CA

71233 Pharmaceutical Service General Requirements

(a)

All hospitals having 100 beds or more shall have a pharmacy on the premises licensed by the California Board of Pharmacy. Those hospitals having less than 100 beds shall have a pharmacy license issued by the Board of Pharmacy pursuant to Section 4029 or 4056 of the Business and Professions Code.

(b)

The responsibility and the accountability of the pharmaceutical service to the medical staff and administration shall be defined.

(c)

A pharmacy and therapeutics committee shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems of procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist, in consultation with other appropriate health professionals and administration shall be responsible for the development and implementation of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. (2) The committee shall be responsible for the development maintenance of a formulary of drugs for use throughout the hospital.

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The committee shall be responsible for the development maintenance of a formulary of drugs for use throughout the hospital.

(d)

There shall be a system maintained whereby no person other than a pharmacist or an individual under the direct supervision of a pharmacist shall dispense medications for use beyond the immediate needs of the patient.

(e)

There shall be a system assuring the availability of prescribed medications 24 hours a day.

(f)

Supplies of drugs for use in medical emergencies only shall be immediately available at each nursing unit or service area as required.(1) Written policies and procedures establishing the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply shall be developed. (2) The emergency drug supply shall be stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container shall be listed on the outside cover and

shall include the expiration earliest date or lot number of any drugs within. (3) The supply shall be inspected by a pharmacist at periodic intervals specified in written policies. Such inspections shall occur no less frequently than every 30 days. Records of such inspections shall be kept for at least three years.

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(g)

No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person legally authorized to prescribe. The order shall include the name of the drug, the dosage, the frequency of administration, the route of administration if other than oral, and the date, time and signature of the prescriber. Orders for drugs should be written by the prescriber. Verbal orders for drugs shall be given only to a registered nurse or licensed pharmacist by a person legally authorized to prescribe and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The

prescriber shall countersign the order within 48 hours.

(h)

Standing orders for drugs may be used for specified patients when authorized by a person licensed to prescribe. These standing orders shall: (1) Specify the circumstances under which the drug is to be administered. (2) Specify the types of medical conditions of patients for whom the standing orders are intended. (3) Be initially approved by the pharmacy and therapeutics committee or its equivalent and be reviewed at least annually by that committee. (4) Be specific as to the drug, dosage, route and frequency of administration. (5) A copy of standing orders for a specific patient shall be dated, promptly signed by the physician and included in the patient's medical record.

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(i)

An individual prescriber may notify the hospital in writing of his own standing

orders, the use of which is subject to prior approval and periodic review by the pharmacy and therapeutics committee or its equivalent.

(j)

The hospital shall develop policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. The limitations shall be established for classes of drugs and/or individual drug entities.

(k)

If drugs are supplied through a pharmacy, orders for drugs shall be transmitted to the pharmacy either by written prescription of the prescriber, by an order form which produces a direct copy of the order or by an electronically reproduced facsimile. When drugs are not supplied through a pharmacy, such information shall be made available to the hospital pharmacist.

(l)

No medications shall be left at the patient's bedside.

(m)

Medications brought by or with the patient to the hospital shall not be administered to the patient unless all of the following conditions are met: (1) The drugs have been ordered by the patient's attending physician and the order entered in the patient's medical record. (2) The medication containers are clearly and properly labeled. (3) The contents of the containers have been examined and positively identified, after arrival at the hospital, by the patient's physician or the hospital pharmacist.

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The hospital shall establish a supply of medications which is accessible without entering the pharmacy during hours when the pharmacist is not available. Access to the supply shall be limited to designated registered nurses. Records of drugs taken from the supply shall be maintained and the pharmacist shall be notified of such use. The records shall include the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. The pharmacist shall be responsible for maintenance of the supply and assuring that all drugs are properly labeled and stored. The drug supply shall contain that type and quantity of drugs necessary to meet the immediate needs of patients as determined by the pharmacy and therapeutics committee.

(o)

Investigational drug use shall be in accordance with applicable state and federal laws and regulations and policies adopted by the hospital. Such drugs shall be used only under the direct supervision of the principal investigator, who shall be a member of the medical staff and be responsible for assuring that informed consent is secured from the patient. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects,

interactions and symptoms of toxicity of investigational drugs shall be available at the nursing station where such drugs are being administered and in the pharmacy. The pharmacist shall be responsible for the proper labeling, storage and distribution of such drugs pursuant to the written order of the investigator.

(p)

No drugs supplied by the hospital shall be taken from the hospital unless a prescription or medical record order has been written for the medication and the medication has been properly labeled and prepared by the pharmacist in accordance with state and federal laws, for use outside of the hospital.

(q)

Labeling and storage of drugs shall be accomplished to meet the following requirements: (1) Individual patient medications may be returned to the pharmacy provided that lot control is maintained if the drugs are to be reissued. (2) All drug labels must be legible and in compliance with state and federal requirements. (3) All labeling of drugs shall be performed by one legally authorized to prescribe or dispense or under the supervision of a pharmacist. (4) Test agents, germicides, disinfectants and other household substances shall be stored separately from drugs. (5) External use drugs in liquid, tablet, capsule or powder form shall be segregated from drugs for internal use. (6) Drugs shall be stored at appropriate temperatures. Refrigerator temperature shall be from 2.2°C (36°F) to 7.7°C (46°F) and room temperature shall be between 15°C (59°F) and 30°C (86°F). (7) Drugs shall be stored in an orderly manner in well lighted cabinets, shelves, drawers or carts of sufficient size to prevent crowding. (8) Drugs shall be accessible only to responsible personnel designated by the hospital. (9) Drugs shall not be kept in stock after the expiration date on the label and no contaminated or deteriorated drug shall be available for use. (10) Drugs

maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing services and as required by hospital policy. (11) Discontinued individual patient's drugs not supplied by the hospital may be sent home with the patient. Those which remain in the hospital after discharge that are not identified by a lot number shall be destroyed in the following manner: (A) Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be recorded in the patient's medical record or in a separate log. Such a log shall be retained for at least three years. (B) Drugs not listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of pharmacist or registered nurse. The name of the patient, the name and strength of the drug, the prescription number if applicable, the amount destroyed, the date of destruction and the signatures of two witnesses shall be recorded in the patient's medical record or in a separate log. Such a log shall be retained for at least three years.

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(r)

The pharmacist shall develop and implement written quality control procedures for all drugs which are prepackaged or compounded in the hospital, including intravenous solution additives. He shall also develop and implement written quality control procedures for intravenous solution additives and shall establish a training program of physicians and registered nurses to assure compliance therewith.

(s)

The pharmacist shall be consulted on proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals and poisons used throughout the hospital.

(t)

Periodically, an appropriate committee of the medical staff shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration