S 72353. PHARMACEUTICAL SERVICE -GENERAL.

(a) Arrangements shall be made to assure that pharmaceutical services are available to provide patients with prescribed drugs and biologicals.

(b) Dispensing, labeling, storage and administration of drugs and biologicals shall be in conformance with state and federal laws.

(c) If a pharmacy is located on the premises, the pharmacy shall be licensed by the California State Board of Pharmacy and approved by the Department. The pharmacy shall not serve the general public unless a separate public entrance or a separate public serving window is utilized. Pharmacies located on the licensed premises of skilled nursing facilities shall be opened for inspection upon the request of an authorized Department representative.

(d) The facility shall not accept money, goods or services free or below cost from any pharmacist or pharmacy as compensation or inducement for referral of business to any pharmacy.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code; Sections 650 and 651, Business and Professions Code.

s 72355. Pharmaceutical Service -Requirements.

(a) Pharmaceutical service shall include, but is not limited to, the following:
(1) Obtaining necessary drugs including the availability of 24-hour prescription service on a prompt and timely basis as follows:
(A) Drugs ordered "Stat" that are not available in the facility emergency drug supply shall be available and administered within one hour of the time ordered during normal pharmacy hours. For those hours during which the pharmacy is closed, drugs ordered "Stat" shall be available and administered within two hours of the time ordered. Drugs ordered "Stat" which are available in the emergency drug supply shall be administered immediately.
(B) Anti-infectives and drugs used to treat severe pain, nausea, agitation, diarrhea or other severe discomfort shall be available and administered within four hours of the time ordered.
(C) Except as indicated above, all new drug orders shall be available on the same day ordered unless the drug would not normally be started until the next day.
(D) Refill of prescription drugs shall be available when needed.
(2) Dispensing of drugs and biologicals.
(3) Monitoring the drug distribution system which includes ordering, dispensing and administering of medication.
(4) Provision of consultative and other services furnished by pharmacists which assist in
the development, coordination, supervision and review of the pharmaceutical services within the facility.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72357. PHARMACEUTICAL SERVICE -LABELING AND STORAGE OF DRUGS.

(a) Containers which are cracked, soiled or without secure closures shall not be used. Drug labels shall be legible.

(b) All drugs obtained by prescription shall be labeled in compliance with state and federal laws governing prescription dispensing. No person other than the dispenser of the drug shall alter any prescription label.

(c) Nonlegend drugs shall be labeled in conformance with state and federal food and drug laws.

(d) Test reagents, germicides, disinfectants and other household substances shall be stored separately from drugs and shall not be accessible to patients.

(e) External use drugs in liquid, tablet, capsule or powder form shall be stored separately from drugs for internal use.

(f) Drugs shall be stored in appropriate temperatures. Drugs required to be stored at room temperature shall be stored at a temperature between 15 degrees C (59 degrees F) and 30 degrees C (86 degrees F). Drugs requiring refrigeration shall be stored in a refrigerator between 2 degrees C (36 degrees F) and 8 degrees C (46 degrees F). When drugs are stored in the same refrigerator with food, the drugs shall be kept in a closed container clearly labeled "drugs."

(g) Drugs shall be stored in an orderly manner in cabinets, drawers or carts of sufficient size to prevent crowding.

(h) Dose preparation and administration areas shall be well-lighted.

(i) Drugs shall be accessible only to personnel designated in writing by the licensee.

(j) Storage of nonlegend drugs at the bedside shall meet the following conditions:

(1) The manner of storage shall prevent access by other patients. Lockable drawers or cabinets need not be used unless alternate procedures, including storage on a patient’s person or in an unlocked drawer or cabinet are ineffective.

(2) The facility shall record in the patient health record the bedside medications used by the patient, based on observation by nursing personnel and/or information supplied by the patient.

(3) The quantity of each drug supplied to the patient for bedside storage shall be recorded in the health record each time the drug is so supplied.
(k) Storage of legend drugs at the bedside shall meet the conditions of 72357(j) and shall in addition:

(1) Be specifically ordered by the prescriber of the drugs, and

(2) Be limited to sublingual or inhalation forms of emergency drugs.

(l) Drugs shall not be kept in stock after the expiration date on the label and no contaminated or deteriorated drugs shall be available for use.

(m) The drugs of each patient shall be kept and stored in their originally received containers. No drug shall be transferred between containers.

(n) Discontinued drug containers shall be marked, or otherwise identified, to indicate that the drug has been discontinued, or shall be stored in a separate location which shall be identified solely for this purpose. Discontinued drugs shall be disposed of within 90 days of the date the drug order was discontinued, unless the drug is reordered within that time.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Sections 1418.5 and 1276, Health and Safety Code.

S 72359. PHARMACEUTICAL SERVICE - STOP ORDERS.

