packaging, labeling, dispensing and distributing all drugs to be administered to patients;

(ii) monitoring patient drug therapy for potential drug interactions and incompatabilities at least monthly with documentation of same; and

(iii) inspecting all areas within the facility where drugs (including emergency supplies) are stored at least monthly to assure that all drugs are properly labeled, stored and controlled.

(3) Proper space and equipment shall be provided within the facility for the storage, safeguarding, preparation, dispensing and administration of drugs.

(A) Any storage or medication administration area shall serve clean functions only and

shall be well illuminated and ventilated. When any mobile medication cart is not being used in the administration of medicines to patients, it shall be stored in a locked room that meets this requirement.

(B) All medication cabinets (stationary or mobile) shall be closed and locked when not in current use unless they are stationary cabinets located in a locked room that serves exclusively for storage of drugs and supplies and equipment used in the administration of drugs.

(C) Controlled substances shall be stored and handled in accordance with provisions set forth in Chapter 420b of the Connecticut General Statutes and regulations thereunder.

(D) When there is an institutional pharmacy:

(i) The premises shall be kept clean, lighted and ventilated, and the equipment and facilities necessary for compounding, manufacturing and dispensing drugs shall be maintained in good operational condition.

(ii) Adequate space shall be provided to allow specialized pharmacy functions such as sterile IV admixture to be performed in discrete areas.

(4) Each facility shall develop, implement and enforce written policies and procedures for control and accountability, distribution, and assurance of quality of all drugs and biologicals, which shall include the following specifics:

(A) Records shall be maintained for all transactions involved in the provision of pharmaceutical services as required by law and as necessary to maintain control of, and accountability for, all drugs and pharmaceutical supplies.

(B) Drugs shall be distributed in the facility in accordance with the following requirements:

(i) All medications shall be dispensed to patients on an individual basis except for predetermined floor stock medication.

(ii) Floor stock shall be limited to emergency drugs, contingency supplies of legend drugs for initiating therapy when the pharmacy is closed, and routinely used non-legend drugs. Floor stock may include controlled substances in facilities that operate an institutional pharmacy.

(iii) Emergency drugs shall be readily available in a designated location.

(C) Drugs and biologicals shall be stored under proper conditions of security, segregation and environmental control at all storage locations.

(i) Drugs shall be accessible only to legally authorized persons and shall be kept in locked storage at any time such a legally authorized person is not in immediate attendance.

(ii) All drugs requiring refrigeration shall be stored separately in a refrigerator that is locked or in a locked room and that is used exclusively for medications and medication adjuncts.

(iii) The inside temperature of a refrigerator in which drugs are stored shall be maintained within a thirty-six degree (36°) to forty-six degree (46°) fahrenheit range.

(D) All drugs shall be kept in containers that have been labeled by a pharmacist or in their original containers labeled by their manufacturer and shall not be transferred from the containers in which they were obtained except for preparation of a dose for administration. Drugs to be dispensed to patients on leaves of absence or at the time of discharge from the facility shall be packaged in accordance with the provisions of the Federal Poison Prevention

Act and any other applicable Federal or State Law.

(E) Drugs and biologicals shall be properly labeled as follows:

(i) Floor stock containers shall be labeled at least with the following information: name and strength of drug; manufacturer's lot number or internal control number; and, expiration date.

(ii) The label for containers of medication dispensed from an institutional pharmacy for inpatient use shall include at least the following information: name of the patient; name of prescribing practitioner; name, strength and quantity of drug dispensed; expiration date.

(iii) The label for containers of medication obtained from a community pharmacy for inpatient use shall include at least the following information: name, address and telephone number of the dispensing pharmacy; name of the patient; name of the prescribing practitioner; name, strength and quantity of drug dispensed, date of dispensing the medication; expiration date. Specific directions for use must be included in the labeling of prescriptions containing controlled substances.

(iv) The label for containers of medication dispensed to patients for inpatient self care use, or during leaves of absence or at discharge from the facility shall include at least the following information: name, address and telephone number of the dispensing pharmacy; name of the patient; name of the prescribing practitioner; specific directions for use; name, strength and quantity of the drug dispensed; date of dispensing.

