Title 22. Social Security
Division 5. Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies
Chapter 1. General Acute Care Hospitals
Article 3. Basic Services

Amend section 70241 to read as follows:

Section 70241. Clinical Laboratory Service Definition.

"Clinical laboratory service" means the performance of clinical laboratory tests with ~~appropriate~~ staff, space, equipment, and supplies to meet the needs of the patients.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1276, 131000, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70243 to read as follows:

Section 70243. Clinical Laboratory Service General Requirements.

(a) Clinical laboratories ~~shall~~must operate in conformance with the ~~California~~ Business and Professions Code, ~~Division 2, Chapter 3 (S~~sections 1200 to 1327. ~~1322, inclusive)~~ ~~and the California Administrative Code, Title 17, Chapter 2, Subchapter 1, Group 2 (Sections 1030 to 1057, inclusive).~~ All hospital blood banks and transfusion services must comply with:

(1) The Standards for Blood Banks and Transfusion Services pursuant to Health and Safety Code sections 1602.5 and 1602.6 must implement the amendments to these standards pursuant to the effective date set forth in Health and Safety Code section 1602.5(d)(1), unless otherwise noticed by the department pursuant to Health and Safety Code sections 1602.5(d)(2) and 1602.6(b).

(2) Health and Safety Code sections 1600 to 1630, as applicable.

(b) All hospitals ~~shall~~must maintain clinical laboratory services and equipment for routine laboratory work, such as urinalysis, complete blood count~~s~~, ABO/Rh blood

typing, cross matching (compatibility tests), antibody screening, routine chemistry, microbiology, serology, and such other tests as are required by these regulations.

(c) All hospitals ~~shall~~must maintain or make provision for clinical laboratory services for the performance of tests in chemistry, microbiology, serology, hematology, pathology, and such other tests as are required by these regulations.

(d) The clinical laboratory service must develop, implement, and maintain documented medical and technical policies and procedures pertaining to laboratory staff, specimen collection, and test performance. ~~Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration.~~ Policies ~~shall~~must be approved by the governing body. Documented ~~P~~procedures must~~shall~~ be approved by the ~~administration and~~ medical staff and facility administration.~~where such is appropriate.~~

(e) The responsibility and the accountability of the clinical laboratory service to the medical staff and administration ~~shall~~must be defined in writing and documented.

(f) The clinical laboratory service must ensure that the consultative and support services that relate to the care and safety of donors and transfusion recipients are directed by an individual pursuant to Health and Safety Code sections 1602.5 and 1602.6.

~~(f)~~(g) The ~~director of the~~ clinical laboratory service ~~shall~~must ~~assure~~ensure that:

(1) Laboratory staff perform all ~~E~~examinations ~~are performed~~ accurately and ~~in a timely fashion.~~ within a timeframe that meets the needs of the patients as determined by patient care plans and physicians' orders.

(2) Policies and ~~P~~procedures are established:

(A) For the collection of specimens which must include the integrity of the collection, and;

(B) G~~g~~overn~~ing~~ the provision of all laboratory services for all ~~out~~patients.

(3) ~~Laboratory Systems identify~~ All specimens must be identified and tracked by: the patient's name or identifier, the date and time the test was requested, the date and time the specimen was obtained, the time the request reached the laboratory, the time the laboratory completed the test, ~~and~~ the date and time test results were made available to

medical staff, any special handling ~~which was~~ required~~d~~ments, and any additional information required by laboratory procedures or requested by a physician for test result interpretation. Specimens and the required information must be maintained and documented.

~~(4) Procedures are established to ensure the satisfactory collection of specimens~~.

~~(5)~~(4) A communications system ~~to~~ that provides efficient information exchange between the laboratory and ordering clinicians, departments, and other lawfully authorized parties ~~related areas of the hospital~~ is established and maintained.

~~(6)~~(5) A Q~~q~~uality Assessment and Performance Improvement (QAPI) program is developed, implemented, and maintained according to Title 42, Code of Federal Regulations 482.21. The clinical laboratory service QAPI program ~~control system within the laboratory~~ must be designed to ensure the medical reliability of laboratory data is established and maintained, and that the QAPI program has a process to collect and evaluate quality indicator data on a scheduled basis. The results of control tests ~~shall~~must be readily available to ~~in the~~ hospital staff. The clinical laboratory QAPI program must be integrated into the hospital-wide QAPI program.

~~(7)~~(6) Reports of all laboratory examinations and test results are recorded and made a part of the patient's medical record ~~as soon as is practical~~.

~~(8)~~(7) No laboratory procedures are performed except on the order of a person lawfully authorized to give such an order.

~~(g)~~(h) Tissue specimens ~~shall~~ must be examined by a physician who is certified or eligible for certification in ~~anatomical, and/or~~ anatomic pathology or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology ~~or possesses qualifications which are equivalent to those required for certification~~. Oral specimens may be examined by a dentist who is certified or eligible for certification as an oral pathologist by the American Board of Oral and Maxillofacial Pathology. A record of the ~~his~~ findings ~~shall~~ must become a part of the patient's medical record. A tissue file ~~shall~~must be maintained at the hospital or at the principal office of the consulting pathologist.

~~(h)~~(i) ~~The~~ All radioactive materials used, ~~storage~~ stored, and ~~disposal of~~ disposed of ~~radioactive materials~~ by the clinical laboratory ~~shall~~ must comply with the ~~California~~ Radiation Control Regulations, ~~Subchapter 4, Chapter 5, Title 17, California Administrative Code.~~ Title 17, California Code of Regulations section 30100 et seq.

~~(i)~~(j) Where the hospital depends on outside blood banks, there ~~shall~~must be a ~~written~~ documented agreement governing the procurement, transfer, and availability of blood. The blood bank and transfusion service must have documented policies and procedures in place to evaluate the ability of suppliers of critical materials, equipment, and services to meet blood bank and transfusion service needs. The blood bank and transfusion service must participate in the evaluation and selection of suppliers prior to the acceptance of an agreement. Documented agreements and any documented changes to agreements with blood bank and transfusion service suppliers must delineate the expectations of the blood bank and transfusion service, and the supplier, and include an explanation of how those expectations are met.

~~(j) 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.~~

NOTE: Authority cited: Sections ~~208(a) and~~ 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1602.5, 1602.6, 1276, 131000, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70245 to read as follows:

Section 70245. Clinical Laboratory Service Staff.

(a) A physician ~~shall have overall responsibility for the clinical laboratory service. This physician shall be~~must be certified or eligible for certification in either anatomic pathology or clinical pathology ~~and/or pathologic anatomy~~by either the American Board of Pathology or the American Osteopathic Board of Pathology. The Director of the Clinical Laboratory Service must have the overall responsibility for the service. If such a

pathologist is not available on a full-time or regular part-time weekly basis, a physician or a licensed clinical laboratory bioanalyst who is available on a full-time or regular part-time basis ~~may administer~~ must serve as the director of the clinical laboratory. In this circumstance, a pathologist, qualified as above, ~~shall~~must provide consultation at ~~suitable~~ intervals ~~to~~ that ~~assure high quality service~~ meet the needs of the patients.
(b) The director of the clinical laboratory service must ensure that they fulfill their duties in accordance with the federal Clinical Laboratory Improvement Amendments (CLIA), the Business and Professions Code, pursuant to Health and Safety Code sections 1602.5 and 1602.6.
~~(b)~~(c) There ~~shall~~ must be a physician, clinical laboratory bioanalyst, or clinical laboratory ~~technologist~~ scientist on duty or on call ~~at all times~~ 24 hours per day, 7 days per week, to assure the availability of emergency laboratory services.
~~(c)~~(d) There ~~shall~~must be ~~sufficient~~ staff who are certified or licensed by the Department and can provide ~~with adequate training and experience~~ all clinical laboratory services offered to meet the needs of the patients. ~~service being offered.~~ Staff may included, but are not limited to,
(1) Phlebotomists
(2) Clinical laboratory scientist
(3) Clinical laboratory director

NOTE: Authority cited: Sections ~~208(a) and~~ 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1276, 131000, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70247 to read as follows:
Section 70247. Clinical Laboratory Service Equipment and Supplies.
(a) There ~~shall~~must be ~~sufficient~~ equipment and supplies maintained to ~~perform the laboratory services being offered~~ensure the service can meet the needs of the patient as determined by patient care plans and physicians' orders.