Written policies shall be established and implemented limiting the duration of new drug orders in the absence of a prescriber's specific indication for duration of therapy. The prescriber shall be contacted for new orders prior to the termination time established by the policy. Such policies shall include all categories of drugs.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72361. PHARMACEUTICAL SERVICE - ORDERS FOR DRUGS.

(a) No drugs shall be administered except upon the order of a person lawfully authorized to prescribe for and treat human illness.

(b) All drug orders shall be written, dated, and signed by the person lawfully authorized to give such an order. The name, quantity or specific duration of therapy, dosage and time or frequency of administration of the drug, and the route of administration if other than oral shall be specified. “P.R.N.” order shall also include the indication for use of a drug.

(c) Verbal orders for drugs and treatments shall be received only by licensed nurses, psychiatric technicians, pharmacists, physicians, physician’s assistants from their supervising physicians only, and certified respiratory therapists when the orders relate specifically to respiratory care. Such orders shall be recorded immediately in the patient’s health record by the person receiving the order and shall include the date and time of the order. The order shall be signed by the prescriber within five days.
(d) The signing of orders shall be by signature or a personal computer key. Signature stamps shall not be used.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72363. PHARMACEUTICAL SERVICE - DRUG ORDER PROCESSING.

Signed orders for drugs shall be transmitted to the issuing pharmacy within 48 hours, either by written prescription of the prescriber or by an order form which produces a direct copy of the order or by an electronically reproduced facsimile.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72365. PHARMACEUTICAL SERVICE - DRUG ORDER RECORDS.

Facilities shall maintain a record which includes, for each drug ordered by prescription, the name of the patient, the drug name, and strength, the date ordered, the date and amount received and the name of the issuing pharmacy. The records shall be kept at least one year.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72367. PHARMACEUTICAL SERVICE - PERSONAL MEDICATIONS.

(a) Medications brought by or with the patient on admission to the facility shall not be used unless the contents of the containers have been examined and positively identified after admission by the patient's physician or a pharmacist retained by the facility.

(b) The facility may use drugs transferred from other licensed health facilities or those drugs dispensed or obtained after admission from any licensed or governmental pharmacy and may accept the delivery of those drugs by any agent of the patient or pharmacy without the necessity of identification by a physician or pharmacist.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72369. PHARMACEUTICAL SERVICE - CONTROLLED DRUGS.

(a) Drugs listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall not be accessible to other than licensed nursing, pharmacy and medical personnel designated by the licensee. Drugs listed in Schedule II of the above Act shall be stored in a locked cabinet or a locked drawer separate from
noncontrolled drugs unless they are supplied on a scheduled basis as part of a unit dose medication system.

(b) Separate records of use shall be maintained on all Schedule II drugs. Such records shall be maintained accurately and shall include the name of the patient, the prescription number, the drug name, strength and dose administered, the date and time of administration and the signature of the person administering the drug. Such records shall be reconciled at least daily and shall be retained at least one year. If such drugs are supplied on a scheduled basis as part of a unit dose medication system, such records need not be maintained separately.

(c) Drug records shall be maintained for drugs listed in Schedules III and IV of the above Act in such a way that the receipt and disposition of each dose of any such drug may be readily traced. Such records need not be separate from other medication records.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

**S 72371. PHARMACEUTICAL SERVICE - DISPOSITION OF DRUGS.**

(a) Drugs which have been dispensed for individual patient use and are labeled in conformance with State and Federal law for outpatient use shall be furnished to patients on discharge on the orders of the discharging physician. If the physician's discharge orders do not include provisions for drug dispositions, drugs shall be furnished to patients unless:

(1) The discharging physician specifies otherwise or,

(2) The patient leaves or is discharged without a physician's order or approval or,

(3) The patient is discharged to a general acute care hospital, acute psychiatric hospital, or acute care rehabilitation hospital or,

(4) The drug was discontinued prior to discharge or,

(5) The labeled directions for use are not substantially the same as most current orders for the drug in the patient's health record.

(b) A record of the drugs sent with the patient shall be made in the patient's health record.

(c) Patient's drugs supplied by prescription which have been discontinued and those which remain in the facility after discharge of the patient shall be destroyed by the facility in the following manner:

(1) Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist and a registered nurse employed by the facility. 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 health record or in a separate log. Such log shall be retained for at least three years.

(2) Drugs not listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist or licensed 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 the person named above and one other person shall be recorded in the patient’s health record or in a separate log. Such log shall be retained for at least three years.

(d) Unless otherwise prohibited under applicable federal or state laws, individual patient drugs supplied in sealed containers may be returned, if unopened, to the issuing pharmacy for disposition provided that:

(1) No drugs covered under the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 are returned.

(2) All such drugs are identified as to lot or control number.