(v) In cases where a multiple dose package is too small to accommodate a standard prescription label, the standard label may be placed on an outer container into which the multiple dose package is placed. A reference label containing the name of the patient, prescription serial number and the name and strength of the drug shall be attached to the actual multiple dose package. Injectables intended for single dose that are ordered in a multiple quantity may be banded together for dispensing and one (1) label placed on the outside of the banded package.

(vi) In lieu of explicitly stated expiration dating on the prescription container label, a system established by facility policy may be used for controlling the expiration dating of time-dated drugs.

(F) Drugs on the premises of the facility which are outdated, visibly deteriorated, unlabeled, inadequately labeled, discontinued, or obsolete shall be disposed of in accordance with the following requirements:

(i) Controlled substances shall be disposed of in accordance with Section 21a-262-3 of the regulations of Connecticut State Agencies.

(ii) Non-controlled substances shall be destroyed on the premises by a licensed nurse or pharmacist in the presence of another staff person, in a safe manner so as to render the drugs non-recoverable. The facility shall maintain a record of any such destructions which shall include as a minimum the following information: date, strength, form and quantity of drugs destroyed; and the signatures of the persons destroying the drugs and witnessing the destruction.

(iii) Records for the destruction of drugs shall be kept on file for three (3) years.

(G) Current pharmaceutical reference material shall be kept on the premises in order to provide the professional staff with complete information concerning drugs.

(H) The following additional requirements shall apply to any unit dose drug distribution

system:

(i) Each single unit or unit dose of a drug shall be packaged in a manner that protects the drug from contamination or deterioration and prevents release of the drug until the time the package is opened deliberately.

(ii) A clear, legible label shall be printed on or affixed securely to each package of a single unit or unit dose of a drug. Each drug label shall include the name; strength; for each unit dose package, the dosage amount of the drug; the lot or control number; and the expiration date for any time-dated drugs.

(iii) Packages of single unit or unit doses of drugs shall be placed, transported and kept in individual compartments.

(iv) Each individual drug compartment shall be labeled with the full name of the patient, and the patient's room number or bed number.

(I) The facility shall implement a drug recall procedure which can be readily implemented.

(5) Each facility shall develop and follow current written policies and procedures for the safe prescribing and administration of drugs.

(A) Medication orders shall be explicit as to drug, dose, route, frequency, and if P.R.N., reason for use.

(i) Medications not specifically limited as to time or number of doses shall be stopped in accordance with the following time frame: controlled substances shall be stopped within three (3) days; antibiotics and other antiinfectives (topical and systemic), anti-coagulants, antiemetics, cortico steroids (topical and systemic), cough and cold preparations, and psychotherapeutic agents shall be stopped within ten (10) days.

(ii) Orders for all other drugs shall remain in effect until the time of the next scheduled visit of the physician.

(iii) A staff member shall notify the practitioner of the impending stop order prior to the time the drug would be automatically stopped in accordance with the preceding policy.

(B) Patients shall be permitted to self-administer medications on a specific written order from the physician. Self-administered medication shall be monitored and controlled in accordance with procedures established in the facility.

(C) Medication errors and apparent adverse drug reactions shall be recorded in the patient's medical record, reported to the attending physician, director of nursing, and consultant pharmacist, as appropriate, and described in a full incident report in accordance with Section 19-13-D8t (g) of the Regulations of Connecticut State Agencies.

(6) A pharmacy and therapeutics committee shall oversee the pharmaceutical services provided to each facility, make recommendations for improvement thereto, and monitor the service to ensure its accuracy and adequacy.

(A) The committee shall be composed of at least one pharmacist, the facility's director of nursing, the facility's administrator, and a physician.

(B) The committee shall meet, at least quarterly, and document its activities, findings and recommendations.

(C) Specific functions of the committee shall, as a minimum, include the following:

(i) Developing procedures for the distribution and control of drugs and biologicals in the facility in accordance with these regulations;

(ii) Reviewing adverse drug reactions that occur in the facility and reporting clinically significant incidents to the Federal Food and Drug Administration; and

(iii) Reviewing medication errors that occur in the facility and recommending appropriate action to minimize the recurrence of such incidents.

(Effective March 30, 1994)