### TITLE 11

### DEPARTMENT OF HEALTH

## CHAPTER 93

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### DEPARTMENT OF HEALTH

## Amendment to Chapter 11-93

May 1, 1992

### SUMMARY

1. Chapter 11-93, Subchapter 1, is amended to read as follows:

#### "SUBCHAPTER 1

#### BROAD SERVICE HOSPITALS

§11-93-1 <u>Purpose</u>. The purpose of this chapter is to establish minimum requirements for the protection of the health, welfare, and safety of patients, hospital personnel, and the general public in hospitals. This subchapter shall not be construed to lower standards established through rules adopted by other agencies of government. In all instances the more stringent rules shall apply. [Eff. 3/3/86] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

§11-93-2 <u>Definitions</u>. As used in this subchapter: "Administrator" is the person to whom is delegated the responsibility for the interpretation and implementation of the policies and programs established by the governing body.

"Birthing room" means a "labor delivery recovery" (LDR) room or "labor delivery recovery postpartum" (LDRP) room designed, equipped and arranged to provide for the care of a woman and her newborn child and to accommodate her support persons during the process of vaginal birth and immediate recovery thereafter.

"Broad service hospital" means a hospital which is staffed and equipped to provide inpatient medical or surgical care, or both, for acute and chronic illness, injury, or obstetrics.

"Clinical privileges" means permission to provide medical and other patient care services in the granting institution, within well-defined limits, based on the individual grantee's professional license, experience, competence, ability and judgment.

"Department" means the department of health, State of Hawaii.

"Dentist" means any person holding a valid license to practice dentistry in the State of Hawaii, pursuant to chapter 448, HRS.

"Dietetic service supervisor" is a person who:

- (1) Is a qualified dietitian; or
- (2) Is a graduate of a training program for

- dietetic technicians approved by the American Dietetic Association, or is a dietary manager approved by a Dietary Managers Association; or
- (3) Is a graduate of a state approved course that provided ninety or more hours of classroom or correspondence instructions in food service supervision and has had experience as a supervisor in a health care institution with consultation from a dietitian; or
- (4) Is a graduate of a college or university with a baccalaureate degree after majoring in studies of food and nutrition, dietetics, or food service management and has had one year of supervisory experience in providing dietetic services of a health care institution; or
- (5) Has training and experience in food service supervision and management in a military service equivalent in content to the programs in paragraphs (2), (3), and (4) of this definition.

"Dietitian" means a person who:

- (1) Is registered by the American Dietetic Association Commission for Dietetic Registration; or
- (2) Has eligibility for registration approved by the American Dietetic Association and is working with consultation from or under the supervision of a registered dietitian.

"Director" means the director of health, State of Hawaii.

"Drug administration" means the act in which a single dose of a prescribed drug or biological substance is given to a patient by an authorized person in accordance with all existing laws and regulations governing such acts. The entire act of administration entails:

- (1) Removing an individual dose from a previously dispensed properly labeled container (unit dose);
- (2) Giving the specified dose to the proper patient;

- (3) Promptly recording the time, dose, and route given to the patient; and
- (4) Signing the record.

Only licensed personnel may administer medications.

"Drug dispensing" means the act which involves the interpretation of a physician's order and, pursuant to that order, the proper selection, measurement, packaging, labeling and issuance of the drug or biological for a patient or a specified unit of the facility.

"Governing body" means the policy making authority, whether an individual or a group, who exercises general direction over the affairs of a facility and establishes policies concerning its operation and the welfare of the individuals it serves.

"Hospital" means any institution with an organized medical staff which admits patients for inpatient care, diagnosis, observation, and treatment.

"License" means a license issued by the department certifying the compliance with all existing Hawaii state laws and rules relative to the operation of a hospital.

"Licensed nurse" means either a registered nurse or a licensed practical nurse.

"Licensed practical nurse" means a person licensed as such by the State of Hawaii, pursuant to chapter 457, HRS.

"Licensed psychologist" means a person who has a doctoral degree in psychology and is licensed by the state Board of Psychology under chapter 465, HRS or is eligible for licensure and obtains licensure within two years of employment as provided for in chapter 465, HRS.

"Medical staff" means physicians, dentists, podiatrists and other individuals licensed by the state, who are permitted by law and who have been authorized by the governing body to provide patient care services within the facility. All medical staff members and other individuals who are permitted by law and by the hospital to provide patient care services independently in the hospital shall have delineated clinical privileges that allow them to provide patient care services within the scope of their clinical

privileges.

"Nurse aide" means a person who is certified as such by the State of Hawaii, or a person who is not so certified but has successfully completed a nurse aide training program in the tasks to be performed and who works under the supervision of a licensed nurse.

"Occupational therapist" means a person currently registered or eligible for registration by the American Occupational Therapy Association, and meets the qualifications under chapter 457G, HRS.

"Pathologist" means a physician certified or eligible to be certified by the American Board of Pathologists.

"Pharmacist" means a person who is licensed as a "registered pharmacist" by the State of Hawaii, pursuant to chapter 461, HRS.

"Physical therapist" means a person who has a license to practice as a physical therapist issued by the State of Hawaii, pursuant to chapter 461J, HRS.

"Physician" means a doctor of medicine or osteopathy who has a valid license to practice medicine and surgery issued by the State of Hawaii in accordance with chapter 453, or 460, HRS.

"Psychiatrist" means a person licensed to practice medicine in the State of Hawaii and who is certified or is eligible to be certified in psychiatry by the American Board of Psychiatry or Neurology.

"Radiologist" means a physician certified or eligible to be certified by the American Board of Radiology.

"Registered professional nurse" means a person who is licensed as a registered nurse in the State of Hawaii, under chapter 457, HRS.

"Seclusion room" means a room reserved for use by individual patients who require security and protection from either themselves or others. It shall be a single room constructed to minimize the patient's hiding, escape, injury, or suicide. Doors shall have provisions for staff observation while maintaining privacy from public and other patients.

"Social worker" means a person who:

(1) Has a master's degree from a school of social work accredited by the Council on Social Work Education or

(2) Has a bachelor's degree from a school of social work accredited by the Council on Social Work Education and two years of social work supervised experience in a health care setting working directly with individuals.

"Social work designee" means a staff person other than a social worker but with similar professional qualifications (such as nursing, psychology, psychiatry, counseling, and human development) and two years of social work supervised experience in a health care setting working directly with individuals and who is supervised by means of consultation with a social worker.

"Speech pathologist or audiologist" means a person who is licensed by the State pursuant to chapter 468E, HRS, and:

- (1) Is eligible for a certificate of clinical competence in the appropriate area of speech pathology, or audiology granted by the American Speech and Hearing Association under its requirements in effect on the publication of this provision; or
- (2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for examination for certification; or
- (3) Is already clinically certified.

"Tuberculin skin test" means an intradermal injection of .0001 mg (5 tuberculin units) of purified protein derivative in 0.1 cc of sterile diluent.

"Waiver" means an exemption from a specific rule or regulation which may be granted to a facility for a specified period of time at the discretion of the director. A waiver may be renewed at the discretion of the director. [Eff. 3/3/86; am August 3, 1992] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

§11-93-3 <u>Licensing</u>. (a) The facility shall meet all requirements for licensure under state law. All hospitals shall be licensed except those operated by the federal government or agency thereof. The

proprietor, the governing body, or the person in charge shall formally apply in writing to the director, and the facility shall be licensed pursuant to this chapter prior to admitting patients.

- (b) The director or a designated representative shall inspect each hospital unannounced at least annually for relicensing. Any designated representative of the director may enter the premises at any time to secure compliance with or to prevent a violation of this chapter.
- (c) Summary reports of annual licensing inspections shall be kept on file in the facility.
- (d) The director shall prescribe the content and form of the license and may authorize a waiver or waivers for a particular facility.
- (e) In the event of a change of name, location, ownership, change in the number of beds, or level of services, the director shall be notified fifteen days prior to the change; an inspection shall be conducted at the discretion of the director, and if qualified, a new license issued.
- (f) If a facility is not qualified to receive a regular twelve month license, the director may issue a provisional license for a period of up to twelve months if the director is satisfied that the health and welfare of the patients and personnel are not endangered and preparations are being made to meet the requirements. Provisional licenses may be issued for only two consecutive periods. A provisional license shall carry with it the same requirements and responsibilities as a regular license except that the provisional license is for a specified period which may be less than twelve months.
- (g) Every regular license shall continue in force for a period of one year unless otherwise specified, or unless it is suspended or revoked.
- (h) Following the annual inspection, facilities may be allowed a reasonable time to implement a department-approved plan of correction. A follow-up survey shall may be made by the department to determine the progress in the plan of correction.
- (i) The current license shall be posted in a place within the facility visible to the public.
  - (j) The director may deny, suspend, or revoke a

license for failure to comply with the requirements of this chapter or for any cause deemed a hazard to the health and safety of the patients and employees.

- (k) Infractions which may require invoking of penalties under chapter 321, HRS, include, but are not limited to:
  - (1) Operation of a hospital without a license granted by the department.
  - (2) Violations of the provisions of this chapter which have been found as a result of routine or unannounced inspections of a hospital which has a license.
- (1) Any person or organization affected by the director's decision of denial, suspension, or revocation of a license may appeal the decision in accordance with chapter 91, HRS. [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-4 Anesthesia services. (a) There shall be available in any hospital which provides surgical or obstetrical services an anesthesia service.
- (b) The anesthesia service shall be directed by a physician member of the medical staff. The anesthesia service shall comply with the provisions of the N.F.P.A Code 99 as it existed at the time of the adoption of this chapter.
- (c) Appropriate physical facilities including a recovery room shall be provided. [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-5 Arrangement for services. Where the facility does not employ a qualified person to render a required or necessary service, it shall contract in writing with a qualified person or provider. Written contracts shall include, but not be limited to:
  - (1) The responsibilities and scope of employment of parties, objectives of agreement, and terms of agreement.
  - (2) Signatures of the administrator and provider, or authorized representative of

the provider and administrator authorizing the contract.

[Eff. 3/3/86] (Auth: HRS §§321-9, 321-11)(Imp: HRS §§321-9, 321-11)

- §11-93-6 <u>Construction requirements</u>. (a) The hospital shall be accessible to and functional for physically handicapped patients, hospital personnel, and the general public.
  - (b) Accessibility to living and service areas.
  - (1) There shall be adequate space to allow free movement of persons using wheelchairs, walkers, canes, and crutches to bed, bathroom, closet, and common hallway areas.
  - (2) Areas used for recreation, cooking, dining, storage, bathrooms, laundries, foyers, corridors, lanais, libraries, and other areas not suitable for sleeping shall not be used as bedrooms.
  - (3) Access from each bedroom to a bathing facility, toilet, corridor, central utility or other areas of the hospital shall not require passing through a sleeping, cooking, dining, or recreation area.
  - (c) Toilet and bath facilities.
  - (1) Each toilet shall serve no more than eight beds.
  - (2) The toilet room shall contain a toilet and a washbasin. The washbasin may be omitted from a toilet room which serves single and multi-bed rooms if each such patient's room contains a washbasin.
  - (3) There shall be one shower or tub for each fourteen beds which are not otherwise served by a bathing facility within a patient's room.
  - (4) Appropriately placed grab bars shall be provided for each toilet, bathtub, and shower.
  - (5) Curtains or doors to insure privacy shall be provided.
  - (6) Separate toilet and bathing facilities for each sex, except where couples occupy a

- semi-private room with a bathroom, shall be provided.
- (7) An adequate supply of hot and cold potable running water must be provided at all times. Temperatures of hot water at plumbing fixtures used by patients shall be automatically regulated and shall not exceed 120°F.
- (8) Each toilet and bath facility shall have a call system which permits the occupant to signal the nursing station in an emergency.
- (9) Where bedpans are used, equipment for their care shall be provided in an appropriate area of the hospital. Where toilets adjoin patient's bedroom and are used for bedpan cleaning, they shall be equipped with bedpan flushing attachments with vacuum breaker.
- (10) Provision must be made for terminal sterilization of permanent personal care equipment.
- (11) Toilet facilities solely for the use of hospital personnel and toilet facilities solely for the use of the public shall be provided.
- (d) Patient bedrooms.
- (1) Each room shall be at or above grade level.
- (2) Windows in each bedroom shall have adequate means of insuring privacy.
- (3) Bedrooms to be occupied by patients shall have no more than four beds.
- (4) Rooms for a single patient shall measure at least one hundred square feet of usable space, excluding closets, bathrooms, alcoves, and entryways.
- (5) Rooms for more than one patient shall measure eighty (80) square feet per bed excluding closets, bathrooms, alcoves, and entryways.
- (6) Bedside screens or curtains shall be provided in rooms to be occupied by more than one patient to insure privacy for each patient.
- (7) Beds shall be placed at least three feet apart and three feet from the wall at the

side of the bed.

- (8) Each patient shall be provided with:
  - (A) A bed of proper size and height for the convenience of the patient and permitting an individual in a wheelchair to get in and out of bed unassisted.
  - (B) A comfortable mattress with impermeable mattress cover, and a pillow.
  - (C) Sufficient clean bed linen and blankets to meet the patient's needs.
  - (D) Appropriate furniture such as a chair and individual storage for personal clothing and belongings.
  - (E) An effective signal call system at the patient's bedside.
- (9) No patient's bedroom shall be located more than one hundred twenty feet from a nurses' station, measured along the line of travel.
- (10) All occupants of any bedroom shall be of the same sex except for:
  - (A) Those semi-private rooms which may be occupied by couples upon request;
  - (B) Special intensive care units.
- (e) Floors and walls.
- (1) Floors shall be of slip resistant material which does not retain odors.
- (2) Walls, floors and ceilings of rooms used by patients shall be made of materials which are in compliance with section 11-93-15(e) and (g).
- (f) Windows and lighting.
- (1) Each bedroom shall have at least one outside window sufficient to provide outside visibility to bed and wheelchair patients.
- (2) A habitable room shall have an aggregate window area of not less than one-tenth of the gross floor area.
- (3) Each bedroom shall have artificial light adequate for reading at bedside.
- (4) There shall be night lighting in bedrooms, rooms with toilets, and service areas.
- (g) Screening of doors and windows shall be provided, where appropriate, using screening having

sixteen meshes per inch.

- (h) Doors.
- (1) Sliding doors or folding doors shall not be used as exit doors and, if used in other areas, shall be of light material and easy to handle.
- (2) Double acting doors, if used, shall be provided with vision panels.
- (i) The minimum clear width of a corridor shall be forty-four inches except that corridors serving one or more non-ambulatory or semi-ambulatory patients shall be not less than eight feet in width.
  - (j) Storage space.
  - (1) Locked space shall be provided for janitorial supplies and equipment.
  - (2) Space for other equipment shall be provided and conveniently located.
- (k) The water supply shall be in accordance with chapter 340E, HRS.
- (1) Chapter 11-39, Administrative Rules, relating to air conditioning and ventilation shall be followed.
- (m) Additions and alterations or repairs to existing buildings.
  - (1) Where the structure was in use as a hospital prior to the effective date of this chapter, the director may waive or modify any portion of the construction standards, provided such exceptions do not create a hazard to patients, hospital personnel, or the general public.
  - (2) Drawings and specifications for all new construction or additions, alterations, or repairs to existing buildings subject to this chapter shall be submitted to the licensing branch of the department for review. Construction shall not commence prior to the department's approval of construction drawings. Drawings and specifications shall comply with the rules of the county building ordinances, fire codes, and zoning codes.
  - (3) The department shall review drawings and specifications and advise the applicant in

- writing of its determination.
- (4) The department may make written recommendations to the applicant but the recommendations shall not be mandatory.
- (5) Construction shall commence within one year of the approval of final construction drawings and specifications. If construction does not commence within one year, the construction drawings and specifications together with the application for a license shall be resubmitted for the department's review and approval.
- (6) Minor alterations which do not affect structural integrity, fire safety, functional operation, or increase beds or services which the facility is licensed to operate may be submitted either by free hand drawings or by more conventional architectural drawings and specifications.
- (7) Maintenance and repair routinely performed by the facility shall not require review or approval by the department.
- (8) Facilities shall be constructed and maintained in accordance with provisions of state and county zoning, building, fire safety and sanitation laws and rules applicable in the State of Hawaii.
  [Eff. 3/3/86; am August 3, 1992]
  (Auth: HRS §§321-9, 321-11)
  (Imp: HRS §§321-9, 321-11)
- §11-93-7 <u>Dental services</u>. (a) Where a dental service is provided, the governing body shall appoint a dentist, or dentist, to the medical staff and grant appropriate privileges.
- (b) A dentist shall be appointed as head of the service.
- (c) Patients admitted for dental care shall be given an appropriate medical appraisal by a medical staff member. [Eff. 3/3/86] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-8 <u>Dietetic service</u>. (a) The food and nutrition needs of patients shall be met through a nourishing, well-balanced diet in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council and adjusted for age, sex, activity, and disability.
- (b) At least three meals shall be served daily, at regular times with:
  - (1) Not more than a fourteen hour span between a substantial evening meal and breakfast on the following day.
  - (2) Between meal nourishments consistent with need shall be offered routinely to all patients.
  - (c) All modified diets shall be:
  - (1) Prescribed by the patient's physician with a record of the diet as ordered kept on file.
  - (2) Planned, prepared, and served by qualified personnel using the current Hawaii Dietetic Association manual or the American Dietetic Association manual, or both.
  - (3) Reviewed and adjusted as needed.
- (d) Therapeutic diets shall be planned by a qualified dietitian, as prescribed by the patient's physician. Nutrition assessment and dietary counseling shall be provided by a dietitian when indicated for a patient. Nutrition plans and follow-ups shall be documented in the individual medical record.
  - (e) Food services, meal planning and storage:
  - (1) Menus:
    - (A) Shall be written at least one week in advance;
    - (B) Shall provide a sufficient variety of foods served in adequate amounts at each meal, and be adjusted for seasonal changes along with patient's preferences as much as possible;
    - (C) Shall consist of a different menu for each day of the week;
    - (D) Shall be filed and maintained with any recorded changes, for at least three months;
    - (E) Shall be reviewed for nutritional

- adequacy by the dietitian or the dietitian designee if patient selective menus are used;
- (F) Shall be available for at least three to five days meal service in the case of a disaster. These menus shall be integrated into the disaster plan of the facility.
- (2) Records of food purchased shall be filed and maintained for at least thirty days.
- (3) Storing and handling of food:
  - (A) All food shall be procured, stored, prepared, distributed, and served under sanitary conditions.
  - (B) Dry or staple food items shall be stored above the floor in a ventilated room not subject to seepage or waste water backflow, or contamination by condensation.
  - (C) Perishable foods shall be stored at the proper temperatures to conserve nutritive values and prevent spoilage.
- (4) Food service:
  - (A) Food shall be served in a form consistent with the needs of the patient and his ability to consume it.
  - (B) Food shall be served with appropriate utensils.
  - (C) All equipment and work areas shall be promptly cleaned in accordance with acceptable written procedures.
  - (D) Handwashing facilities, including hot and cold water, soap, and paper towels adjacent to work areas shall be provided.
  - (E) Individuals needing special equipment, implements, or utensils to assist them when eating shall have such items provided.
  - (F) If a patient misses a meal, a substitute meal shall be provided with equal nutritive value.
- (f) Organization and staffing.
- (1) The dietary department shall be directed by

- a dietitian and have sufficient dietitians and trained personnel to carry out the dietetic services. In facilities licensed for less than twenty-five patients, the dietary department may be directed by a full time trained dietetic service supervisor with consultation from a dietitian.
- (2) If the food service is directed by a dietetic service supervisor, there shall be frequent and regularly scheduled consultations by a dietitian. Consultation, training, and inservice education shall be appropriate to the staff and patient needs and shall be documented.
- (3) There shall be appropriate coordination between dietetic services staff and other hospital departments in the planning and evaluation of patient care.
- (4) The policies and procedures for the dietary department shall be current, and planned or reviewed by the dietitian at least annually.
- (5) Inservice training shall be provided at least quarterly for all dietary staff.
- (6) The current Hawaii Dietetic Association diet manual shall be readily available to all medical, nursing, and food service personnel.
  - [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-9 Disaster plan. (a) The facility shall establish a written external disaster plan for the reception, treatment, and disposition of mass casualties. The plan should be developed in conjunction with other emergency facilities and services in the county, and appropriate civil authorities, and shall address disaster relief pursuant to chapter 127, HRS. Disaster drills shall be held at least once yearly.
- (b) The facility shall have a written internal disaster plan which incorporates general evacuation procedures, emergency procedures in the event of fire, disruption of electrical power, or water supply, and

- any special procedures to be observed in the event of a hurricane, earthquake, tsunami or any other disaster which might affect the facility.
- (c) Copies of all disaster plans shall be made available to the director. [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §321-9, 321-11) (Imp: HRS §321-9, 321-11)
- §§11-93-10 <u>Emergency services</u>. (a) An appraisal, advice and initial emergency treatment, shall be rendered to any ill or injured person who requests treatment at a hospital which has an emergency service department.
- (b) Emergency patient care shall be provided and guided by written policies and shall be directed by a physician staff member. Adequate facilities and equipment shall be provided. A medical record shall be kept for each patient receiving emergency services. The record shall become an official hospital record. [Eff. 3/3/86; am August 3, 1992] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-11 Engineering and maintenance. (a) The hospital shall have an appropriate preventive maintenance program.
- (b) There shall be sufficiently trained and experienced personnel to accomplish the required engineering and maintenance functions within the facility or available through contract with appropriate community resources.
- (c) Inspection and testing of those devices determined to be essential to the health and safety of patients and personnel shall be carried out in accordance with the manufacturer's instructions, regulatory agencies' requirements and as determined by operational experience, to ensure effective operational performance. [Eff. 3/3/86; am August 3, 1992 ]Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
  - §11-93-12 Fees for licensing. Appropriate fees,

if any, as determined by the director, shall be charged by the department for obtaining a new license or obtaining a license renewal. Prior notice of the amount of the fee will be provided the licensee. [Eff. 3/3/86] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-13 General policies and practices.

  (a) There shall be written policies and procedures available to staff, patients and the public which govern all areas of service provided by the facility. They shall assure that the hospital buildings are constructed and equipped to protect the health and assure the safety of patients, personnel and visitors.
- (b) The policies shall ensure that the facility shall not deny admission to any individual on account of race, color, religion, ancestry, or national origin. [Eff. 3/3/86] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-14 Governing body and management. (a) Each hospital shall have an organized governing body or designated persons with overall responsibility for the conduct of all activities.
- (b) The governing body or designated persons shall adopt by-laws in accordance with legal requirements and with the community responsibility of the hospital, and shall identify through its by-laws the purposes of the hospital and the means of fulfilling them.
  - (c) The governing body shall:
  - (1) Provide for the election of officers and for the appointment of committees as necessary to discharge its responsibilities. In addition, it shall adopt a schedule of meetings, attendance requirements, and methods of recording minutes of proceedings.
  - (2) Provide an administrator whose qualifications, authority, and duties shall be defined in a written statement.
  - (3) Designate in writing a suitable employee to act on the administrator's behalf in the

- administrator's absence.
- (4) Approve, deny, revoke, and suspend staff privileges.
- (5) Delegate to the medical staff authority to evaluate the professional competence of staff members and applicants for staff privileges.
- (6) Delegate to the medical staff responsibility for making recommendations concerning staff appointments, reappointments, and the assignment or curtailment of privileges.
- (7) Approve medical staff by-laws.
- (8) Require the medical staff to establish controls to ensure the achievement and maintenance of high standards of professional practices.
- (9) Require and establish an ongoing quality assurance program that includes effective mechanisms for reviewing and evaluating patient care, as well as an appropriate response to findings.
- (10) Not enter into any contract or agreement with a person or persons limiting the governing body's responsibility.
- (d) The facility shall maintain methods of administrative management which assure that:
  - (1) Staff sufficient in number and qualifications to carry out the policies, responsibilities, and program of the facility shall be on duty at all hours of the day.
  - (2) The number of patients and their particular needs shall determine the numbers and categories of personnel.
  - (e) Personnel policies.
  - (1) There shall be written job descriptions available for all positions.
  - (2) Licensure, certification, or standards such as are required in community practice shall be required for all comparable positions in the facility.
  - (3) The facility's personnel policies and practices shall be in writing and shall be available to all employees.

- (4) Written policy shall prohibit neglect or abuse of patients.
  - (A) Suspected incidences of neglect or abuse shall be reported immediately to the administrator, or his representatives, to the department of health, State of Hawaii and to appropriate government agencies as required by law; and
  - (B) All alleged incidences of abuse or neglect shall be thoroughly investigated by the administrator, or his representative, and documented.
- (5) There shall be an organization chart showing major operating programs of the facility, staff divisions, administrative personnel in charge of programs and divisions, and line of authority, responsibility, and communication.
- (6) There shall be documented evidence that every employee has a pre-placement health assessment which will certify that the employee is free of any infectious disease which is liable to jeopardize the health of a patient. Periodic health evaluations may be ordered by the director to insure that employees are free from infectious disease.
  - (A) A health assessment shall include a clearance for tuberculosis for all employees. Those employees who have patient contact in an outpatient obstetrical clinic or planned parenthood clinic shall have a rubella antibody test. Counseling shall be available to employees with a negative test for rubella antibodies, including education or vaccine side effects.
  - (B) If the tuberculin skin test result is significant, as defined by the tuberculosis branch of the department, appropriate medical follow-up must be obtained. In addition, a yearly chest x-ray for three successive years thereafter shall be required, unless

- the individual has documentation that the individual has received antimicrobial therapy for tuberculosis. Additional chest x-rays may be required at the discretion of the director.
- (C) If the tuberculin skin test result is not significant, a second tuberculin skin test shall be done after one week but not later than three weeks after the first test. The results of the second test shall be considered the baseline test and be used to determine appropriate treatment and follow-up. If the second test is not significant, a single test is required yearly thereafter until it becomes significant.
- (D) Any employee who develops evidence of an infection shall be immediately excluded from any duties relating to food handling and direct patient contact and remain excluded until such time as a physician or a licensed nurse, under the physician's supervision, certifies it is safe for the employee to resume such duties. The appearance of diarrhea, temperature elevation, skin pathology, and respiratory symptoms shall be considered presumptive evidence of infection.

[Eff. 3/3/86; am August 3, 1992]
(Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-15 <u>Housekeeping</u>. (a) A plan shall be made for routine periodic cleaning of the entire building and premises.
- (b) After discharge of any patient, the patient's unit and equipment shall be thoroughly cleaned prior to re-use.
- (c) Floors, lavatories, toilets, and showers in patient areas shall be cleaned at least once daily.

- (d) The facility shall be kept free of unreasonable accumulation of personal possessions.
- (e) All floors, walls, ceilings, windows and fixtures shall be kept clean and in good repair.
- (f) All safety procedures shall be in accordance with the rules of the department of labor and industrial relations, State of Hawaii.
- (g) All areas which have contained infectious patients and material shall be thoroughly cleaned with appropriate sanitizing methods. [Eff. 3/3/86] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-16 <u>Infection control</u>. (a) There shall be an active hospital-wide infection control program to prevent, identify, and control infections acquired in the hospital or brought into the hospital from the community, with specific written infection control policies and procedures for all services throughout the hospital.
- (b) A system for reporting, evaluating and maintaining records of infection among patients and personnel shall be established.
- (c) Policies and procedures shall be written defining the specific indications for isolation in relation to the medical condition involved.
- (d) There shall be written procedures which outline proper isolation techniques and practices.
- (e) Isolation facilities shall be available for all services.
- (f) Isolation rooms shall have accommodations for one patient only and shall have:
  - (1) An adjoining toilet room with nurses' call system, a washbasin and toilet.
  - (2) The washbasin shall be provided with controls not requiring direct contact of the hands for operation.
- (g) Provision shall be made in each isolation room for visual observation of the patient by staff.
  - (1) By means of the view window located in door or walls of the room; or
  - (2) By an approved mechanical system, i.e., closed circuit television monitoring.
  - (h) Appropriate attire (gowns, masks, etc.) if

needed shall be available to staff and visitors immediately outside of the isolation room. Containers for used attire shall also be made available.

- (i) All infectious waste, as defined in Administrative Rules chapter 11-104, shall be handled, treated, transported, stored, and disposed of in accordance with the rules and procedures delineated in chapter 11-104.
- (j) Policies and practices recommended by the Centers for Disease Control regarding "universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health care settings MMWR June 1988" shall be observed. [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-17 <u>Inservice education</u>. (a) There shall be a staff inservice education program that includes:
  - (1) Orientation for all new employees to acquaint them with the philosophy, organization, program, policies and procedures, practices, and goals of the facility.
  - (2) Inservice training for employees who have not achieved the desired level of competence, and continuing inservice education to update and improve the skills and competencies of all employees.
  - (3) Annual training in the prevention and control of infections, fire prevention safety, and accident prevention and training of persons handling hazardous and infectious waste.
- (b) Records shall be maintained to indicate attendance at staff orientation and training programs. [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-18 <u>Laundry service</u>. (a) Laundry service shall be managed so that daily clothing and linen needs are met without delay.

- (b) Provisions shall be made for the handling, storage, and transportation of soiled and clean laundry.
- (c) Procedures shall be established for the satisfactory cleaning of all laundry.
  - (1) Provisions may be made for contract service outside the facility in a laundry approved by the department.
  - (2) Laundry soiled with infectious waste shall be handled in accordance with provisions of section 11-93-16(i) and (j), or any other method approved by the director relating to potentially infectious laundry.
  - (3) Clean linen shall be stored in enclosed areas or covered carts.
  - (4) Hampers shall be provided for soiled linen.
    [Eff. 3/3/86; am August 3, 1992 ] (Auth: HRS
    §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-19 <u>Life safety</u>. (a) Facilities licensed under this chapter shall be inspected at least annually by appropriate fire authorities for compliance with state and county rules and ordinances.
- (b) Smoking regulations shall be adopted. No smoking signs shall be posted where flammable liquids, combustible gases or oxygen are used or stored.
- (c) Every building shall have an electrically supervised, manually operated fire alarm system installed to transmit an alarm automatically to the fire department or to an approved central station.
- (d) Evacuation floor plans or signage shall be posted in prominent locations as recommended by the National Fire Protection Association.
- (e) Fire drills shall include the transmission of a fire alarm signal and be held at least quarterly for each shift under varied conditions. At least twelve drills shall be held every year and reports filed.
- (f) All employees shall be instructed and kept informed in regard to their duties under the fire and disaster programs. [Eff. 3/3/86; am and ren August 3, 1992] (Auth: HRS §§321-9, 321-11)

(Imp: HRS §§321-9, 321-11)

- §11-93-20 <u>Maternity and obstetrical services</u>.

  (a) If maternity and obstetrical services are provided by the hospital, maternity patient bedrooms, labor rooms, and delivery rooms shall be physically separated from all other sections of the hospital.
- (b) Maternity facilities shall not be used for any other purpose other than maternity-related functions except as follows: in the interest of proper bed utilization these facilities may be used for clean surgery or clean gynecology in the event of an emergency.
- (c) Maternity suites shall be located to prevent through traffic, except for emergency exit.
- (d) Delivery rooms shall have a minimum of two hundred fifty square feet.
- (e) Scrub sinks shall be provided for each delivery room on the basis of two sinks for the first delivery room, and one additional sink for each delivery room over one. Scrub sinks shall be located outside of delivery rooms.
- (f) Each delivery area shall provide a separate clean-up room separated from the sterilizing facilities.
- (g) Well-ventilated or air conditioned labor rooms shall be provided in conjunction with the delivery rooms.
  - (h) Birthing rooms:
  - (1) There shall be specific written guidelines available for the use of birthing rooms. The guidelines shall at a minimum include statements about the following:
    - (A) Prerequisites for use of the birthing room.
    - (B) Screening of children and other participants in the birthing room.
    - (C) Handling of the newborn infant by participants.
    - (D) Special dress requirements.
    - (E) Availability of equipment for medical emergencies.
      - (F) Infection control measures.

- (2) Each room shall be equipped with a lavatory for handwashing (handwashing sink with wrist blades is acceptable for scrubbing).
- (3) Each birthing room (labor delivery recovery or labor delivery recovery postpartum) shall be for single occupancy and have access to adjoining toilet. A shower or tub shall be accessible postpartum.
- (4) Each birthing room (labor delivery recovery or labor delivery recovery postpartum) shall have a minimum of one hundred eighty square feet.
- (i) Newborn facilities.
- (1) The newborn room or rooms, referred to in this chapter as "nurseries", shall be physically separated from all other sections of the hospital and shall not be used for any purpose other than for the care of the newborn.
- (2) The nurseries shall be designed and equipped to maintain infants' optimum body temperature.
- (3) Provision shall be made in each nursery for resuscitation, administration of oxygen, prevention of infection, and prevention of accidents.
- (4) Each nursery shall be provided with means for the viewing of the newborns.
- (5) No person shall enter the nursery except those immediately concerned with the care of the newborn.
- (6) Nurseries shall provide a minimum of twenty-four square feet of floor area per bassinet and shall be arranged so as to maintain at least two feet between bassinets and with bassinets placed no closer than six inches from the wall. The maximum capacity of each normal newborn nursery shall be sixteen bassinets.
- (7) In addition to the nursery or nurseries, each unit shall provide for handwashing facilities, space for charting, examination space (unless a separate examination room is provided), and space for gowning.

- (8) Facilities for storage and preparation of formula shall be provided.
- (j) Hospitals providing a rooming-in program shall have policies and procedures relating to the nursing care of the newborn. [Eff. 3/3/86; am and ren August 3, 1992] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-21 <u>Medical record system</u>. (a) There shall be available sufficient, appropriately qualified staff and necessary supporting personnel to facilitate the accurate processing, checking, indexing, filing, and prompt retrieval of records and record data.
- (b) If the director of the medical record system is not a registered record administrator or accredited record technician, there shall be regularly scheduled visits by a qualified consultant who provides reports to the administrator at least quarterly.
- (c) The medical records shall clearly and accurately document a patient's identity, the diagnosis of the patient's illness, treatment, orders by medical staff, observations, and conclusion concerning the patient.
- (d) When a patient is transferred to another facility or discharged, there shall be a complete medical summary including current status and care, and final diagnosis.
- (e) There shall be a master alphabetical index of all patients admitted to the facility.
- (f) Patient records shall be completed on a timely basis and retained in accord with existing state laws governing retention of medical records.
- (g) All information contained in a patient's record, including information contained in an automated data bank, shall be considered confidential.
- (h) The patient's record shall be the property of the hospital whose responsibility shall be to secure the information against loss, destruction, defacement, tampering, or use by unauthorized persons.
- (i) There shall be written policies prepared by the hospital administration which shall govern access to, duplication of, and dissemination of information from the patient's record.

- (j) Written consent of the patient, if competent, or otherwise the patient's guardian, shall be required for the release of information to persons not otherwise authorized by hospital policy to receive it. Appropriate consent forms shall include:
  - (1) Use for which requested information is to be released.
  - (2) Specific sections or elements of information to be released.
  - (3) Name and appropriate identification of the individual or organization desiring the information.
  - (4) Dated signature of patient, or legal guardian, approving the release of medical record information.
- (k) Records shall be readily accessible and available to authorized department of health licensing personnel.
- (1) Histories and physicals, dictated medical reports, orders, nursing observations, discharge summaries, operative reports, and consultative reports entered in the patient's record shall be:
  - (1) Legible, typed or written in ink;
  - (2) Dated; and
  - (3) Authenticated by signature and title of the
    individual making the entry.
    [Eff. 3/3/86; am and ren August 3, 1992]
    (Auth: HRS §§321-9, 321-11) (Imp: HRS §§3219, 321-11)
- §11-93-22 <u>Medical staff</u>. (a) There shall be an organized medical staff that has overall responsibility for the quality of medical care provided to patients, and for the ethical conduct and professional practices of its members.
- (b) The medical staff shall develop and adopt
  by-laws and rules to:
  - (1) Establish a framework for self government and a means of accountability to the governing body.
  - (2) Provide for the election or appointment of officers, executive committees, department heads and service chiefs.

- (3) Specifically define and delineate medical staff clinical privileges of all individuals who are permitted by law and by the hospital to provide patient care independently in the hospital and review and evaluate each member's clinical activities.
- (4) Hold regular staff and departmental meetings to review administrative and clinical duties. Minutes of all meetings shall be kept.
- (5) Promote a continuing program of professional education.
- (c) All patients admitted to a hospital shall be under the general care of a physician member of the medical staff. Individuals admitted by a nonphysician member of the medical staff who has been granted admitting privileges will have a qualified physician who is a member of the medical staff designated to be responsible for the general medical evaluation and medical care of the patient in accordance with requirements of the governing board.
- (d) The hospital shall not permit interns, residents, fellows, graduates of foreign medical schools or medical students in an approved training program to perform a service for which a license is required by the State of Hawaii unless they are at the time licensed or under the direct control and direct supervision of a licensed physician or a medical staff member of the same profession. [Eff. 3/3/86; am and ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-23 <u>Nuclear medicine service</u>. (a) Nuclear medicine services, when provided, shall be under the direction of a physician qualified in nuclear medicine. Appropriate space and facilities shall be provided for this activity. [Eff. 3/3/86; ren August 3, 1992] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-24 <u>Nursing services</u>. (a) Each hospital shall have nursing staff sufficient in number and

qualifications to meet the nursing needs of the patients.

- (b) The hospital shall maintain an organized nursing staff which will be responsible to the hospital administrator for the professional performance of its members.
- (c) The nursing department shall be under the direction of a registered nurse who shall administer the nursing program on a full time basis.
- (d) There shall be a written plan for the nursing department which includes objectives, administrative authority, staffing patterns, as well as job descriptions for each category of nursing personnel.
- (e) There shall be appropriate written nursing policies and procedures specifying the scope of services.
- (f) There shall be a registered nurse or registered nurses with current licensure on duty at all times to render safe and therapeutic nursing care.
- (g) Nursing services shall include, as a minimum, the following:
  - (1) Adequate care to keep patients clean, comfortable, well-groomed, and protected from accident and nosocomial infection.
  - (2) A nursing care plan for each patient shall be developed upon admission by a registered nurse and be based on the patient's medical and nursing care needs. The plan shall reflect current standards of nursing practice and shall be appropriately documented.
- (h) There shall be an appropriately equipped nurses' station in each unit. At a minimum it shall include a telephone, writing space, storage cabinets, and medical record space.
- (i) There shall be a nurses' call system which registers calls within hearing range and is directly visible to on-duty personnel.
- (j) There shall be appropriately equipped utility rooms within each nursing unit or on each patient floor. There shall be adequate physical and bacteriologic separation between clean and used equipment and supplies. [Eff. 3/3/86; am and

ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-25 Anatomic pathology and clinical laboratory. (a) Anatomical pathology and clinical laboratory services shall be available at all times to meet patient needs, either within the hospital or by contract with a laboratory approved by the department. Pathology services shall be directed and supervised by a physician certified, or eligible for certification, by the American Board of Pathology or the American Osteopathic Board of Pathology, and is a member of the hospital's medical staff.
- (b) The medical staff shall determine which tissue or surgical specimens are to be sent to the laboratory for processing and examination by a pathologist. Such specimens shall be properly labeled, packaged in preservative as designated, and accompanied by pertinent clinical information. Reports of all examinations shall be made a part of the patient's medical record.
- (c) Autopsy services shall be available. Hospitals shall provide adequate morgue and autopsy facilities or make arrangements for such services with other sources. Gross and microscopic reports of autopsy performed within or outside the hospital, shall be made part of the patient's completed medical record.
- (d) In the event that anatomic and clinical pathology are separate departments, clinical laboratory services shall be directed and supervised by a physician, a doctoral scientist, or a clinical scientist with equivalent training and experience, and holds a valid clinical laboratory director's license. If the hospital provides blood transfusion services, each service shall be rendered under the technical supervision of a pathologist or other physician who is qualified in immunohematology and hemotherapy.
- (e) For emergency situations, the hospital shall ensure that there are provisions for procurement, safe storage, and transfusion of blood and blood products.
- (f) There shall be a sufficient number of licensed clinical laboratory technologists and

supportive technical staff to perform, promptly and proficiently, the laboratory tests required.

- (g) The clinical laboratory shall comply with the licensing requirements of chapter 11-110 Administrative Rules.
- (h) There shall be a written description of the services available and the location of those services within the organization of the hospital. The clinical laboratory director shall be responsible for the laboratory tests performed; and shall assure that the tests and procedures are properly performed, recorded, and reported. [Eff. August 3, 1992]
  (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

§11-93-26 Patient's rights. (a) Written policies regarding the rights and responsibilities of patients during their stay in the facility shall be established and shall be made available to the patient, to any guardian, next of kin, sponsoring agency or representative payee, and to the public. The facility's policies and procedures shall provide that each individual admitted to the facility shall:

- (1) Be informed, as evidenced by the patient's written, and signed acknowledgement, prior to or at the time of admission and during stay, of the rights and rules governing patient conduct.
- (2) Be informed of services available in or through the facility and of related charges.
- (3) Be advised that the patient has a right to have the patient's medical condition and treatment discussed with the patient by a physician of the patient's choice, unless medically contraindicated, and to be afforded the opportunity to participate in the planning of the patient's medical treatment, and to refuse to participate in experimental research.
- (4) Have the right to refuse treatment after being informed of the medical consequences of that refusal.
- (5) Be transferred or discharged only for the patient's welfare, or of other patients'

- welfare, or other causes as determined by the director, and be given reasonable advance notice to ensure orderly transfer or discharge.
- (6) Be encouraged and assisted throughout the patient's period of stay to exercise the patient's rights as a patient, to voice grievances, and to recommend changes in policies and services to the facility's staff; and to do so free from restraint, interference, coercion, discrimination, or reprisal from the hospital staff.
- (7) Be allowed to manage their personal financial affairs. In the event the facility agrees to manage the patient's personal funds, the delegation shall be in writing, and the conditions under which the facility shall exercise the responsibility shall be explained to the patient.
- (8) Not be humiliated, harassed, injured, or threatened, and shall be free from chemical and physical restraints except as authorized by a physician or in an emergency when necessary to protect the patient from injury to the patient's self or to others.
- (9) Be entitled to have the patient's personal and medical records kept confidential and subject to release only as provided in section 11-93-21.
- (10) Be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care.
- (11) Not be required to perform services for the facility, its licensee or staff that are not included for therapeutic purposes in the patient's plan of care.
- (12) Have the right to associate and communicate privately with persons of the patient's choice, and to send and receive the patient's personal mail unopened unless medically contraindicated. At the patient's request, be visited by members of the clergy at any time.

- (13) Have the right to meet with and participate in activities of social, religious, and community groups at the patient's discretion unless medically contraindicated.
- (14) Retain and use the patient's personal clothing and possessions as space permits, unless to do so would infringe upon rights of other patients, or unless medically contraindicated.
- (15) Be assured privacy for visits. If a couple are patients in the facility, be permitted to share a room if available unless medically contraindicated.
- (16) Have daily visiting hours established.
- (17) Have the right to receive discharge planning by qualified hospital staff to ensure appropriate post-hospital placement.
- (b) The patient or responsible agent shall be informed of the policies of the facility with which the patient must comply. [Eff. 3/3/86; am and ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-27 <u>Pediatric</u>. (a) When a hospital has a pediatric unit, it shall be maintained as follows:
  - (1) The facilities for the care and treatment of children shall be designated and set apart from all other services including the newborn service.
  - (2) Pediatric bedrooms shall have a maximum of four patients.
  - (3) Pediatric bedrooms shall have a minimum floor area, exclusive of toilet rooms, closets, lockers, vestibules, of one hundred square feet for single-bed rooms and eighty square feet for multi-bed rooms.
  - (4) Each pediatric nursing unit shall have at least one bedroom to be used as an isolation room.
  - (5) The pediatric unit shall be directed by a physician member of the medical staff who has special training, experience, and demonstrated competence in pediatrics.

