SUBCHAPTER 2
FREESTANDING BIRTHING FACILITIES

§11-93-50  Purpose.  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.


§11-93-51  Definitions. 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 definite 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 connection 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.
4. Hypertension or preeclampsia.
5. Renal disease.
6. Thrombophlebitis.
7. Multiple fetuses.
8. Active herpes genitalis, 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 then a pudendal or local nerve block.
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 .0001mg (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 10mm or greater in its transverse diameter, the reaction to the skin test shall be considered significant.

§11-93-52 Licensing. (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.

§11-93-53 License revocation. (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.


§11-93-54 Administration. (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.
§11-93-55 Construction and physical environment requirements. (a) The facility shall be
created 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 degrees to 80 degrees 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.

(l) 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.


§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.
§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.

§11-93-58 Infection control. (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.
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.
§11-93-59  **Inservice education.** 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  **Laundry service.** (a) Provision shall be made for the handling, storage and transportation of soiled and clean laundry and for satisfactory cleaning procedures.  

§11-93-61  **Medical director.** (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.  

§11-93-62  **Medical records.** (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 ophthalmic 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.


§11-93-63 Nursing service. (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.


§11-93-64 Pathology. (a) All abnormal tissues and fetuses shall be appropriately preserved for examination by a pathologist at the freestanding birthing facility.

(a) A report of such examination shall be placed in the patient’s record.

§11-93-65  **Patient care.** (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 postdelivery.

(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 ophthalmic preparations containing tetracycline or erythromycin. These latter are the only antibiotics of approved effectiveness in preventing development of opthalmia neonatorum. 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.


§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 medication 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.


§11-93-67 Professional staff. 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.


§§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, endotracheal 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.
10. Sterile suturing equipment and supplies.
11. Adjustable examination light.
12. Containers for soiled linen and waste materials which shall be closed or covered.


§11-93-69 Transfer agreement. 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.


§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.


§11-93-71 through §11-93-99 reserved.
§11-93-100 Severability. 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 provisions to other persons or circumstances shall not be affected thereby.


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 Kauai 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.
LESLIE S. MATSUBARA
Director
Department of Health

APPROVED:

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GEORGE R. ARIYOSHI
Governor
State of Hawaii

Dated: ________________________

APPROVED AS TO FORM:

_____________________________

Deputy Attorney General

Filed: _________________________

Effective Date: ________________