(b) The hospital ~~shall~~must maintain blood storage facilities pursuant to Title 24, California Building Code section 1224.17.2.3 Refrigerated Blood Storage Facilities and ~~in conformance with the provisions of Section 1002(g), Article 10, Group 1, Subchapter 1, Chapter 2, Title 17, California Administrative Code. Such facilities shall~~must be inspected every seven days ~~at appropriately short intervals each day of the week to assure~~to ensure these requirements are being ~~fulfilled~~met.

NOTE: Authority cited: Sections 20, 1254, 1275 and 131200, Health & Safety Code. Reference: Sections 1276, 1602.5, 1602.6, 131000, 131050, 131051, and 131052, Health & Safety Code.

Amend section 70249 to read as follows:

Section 70249. Clinical Laboratory Service Space.

(a) ~~Adequate laboratory space a determined by the Department must be maintained.~~ The clinical laboratory service space must have laboratory workspace, refrigerated blood storage facilities, and hand washing fixtures pursuant to requirements in Title 24, California Building Code section 1224.17.

(b) There must be space in the laboratory for storage of specimens and equipment. There must be enough clear space to permit staff to work and move about without damaging specimens or injuring themselves.

~~(b)~~(c) ~~If~~ When tests on outpatients are ~~to be~~ performed at the hospital, outpatient access to the laboratory ~~shall~~must not traverse a nursing unit.

NOTE: Authority cited: Sections 20, 1254, 1275 and 131200, Health & Safety Code. Reference: Section 1276 131000, 131050, 131051, and 131052, Health & Safety Code.

Amend section 70261 to read as follows:

§ 70261. Pharmaceutical Service Definition.

"Pharmaceutical service" means the procuring, storing, ~~manufacturing,~~ compounding, repackaging, distributing, dispensing, ~~distributing, storing, and~~ administering, and disposing of all drugs, biologicals, and chemicals by ~~appropriate~~ pharmaceutical staff, with ~~which has adequate~~ space, training, equipment, and supplies to allow the pharmaceutical service to meet the needs of the patients. Pharmaceutical service~~s also~~ include the evaluation and monitoring of the appropriate use of drugs and drug-related devices and the provision of ~~drug~~ information about drugs and drug-related devices to other health professionals and patients. Pharmaceutical service may also include participation in drug-therapy management by licensed pharmacists who have been granted privileges by the governing board.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health & Safety Code. Reference: Sections 131050, 131051, and 131052, Health & Safety Code.

Amend section 70263 to read as follows:

§ 70263. Pharmaceutical Service General Requirements.

(a) All hospitals having a licensed bed capacity of ~~100 or~~ more than 100 beds ~~shall~~must have a pharmacy on the premises licensed by the California Board of Pharmacy pursuant to the Business and Professions Code section 4029. ~~Those~~ H~~h~~ospitals having ~~fewer than~~ 100 licensed beds or less ~~shall~~must have a ~~pharmacy~~ license issued by the California Board of Pharmacy pursuant to the Business and Professions Code section 4029 or 4056.

(b) The responsibility and accountability of the pharmaceutical service to the medical staff and administration ~~shall~~must be defined in writing and documented and made available to the Department upon request.

(c) ~~A~~ The pharmaceutical service must establish a pharmacy and therapeutics committee~~, or a committee of equivalent composition, shall be established~~. The C~~c~~ommittee ~~shall~~must consist of at least one physician, ~~one pharmacist,~~the Director of

the Pharmaceutical Service, or their representative, the ~~d~~Director of Nursing ~~service~~ or ~~his or her~~ their representative, and the A~~a~~dministrator or ~~his or her~~ their representative.

(d) The Pharmacy and Therapeutics Committee must:

(1) ~~The committee shall develop written~~ Develop, implement, and maintain documented policies and procedures, consistent with state and federal laws and regulations and accepted professional standards of practice for safe and effective drug ~~establishment of safe and effective systems for~~ procurement, storage, compounding, repackaging, distribution, dispensing, administration, and use of drugs and chemicals.

(2) Develop, implement, and maintain documented policies, procedures, consistent with state and federal laws and regulations and accepted professional standards of practice for safe and effective:

(A) Disposal of all drugs.

(B) Selection, use, and disposal of chemicals and cleaning agents in areas where sterile compounding is performed.

(C) Drug error reporting and prevention.

(D) Drug reconciliation for high-risk patients upon admission to the hospital.

~~The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations 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~~

(E) Development, implementation, and maintenance of a formulary and a formulary system of drugs for use throughout the hospital.

(F) Use and procurement of non-formulary drugs as necessary.

(G) Minimization of drug diversion.

(H) Management of drug recalls and shortages.

(I) Use of drug delivery systems and drug-related devices, including automated drug dispensing systems (ADDS), drug compounding devices, and drug administration devices.

(J) Use of medicinal cannabis pursuant to Health and Safety Code sections 1649 – 1649.6.

(K) Provisions for all future drugs, devices, and treatments of pharmaceutical services in the hospital.

(3) Participate in the procurement decisions, evaluation, and monitoring of drug delivery systems and drug-related devices.

(e) The Director of the Pharmaceutical Service, in consultation with administration and other health care professionals with experience and training or knowledge in pharmaceutical services must approve procedures.

(f) The governing body must approve policies.

~~(d)~~(g) The~~re~~ pharmaceutical service ~~shall~~must ~~be~~ establish and maintain a system ~~maintained~~ whereby no person other than a pharmacist or an individual under the direct supervision of a pharmacist ~~shall~~must dispense ~~medications~~ drugs for use beyond the immediate needs of the patients.

~~(e)~~(h) The~~re~~ pharmaceutical service ~~shall~~must establish and maintain ~~be~~ a system ~~assuring~~ ensuring the availability of prescribed ~~medications~~ drugs 24 hours a day.

(i) The pharmaceutical service must establish and maintain an alternate system that ensures current information on drugs is available 24 hours a day in the event the current system fails.

~~(f)~~(j) Supplies of drugs for use in medical emergencies ~~only~~ ~~shall~~must be immediately available at each nursing unit or service area as required.

(1) The Pharmacy and Therapeutics Committee, must develop, implement, and maintain documented ~~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~~must be stored in a clearly marked portable cart or container. ~~which is sealed by the pharmacist~~ The emergency drug supplies must be stocked and sealed by pharmacy staff as permitted by law in such a manner that ~~a~~the seal must be broken to gain access to the contents. ~~drugs.~~ The contents of the cart or

container ~~shall~~must be listed on the outside cover and ~~shall~~must include the earliest expiration date of any drugs within the cart or container. If the emergency drug supply container is stored within another cart or container, the contents of the emergency drug supply container and their earliest expiration date must be listed on the outside of the outer cart or container. The outer cart or container must be sealed in such a way that the seal must be broken to gain access to the contents.

(3) The pharmaceutical service must establish and maintain a monitoring system to ensure proper stocking and sealing of emergency drug supply carts and containers.

~~(3)~~(4) ~~The supply shall be inspected by a~~A pharmacist, an intern pharmacist, or a pharmacy technician under the direct supervision and control of a pharmacist, must inspect the emergency drug supply containers and carts at periodic intervals ~~specified~~ established in documented ~~written~~ policies. Such inspections ~~shall~~ must occur ~~no less frequently than~~ every 30 days. The pharmaceutical service must keep ~~R~~records of such inspections ~~shall be kept~~ for at least three years.

