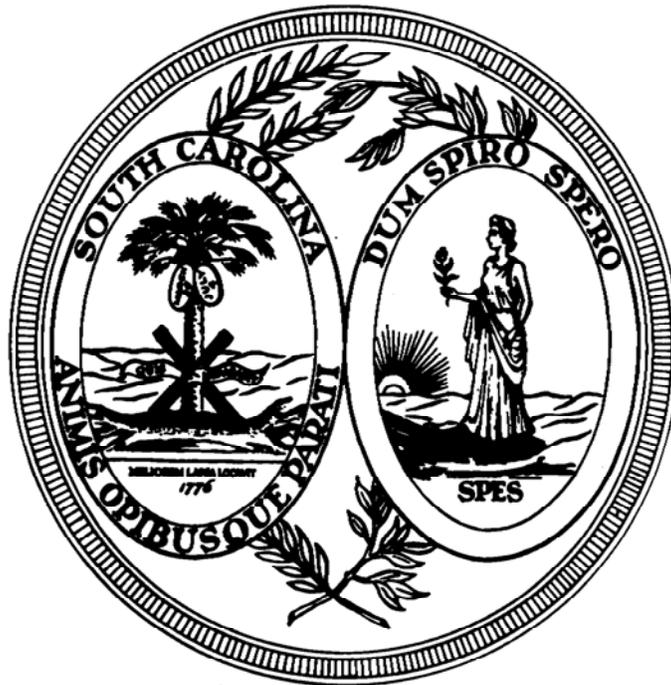




South Carolina Department of Health
and Environmental Control

Regulation Number 61-102 Standards for Licensing Birthing Centers For Deliveries By Midwives



Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

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The official document is on record in the *State Register* and the S.C. Code Ann. (2002). This regulation is provided by DHEC for the convenience of the public. Every effort has been made to ensure its accuracy; however, it is not the official text. DHEC reserves the right to withdraw or correct this text if deviations from the official text as published in the *State Register* are found.



DIVISION OF HEALTH LICENSING REGULATIONS

Provider-Wide Exceptions

In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable. A Provider-Wide Exception (PWE) is the tool that is used to achieve a working relationship between the facility and their regulators.

Provider-Wide Exceptions for the facilities and activities that are licensed by the Division of Health Licensing can be downloaded from our Internet Website:

<http://www.scdhec.gov/health/licen/pwe.htm>

This website may also contain Position Statements that give guidance or interpretations of the regulation.

Provider-Wide Exceptions and Position Statements may also be obtained by contacting our office at (803) 545-4370. There is a ten-dollar (\$10.00) processing and handling fee assessed when copies are obtained through our office. Copies obtained over the Internet through our Website are free of charge. Payment must be by credit card, personal check or money order (no cash can be accepted).

Note: Some Provider-Wide Exceptions pre-date the publishing dates of specific Regulations established by the *State Register* and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE.

**REGULATION 61-102 - STANDARDS FOR LICENSING
BIRTHING CENTERS FOR DELIVERIES BY MIDWIVES**

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DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
STATUTORY AUTHORITY: 1976 Code 44-89-60 & 44-7-260

**Regulation 61-102, Standards for Licensing Birthing Centers
for Deliveries by Midwives**

A. Definitions, Interpretations and Penalties

1. Definitions: For the purpose of these Standards, the following definitions shall apply:

a. Administrator means the person who is delegated the responsibility for interpreting, implementing, and applying policies and programs established by the governing authority. He/she is delegated responsibility for the establishment of safe and effective administrative management, and the control and operation of the services provided.

b. Birthing center means a facility or other place where human births are planned to occur. This does not include the usual residence of the mother or any facility which is licensed as a hospital.

c. Birthing room means a room and environment designed, equipped and arranged to provide for the care of a woman and newborn and to accommodate her support person(s) during the process of vaginal birth.

d. Board means the South Carolina Board of Health and Environmental Control.

e. Certified Nurse Midwife (CNM) means a person licensed by the South Carolina State Board of Nursing as a Registered Nurse with official recognition as a Certified Nurse Midwife.

f. Clinical staff means the physicians, certified nurse midwives and lay midwives appointed by the governing authority to practice within the birthing center and governed by rules approved by the governing body.

g. Department means the South Carolina Department of Health and Environmental Control (DHEC).

