

.15 Pharmaceutical Services.

A. Facility Responsible for Pharmacy Services. The facility shall provide appropriate methods and procedures for administering drugs and biologicals. The facility shall be responsible for providing drugs and biologicals for its patients. Pharmaceutical services shall be provided in accordance with accepted professional principles and appropriate federal, State, and local laws. Any regulation in this chapter shall govern if higher.

B. Composition of Pharmaceutical Services Committee.

(1) A pharmaceutical services committee (or its equivalent) shall develop written policies and procedures for safe and effective drug therapy, distribution, control, and use. The composition of the committee shall include at least:

- (a) The pharmacist;
- (b) The director of nursing services;
- (c) The consultant dietitian;
- (d) One physician;
- (e) The administrator.

(2) All members of the committee are not required to be present at all meetings. The participation of members at a specific meeting shall be controlled by the agenda items to be discussed.

(3) Policies and procedures developed by the pharmaceutical services committee may not prohibit or restrict a resident from receiving medications from the pharmacy of the resident's choice except that, when the cost of any medication obtained from the pharmacy selected by the resident exceeds the cost of the same or equivalent medication available through a pharmacy that the facility has contracted with to provide pharmaceutical services, the resident shall be responsible for the excess amount. The committee may not require the pharmacy to provide drugs by way of a specific drug distribution system such as unit dose or utilization of a particular packaging system.

C. Duties of Pharmaceutical Services Committee. Unless the Department decides that semiannual meetings are appropriate, the committee shall meet at least quarterly to:

(1) Establish policies and procedures which shall include, at least, statements which assure that:

- (a) Medications, legend and non-legend, administered to patients shall be ordered in writing by the patient's physician.
- (b) Medications shall be administered by appropriately licensed personnel in accordance with laws and regulations governing these acts or by certified graduates of a State-approved medication aide course.
- (c) The person who prepares medications shall give and record them.
- (d) Medicine may not be returned to the container. If the patient refuses the drug or a mistake occurs, the drug shall be discarded and an annotation entered on the patient's chart. For unit dose policy see §E of this Regulation.
- (e) Nurses may not package, repackage, bottle, or label in whole or in part any medication, or alter in any way by tampering or defacing any labeled medication.
- (f) Medications not specifically limited as to time or number of doses, when ordered, shall be automatically stopped in accordance with the written policy originated by the committee.
- (g) Before invoking stop order policies, the patient's attending physician shall be contacted for instructions so that continuity of the patient's therapeutic regimen is not interrupted.

(h) Medications shall be accurately and plainly labeled. Except for those over-the-counter medications which the Department may list as suitable for purchasing in bulk and dispensing as needed, the labels for all medications shall bear at

least:

- (i) The patient's full name;
- (ii) The name of the drug;
- (iii) Potency;
- (iv) Original filling date and date refilled, if applicable;
- (v) Name of prescribing physician;
- (vi) Expiration date of medication (month, year);
- (vii) Appropriate special handling instructions regarding special storage;
- (viii) Name and address of dispensing pharmacy;
- (ix) Serial number;
- (x) Number of tablets or capsules;
- (xi) Accessory federal labels.

(i) Medications shall be stored in a locked medication storage area provided at, or convenient to, the nurses' station, which:

- (i) Is well lighted;
- (ii) is located where personnel preparing drugs for administration will not be interrupted;
- (iii) Is sufficiently spacious to allow storage of external medications separately from internal medications;
- (iv) Is kept in a clean, orderly and uncluttered manner; and
- (v) Contains a refrigerator if medications are to be maintained in it.

(j) Poisons and medications marked "for external use only" shall be kept separate from general medications and Schedule II drugs.

(k) Schedule II drugs shall be kept in separately locked, securely fixed boxes or drawers in the storage area, under two locks. The lock on the door of a medication room shall be counted as one of the two locks.

(l) Facilities which administer Schedule II Drugs shall maintain a drug record in which is recorded:

- (i) The name of the patient, the date, time, kind, dosage, and method of administration of all Schedule II Drugs;
- (ii) The name of the physician who prescribed the medication;
- (iii) The name of the nurse or medicine aide who administered the medication.

(m) Each facility, whether or not operating a licensed pharmacy, shall maintain a record and signed Schedule II count at each change of shift.

(n) Two members of the nursing home staff (administrator or nurse) may destroy controlled dangerous substances in Schedules II—V on the premises of the nursing home. In addition to any other required records, a record of the disposal shall be maintained in the facility. A copy of the record of disposal shall be forwarded to the Division of Drug Control.

(o) All medications written on prescription for patients who have left the institution shall be destroyed in the presence of an authorized representative of the Department or two witnesses, authorized by the facility, who shall sign a notation on the patient's chart. Any adulterated, deteriorated, or out-dated medications shall be destroyed in the presence of an authorized representative of the Department or two witnesses, authorized by the facility, who shall sign an appropriate record of the

action.

(p) Medications shall be released to patients on a discharge only basis with the written authorization of the patient's physician.

(2) Establish the contents of sealed, emergency drug kits. A sealed kit shall be kept readily available in each nurses' station. A list of contents, with expiration dates, shall be attached to the kit. The kits shall be of durable construction and easily cleaned.

(3) Oversee the pharmaceutical service to the facility to ensure accuracy and adequacy.

(4) Make recommendations for improvements.

(5) Document actions and recommendations.

D. The pharmacist, or his agent, shall be responsible for delivering medications to the facility. Members of the patient's family or the sponsor for the patient may not deliver medications to the patient or to the facility.

E. Pharmacist Supervises Services. If the facility does not employ a licensed pharmacist, it shall arrange for, by written contract, a licensed pharmacist to provide consultation on the administering of the pharmacy services in accordance with the policies and procedures established by the pharmaceutical services committee. The pharmaceutical services shall be under the general supervision of a qualified pharmacist who shall:

(1) Be responsible, with the advice of the pharmaceutical services committee, to develop, coordinate, and supervise the pharmaceutical services and provide in-service at least twice yearly.

(2) Visit the facility frequently enough to assure that policies and procedures established by the pharmaceutical services committee are enforced.

(3) If a patient desires to designate a particular pharmacy to provide his drugs, he shall inform the pharmacist that he must conform with the facility's written policies concerning the provision of drugs. If the pharmacist agrees to comply with the facility's policies, the patient may request that the consenting pharmacist perform the service. If the pharmacist fails to comply with the policies, a representative of the facility shall discuss with the patient the policy infractions. If after being informed of the infractions the pharmacist then refuses to cooperate, the patient shall select another pharmacist who will agree to comply with the facility's policies. Providers of drugs, pharmacists, shall have access to a copy of the written patient care policies.

(4) Arrange for pharmacies which provide medications for patients in the facility to agree, in a written agreement with the facility, to maintain at the pharmacy a patient profile record system for each patient in the facility for whom prescriptions are dispensed.

(5) At least monthly, review at the facility the individual patient records, performing a drug regimen review, and document the findings in the patient's medical record.

(6) Bring to the attention of the attending physician any potential drug problems found during the drug regimen review.

(7) At least quarterly, submit a report to the pharmaceutical services committee on the status of the facility's pharmaceutical service and staff performance.

F. Unit Dose System. A facility, before installing a unit dose system which has not been approved by the Office of Health Care Quality, shall obtain this approval before installing the system. Prior approval is not required for a system which has been approved unless the facility plans to make substantial changes in the system. Departmental approval of the unit dose system indicates compliance with these regulations.

G. Administration of Medications for Leave of Absence of 24 Hours or Less.

(1) A facility shall develop policies and procedures to ensure that a resident or, if the resident lacks capacity, the resident's family or other person accompanying the resident is informed, both orally and in writing, on how the resident must safely and correctly take the resident's medications during a short-term leave of absence of 24 hours or less.

(2) A licensed nurse shall prepare, in accordance with a facility-developed procedure, medications to be sent with a

resident on short-term leave from the facility of 24 hours or less.