~~(g)~~(k) ~~No d~~Drugs ~~shall~~must only be administered ~~except~~ by licensed ~~personnel~~staff lawfully authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or a practitioner acting in accordance with scope-of-practice laws and hospital policies~~furnish~~. This ~~shall~~must not preclude the administration of aerosol drugs by respiratory care practitioners.

(1) The order ~~shall~~must include the name of the drug, the dosage, ~~and the~~ frequency of administration, ~~the~~ route of administration, ~~if other than oral,~~ indication for use, and ~~the~~ date, time, and signature or electronic signature of the prescriber or practitioner acting in accordance with scope-of-practice laws and hospital policies~~furnisher~~.

(2) Orders for drugs ~~should~~must be written or electronically transmitted in a secure manner by the prescriber or practitioner acting in accordance with scope-of-practice laws and hospital policies ~~furnisher~~.

(3) Verbal and telephone orders for drugs ~~shall~~must ~~be given only by a person lawfully authorized to prescribe or furnish and shall~~ be recorded promptly in the patient's medical record, noting the name ~~of the person giving the verbal order~~ of the prescriber,

the name of the lawfully authorized individual calling in the order (the agent of the prescriber), and the name and the signature or electronic signature of the individual receiving the order. The individual receiving the order shall sign the order. Verbal and telephone orders for drugs must be avoided to the extent possible. The prescriber ~~or furnisher~~or practitioner acting in accordance with scope-of-practice laws and hospital policies ~~shall~~must countersign the order in writing or electronically within 48 hours.

~~(1)~~(A) ~~Verbal orders for administration of medications shall be received and recorded o~~Only ~~by those~~ health care professionals whose scope of licensure authorizes them to receive orders for ~~medication~~ drugs may receive and record verbal or telephone orders. The person receiving a verbal or telephone order must read the order back to the individual making the order to ensure its accuracy and record the read-back in the patient's medical record.

(B) Verbal or telephone orders for chemotherapeutic drugs are not permitted except to discontinue the drug.

~~(2)~~(C) ~~Medications~~Verbal and telephone order for drugs and treatments ~~shall~~must be administered as ordered.

~~(h)~~(I) Printed and electronic pre-approved order sets ~~Standing orders~~ and drug therapy protocols ~~for drugs~~ may be used for specified ~~patents~~ patients when authorized by a person lawfully authorized ~~licensed~~ to prescribe. ~~A copy of standing order for a specific patient shall be dated, promptly signed by the prescriber and included in the patient's medical record.~~ These ~~standing orders~~order sets and drug therapy protocols ~~shall~~must:

(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~~ order set or drug therapy protocol are intended.

(3) Be ~~initially~~ approved by the P~~p~~harmacy and T~~t~~herapeutics C~~c~~ommittee~~ or its equivalent~~ and ~~be~~ reviewed at least annually by that committee.

(4) Be specific as to the drug, dosage, route, indication, and frequency of administration.

(5) Be signed when the order is given by a lawfully authorized prescriber for a specified patient and included in the patient's medical record.

(m) Hospitals may use standing orders that authorize the administration of a drug to a patient by authorized personnel without a patient-specific order from a physician when the patient meets specific criteria clearly identified in the standing order or associated protocol. Standing orders must:

(1) Specify the circumstances under which the drug is to be administered.

(2) Specify the criteria that must be observed to establish the patient has the medical condition for which the standing order is intended.

(3) Be approved by the Pharmacy and Therapeutics Committee and reviewed at least annually by that committee.

(4) Be specific as to the drug dosage, route, indication, and frequency of administration.

(5) Be documented in the patient's medical record at the time of initiation or as soon as possible thereafter. The attending physician or another authorized practitioner must retrospectively review the execution of the order and document the medical necessity, or lack thereof, in the patient's medical record.

~~(i)~~(n) An individual prescriber may notify the hospital in writing of their ~~his or her~~ own standing orders, the use of which is subject to prior documented approval and ~~periodic~~ at least annual review by the P~~p~~harmacy and T~~t~~herapeutics C~~c~~ommittee ~~or its equivalent~~.

~~(j)~~(o) The hospital ~~shall~~must develop policies limiting the duration of drug therapy in the absence of a prescriber~~'s~~ specifically indicating~~on~~ the ~~of~~ duration of drug therapy ~~or~~ and under other circumstances documented~~recommended~~ by the P~~p~~harmacy and T~~t~~herapeutics C~~c~~ommittee ~~or its equivalent~~ and approved by the executive committee of the medical staff. ~~The~~Such limitations ~~shall~~must be established for classes of drugs and/or individual drug entities.

~~(k)~~(p) ~~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.~~ All drug orders must be recorded in the patient's medical

record. The pharmacist must receive a copy of every drug order. A pharmacist must review all drug orders for appropriateness. This must be done before the first dose is administered to the patient or released by an automated dispensing device, except in emergency situations in which patient care would be negatively impacted by the delay from a pharmacist's review of the order. A pharmacist must, in accordance with hospital policies and procedures, retrospectively review all emergency drug orders where drugs were administered or released from an automated dispensing machine prior to a pharmacist's review of the drug order.

~~(l)~~(q) ~~Medications~~Except for drugs being administered parenterally, drugs ~~shall~~must not be left at the patient's bedside unless the prescriber so orders. Such bedside ~~medications~~drugs ~~shall~~must be kept in a manner to prevent unauthorized access. ~~cabinet, drawer or in possession of the patient.~~ Medicinal cannabis must be kept in a locked container, pursuant to Health and Safety Code section 1649.2. Except for drugs being administered parenterally, ~~D~~ddrugs ~~shall not be left at the bedside which are~~ listed in Schedules II, III, ~~and~~ IV, and V of Title 21, United States Code section 812.~~the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended,~~ must not be left at the bedside. If the ~~hospital~~ prescriber permits bedside storage of ~~medications~~ drugs, the pharmaceutical service must have documented ~~written~~ policies and procedures for dispensing, storing~~age~~, administering, monitoring, and documenting ~~records of~~ the use of such ~~medications~~ drugs.

~~(m)~~(r) ~~Medications~~ Drugs brought by or with the patient to the hospital ~~shall~~must not be administered to the patient unless ~~all of~~ the following conditions are met:

(1) The drugs have been ordered by an authorized ~~person lawfully~~ prescriber or a practitioner acting in accordance with scope-of-practice laws and hospital policies ~~authorized to give such an order~~ and the order ~~entered~~ is recorded in the patient's medical record.

(2) The ~~medication~~ drug containers are clearly and properly labeled.

(3) The contents of the containers have been examined and the drugs can be positively identified, after arrival at the hospital, by the patient's prescriber ~~physician~~ or ~~the~~a hospital pharmacist.

(4) The verification must be recorded in the patient's medical record.

(5) When a terminal patient brings medicinal cannabis to the hospital, the conditions in Health and Safety Code sections 1649 – 1649.6 must also be met.

~~(n)~~(s) The hospital ~~shall~~must establish a supply of ~~medications~~drugs which is accessible without entering either the pharmacy or drug storage room during hours when the ~~pharmacist is not available.~~pharmacy is closed. Except in emergency situations, a pharmacist must review all drug orders prior to removal from the drug supply. Access to the supply ~~shall~~must be limited to designated and trained health care professionals who may administer drugs under their scope of practice, as permitted by hospital policy~~registered nurses~~. The healthcare professional must have either an electronic or paper copy of the order immediately available to verify the drug selection when removing a drug from the supply. Records of drugs taken from the supply ~~shall~~must be maintained and the pharmacist ~~shall~~must be notified of such use. The records ~~shall~~must include the name, ~~and~~ strength of the drug, and dosage form of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered, and the signature or electronic signature of the authorized health care professional~~registered nurse~~. The pharmacist ~~shall~~must be responsible for maintenance of the supply and assuring that all drugs are properly labeled and stored. The drug supply ~~shall~~must contain ~~that~~the type and quantity of drugs necessary to meet the immediate needs of patients as determined by the P~~p~~harmacy and T~~t~~herapeutics C~~c~~ommittee.