(3) The signatures of the receiving pharmacist and a registered nurse employed by the facility are recorded in a separate log which lists the name of the patient, the name, strength, prescription number (if applicable), the amount of the drug returned and the date of return. The log must be retained for at least three years.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

HISTORY Change without regulatory effect relettering duplicate subsection (c) to (d) filed 1–11–95 pursuant to section 100, title 1, California Code of Regulations (Register 95, No. 2).

S 72373. PHARMACEUTICAL SERVICE - UNIT DOSE MEDICATION SYSTEM.

In facilities utilizing a unit dose medication system, there shall be at least a 24-hour supply of all patient medications on hand at all times, except those drugs which are to be discontinued within the 24-hour period. Drugs that are part of a unit dose medication system shall not exceed a 48-hour supply.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72375. PHARMACEUTICAL SERVICE - STAFF.

(a) Facilities shall retain a consulting pharmacist who devotes a sufficient number of hours during a regularly scheduled visit, for the purpose of coordinating, supervising and reviewing the pharmaceutical service committee, or its equivalent, at least quarterly. The report shall include a log or record of time spent in the facility. There shall be a written agreement between the pharmacist and the facility which includes duties and
 responsibilities of both.
(b) A pharmacist shall serve on the pharmaceutical service committee and the patient care policy committee.
(c) A pharmacist shall review the drug regimen of each patient at least monthly and prepare appropriate reports. The review of the drug regimen of each patient shall include all drugs currently ordered, information concerning the patient's condition relating to drug therapy, medication administration records, and where appropriate, physician's progress notes, nurse's notes, and laboratory test results. The pharmacists shall be responsible for reporting, in writing, irregularities in the dispensing and administration of drugs and other matters relating to the review of the drug regimen to the administrator and director of the nursing service.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

S 72377. PHARMACEUTICAL SERVICE -EQUIPMENT AND SUPPLIES.

(a) There shall be adequate equipment and supplies necessary for the provision of pharmaceutical services within the facility including at least the following:

(1) Refrigerator with an accurate thermometer.
(2) Lockable drug cabinets, drawers, closets or rooms.
(3) Drug service trays and/or carts.
(4) Drug preparation counter area and convenient water source.
(5) Reference materials containing drug monographs on all drugs in use in the facility. Such monographs shall include information concerning generic and brand names, if applicable, available strengths and dosage forms and pharmacological data including indications and side effects.

(b) Emergency supplies as approved by patient care policy committee or pharmaceutical service committee shall be readily available to each nursing station. Emergency drug supplies shall meet the following requirements:

(1) Legend drugs shall not be stored in the emergency supply, except under the following conditions:

(A) Injectable supplies of legend drugs shall be limited to a maximum of three single doses in ampules or vials or one container of the smallest available multi-dose vial and shall be in sealed, unused containers.
(B) Sublingual or inhalation emergency drugs shall be limited to single sealed containers of the smallest available size.
(C) Not more than six emergency drugs in solid, oral dosage form or suppository dosage form for anti-infective, anti-diarrheal, antinausea, or analgesic use may be stored if in sealed containers. Not more than four doses of any one drug may be so stored.

(2) The emergency drug supply shall be stored in a portable container which is sealed in such a manner that the tamper-proof seal must be broken to gain access to the drugs. The director of nursing service or charge nurse shall notify the pharmacist when drugs have been used from the emergency kit or when the seal has been broken. Drugs used from the kit shall be replaced within 72 hours and the supply resealed by the pharmacist.

(3) The contents of the supply shall be listed on the outside of the container.

(4) The supply shall be checked at least monthly by the pharmacist.

(5) Separate records of use shall be maintained for drugs administered from the supply. Such records shall include the name and dose of the drug administered, name of the patient, the date and time of administration and the signature of the person administering the dose.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code; Section 4035, Business and Professions Code.

S 72523. PATIENT CARE POLICIES AND PROCEDURES.

... (c) Each facility shall establish and implement policies and procedures, including but not limited to:

...(5) Pharmaceutical services policies and procedures.

S 72525. REQUIRED COMMITTEES.

... (c) Committee composition and function shall be as follows:

(3) Pharmaceutical service committee.

(A) A pharmaceutical service committee shall direct the pharmaceutical services in the facility.

(B) The committee shall be composed of the following: a pharmacist, the director of nursing service, the administrator and at least one physician.

(C) The committee shall meet at least quarterly.

(D) The functions of the pharmaceutical service committee shall include, but not be limited to:

1. Establishing, reviewing, monitoring and approving policies and procedures for safe procurement, storage, distribution and use of drugs and biologicals.

2. Reviewing and taking appropriate action on the pharmacist’s quarterly report.
3. Recommending measures for improvement of services and the selection of pharmaceutical reference materials.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Sections 1276, 1315, 1316 and 1316.5, Health and Safety Code.