- (6) This unit shall have a licensed and ancillary nursing staff who have had the education, experience and demonstrated competence to meet the nursing needs of children.
- (b) If no special pediatric unit is provided by the hospital, but pediatric patients are cared for by the facility, the following conditions shall be met:
  - (1) Pediatric patients must not be lodged in the same room as adult patients;
  - (2) There must be documented evidence of
     continuing inservice training in pediatric
     nursing care techniques for the nursing
     staff. [Eff. 3/3/86; ren August 3, 1992 ]
     (Auth: HRS §§321-9, 321-11)
     (Imp: HRS §§321-9, 321-11)
- §11-93-28 Pharmaceutical services. (a) The hospital shall either employ sufficient licensed pharmacists or have a written contract with a licensed pharmacist to provide services necessary to meet patients' medication needs, to provide consultation on methods and procedures for ordering, monitoring and assessment, storage, administration, disposal, and record keeping of pharmaceuticals and drugs.
- (b) There shall be a current pharmacy policy manual developed and approved by the pharmacist, physicians, and professional nursing staff which:
  - (1) Includes policies, procedures, functions, and responsibilities of the pharmacy service.
  - (2) Provides for regular periodic revision.
  - (3) Governs the safe administration, preparation, handling and storage of all drugs.
  - (4) Includes policies regarding selfadministration of drugs.
  - (5) Includes a formulary appropriate to the hospital.
- (c) Medications administered to a patient shall be ordered either in writing or verbally by an individual so authorized by hospital policy.
  - (1) Verbal orders for prescription drugs shall

- be given only by a physician and shall be accepted only by a licensed nurse, pharmacist, or physician.
- (2) All verbal or telephone orders for medication shall be recorded and signed by the person receiving them and shall be countersigned by the attending physician within twenty-four hours.
- (d) Each drug, dose and dosage route shall be identified immediately prior to administration and each patient receiving the ordered drug shall be identified immediately prior to administering of the drug.
- (e) Medication shall not be used for any patient other than the one for whom it was prescribed.
- (f) Only appropriately licensed and trained staff shall be allowed to administer drugs and shall be responsible for proper recording of the medication including the route of administration. Medication errors and drug reactions shall be recorded in the patient's chart, and reported immediately to a physician. A report shall be prepared and shall be submitted promptly to the administrator or the designated representative.
- (g) Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
  - (1) All drugs shall be kept under lock and key except when authorized personnel are in attendance.
  - (2) All security requirements of federal and state laws shall be satisfied as they refer to storerooms and pharmacies.
  - (3) Drugs intended to be used only externally, and drugs taken internally shall be stored in separate well-marked cabinets or drawers, at all locations.
  - (4) Medications that are stored in a refrigerator, which contains things other than drugs, shall be stored separately in a locked container.
  - (5) If there is a drug storeroom separate from the pharmacy, there shall be a perpetual inventory of receipts and issues of all

- drugs by such storerooms.
- (6) Discontinued and outdated drugs, and containers with worn, illegible, or missing labels, and drugs dispensed to a specific patient and left on the floor after discharge of the patient, shall be returned to the pharmacy or drug room for proper disposition.
- (7) There shall be automatic stop order policies.
- (8) There shall be a drug recall procedure that can be readily implemented.
- (9) Only specifically authorized personnel shall have access to locked compartments, drawers, and cabinets.
- (10) In no case shall chemical agents not
   intended for patient use be stored in the
   same cabinets or drawers with medications.
   [Eff. 3/3/86; am and ren August 3, 1992 ]
   (Auth: HRS §§321-9, 321-11) (Imp: HRS
   §§321-9, 321-11)
- §11-93-29 <u>Psychiatric services</u>. (a) If individuals suffering from mental illness or substance abuse are cared for in the hospital, the requirements of this section, in addition to the basic rules contained in this subchapter, shall be required in order to provide the psychiatric services. This section shall apply to either an entire hospital or a distinct part of a hospital.
  - (b) As used in this section:
- "Psychiatric facility" means a public or private hospital or a distinct part thereof which provides inpatient care, custody, diagnosis, treatment or rehabilitation services for mentally ill persons or persons habituated to the excessive use of drugs or alcohol. A distinct part of a hospital means a physically identifiable unit designated as the psychiatric inpatient facility where the beds are reserved for such patients.
- (c) Program requirements. The following shall be met by the psychiatric facility in addition to those requirements enumerated under section 11-93-14,

governing body and management, and section 11-93-22, medical staff.

- (1) The facility shall develop, maintain, and update at least annually, a comprehensive written program plan which serves as the basis for the overall administration of its functions.
  - (A) The purpose, functions, activities, and services shall be clearly described in the plan.
  - (B) The plan shall include a clear statement of program goals and objectives as well as procedures for achieving these goals and objectives.
- (2) The facility shall establish and maintain a current policy and procedures manual governing its overall procedures.
  - (A) The policies and procedures shall be in compliance with all applicable federal, state, and local requirements and shall include but not be limited to the following:
    - (i) Administration of electroconvulsive therapy.
    - (ii) Administration of drugs.
    - (iii) Use of restraints on patients.
      - (iv) Use of seclusion room.
      - (v) Assurance and protection of patient's rights including grievance mechanism and confidentiality, and the rights enumerated under chapter 334E, HRS.
      - (vi) Type and method of program
         evaluation, research and data
         collection.
  - (B) All staff shall be familiar with these policies and procedures and have ready access to the manual.
  - (C) The policies and procedures shall be reviewed and updated at least annually by appropriate personnel in the facility.
- (3) A wide range of mental health services shall

be provided to patients and their families.

- (A) Services to all patients shall be appropriate to their disability, age, level of development, social, ethnocultural, educational, religious, and economic background.
- (B) Services shall be available to voluntary and involuntary patients, providing at a minimum, evaluation, diagnosis, treatment, and discharge plans. In those instances where the facility lacks the capacity to adequately manage and provide the needed services, arrangements shall be made to transfer the patient to another suitable psychiatric facility. Transfer or referral documents and records shall be complete and in proper order at the time of the transfer or referral.
- (C) All services shall be coordinated and integrated with other service units within the facility, patient support system, and with human service agencies in the community.
- (D) Any service or activity shall be conducted in conformance with all applicable federal, state and local requirements and consistent with good medical practice.
- (E) Services shall be provided in a timely manner.
- (F) An individualized treatment plan shall be formulated for each patient within forty-eight hours following admission, reviewed, and modified periodically as changes occur in the patient's condition or status. In every instance, to the extent possible, the patient shall participate in the patient's treatment planning.
- (G) Therapeutic interventions shall be based upon the patient's individualized treatment plan, and provided at the

- level of frequency, intensity, and duration to facilitate the patient's return to community living.
- (4) The environment of the psychiatric service shall contribute to establishing and enhancing a positive self-image for each patient.
  - (A) The physical facilities and equipment shall be pleasant, comfortable and promote the patient's perception and awareness of the surroundings.
  - (B) Rules of daily living shall be communicated to the patient and shall be consistent in preserving and enhancing human dignity and individuality.
- (5) Facilities and equipment necessary for the proper management of agitated, aggressive, disoriented, or otherwise disturbed patients shall be provided to protect the safety of the patient and of others.
  - (A) Physical restraints used on patients, including use of seclusion rooms, shall, except for emergencies, require prior authorization by a physician. In the event of an emergency requiring unanticipated use of restraints, prompt notification of a physician shall be made and written authorization shall be obtained from a physician within twenty-four hours. No "as needed" orders will be allowed without specific circumstances being delineated.
  - (B) Written policies and procedures on the use of restraints, including the use of seclusion rooms, shall be developed and maintained to ensure safe and humane care of patients.
  - (C) The policies and procedures shall identify the staff authorized to apply physical restraints in an emergency.
- (6) Post discharge and follow-up services, as needed, shall be arranged to promote continuity of care for patients.

- (d) Staffing requirements. The facility shall have staff adequate in number and qualifications to carry out an active treatment program.
  - (1) The facility shall be staffed with sufficient qualified personnel, technical, support personnel and consultants to carry out an intensive and comprehensive treatment program. The program shall include assessment of individual patient needs, establishment of treatment goals, and implementation, either directly or by arrangement, of a broad range of therapeutic services. Therapeutic services shall include at a minimum, psychiatric, medical, nursing, social work, psychological and recreational activity as required to carry out an individualized treatment plan for each patient.
  - (2) The services shall be under the supervision of a clinical director or service chief.
    - (A) The clinical director or service chief shall be certified by the American Board of Psychiatry and Neurology or meet the training and experience requirements for examination by the board ("board eligible").
    - (B) The medical staff shall meet the qualifications required by law.
    - (C) The number of psychiatrists and psychologists shall be commensurate with the size and scope of the treatment services.
  - (3) A psychiatrist shall be available to provide services for psychiatric emergencies at all times and to provide consultation as requested by staff.
  - (4) When certain necessary diagnostic and therapeutic services are not available within the psychiatric facility, qualified consultants or attending physicians shall be promptly available, or else provisions shall be made for prompt transfer of a patient to an appropriate facility providing the needed services.

- (5) Nursing services shall be under the direct supervision of a registered professional nurse who is qualified by education and experience for the position. The number of registered professional nurses, licensed practical nurses, and other nursing personnel shall be sufficient to formulate and carry out the nursing components of the individualized treatment plan for each patient.
  - (A) The registered professional nurse supervisor shall have a master's degree in psychiatric nursing from a school of nursing accredited by the National League of Nursing, or two years of psychiatric nursing experience.
  - (B) The staffing pattern on a psychiatric unit shall have a registered professional nurse on duty twenty-four hours each day.
  - (C) The nursing staff shall be sufficient in number, training, and ability to meet the needs of the patients.
- (6) Adequate psychological services shall be available to all patients. These services shall be provided by a licensed psychologist who may be employed on a full time, regular part time, or consulting basis, or be a member of the medical staff.
- (7) Social work services shall be available to all patients. The social work staff shall be sufficient in number to meet the needs of the patients. The social work services shall be under the supervision of a full time qualified social worker.
- (8) Qualified therapist, consultants, volunteers, assistants or aides shall be sufficient in number to provide comprehensive therapeutic activities, including occupational and recreational therapies, and to ensure that appropriate treatment is rendered for each patient.
  - (A) Occupational therapy services shall be conducted or supervised by a qualified

- occupational therapist who may be employed on a full time, regular part time, or consulting basis.
- (B) Recreational or activity therapy services shall be available under the direct supervision of a member of the staff who has demonstrated competence in therapeutic recreation programs.
- (C) Volunteers shall work under the supervision of the facility staff and shall be provided appropriate orientation and training.
- (e) Medical record requirements. In addition to those requirements covered under section 11-93-21, the medical records of the psychiatric patient shall contain:
  - (1) The results of a psychiatric evaluation including a mental status examination.
  - (2) Neurological findings.
  - (3) The results of any psychological tests.
  - (4) Psychosocial evaluations.
  - (5) An individualized comprehensive treatment plan based on an inventory of the patient's assets and liabilities, including a diagnostic formulation, prognosis, short and long range treatment goals in measurable time frames, the specific treatment modalities to be carried out, and by whom, as well as any modifications to the treatment plan as changes may occur in the patient's condition or status.
  - (6) Progress notes which:
    - (A) Document the patient's behavior and response to all treatments rendered.
    - (B) Document contacts made with outside persons on behalf of the patient.
  - (f) Physical facility requirements.
  - (1) Sociotherapeutic areas. There shall be appropriate areas allowing for thirty square feet per patient, which may be used for patients' socialization, activity therapy, and other therapeutic functions. It shall be suitably equipped for such activities and functions.