~~(o)~~(t) Investigational drug use ~~shall~~must 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.~~

(1) Hospitals must have documented, implemented, and maintained policies and procedures addressing the use of investigational drugs, and patients must be allowed to continue the use of an investigational drug if the hospital:

(A) Receives approval from the Pharmacy and Therapeutics Committee Chair or designated medical specialist.

(B) Receives a copy of the study protocol with documented guidance from the main investigator in regard to preparing, dosing, administering, and monitoring.

(C) Receives copies of the patient's informed consent documentation.

(D) Has a usage and dosing accountability and tracking system conducted by the pharmaceutical service.

(E) Provides necessary laboratory monitoring and assessment.

(2) The pharmacist is responsible for the proper labeling, storage, and distribution of investigational drugs. Investigational drugs must be dispensed only on the documented order of an individual authorized to prescribe the drugs and in accordance with the protocol for the drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational drugs must be available at all times:

(A) In the nursing station where such drugs are being administered.

(B) To the staff responsible for administering the drugs and monitoring the patient.

(C) In the pharmacy.

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

~~(q)~~(v) Labeling and storage of drugs ~~shall~~must be accomplished to meet the following requirements:

~~(1) Individual patient medications except those that have been left at the patient's bedside, may be returned to the pharmacy for appropriate disposition.~~

~~(2)~~(1) All drug labels must be legible and in compliance with state and federal requirements.

~~(3)~~(2) Drugs ~~shall~~must be labeled only by persons legally authorized to prescribe or dispense or under the supervision of a pharmacist.

(3) Drugs brought in, by, or with the patient that will not be continued in the hospital must be sent to the pharmacy for documentation and storage or sent home with the patient's designated representative.

(4) Test agents, germicides, disinfectants, and other household substances ~~shall~~must be stored separately from drugs.

(5) External use drugs in liquid, tablet, capsule, or powder form ~~shall~~must be segregated from drugs for internal use.

(6) Drugs ~~shall~~must be stored at ~~appropriate~~ temperatures specified in the manufacturer's instructions or, if the temperature is not specified, must be stored as required by Title 21, Code of Federal Regulations subdivision (c) of section 205.50.

(A) Refrigerator temperature ~~shall~~must be between 2~~.2°~~ degrees Celsius (36~~°~~ degrees Fahrenheit) and ~~7.7°~~ 8 degrees Celsius (46~~°~~ degrees Fahrenheit).

(B) Freezer temperature must be between -25 degrees Celsius (-13 degrees Fahrenheit) and -10 degrees Celsius (14 degrees Fahrenheit). ~~and~~

(C) Controlled room temperature ~~shall~~must be between ~~15°~~ 20 degrees Celsius (~~59°~~ 68 degrees Fahrenheit) and ~~30°~~ 25 degrees Celsius (~~86°~~ 77 degrees Fahrenheit).

Fluctuation in temperatures between 15 degrees Celsius (59 degrees Fahrenheit) and 30 degrees Celsius (86 degrees Fahrenheit) that are experienced in pharmacies, hospitals, warehouses, and during shipping are allowed.

(D) Temperature records must be maintained for all drug and vaccine storage areas and records must be kept available for three (3) years.

(7) Drugs ~~shall~~must be stored in a~~n~~ clean and orderly manner in well-lighted cabinets, shelves, drawers, or carts ~~of sufficient size to~~ prevent overcrowding. The cabinets, shelves, drawers, or carts must be free from foreign and organic material including, but not limited to, dust, soil, blood, or secretions.

(8) Drugs ~~shall~~must be accessible only to ~~responsible personnel~~staff designated by the hospital, or to the patient as provided in section 70263~~(l)~~(q) above.

(9) Drugs ~~shall~~must not be kept in stock after the expiration date on the label. Mislabeled, ~~and no~~ contaminated, ~~or~~ deteriorated, or drugs otherwise unusable ~~shall~~must not be available for patient use.

(10) Drug~~s~~ stock maintained outside the pharmacy ~~on the nursing unit shall~~must be inspected at least monthly by a pharmacist, or an intern pharmacist or pharmacy technician under the direct supervision and control of a pharmacist. ~~Any~~ When there are irregularities during the inspection, the, ~~i~~irregularities ~~shall~~must be reported within 24 hours to the Director of the Pharmaceutical Service, the ~~d~~Director of ~~n~~Nursing ~~service~~, and ~~as required by hospital policy.~~ the Director or Chief Executive Officer of the hospital in accordance with the hospital's documented policies and procedures.

(11) Discontinued individual patient's drugs not supplied by the hospital may be sent home with the patient. ~~Those which remain~~ Individual patient drugs left in the hospital after discharge ~~that are not identified by lot number~~ ~~shall~~must be destroyed in the following manner:

(A) Drugs listed in Schedules II, III, ~~or~~ IV, or V of Title 21, United States Code section 812, ~~of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall~~must 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~~must be recorded in the patient's medical record ~~or~~ and in a separate log. ~~Such log~~ The pharmaceutical service ~~shall~~must ~~be~~ retain~~ed~~ the log for at least three years.

(B) Drugs not listed under Schedules II, III, ~~or~~ IV, or V of Title 21, United States Code section 812, ~~of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall~~must be destroyed in the presence of a pharmacist.

~~(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 or she shall develop and conduct an in-service training program for the professional staff 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.~~

(w) The pharmacy must maintain accurate records of the receipt, distribution, use, and disposition of all Schedule II, III, IV, and V drugs listed in Title 21, United States Code section 812. The pharmacy record system for Schedule I, II, III, IV, and V drugs listed in Title 21, United States Code section 812, must:

(1) Be available in an immediately retrievable manner, either digital or hard copy, to pharmaceutical staff.

(2) Facilitate the identification of, and the extent of, the loss or diversion of controlled substances.

(x) The pharmaceutical service must develop, implement, and maintain a Quality Assessment and Performance Improvement (QAPI) program as defined according to Title 42, Code of Federal Regulations section 482.21. for the pharmacy and for drugs-use processes throughout the hospital. The results of the QAPI program must be integrated into the hospital-wide QAPI program.

(1) Documented monitoring systems must be established and maintained, in accordance with applicable state and federal laws and regulations and accepted professional standards of practice, for all drugs repackaged or compounded in the hospital. A pharmacist licensed by the state of California and who is part of the hospital staff must develop and conduct in-service training for professional staff to ensure compliance with repackaging and compounding quality control procedures.

(2) The pharmaceutical service must develop and assess performance indicators for all

contracted pharmaceutical services.

(3) The pharmaceutical service must conduct periodic audits to assess the use, and accurate execution of, drug therapy protocols for high-risk/high-alert drugs.

~~(t)~~(y) Periodically, the P~~p~~harmacy and T~~t~~herapeutics C~~c~~ommittee~~, or its equivalent, shall~~must evaluate the pharmaceutical services provided and make ~~appropriate~~ recommendations to the executive committee of the medical staff on an ongoing basis. ~~and administration~~.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1276, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70265 to read as follows:

§ 70265. Pharmaceutical Service Staff.

(a) The Director of the Pharmaceutical Service ~~A pharmacist shall~~must have overall responsibility for the pharmaceutical service~~. He shall be responsible for the procurement, storage and distribution of all drugs as well as~~ including the development, implementation, coordination, and supervision ~~and review~~ of all pharmaceutical services provided throughout ~~in~~ the hospital.

(1) The Director of the Pharmaceutical Service must be a California licensed pharmacist and must have experience in hospital pharmacy practice.

(2) Hospitals with a license issued pursuant to Business and Professions Code section 4056 must retain the services of a California licensed pharmacist on a part-time or ~~limited permit shall employ a pharmacist on at least~~ a consulting basis to meet the specific drug-use needs of the hospital's patients.

(3) ~~Responsibilities shall be set forth in a~~ The job description or agreement between the ~~pharmacist~~ Director of the Pharmaceutical Service and the hospital must set forth the qualifications for, and responsibilities of, the position. The Director of the Pharmaceutical Service ~~pharmacist shall~~must be responsible to and report directly to the hospital administrator, and ~~shall~~must furnish the Administrator ~~him written~~ with

reports and recommendations regarding the pharmaceutical services within the hospital. Such reports ~~shall~~must be provided no less often than quarterly.

(b) The hospital must have a number of pharmaceutical service staff to ensure the quality of pharmaceutical services provided meets the needs of the patients given the scope and complexity of the hospital patient population.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health & Safety Code. Reference: Sections 131050, 131051, and 131052, Health & Safety Code.

Amend section 70267 to read as follows:

§ 70267. Pharmaceutical Service Equipment and Supplies.

(a) ~~There shall be~~ The pharmaceutical service must have ~~adequate~~ equipment and supplies for the provision of pharmaceutical services within the hospital.

(b) Reference materials containing monographs on all drugs in use in the hospital ~~shall~~must be available ~~in~~ at each nursing unit and patient care area where drugs are available for distribution to patients. Such monographs must include information concerning generic and brand names, if applicable, available strengths and dosage forms and pharmacological data including indications, side effects, adverse effects, and drug interactions.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health & Safety Code. Reference: Sections 131050, 131051, and 131052, Health & Safety Code.

Amend section 70269 to read as follows:

§ 70269. Pharmaceutical Service Space.

(a) The pharmaceutical service must have space requirements to accommodate the drug distribution system used and the number of patients to be served pursuant to Title 24, California Building Code section 1224.19 .

~~(a)~~ (b) ~~Adequate space shall be available at each nursing station~~ Each nursing station

must have space available and maintain ~~for~~ the storage of drugs and preparation of drug ~~medication~~ doses in pursuant of Title 24, California Building Code section 1224.4.4.4 Medication Station.

~~(b)~~ (c) All spaces and areas used for the storage of drugs ~~shall~~must be ~~lockable~~ securable and accessible only to ~~authorized~~ licensed health care ~~personnel~~ staff authorized by the Pharmaceutical and Therapeutics Committee ~~only~~.

(d) The pharmaceutical service must provide and maintain space in the hospital for the following:

(1) The storage of drugs.

(2) The packaging of drugs.

(3) The labeling and dispensing of drugs.

(4) Sterile and non-sterile compounding.

(5) Pharmaceutical service staff to perform clinical functions.

(6) In hospitals licensed pursuant to Business and Professions Code section 4029, office space for the person who directs the pharmaceutical service and the pharmaceutical service's managers.

NOTE: Authority cited: Sections 20, 1245, 1275, and 131200, Health & Safety Code. Reference: Sections 131050, 131051, 131052, Health & Safety Code.

Amend section 70271 to read as follows:

§ 70271. Dietetic Service Definition.

"Dietetic service" means ~~providing safe, satisfying and nutritionally adequate food for patients~~ an organized department of food and nutrition with ~~appropriate~~ staff, space, equipment, and supplies that follows a plan of operation designed to provide safe and nutritionally satisfying food to meet the needs of patients. Dietetic service includes providing medical nutrition assessment and medical nutrition therapy when ordered by an authorized prescriber.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health & Safety Code. Reference: Sections 131050, 131051, and 131052, Health & Safety Code.

Amend section 70273 to read as follows:

§ 70273. Dietetic Service General Requirements.

(a) The dietetic service ~~shall~~must provide ~~food of~~ the quality and quantity of food required to meet the patient's needs in accordance with ~~physicians'~~ the practitioner's orders and, to the extent medically possible, to meet ~~the Recommended Daily Dietary Allowances, 1974 Edition, adopted by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences, 2107 Constitution Avenue, Washington, DC 20418, and the following:~~ the recommended dietary intake allowances in "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements (2006)" published by the National Research Council of the National Academy of Sciences, Institute of Medicine, hereby incorporated by reference.

(b) The dietetic service ~~shall~~must ~~provide~~ensure:

(1) Not less than three meals ~~shall~~must be provided~~served~~ daily.

(2) Not more than 14 hours ~~shall~~must elapse between the evening meal and breakfast of the following day.

(3) Nourishment ~~or~~ and between meal feedings ~~shall~~must be provided as required by the diet order ~~prescription~~ and ~~shall~~must be ~~offered~~ available to ~~all~~ every patient~~s~~ unless ~~counterordered~~ counter ordered by the ~~physician~~ practitioner responsible for the patient.

(4) Meals must honor ~~Patient~~ a patient's food preference~~s shall be respected as much as~~ to the extent possible. ~~and substitutes~~ Substitutions ~~shall~~must be available ~~offered through the use of~~ using a selective menu or substitutes from ~~appropriate~~ variety food groups.

(c)~~(a)(5)~~ When food is provided by an outside food service company, all applicable requirements herein set forth ~~shall~~must be met. The hospital must require the outside food service company to provide a liaison for the medical staff and administration to

communicate regarding food service operations and dietetic polices affecting patient treatment.

(d)~~(a)(5)~~ The hospital ~~shall~~must maintain a documented plan, ~~adequate~~ space for preparation and serving food in accordance with Title 24, California Building Code section 1224.20, equipment, and staple food supplies to provide patient food services in emergencies.

(e) ~~(b) Policies and procedures shall be developed and maintained i~~In consultation with representatives of the medical staff, nursing staff, and administration, the dietetic service must develop, implement, and maintain documented policies and procedures to govern the provision of dietetic services. Policies ~~shall~~must be approved by the ~~medical staff, administration and~~ governing body. Procedures ~~shall~~must be approved by the medical staff and administration. ~~p~~ Policies and procedures ~~shall~~must:

(1) Cover the scope of dietetic services including food procurement, storage, preparation, and service.

(2) Be reviewed at least annually, revised as necessary, and dated to indicate the time of the last review.

(f)~~(c)~~ The responsibility and the accountability of the dietetic service to the medical staff and administration ~~shall~~must be defined in writing and documented.

(g)~~(d)~~ ~~A current~~An up to date diet manual approved by the registered dietitian and the medical staff ~~shall~~must be used as the basis for diet orders and as a guide for planning, ordering, and serving routinely ordered regular, therapeutic, and modified diets for the facility.

(1) The diet manual must include the purpose and principles of each type of diet, the meal pattern, the foods allowed and not allowed, and the nutritional adequacy for each type of diet provided.

(2) The dietetic service must maintain ~~C~~copies of the diet manual, either on paper or via an electronic format, ~~shall be available at each nursing station~~ at each patient care unit and in the dietetic service area for use by physicians, nurses, and other dietetic service staff.

(3) The dietary service must review and update the diet manual as often as necessary, at minimum every five years, to maintain accurate information, and must record the date of each review.

(h) Procedures for the preparation of infant feedings, whether breast milk, formula, or an admixture, must follow "Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities, 3rd Edition" (2018) by the Pediatric Nutrition Practice Group of the Academy of Nutrition and Dietetics, Steele, C. and Collins, E. editors, hereby incorporated by reference, and the compounding practices of the United States Pharmacopeia (USP) that are recommended by the American Society for Parenteral and Enteral Nutrition, and safe food handling practices.

(i) The service must develop, implement, and maintain documented policies and procedures for preparing infant feedings to minimize the risk of food-borne illness and ensure safe and sanitary handling practices.

(j)~~(e)~~ Therapeutic and modified diets ~~shall~~must be provided as prescribed by a person lawfully authorized to give such an order and ~~shall~~must be planned, prepared, and served with supervision ~~and/~~ or consultation from the registered dietitian. Persons responsible for therapeutic and modified diets ~~shall~~must have ~~sufficient~~ knowledge of food values to make ~~appropriate~~ substitutions when necessary to meet the dietary needs of the patient. All diets must conform to the hospital's diet manual.