- (2) Dining area. There shall be designated a common dining area for patients allowing twenty square feet per patient. If the dining room is combined with the sociotherapeutic areas, such combined area shall allow for fifty square feet per patient.
- (3) Conference or interview areas. There shall be one or more rooms which are adequate to provide privacy for individual, family, small group therapy, and consultation. Each unit shall have at least one conference room.
- (4) Visiting areas. There shall be comfortably and attractively furnished areas to allow patients to visit with families, friends and others in reasonable privacy.
- (5) Outdoor areas. There shall be outdoor areas for recreation, social, and visiting purposes.
- (6) Seclusion room. If a room or specialized area is used for seclusion purposes, it shall include adequate ventilation and lighting, access to bathroom facilities, visual observation of the patient, and other measures to protect the patient. If a patient is confined in a seclusion room for more than twelve hours in any twenty-four hour period, the room shall be a minimum of one hundred square feet in size excluding closets, bathrooms, alcoves, and entryways.
- (7) Drinking water shall be conveniently located and in sufficient number of places for patients and personnel.
- (8) Smoking shall be permitted only in approved areas.
- (g) Patient's rights and responsibilities. All patients shall have the following rights in addition to those stated in section 11-93-26.
  - (1) To obtain from the patient's physician complete current information concerning the patient's diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand. When it is not medically advisable to give such

- information to the patient, the information shall be made available to an appropriate person in the patient's behalf. The patient shall have the right to know by name, the physician responsible for coordinating the patient's care.
- To receive from the patient's physician (2) information necessary to give consent prior to the start of any procedure or treatment. Except in emergencies, the information for consent shall include but not be limited to the proposed specific procedure or treatment, the reasons for and benefits of proposed procedure or treatment, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist or when the patient requests information concerning medical alternatives, the patient shall have the right to the information. The patient shall also have the right to know the name of the person responsible for the procedure or treatment.
- (3) To participate in the patient's treatment plan designed to achieve maximum recovery. [Eff. 3/3/86; am and ren August 3, 1992] (Auth: HRS §§321-9, 321-11) (Imp. HRS §§321-9, 321-11)
- §11-93-30 <u>Radiology services</u>. (a) Radiology consultation and services shall be regularly and conveniently available to meet the needs of the patients.
- (b) Radiology services shall be directed by a radiologist and be staffed by qualified technical personnel. Space, equipment and supplies shall be made available for radiology services.
- (c) There shall be written policies governing all radiological procedures.
- (d) Reports of all procedures shall be made a part of the patient's record.
  - (e) All procedures and policies shall be

compliance with chapter 11-40, Administrative Rules, entitled "Radiation". [Eff. 3/3/86; am and ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-31 <u>Rehabilitative services</u>. (a) If the facility provides specialized and supportive rehabilitation services (e.g., occupational therapy, physical therapy, or speech therapy), either directly or through arrangements, the services shall be organized and shall be directed by an appropriately qualified physician, therapist, or member of the medical staff.
- (b) There shall be appropriate policies, procedures, and job descriptions which delineate the scope, organization, and method for implementation of services.
  - (1) A written rehabilitative plan of care shall be provided for each patient which is based on the attending member of the medical staff's and interdisciplinary team's assessment of patient's needs.
  - (2) The patient's progress shall be reviewed regularly, and the rehabilitative plan of care shall be altered as necessary.
- (c) There shall be available sufficient, appropriately qualified professional staff and supporting personnel to carry out the various treatment services in accordance with the plan of care.
- (d) Treatment personnel shall be assigned responsibilities according to their qualifications.
- (e) Treatment services shall have adequate
  designated space, equipment, supplies, and other
  related resources. [Eff. 3/3/86; am and
  ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11)
  (Imp: HRS §§321-9, 321-11)
- §11-93-32 <u>Sanitation</u>. (a) Sanitation shall comply with all applicable laws of the State of Hawaii and rules of the department relating to sanitation.
  - (b) Written summary reports of inspections by

state or local health authorities, records of action taken to correct deficiencies, and to follow recommendations shall be kept on file at the facility.

- (c) Every facility shall provide a sufficient number of watertight receptacles of metal, or other materials acceptable to the department, for rubbish, garbage, refuse, and other discarded matter.
  - (1) In kitchen and food preparation areas, receptacles shall be kept closed by tight fitting covers except during peak hours of food preparation.
  - (2) An area shall be provided for the washing and cleaning of garbage containers and for the storing of garbage, trash, and solid waste. [Eff. 3/3/86; ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
  - §11-93-33 Social work services. (a) Staffing:
  - (1) If the facility offers social services, a member of the staff of the facility shall be designated as responsible for social services;
  - (2) The director of the social work department, or a social worker consultant shall be licensed, certified, or registered in accordance with applicable federal and state laws. In the event such laws provide for voluntary licensure, registration or certification, the director of the social work department or the consultant shall meet eligibility requirements of those federal and state laws. If the designated person is not a social worker, the facility shall have a written agreement with a social worker for consultation and assistance as frequently as necessary but at least on a quarterly basis;
  - (3) The social work staff shall be sufficient in number to meet the needs of the patients;
  - (4) The social work staff shall have appropriate facilities to provide for privacy during interviews and counseling;
  - (5) Inservice training appropriate to the staff

- and patient needs shall be provided at least quarterly for all social work staff, and shall be documented.
- (b) Social work services:
- (1) Social work services shall be available to patients and their families to assist them in dealing with the impact of illness on individual and family functioning and to achieve maximum benefits from health care services.
- (2) Social work assessment and treatment shall be provided by the social worker or social work designee when indicated for a patient. Social work plans with measurable goals, objectives, and time frames shall be documented in the patient's medical record.
- (3) If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.
- (4) Records of pertinent social data about personal and family problems medically related to the patient's illness and care, and of action taken to meet the patient's needs shall be maintained in the patient's medical record.
- (5) If the facility does not provide social services, it has written procedures for referring patients in need of social services to appropriate social agencies. If social services are provided by an outside resource, a record shall be maintained of each referral to such resource.
- (6) Policies and procedures shall be established for ensuring the confidentiality of all patients' social information.
- (7) The policies and procedures for the social work department shall be current, and planned or reviewed by the director of the social work department, or a social work consultant at least annually.
  [Eff. 3/3/86; am and ren August 3, 1992]
  (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

- §11-93-34 <u>Special care units</u>. (a) The scope of services provided in each special care unit shall be specified in writing.
- (b) Each special care unit shall have policies and procedures which relate to the care provided in the unit and shall be reviewed annually.
- (c) The special care unit shall be directed by a physician member of the medical staff who has special training, experience, and demonstrated competence in a specialty related to the care provided in the unit.
- (d) Supervision of nursing care in the unit shall be provided by a registered professional nurse with relevant education, training, experience, and demonstrated current competence.
- (e) A planned orientation program shall be required for all employees who perform patient care services in the unit.
- (f) Relevant inservice education programs or activities shall be provided on a regular basis to all staff members.
- (g) A sufficient number of permanently assigned qualified registered nurses shall be on duty within the unit at all times when patients are in the unit.
- (h) Special care units shall be designed and equipped to facilitate the safe and effective care of patients. [Eff. 3/3/86; ren August 3, 1992 ]
  (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-35 <u>Surgical department</u>. (a) If surgical services are provided, the surgical department shall:
  - (1) Be directed by an appropriately qualified physician.
  - (2) Have effective policies and procedures regarding surgical privileges, maintenance of the operating rooms and evaluation of the surgical patient.
  - (3) Have a registered professional nurse in charge of the operating room suite.
  - (4) Have a roster of physicians specifying the surgical privileges of each.
  - (5) Have an operating room register which is complete and current.

- (b) For each patient, prior to surgery, there
  shall be:
  - (1) Except in case of emergency, a complete history and physical work-up in the chart with all pertinent laboratory and other data supporting the diagnosis.
  - (2) In an emergency, a fully informative admitting note on the chart, by the operating surgeon, and there shall be a sufficient replacement for a complete history and physical examination report.
  - (3) A properly executed consent form for the proposed operation in the chart.
  - (4) Evidence of execution of an effective procedure for accurate identification of the patient.
  - (5) A pre-operative note, on the chart, specifically identifying the surgical procedure to be done and the anatomical location of the procedure and this note must be initialed or signed by both the operating surgeon and the person administering the anesthesia.
- (c) Each operating room shall be supervised by an experienced registered professional nurse.
- (d) The following minimum equipment shall be readily available, and in a fully operating condition, in the operating suite:
  - (1) Emergency call-in system.
  - (2) Cardiac monitor.
  - (3) Cardiac defibrillator.
  - (4) Aspirator.
  - (5) Intubation equipment.
  - (6) Resuscitator.
  - (7) Thoracotomy set
  - (8) Tracheotomy set.
- (e) The operating room suite and accessory services shall be so located that traffic in and out can be, and is, controlled and there is no through traffic.
- (f) There shall be adequate scrub-up facilities and work areas for the preparation, sterilization, and storage of instruments and supplies.
  - (q) Surgical technicians and licensed practical

nurses are not permitted to serve as circulating nurses in the operating rooms.

- (h) An operative report describing techniques and findings shall be written or dictated immediately following surgery and shall be signed by the surgeon. [Eff. 3/3/86; ren August 3, 1992 ] (Auth: HRS §§321-9, 321-11)
- §11-93-36 <u>Transfer agreement</u>. The facility shall establish transfer agreements which make feasible the transfer of patients and transfer summaries between hospitals, skilled nursing, and intermediate care facilities. [Eff. 3/3/86; ren August 3, 1992 ](Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)
- §11-93-37 Penalty. Every person who violates any of the provisions of this chapter shall be penalized as provided in chapter 321, HRS. [Eff. 3/3/86; ren August 3, 1992] (Auth: HRS §§321-9, 321-11, 321-18)
  - §11-93-38 through §11-93-48 reserved.
- §11-93-49 Severability. If any provision of this chapter or the application thereof to any person or circumstances is held invalid, the remainder of this chapter, or the application of the provision to other persons or circumstances shall not be affected thereby." [Eff. 3/3/96; ] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

## DEPARTMENT OF HEALTH

Amendments to chapter 11-93, Hawaii
Administrative Rules, on the Summary Page dated May 1, 1992, were adopted on May 1, 1992, following public hearings held on Oahu on April 2, 1992, on Hawaii on April 3, 1992, on Maui on April 7, 1992, and on Kauai

on April 9, 1992, after public notice was given in the Honolulu Advertiser, the Maui News, and the Garden Island News on February 24, 1992, and in the Hawaii Tribune-Herald on February 23, 1992.

These amendments shall take effect ten days after filing with the Office of the Lieutenant Governor.

s/ John C. Lewin, M.D.

JOHN C. LEWIN, M.D.

Director

Department of Health

APPROVED AS TO FORM:

s/ John Wong JOHN WONG Deputy Attorney General

> s/ John Waihee JOHN WAIHEE Governor State of Hawaii

Date: July 24, 1992

\_\_\_\_\_July 24, 1992 Filed

## SUBCHAPTER 2

## FREESTANDING BIRTHING FACILITIES

§11-93-50 <u>Purpose</u>. The provisions of this subchapter are to establish minimum requirements for the protection of the health, welfare and safety of

patients, newborns, personnel and the public in freestanding birthing facilities. These shall not be construed as lowering standards, ordinances, or regulations established by other divisions or subdivisions of government. In all instances the more stringent rules shall apply. [Eff. March 3, 1986] (Auth: HRS §§321-9, 321-11) (Imp: HRS §§321-9, 321-11)

§11-93-51 <u>Definitions</u>. As used in this subchapter:

"Administrator" means the person to whom it is delegated the responsibility for interpretation and implementation of the policies and program established by the governing body. This may be the same person as the medical director or midwife.

"Birthing room" means a room designed, equipped and arranged to provide for the care of a woman and her newborn child and to accommodate her support persons during the process of vaginal birth.

"Broad service hospital" means a medical facility which is staffed and equipped to provide definitive inpatient medical, surgical and obstetrical care for a twenty-four hour period or longer.

"Cardiopulmonary resuscitation" or "CPR" means an emergency first aid procedure that consists of opening and maintaining a patient's airway, providing artificial ventilation by means of rescue breathing, and providing artificial circulation by means of external cardiac compression.