(k)~~(f)~~ A record of a patient's food preferences must be maintained and used as a guide for the patient's meals and must ~~current profile card shall be maintained for each patient indicating diet~~, indicate, at a minimum, the patient's likes, dislikes, ~~and other pertinent information concerning the patient's dietary needs.~~ food allergies, and current diet order.

(l)~~(g)~~ Menus~~.~~ must be specific to the patient in accordance with practitioners' orders, and to the extent possible following the recommended dietary intake allowances from "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements (2006)" by the National Research Council of the National Academy of Sciences, Institute of Medicine, hereby incorporated by reference.

(1) Menus for regular and routine modified diets ~~shall~~must be ~~documented~~ written at least one week in advance, dated, and posted in the kitchen at least three days in advance.

(2) If any meal served varies from the planned menu, the change ~~shall~~must be approved by the registered dietitian and noted in writing on the posted menu in the kitchen.

(3) Menus ~~shall~~must provide a variety of foods ~~in adequate amounts at~~ for each meal.

(4) Menus should be planned with consideration for cultural and religious background and food habits of the patient.

(5) A copy of the menu as served ~~shall~~must be kept on file for at least 30 days.

(6) Records of food purchased ~~shall~~must be kept available for one year.

(7) Standardized recipes, adjusted to ~~appropriate yield~~ the amount needed for the patient census, ~~shall~~must be maintained and used in food preparation.

(m)~~(h)~~ Food ~~shall~~must be prepared by methods ~~which~~ that conserve nutri~~tive~~ional value, flavor, and appearance. Food ~~shall~~must be served ~~attractively~~ at appropriate temperatures set by food and safety guidelines according to Health and Safety Code section 114002 and in a form to meet individual needs.

(n)~~(i) Nutritional Care.~~ The nutritional aspects of patient care must be directed by either a physician, or a physician in consultation with the registered dietitian. Patient's dietary orders must be ordered by a physician, or someone lawfully authorized to do so within their scope of practice. The dietary service must complete:

(1) A comprehensive nutritional assessment that includes height, weight, chewing ability, and pertinent laboratory tests must be completed by a registered dietitian, physician, or other medical professional practicing within the scope of their license, within twenty-four (24) hours after the screening of the patient at nutritional risk. Nutritional care ~~shall~~must be integrated in the patient care plan and revised when there are changes to the dietary orders.

(2) ~~Observations and information pertinent to dietetic treatment~~Patient information related to nutritional care ~~shall~~must be recorded in the patient's medical record~~s~~ by a

person lawfully authorized to do so and must include observations, assessment, nutrition diagnosis, intervention, monitoring, goals, and an ongoing evaluation of the patient's response to medical nutrition therapy. ~~by the dietitian.~~

(3) ~~Pertinent dietary records shall be included~~ A discharge summary of the nutrition care provided, and all nutrition care notes, nutrition assessments, and the nutritional care plan must be included in the patient's transfer discharge record to ensure continuity of ~~nutritional~~ care.

(4) The dietetic service must develop, implement, and maintain documented policies and procedures covering medical nutrition therapy.

(5) The dietetic service must review the nutritional manual to determine if updates are needed, at least annually, and dated to indicate the date of review.

(6) The nutritional manual must be revised as necessary following the review required in paragraph (5). If revised, the date of the revision must be identified on the manual.

(o)~~(j)~~ In-service education and training programs ~~shall~~must be provided for all dietetic service ~~personnel~~staff. ~~and a~~A record of subject areas covered, date, and duration of each session, competency assessments, and attendance lists ~~shall~~must be maintained~~.~~ and made available to the Department upon request. The registered dietitian must be involved in the planning and conducting of in-service education and training programs and competency assessments.

(1) Education and training programs must include instruction in the following:

(A) Personal hygiene.

(B) The proper inspection, handling, preparation, and serving of food.

(C) The proper cleaning, and the safe operation of, equipment.

(D) Regular, therapeutic, and modified diets.

(E) Sanitation and dishwashing.

(2) Training programs may be informal if a record of the subject areas covered, the date and duration of each session, and attendance lists are maintained and made available to the Department.

(p)~~(k) Food Storage.~~ All kitchens, kitchen areas, and food storage areas must be free from plainly visible dirt, litter, not subject to sewage or wastewater backflow, and protected from contamination by condensation, leakage, or vermin, including but not limited to rodents and insects.

~~(1) Food storage areas shall be clean at all times.~~

~~(2)~~(1) Dry ~~or~~ and staple items ~~shall~~must be stored ~~at least 30 cm (12 inches) above the floor,~~ in a well-ventilated room with a temperature of between 10 degrees Celsius (50 degrees Fahrenheit) and 21 degrees Celsius (70 degrees Fahrenheit). All foods must be stored at least 15.24 cm (6 inches) above the floor, ~~not subject to~~ and protected from sources of contamination such as sewage or wastewater backflow, ~~or contamination by~~ condensation, leakage, and wet cleaning. ~~rodents or vermin.~~

~~(3)~~(2) All readily perishable foods or beverages capable of supporting rapid and progressive growth of microorganisms ~~which~~ that can cause food infections or food intoxication ~~shall~~must be maintained at temperatures ~~of 7° C (45° F) or below, or at 60° C (140°F)~~ below 5 degrees Celsius (41 degrees Fahrenheit) or above 57 degrees Celsius (135 degrees Fahrenheit) ~~or above,~~ at all times, except during necessary periods of preparation and service. Frozen food must remain frozen, ~~shall be stored at~~ with the freezer temperature kept at or below -18° degrees Celsius (0° degrees Fahrenheit).

(3) Foods held in refrigerated or other storage areas must be covered. Food that was prepared and not served must be stored, clearly labeled, and dated.

(4) ~~There shall be a reliable thermometer in e~~Each refrigerator, freezer, and ~~in~~ storerooms ~~used for perishable food~~must have a thermometer. A daily log of recorded temperatures for all refrigerators and freezers must be maintained. The log must be available to the Department upon request for inspection for the previous ninety (90) days.

(5) Pesticides, other toxic substances, and drugs ~~shall~~must not be stored in the kitchen area or in storerooms for food and~~/or~~ food preparation equipment and ~~utensils~~tableware.

(6) Soaps, detergents, cleaning compounds, or similar substances ~~shall~~must not be stored in a manner that could result in cross-contamination of food.~~in food storerooms or food storage areas.~~

(q)~~(l)~~ Sanitation.

~~(1) All kitchens and kitchen areas shall be kept clean, free from litter and rubbish and protected from rodents, roaches, flies and other insects.~~

~~(2)~~(1) All ~~utensils~~ tableware, counters, shelves, and equipment ~~shall~~must be kept clean, maintained in good repair, and ~~shall~~must be free from breaks, corrosions, open seams, cracks, and chipped areas.

~~(3)~~(2) ~~Plasticware, china and glassware~~ Tableware that is ~~unsightly~~, unsanitary, or hazardous because of chips, cracks, or loss of glaze ~~shall~~must be discarded.

~~(4)~~(3) Ice ~~which is~~ used in connection with food or drink ~~shall~~must be from a sanitary source and ~~shall~~must be handled and dispensed in a sanitary manner. If ice is obtained from an ice machine on the premises, the machine must be kept free from organic and foreign matter, and at a minimum, machine use and maintenance must follow the manufacturer's and the hospital's infection control guidelines.

~~(5)~~(4) Kitchen wastes that are not disposed of by mechanical means ~~shall~~must be kept in leak-proof, nonabsorbent, tightly closed containers and ~~shall~~must be disposed of as frequently as necessary to prevent a nuisance or unsightliness.

(r)~~(m)~~ All tableware ~~utensils~~ used for eating, drinking, and in the preparation and serving of food and drink, ~~shall~~must be cleaned and ~~disinfected~~ sanitized or discarded after each ~~usage~~ use. Any single use article must not be reused.

(1) ~~Gross food particles shall be removed by scraping and prerinsing in running water.~~ During manual or mechanical ware washing, food debris on equipment, and tableware must first be scraped off prior to washing. If necessary for effective cleaning, tableware and equipment must be pre-flushed, presoaked, or scrubbed with abrasives.

(2) Manual ware washing must be accomplished using a three (3)-compartment sink for all sinks installed on or after January 1, 2008. A two (2)-compartment sink in use on December 31, 2007, does not need to be replaced to meet this standard, but after that

date, if a two (2)-compartment sink is replaced, this standard must be followed. ~~The utensils~~ Tableware ~~shall~~must be thoroughly washed in hot water with a minimum temperature of ~~43° C (110° F)~~ 37.77 degrees Celsius (100 degrees Fahrenheit) using soap or detergent, or at a temperature specified by the manufacturer of the soap or detergent, rinsed in ~~hot~~ clear water to remove soap or detergent, and ~~disinfected~~sanitized by a final rinse of one of the following methods or an equivalent method approved by the Department:

(A) Immersion for at least ~~two minutes in clean~~ 30 seconds in water with the temperature maintained at or above 77~~°~~ degrees Celsius ~~(180° F)~~ (171 degrees Fahrenheit). For sinks installed on or after January 1, 2008 used for hot water sanitization, the sanitizing compartment of the sink must be designed with an integral heating device that is capable of maintaining water at a temperature not less than 77 degrees Celsius (171 degrees Fahrenheit) and provided with a rack or basket to allow complete immersion of equipment and tableware into the hot water. If a sink without an integral heating device and a rack or basket for complete immersion is in use for hot water sanitization on December 31, 2007, it need not be replaced to meet this standard, but after that date, if a new sink for hot water sanitizing use is purchased, this standard must be followed.

(B) ~~Immersion for at least 30 seconds in clean water at 82° C (180° F).~~ The application of sanitizing chemicals must occur by immersion, manual swabbing, or brushing, using one of the following solutions: contact with a solution of 100 parts per million (ppm) available chlorine solution for at least 30 seconds; contact with a solution of 25 ppm available iodine for at least one minute; contact with a solution of 200 ppm quaternary ammonium for at least one minute; or contact with any chemical sanitizer that meets the requirements of Title 40, the Code of Federal Regulations section 180.940 of , 07-01-10 Edition and when used in accordance with the manufacturer's instructions.

~~(C) Immersion in water containing bactericidal chemical as approved by the Department.~~

(3) After disinfection the ~~utensils~~ tableware ~~shall~~ must be allowed to drain and dry in racks or baskets on nonabsorbent surfaces. Drying cloths ~~shall~~must not be used.
(4) Results obtained with dishwashing machines ~~shall~~must be equal to those obtained by the methods outlined ~~above~~ in this subdivision and all dishwashing machines installed on or after January 1, 2024 ~~shall~~must meet the requirements contained in the standards in NSF 3-2019, “Commercial Warewashing Equipment” ~~Standard No. 3 as amended in April 1965~~ of the National Sanitation Foundation International, published April 11, 2017, hereby incorporated by reference. ~~P.O. Box 1468, Ann Arbor, MI 48106.~~ Any dishwashing machine in use on December 31, 2023, does not need to be replaced to meet this standard, but on or after January 1, 2024, when such machines are replaced, this standard must meet the requirements in NSF 3-2019.
(5) Mechanical sanitization shall be accomplished in the final sanitizing rinse by one of the following:
(A) Being cycled through equipment that is used in accordance with the manufacturer’s instructions and achieving a tableware surface temperature of 71 degrees Celsius (160 degrees Fahrenheit) as measured by an irreversible registering temperature indicator.
(B) The mechanical application of sanitizing chemicals creating contact by pressure spraying methods using one of the following solutions: 50 parts per million (ppm) of available chlorine for at least 30 seconds; 25 ppm available iodine for at least one minute.
(C) Any chemical sanitizer that meets the requirements of Title 40 of the Code of Federal Regulations section 180.940, 7-01-10 Edition, when applied in accordance with the sanitizer manufacturer’s use directions as specified on the product label and following the machine manufacturer’s specifications.

NOTE: Authority cited: Sections ~~208(a) and~~ 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Section 1276, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70275 to read as follows:

§ 70275. Dietetic Service Staff.

~~(a) A registered dietitian shall be employed on a full-time, part-time or consulting basis. Part-time or consultant services shall be provided on the premises at appropriate times on a regularly scheduled basis and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, patient counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus and participation in development or revision of dietetic policies and procedures and in planning and conducting in-service education programs.~~

~~(b)~~(a) ~~If a registered dietitian is not employed full-time, a full-time person who meets the training requirements to be a dietetic services supervisor specified in section 1265.4(b) of the Health and Safety Code shall be employed to be responsible for the operation of the food service.~~ A dietitian must be registered by the Commission on Dietetic Registration. The dietician must administer the hospital's dietetic service and must:

(1) Provide nutrition care services upon determination of need by screening, assessment, or consult, and ordered by an authorized prescriber, and make nutrition care recommendations to the medical staff.

(2) Provide medical nutritional therapy to the patient and educate the patient, the patient's family, representatives, and caregivers on the nutritional therapy.

(3) Serve as a liaison to, and resource for, the medical and nursing staff.

(4) Approve all patient menus and the hospital diet manual.

(5) Participate in the development and revision of all dietetic service policies and procedures.

(6) Develop, implement, and maintain a Quality Assessment and Performance Improvement (QAPI) program according to Title 42, Code of Federal Regulations section 482.21. The results of this QAPI program must be integrated into the hospital-wide QAPI program.

(7) Provide direction and guidance to the food service manager and dietetic service

staff.

(8) Plan and conduct in-service education and training programs for the dietetic service staff.

(9) Advise the hospital administration on dietetic issues.

(10) Participate with administration and department heads in conferences for dietetic issues.

(11) Participate on hospital committees relevant to dietetic service operations.

(b) If the registered dietitian is not employed full-time, the dietetic service must have part-time registered dietitians, or consultant registered dietitians, scheduled to work on the premises during the days and hours needed to administer the service and to meet patient needs based on the patient population and census.

(1) If the registered dietitian is a consultant, the registered dietitian's contract must clearly define the responsibilities and required frequency and duration of the registered dietitian's visits so that the registered dietitian must be able to meet the needs of the dietetic service operations and the nutritional needs of the patient in accordance with accepted standards of practice.

(2) A consultant registered dietitian must create documented reports of all dietary modifications and services performed.

(3) The consultant registered dietitian's contract and résumé must be kept in the hospital's personnel files, and the registered dietitian's regular reports must be kept in the dietetic service personnel files and must be available for inspection by the Department.

(c) If the registered dietitian responsible for the administration of the dietetic service is not employed full-time, a dietetic service supervisor who is qualified under section 1265.4(b) of the Health and Safety Code must be employed full-time to manage the food service operations of the dietetic service. This dietetic services supervisor must consult with the registered dietitian who retains responsibility for the administration of the dietetic service. The dietetic service supervisor must:

(1) Implement all dietetic service policies and procedures.

(2) Implement the diet manual and menu.

(3) Implement the continuous Quality Assessment and Performance Improvement (QAPI) program developed by the registered dietitian.

(4) Participate in hospital-wide emergency preparedness planning.

(5) Participate with administration and department heads in conferences for dietetic issues.

(6) Participate on hospital committees relevant to the dietetic service operations.

~~(c)~~(d) ~~Sufficient dietetic~~ Dietetic service ~~personnel~~ staff ~~shall~~must be employed, oriented, trained, and ~~their working hours~~ scheduled enough working hours to provide for the nutritional needs of the patients and to maintain the dietetic service areas. If dietetic service employees are assigned duties in other service areas, those duties ~~shall~~must not interfere with the sanitation, safety, or time required for dietetic service work assignments.