"Chest x-ray" means a full sized 11" x 14" film taken by standard x-ray techniques.

"Department" means the department of health, State of Hawaii.

"Dietitian" means a person who:

- (1) Is registered by the American Dietetic Association under its requirements in effect on the day of publication of this provision; or
- (2) Is eligible for examination to become a registered dietitian.

"Director" means the director of health of the State of Hawaii.

"Freestanding birthing facility" means a public

or private facility whose only purpose is the reception of maternity patients and the providing of care during pregnancy, delivery, and the immediate postpartum period. The service is limited to the low risk maternity mother and her newborns. It shall not have direct financial or administrative connections with a broad service hospital.

"Governing body" means an individual or group which is legally responsible for the operation and maintenance of the birthing facility.

"Immediate postpartum period" means that period of time starting at birth and ending with the discharge of the patient from the birthing facility.

"Licensee" means the governing body to whom the license is issued.

"Licensed practical nurse" means a nurse licensed as such by the State of Hawaii, pursuant to chapter 457, HRS.

"Low risk mother" means a person who does not exhibit any evidence of:

- (1) Severe anemia or blood disease which will adversely affect the mother or infant during pregnancy or at birth.
- (2) Diabetes mellitus.
- (3) Symptomatic heart disease.
- (4) Hypertension or preeclampsia.
- (5) Renal disease.
- (6) Thrombophlebitis.
- (7) Multiple fetuses.
- (8) Active herpes genitalia, gonorrhea, or syphilis within four weeks of expected date of confinement.
- (9) Viral infections during pregnancy which may adversely affect the infant at birth.
- (10) Placental abnormalities such as placenta previa or placenta abruptio.
- (11) Premature labor, less than thirty-seven weeks, or post-maturity, more than forty-two weeks.
- (12) Prolonged rupture of membranes.
- (13) Potential or realized need for anesthesia or, if in labor, for anesthesia other than a pudendal or local nerve block.
- (14) Intrauterine growth retardation.

- (15) Fetal distress which will adversely affect the infant or at birth.
- (16) Previous caesarean delivery.
- (17) A desire on the part of the mother for transfer from the birth facility.
- (18) Anticipated macrosomia which will adversely affect mother or baby in labor or at birth.
- (19) Breech or other abnormal presentation.
- (20) Five or more (non-miscarriage or non-abortion) pregnancies.
- (21) Toxemia, hydromnios or chorioamnionitis.
- (22) Malformed fetus.
- (23) Alcoholism or drug dependency.
- (24) Decision of the midwife or physician attendant not to accept the patient any longer.
- (25) Problem of a previous pregnancy or a repetitive nature.
- (26) Any other condition or need which will adversely affect the health of the mother or infant during pregnancy, labor, birth, or the immediate postpartum period.

"Medical director" means a suitably qualified physician who is appointed by the governing body to carry out section 11-93-61.

"Midwife" means a person licensed by the State of Hawaii as a midwife.

"Pathologist" means a person certified or eligible to be certified by the American Board of Pathology.

"Pharmacist" means a person having a valid license to practice as a "registered pharmacist" issued by the State of Hawaii, under chapter 461, HRS.

"Physician" is a person licensed by the State of Hawaii to practice medicine and surgery or osteopathy within the State.

"Registered professional nurse" means a person who is licensed as a registered nurse in the State of Hawaii, under chapter 457, HRS.

"Suitably qualified physician" means those physicians who are licensed by the State of Hawaii to practice medicine; is qualified for certification by the American Board of Obstetrics and Gynecology, or have a formal consultive arrangement with an

obstetrician.

"Support person" means the individuals selected or chosen by the mother to provide emotional support and to assist her during the process of labor and childbirth.

"Tuberculin skin test" means an interdermal injection of .0001 mg (5 tuberculin units) of purified protein derivative in 0.1 cc of sterile diluent. If the size of any resulting palpable induration at forty-eight hours to seventy-two hours after injection is 10 mm or greater in its transverse diameter, the reaction to the skin test shall be considered significant. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §§26-38, 321-1, 321-10, 321-14, 453-2, 457-1, 461-1)

- §11-93-52 <u>Licensing</u>. (a) It shall be unlawful for any group or person to operate a freestanding birthing facility unless it is licensed by the director.
- (b) Any person, or group of persons, desiring to operate a freestanding birthing facility shall apply to the director for a license on forms provided by the department. The director shall issue a license if the proposed facility meets the requirements under this chapter.
- (c) A license, unless abandoned or revoked for just cause as determined by the director, shall be renewed every year, on date of issue, or of such other interval of time as may be decided by the director. Application for renewal of license shall be made by the governing body of the freestanding birthing facility at least sixty days prior to expiration date as determined from the license. If application for renewal is not filed, the license shall be automatically cancelled as of the expiration date determined from the license.
- (d) A provisional license may be issued for a specific period of time at the discretion of the director should additional time for correction of deficiencies be deemed advisable. Not more than two successive provisional licenses shall be issued to a particular facility.

- (e) In respect to a particular facility, a specific rule may be waived for a period of one year, at the discretion of the director.
- (f) Each license shall be issued to a physical facility and to a governing body; change in either shall require that the department be notified and, at the discretion of the director, may require that a new license be issued.
- (g) The department shall be notified in writing fifteen days prior to the appointment of a new administrator or a new medical director. A change of administrators or medical directors, at the discretion of the director may require that a new license be issued.
- (h) The license issued by the director shall be posted in a conspicuous place visible to the public on the premises of the freestanding birthing facility.
- (i) Inspection visits may be made to the licensed freestanding birthing facility at any reasonable time without prior notice by the authorized staff of the department.

[Eff. March 3, 1986 ] (Auth: HRS  $\S\S321-9$ , 321-10) (Imp: HRS  $\S\S321-10$ , 321-11)

- §11-93-53 <u>License revocation</u>. (a) After due notice, and after suitable opportunity for hearing, conducted in accordance with chapter 91, HRS, the director may suspend, revoke, or refuse to issue or renew a license to any governing body because of a failure to meet:
  - (1) Requirements of this chapter; or
  - (2) The conditions under which the license was issued.
- (b) Any governing body affected by the director's decision for denial, suspension, or revocation may appeal in accordance with chapter 91, HRS. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§91-14, 91-15, 321-10)
- §11-93-34 <u>Administration</u>. (a) The administrative personnel under the direction of an administrator shall develop and carry out such

administrative procedures as are necessary to achieve the objectives and policies of the governing body.

- (b) The administrator shall establish policies and develop procedures to ensure that all employees are free of infectious diseases. These policies shall include an annual physical examination specifically oriented to rule out infectious disease conducted by a licensed physician.
  - (1) If the tuberculin skin test is significant, a standard chest x-ray and appropriate medical follow up shall be obtained. A yearly chest x-ray for three successive years thereafter shall be required. Additional chest x-rays may be required at the discretion of the director.
  - (2) If the tuberculin skin test is negative, a second skin test shall be done after one week but not later than three weeks after the first test. The results of the second test are to be considered the baseline and are used to determine the appropriate follow up. If the second test is negative it shall be repeated once yearly thereafter until it becomes significant.
  - (3) Any employee who develops evidence of an infectious disease shall be immediately excluded from any duties relating to food handling and direct patient contact and shall remain excluded until such time as a physician certifies that it is safe for the individual to resume normal duties. Skin lesions, respiratory tract symptoms and diarrhea shall be considered presumptive evidence of infectious disease.
  - (4) There shall be adequate documentation that all employees have been fully informed about, and understand, paragraphs (1) to (4).
- (c) The administrator shall formulate written
  patient care policies and procedures which shall
  include but not be limited to:
  - (1) Method for and transfer of mothers and newborns who, during the course of pregnancy or delivery can no longer be considered low

- risk mothers and newborns.
- (2) Arrangements for consultation, backup services, transfer and transport of a mother or newborns to a hospital where appropriate care is available. Each hospital shall not be more than thirty minutes transport from birthing room in the facility to definitive treatment room in the hospital. At the discretion of the director, a demonstration trial run may be required. The transfer policy must include advance notice to the hospital.
- (3) Provision for the education of the mother, family and support persons in birthing and newborn care.
- (4) Plans for the follow up of mother and newborns after discharge from the birthing facility.
- (5) Registration of births and fetal deaths in accordance with the laws of the State of Hawaii. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 338-8, 338-8)
- §11-93-55 Construction and physical environment requirements. (a) The facility shall be constructed and maintained in accordance with state, and local zoning, building, fire safety and sanitation laws.
- (b) The facility shall be accessible to, and functional, for physically handicapped persons.
- (c) There shall be adequate space for preparation, sterilization, and storage of instruments and supplies.
- (d) Adequate toilet, lavatory, and bathing facilities shall be available for patients' and staff use.
  - (e) Each birthing room:
  - (1) Shall be of adequate size and appropriate shape to provide for the equipment, staff, supplies and emergency procedures required for the physical and emotional care of the mother, her support persons, and the newborn during birth, labor, and the postpartum

period.

- (2) Shall have a minimum of one hundred twenty square feet with a minimum dimension of ten feet.
- (3) Shall have doorways and hallways of adequate width and configuration to accommodate maneuvering of ambulance stretchers.
- (4) Shall be located to provide rapid unimpeded access to an exit of the building which shall accommodate emergency transportation vehicles and equipment.
- (f) There shall be an adequate supply of hot and cold running water under pressure suitable for human consumption.
- (g) A safe source of heat or cooling capable of maintaining a room temperature within the range of 72° to 80°F, shall be provided.
- (h) Ventilation shall be sufficient to remove objectionable odors, excessive heat, and condensation.
- (i) Multi-purpose rooms shall be available for interview, education, training, recreation for family support persons, and other purposes.
- (j) There shall be at least two exits from the facility, each remote from the other.
- (k) No cabinets or equipment shall be located in exit corridors.
- (1) Threshold and expansion joint covers shall be made sufficiently flush for the floor surface to accommodate wheel service carts, wheelchairs, gurneys, etc.
- (m) Where appropriate, screening of doors and windows shall be provided using screens having sixteen meshes per inch.
- (n) Suitable locked storage space shall be
  provided for:
  - (1) All medications, medical supplies, and equipment; and
  - (2) All cleaning and maintenance supplies and equipment. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §§46-4, 62-34, 64-91, 65-71, 70-71, 103-50, 132-3, 321-10, 321-11, 42 U.S.C.A. Sec. 4152, 4155 [1977])

- §11-93-56 Fees for licensing. Appropriate fees, if any, as determined by the director, shall be charged by the department for obtaining a new license or obtaining a license renewal. Prior notice of the amount of the fee shall be provided to the licensee. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-93-57 Governing body. (a) The governing body shall be the supreme authority of the facility, responsible for the management, control and operation of the facility; including the appointment of an administrator, medical director, and professional staff.
- (b) The governing body shall specify which obstetrical procedures may be done in the facility.
- (c) The governing body shall be formally organized in accordance with a written constitution and by-laws.
- (d) The governing body shall meet regularly at least once a year, and the minutes of these meetings shall be kept as a permanent record in the facility. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-93-58 <u>Infection control</u>. (a) Definitive procedures governing sterilization techniques shall be developed. The written procedures shall include:
  - (1) The technique to be used for particular instrument or group of instruments.
  - (2) The length of time to accomplish sterilization.
  - (3) Temperature, time and pressure control levels established for steam sterilization.
  - (4) Proper methods of preparation of items for sterilization.
  - (5) Shelf storage for sterile items established.
  - (6) Use of sterilizer indicators.
  - (7) Use of routine bacteriological sterilizer culture controls as might be indicated.
  - (b) Written procedures shall also be developed

to provide for:

- (1) Prohibition of re-use of disposable, one time use, items.
- (2) Biologically safe methods of disposal of contaminated items such as needles, syringes, catheters, gloves, pathological wastes, contaminated dressings, and any other contaminated items which might be present in the facility.
- (c) There shall be an infection control committee established to investigate any patient infection and to take prompt and appropriate remedial action to prevent a recurrence. This committee shall consist at least of a physician and a midwife or a registered nurse.
  - (1) Written reports of all results of investigations of infections and the remedial action taken shall be kept in the permanent files of the facility.
  - (2) The facility shall report promptly to the licensing agency infectious diseases which may represent a potential hazard to patients, personnel and the public. Included, but not limited to, are the reportable diseases and the occurrences of other diseases in outbreak form.
- (d) There shall always be a continuous education program provided to all personnel in the cause, transmission, prevention, and elimination of infections.
- (e) A policy shall be established for strict control of visitors to prevent their casual access to the birthing room.
- (f) There shall be provisions for adequate patient post-discharge follow up in order to discover any patient infection and to record same in the files of the infection control committee.

[Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 321-13)

§11-93-59 <u>Inservice education</u>. There shall be an appropriate inservice education program. This shall include, but not be limited to annual training,

fire prevention, infection control, and accident prevention. There shall be adequate documentation of these educational procedures. [Eff. March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 321-13)

- §11-93-60 <u>Laundry service</u>. (a) Provision shall be made for the handling, storage and transportation of soiled and clean laundry and for satisfactory cleaning procedures.
- (b) Infectious laundry shall be handled in accordance with the provisions of section 325-7, HRS or any method approved by the director. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10, 321-11, 325-7)
- §11-93-61 <u>Medical director</u>. (a) The medical director shall develop appropriate written policies and procedures to provide the necessary preventive, diagnostic and therapeutic services to patients in order to achieve the objectives of the facility.
- (b) The medical director shall cooperate with the administrator to:
  - (1) Approve appropriate staff and professional educational programs; and
  - (2) Recommend to the governing body the names of physicians and midwives to be appointed to the professional staff.
- (c) The medical director shall monitor and supervise all medical and nursing procedures and policies. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-93-62 <u>Medical records</u>. (a) There shall be available sufficient appropriately qualified staff and necessary supporting personnel to facilitate the accurate processing, checking, indexing, filing and prompt retrieval of records and record data.
- (b) All patient records shall be confidential and are the property of the facility which shall secure them against loss, destruction, defacement, tampering, and use by legally unauthorized persons.

- (c) Patient records shall contain the following:
- (1) Prior to delivery, the patient record shall contain the following:
  - (A) Sufficient history, physical examination, x-ray, and laboratory data to support the decision to utilize the birthing facility. The laboratory data must include an Rh factor determination, as well as the result of a serological test for syphilis.
  - (B) Evidence of a search for any special hazards which might confront the patient and evidence of preparation to handle same should they develop.
  - (C) An informed consent form signed by the patient or her guardian.
- (2) During and after delivery the patient record shall contain:
  - (A) A record of all medications including administration of Rh immune globulin, obstetrical and anesthetic techniques used, as well as any surgical procedures.
  - (B) Record of vital signs monitoring during all stages of delivery.
  - (C) The condition and description of the placenta.
  - (D) Condition of the mother and child at the time of discharge or transfer.
- (3) The medical record shall be kept current at all times so that in the event of transfer to another facility no time will be lost bringing records up-to-date.
- (d) Newborn records shall include the following:
- (1) Date and hour of birth; birth weight and length; period of gestation; sex; and condition of infant on delivery. An Apgar score shall be required.
- (2) Mother's name, Social Security number, and facility case number.
- (3) Record of opthalmic prophylaxis.
- (4) Record of any resuscitative procedures used.
- (5) Record of Vitamin K administration, and any other medication which were administered.

- (6) Appropriate physical examination at birth and at time of discharge.
- (7) Record of phenylketonuria, thyroid screening test, and other lab results.
- (e) A daily log with monthly summaries of all procedures performed in the facility and disposition of the patients shall be kept by the facility. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 353-1, 622-57)
- §11-93-63 <u>Nursing service</u>. (a) Each facility shall have a nursing staff which shall be directed by the director of nursing. The director of nursing shall be a qualified registered professional nurse who shall be appointed by the administrator with the approval of the governing body. The director of nursing shall develop such nursing service policies and procedures, recruit such nursing personnel, and provide such supervision as is necessary to achieve the objectives of the facility.
- (b) Each facility shall have a nursing staff sufficient in number and qualifications to meet the nursing needs of the patients in the facility. There shall be at least one registered nurse present and on duty at all times when a patient is in the facility.
- (c) There shall be an organized written departmental plan which includes objectives, administrative authority, staffing patterns, job descriptions, and responsibilities for each category of nursing personnel.
- (d) There shall be appropriate nursing policies and procedures delineating the scope of services.
- (e) Working personnel in each birthing room shall include, in addition to a physician or a midwife, at least one registered professional nurse who shall serve as a circulating nurse.
- (f) All nursing personnel shall be trained in adult and neonatal resuscitation procedures. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
  - §11-93-64 Pathology. (a) All abnormal tissues

and fetuses shall be appropriately preserved for examination by a pathologist at the freestanding birthing facility.

- (b) A report of such examination shall be placed in the patient's record. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-93-65 <u>Patient care</u>. (a) All patients admitted to a facility shall have been under prior care by a member of the professional staff.
- (b) Patients and newborns shall remain under observation in this facility for a reasonable period of time to ensure that no immediate postpartum complications are present. In no case shall they remain longer than twenty-four hours post delivery.
- (c) Arrangements shall be made for all mothers to be screened for blood type and Rh factor. Those determined to be Rh negative shall have provision for appropriate follow up studies both prenatally and at the time of delivery in order to determine the need for anti D immune globulin (human) to prevent sensitization by the postpartum mother. There should be evidence of a plan for appropriate use of Rh immune globulins.
- (d) Every physician or midwife practicing midwifery shall, upon birth of a child, install or cause to be installed in each eye of each newborn one per cent silver nitrate solution contained in a wax ampule, or appropriate opthalmic preparations containing tetracycline or erythromycin. These latter are the only antibiotics of approved effectiveness in preventing development of opthalmia neonatorium. A maximum of thirty minutes shall be allowed between the time of birth and the administration of the approved prophylactic agent.
- (e) At the time of discharge from the facility each patient shall be provided with a document which includes, as a minimum, the following information:
  - (1) The exact procedures which were performed using accepted medical terminology.
  - (2) The precise names, both proprietary and generic of all medications administered to the patient in the facility or given to the

- patient at the time of discharge from the facility.
- (3) Activities to be encouraged, and activities to be avoided by the patients, as well as instructions for care of the infant.
- (4) Specific telephone numbers of the attending midwife or physician, as well as the telephone number of at least one suitable backup person.
- (5) The telephone number and location of the nearest hospital to be used by the patient should emergency complications arise.
- (6) Date and location of the first postpartum
   checkup. [Eff. March 3, 1986 ] (Auth: HRS
  §§321-9, 321-10) (Imp: HRS §321-10)

§11-93-66 Pharmaceutical service. (a) Each facility shall have a list of standing orders and procedures which shall be signed by the medical director.

- (b) Only medications on the standing order list of medications shall be administered in the facility and only given within the dosage ranges so specified. Documentation of all such medications given must be maintained on the patient's medical record and such orders shall be signed by the physician or midwife ordering the medication.
- (c) Medicines maintained in the facility shall be appropriately stored and safeguarded against access by unauthorized persons. Appropriate records shall be kept of the disposition of all medications.
  - (d) If the facility has a pharmacy, it shall:
  - (1) Be of sufficient size to permit orderly storage and accurate identification of all medicines and have appropriate physical facilities to properly carry out its functions.
  - (2) Comply with all applicable state rules and federal regulations.
  - (3) Be under the supervision of a pharmacist who shall do all dispensing of medications.
- (e) Each facility shall maintain reference sources for identifying and describing medications.

- (f) Medicines shall be administered only by a registered nurse or physician. [Eff. March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 461-4, 461-9, 461-11, 461-14)
- §11-93-67 <u>Professional staff</u>. There shall be an organized professional staff consisting of licensed midwives and suitably qualified physicians. The professional staff shall be appointed by the governing body. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)
- §11-93-68 Special equipment and supplies. There shall be appropriate equipment and supplies maintained for the mother and the newborn which shall include, but not be limited to:
  - (1) A bed suitable for labor, birth and recovery.
  - (2) Oxygen with flow meters and masks, or equivalent.
  - (3) Suction and bulb suction immediately available.
  - (4) Resuscitation equipment to include resuscitation bags, endotrachial tubes, and all sized airways for the mother and newborn.
  - (5) Firm surfaces suitable for resuscitation.
  - (6) Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn.
  - (7) Fetal monitoring equipment such as fetoscope or Doppler monitoring device.
  - (8) A means for monitoring and maintaining the optimum body temperature of the newborn.
  - (9) A clock with a sweep second hand.
  - (10) Sterile suturing equipment and supplies.
  - (11) Adjustable examination light.
  - (12) Containers for soiled linen and waste
     materials which shall be closed or covered.
     [Eff. March 3, 1986 ] (Auth: HRS §§321-9,
     321-10) (Imp: HRS §321-10)

§11-93-69 <u>Transfer agreement</u>. The facility shall establish transfer agreements which will expedite the transfer of patients to hospitals when it is desirable to do so. There shall be documented evidence that a local hospital has agreed to admit, without delay, patients from the facility should the staff of the facility feel this is advisable.
[Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)

§11-93-70 Penalty. In addition to any other appropriate action to enforce these rules, the director may initiate procedures for invoking penalties as provided in chapter 321, HRS. [Eff. March 3, 1986] (Auth: HRS §§321-9, 321-10) (Imp: HRS §§321-10, 321-18)

§11-93-71 through §11-93-99 reserved.

§11-93-100 <u>Severability</u>. If a provision of this chapter or the application thereof to any person or circumstances is held invalid, the remainder of this chapter or the application of the provision to other persons or circumstances shall not be affected thereby. [Eff. March 3, 1986 ] (Auth: HRS §§321-9, 321-10) (Imp: HRS §321-10)

The Department of Health authorized the adoption of Chapter 93 of Title 11, Administrative Rules on September 16, 1985, following public hearings held on Oahu on September 16, 1985, on Hawaii on September 16, 1985, on Maui on September 16, 1985, on Maui on September 16, 1985, after public notice was given in the Honolulu Star Bulletin on August 21, 1985, in the Hawaii Tribune-Herald on August 20, 1985, in the Garden Isle on August 16, 1985, and in the Maui News on August 21, 1985.

Chapter 93 of Title 11, Administrative Rules shall take effect ten days after filing with the office of the Lieutenant Governor.

s/ Leslie S. Matsubara
LESLIE S. MATSUBARA
Director
Department of Health

APPROVED;

s/ George R. Ariyoshi GEORGE R. ARIYOSHI GOVERNOR STATE OF HAWAII

Date: February 19, 1986

APPROVED AS TO FORM;

s/ Edwin Y. C. Lum
Deputy Attorney General

Filed: February 20, 1986