~~(d)~~(e) Current work schedules by job titles and weekly duty schedules ~~shall~~must be ~~posted~~ made available in the dietetic service area.

~~(e)~~(f) A record ~~shall~~must be maintained of the ~~number of~~ persons ~~by job title~~ employed full~~-~~ or part-time in the dietetic service~~s~~, including their job title, and the number of hours each person works weekly.

~~(f)~~(g) Hygiene of Dietetic Service Staff.

(1) Dietetic service ~~personnel~~ staff ~~shall~~must be trained in basic food sanitation techniques~~, shall be clean~~ following the hygienic practices in accordance with Health and Safety Code sections 113973 to 113978, must wear clean clothing, including a cap ~~and/~~or a hair net, and ~~shall~~must be excluded from duty when affected by skin infection or communicable diseases. Beards and mustaches ~~which are not closely cropped and neatly trimmed~~ ~~shall~~must be covered by a hairnet and/or beard net. All jewelry is prohibited with the exception of a plain ring in accordance with Health and Safety Code section 113973.

(2) Employee's street clothing and other personal items stored in the kitchen area ~~shall~~must be in ~~a closed~~ an enclosed locker area pursuant to Title 24, California Building Code section 1224.20.2.15.

(3) Kitchen sinks ~~shall~~must not be used for handwashing. Separate handwashing stations ~~facilities~~ with antiseptic soap, running water, and ~~individual~~single use disposable towels ~~shall~~must be provided in the dietetic service area. Hand sanitizers must not be permitted in the place of handwashing.

(4) Persons other than dietetic service ~~personnel~~ staff ~~shall~~must not be allowed in the kitchen area unless required to do so in the performance of their duties.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1265.4, 1276, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70277 to read as follows:

§ 70277. Dietetic Service Equipment and Supplies.

(a) The type and amount of ~~E~~equipment ~~of the type and in the amount~~ necessary for ~~the proper~~ preparation, serving, and ~~storing~~ storage of food, and for ~~proper~~ dishwashing and sanitation, ~~shall~~must be provided and maintained in ~~good working order~~ accordance with manufacturer's recommendations.

(1) The dietetic service area ~~shall~~must be well-ventilated in a manner that will maintain comfortable working conditions, remove ~~objectionable~~ odors and fumes, and prevent ~~excessive~~ condensation~~.~~ pursuant to Title 24, California Mechanical Code, sections 413.

(2) Equipment necessary for preparation and maintenance of menus, records, and references ~~shall~~must be provided.

(3) Fixed and mobile equipment in the dietetic service area ~~shall~~must be located to ~~assure~~ ensure sanitary and safe operation and ~~shall~~must be of sufficient size to ~~handle~~ meet the needs of the hospital.

(b) Food ~~S~~supplies~~.~~ must be provided and meet the following conditions:

(1) At least one week's supply of staple foods and at least two (2) days supply of perishable foods ~~shall~~must be maintained on the premises. Supplies ~~shall be appropriate to~~ must meet the requirements of the menu.

(2) When a hospital is unable to prepare meals or obtain meals from an outside food service, absent an official proclamation or declaration of a disaster, the hospital must provide patients with hot meals that mirror the nutritional adequacy of menus routinely served.

(3) Meals served in a disaster must mirror the macronutrient content of menus routinely served, while considering the supply of essential resources such as gas, electricity, and potable water.

(4) The amount of additional food supplies to be maintained for disaster purposes must be based on the hospital's all-hazards emergency management plan.

(5)~~(2)~~ All food ~~shall~~must be of good quality and procured from sources approved or considered satisfactory by federal, state, and local authorities. Food in unlabeled, rusty, leaking, broken containers, or cans with side seam dents, rim dents, or swells ~~shall~~must not be accepted or retained. Frozen food with evidence of thawing must not be accepted or served.

(6)~~(3)~~ Milk, milk products, and products resembling milk as defined in Food and Agricultural section 38912~~shall~~must be processed or manufactured in milk product plants meeting the requirements of Division 15 of the ~~California~~ Food and Agricultural Code.

~~(4) Milk may be served in individual containers, the cap or seal of which shall not be removed except in the presence of the patient. Milk may be served from a dispensing device which has been approved for such use. Milk served from an approved device shall be dispensed directly into the glass or other container from which the patient drinks.~~

(7)~~(5)~~ Catered foods and beverages from a source outside the hospital ~~shall~~must be prepared, packed, properly identified, stored, and transported in compliance with these

regulations and other applicable federal, state, and local codes ~~as determined by the Department~~.

~~(6) Foods held in refrigerated or other storage areas shall be appropriately covered. Food which was prepared and not served shall be stored appropriately, clearly labeled and dated.~~

~~(7)~~(8) Hermetically sealed foods or beverages served in the hospital ~~shall~~must have been processed in compliance with applicable federal, state, and local codes.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1276, 131050, 131051, and 131052, Health and Safety Code.

Amend section 70279 to read as follows:

§ 70279. Dietetic Service Space.

(a) ~~Adequate space~~ Space for the preparation and serving of food ~~shall~~must be provided and maintained in accordance with these regulations. Equipment ~~shall~~must be ~~placed~~ arranged so ~~as to provide~~ that there are aisles of sufficient width to permit easy movement of ~~personnel~~ staff, mobile equipment, and supplies pursuant to Title 24, California Building Code section 1224.20.

(b) Well-ventilated food storage areas must be ~~of adequate size~~ large enough to contain the dietetic service's food supplies and maintained to ensure food safety and meet the needs of the dietary service operation. ~~shall be provided.~~

(c) ~~A minimum of .057 cubic meters (two cubic feet) of~~ Enough usable refrigerated space ~~per bed shall~~must be maintained for the storage of frozen and chilled foods such that the dietetic service can meet the needs of the patients as determined by patient care plans and physicians' orders, pursuant to Title 24 California Building Code section 1224.20.2.3.

(d) Adequate space ~~shall~~must be maintained to accommodate equipment, ~~personnel~~ staff, and procedures necessary for proper cleaning and sanitizing of ~~dishes and other utensils~~ tableware.

(e) Where employee dining space is provided, ~~a minimum of 1.4 square meters (15 square feet) of floor area per person served,~~ including serving area, space ~~shall~~must be maintained pursuant to Title 24, California Building Code Section 1224.20.2.8.1.

(f) ~~Office or other suitable space shall be provided for the dietitian or dietetic service supervisor for privacy in interviewing personnel, conducting other business related to dietetic service and for~~ The registered dietitian and the dietetic service administrative staff must have office space necessary to conduct business related to the dietetic service. Such space must provide privacy for interviewing personnel and accommodate the preparation and maintenance of menus and other necessary reports and records.

(1) The built dietetic service administrative staff offices must be located and maintained to provide an unobstructed view of the food preparation area. Dietetic service offices in use as of January 1, 2024, do not need to be replaced or remodeled to meet this standard.

NOTE: Authority cited: Sections 20, 1254, 1275, and 131200, Health and Safety Code. Reference: Sections 1276, 131050, 131051, and 131052, Health and Safety Code.

Article 7. Administration

Amend section 70701 to read as follows:

§ 70701. Governing Body.

No change to text (a) through (a)(9).

(10) Develop, implement, and maintain a hospital-wide Quality Assessment and Performance Improvement (QAPI) program, according to 42 Code of Federal Regulations section 482.21. Every supplemental service and basic service within the hospital, including contract services from outside entities, must have an ongoing QAPI program, in accordance with the hospital-wide QAPI program that reflects the type and complexity of care provided.

NOTE: Authority cited: Sections 20, 208(a), ~~and~~ 1254, 1275, 131000, 131050, 131051, 131052, and 131200, Health and Safety Code. Reference: Sections 1276, 1315, 1316, and 1316.5, Health and Safety Code, and Sections 482.12 and 482.22, Title 42 Code of Federal Regulations.