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

i. Lay Midwife means an individual so licensed by the Department.

j. Licensing agency means DHEC.

k. Low risk means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

l. Midwifery means the application of scientific principles in "with woman" care during uncomplicated pregnancy, birth, and puerperium including care of the newborn, support of the family unit, and gynecologic health care.

m. Person means a natural individual, private or public organization, political subdivision, or other governmental agency.

n. Personnel means individual(s) in training and/or employed by the birthing center.

o. Physician means a doctor of medicine or osteopathy with training in obstetrics or midwifery and licensed by the South Carolina State Board of Medical Examiners to practice medicine.

p. Recovery means that period or duration of time starting at birth and ending with the discharge of a client from the birthing center.

q. Registered Nurse means a person licensed by the South Carolina State Board of Nursing as a registered nurse.

2. Interpretations:

a. No person shall establish, conduct or maintain a birthing center without first obtaining a license from the Department.

b. The license shall be posted in a conspicuous place in a public lobby or waiting room. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

c. Any birthing center which is in operation at the time of promulgation of these regulations shall be given a reasonable time, not to exceed one year from date of such promulgation, within which to comply with such regulations.

d. Effective Date and Term of License: A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection is made.

e. Separate Licenses: Separate licenses are required for facilities not maintained on the same premises. Separate licenses may be issued for facilities maintained in separate buildings on the same premises.

f. Licensing Fees: Each applicant shall pay an annual license fee prior to issuance of the license. The annual fee shall be \$200.00.

g. Inspections: Each facility submitting an application for licensing or re-licensing shall be inspected prior to initial licensure and at least annually by authorized representatives of the Department. All licensed and prospective licensed facilities are subject to inspection at any time. All facilities to which these requirements apply shall permit entrance to all properties and access to every area, object and records and reports by representatives of the Department.

h. Initial License: A new facility or one that has not been continuously licensed under these Standards, shall not provide birthing center services until it has been issued an initial license. Section L sets forth the prerequisites for initial license.

i. Noncompliance: When noncompliances with the Licensing Standards are detected, the applicant or licensee will be notified of the violations and at the same time requested to provide information as to how and when such items will be corrected. If an item of noncompliance is of a serious nature and is not promptly corrected, a penalty may be invoked or a license may be denied, suspended or revoked.

j. Exceptions to Licensing Standards: The Department reserves the right to make exceptions to these Standards where it is determined that the health and welfare of the community requires the services of the facility and that the exception, as granted, will have no significant impact on the safety, security or welfare of the facility's occupants.

k. Change of License: A facility shall request issuance of an amended license, by application to the Department, prior to any of the following circumstances:

- (1) Change of ownership by purchase or lease;
- (2) Change of facility's name or address;
- (3) Addition or replacement of a birthing room or any part thereof.

3. Penalties: Facilities shall be subject to a penalty for violating Licensing Regulations. When the Department determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the following conditions shall apply:

a. Class I violations are those which the Department determines present an imminent danger to the patients or other occupants of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

b. Class II violations are those, other than Class I violations, which the Department determines have a direct or immediate relationship to the health, safety or security of the facility's patients or other occupants. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

c. Class III violations are those which are not classified as serious in these regulations or those which are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

d. Class I and II violations are indicated by notation after each applicable section, e.g., (I) or (II). Violations of sections which are not annotated in that manner will be considered as Class III violations.

e. The Department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. The Department shall exercise discretion in arriving at its decision to take any of these actions. The Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions.

f. If a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 24-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$ 200 - 1000	\$ 100 - 500	\$ 0
2nd	500 - 2000	200 - 1000	100 - 500
3rd	1000 - 5000	500 - 2000	200 - 1000
4th	5000	1000 - 5000	500 - 2000
5th	5000	5000	1000 - 5000
6th	5000	5000	5000

B. Licensing Procedures

1. Application:

a. Applicants for a license shall file applications under oath annually with the Department upon forms provided by the Department, and shall pay an annual license fee. The application shall set forth the following:

- (1) Name, address, and telephone number of facility;
- (2) Name and address of licensee;
- (3) Names of all parties with at least five percent ownership;
- (4) Name of governing authority;
- (5) Name of chief executive officer;
- (6) Numerical composition of nurse-midwives and support staff;
- (7) Number of birthing rooms;
- (8) Description of arrangements for emergency transportation of patients from the facility;
- (9) Name of hospital(s) with which a transfer agreement has been made;
- (10) Description of arrangements for obstetric and pediatric consultation and referral.

b. The governing authority shall file application for a new facility or for the renewal of a license for an existing facility. Applications for a new facility or additional birthing rooms shall be submitted at least 30 days prior to opening.

2. Requirements for Issuance of License:

a. Upon receipt of an application for a license a representative of the Department shall make an inspection of that facility.

b. When it is determined that the facility is in compliance with the requirements of these Standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued.

c. No proposed facility shall be named nor may any existing facility have its name changed to the same or similar name as a facility licensed in the State. If it is part of a "chain operation" it shall then have the area in which it is located as part of its name.

3. Termination of License: A license is not assignable or transferable and is subject to revocation at any time by the Department for failure to comply with laws and regulations of the State of South Carolina.

C. Governing Authority and Management

1. General: Every facility shall be organized, equipped, manned and administered to provide adequate care for each person admitted.

2. Governing Authority: The governing authority shall be the supreme authority responsible for the management control of the facility and shall develop a written set of bylaws or other appropriate policies and procedures for operation of the facility. These shall: (II)

a. State the purpose of the facility;

b. Specify by name the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the governing authority for holding such individual responsible;

c. Provide for at least annual meetings of the governing authority;

d. Provide for a policies and procedures manual which is designed to ensure professional and safe care for the patients to include but not limited to:

(1) Admission criteria;

(2) Extent of physician participation in the services offered;

- (3) Rights and responsibilities of patients;
 - (4) Patient grievance procedures;
 - (5) Infection control procedures;
 - (6) Personnel training requirements;
 - (7) Transfer of mothers who, during the course of pregnancy, labor, delivery or recovery, are determined to be ineligible for continued care;
 - (8) The use of IV's, food, fluids, analgesia/anesthesia, oxytocin, episiotomies, positions for delivery;
 - (9) Provisions for the education of mother, family and others, as appropriate in birthing, newborn care, and maternal postpartum care.
 - (10) Plans for follow-up of mother and infant after discharge from the center;
 - (11) Plans for tests/treatments including, but not limited to, PKU, bilirubin, Rh factor, ophthalmic prophylaxis, and prophylaxis for neonatal hemorrhagic disease;
 - (12) Plan for circumcision.
- e. Provide for annual reviews and evaluations of the facility's policies, procedures, management and operation.
 - f. Provide for a facility-wide quality assurance program to evaluate the provision of patient care. The program shall be ongoing and have a written plan of implementation.
3. Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence of the administrator. (II)
4. Administrative Records: The following essential documents and references shall be on file in the administrative office of the facility:
- a. Appropriate documents showing control and ownership;
 - b. Bylaws, policies and procedures of the governing authority;

- c. Minutes of the governing authority meetings if applicable;
- d. Minutes of the facility's professional and administrative staff meetings;
- e. A current copy of these regulations;
- f. Reports of inspections, reviews, and corrective actions taken related to licensure;
- g. Contracts and agreements to which the facility is a party;
- h. A record of each accident or incident occurring in the facility.

5. Personnel: Qualified personnel shall be employed in sufficient numbers to carry out the functions of the facility. The licensee shall obtain written applications for employment from all employees. Such applications shall contain accurate information as to education, training, experience, health and personal background of each employee. All applications for licensed personnel shall contain the South Carolina license number and/or current renewal number, if applicable. (II)

a. All new employees who have contact with patients shall have a physical examination prior to employment, which shall include a tuberculin skin test, unless a previously positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is recommended. (II)

(1) Employees with positive reactions to the pre-employment tuberculin test and those who are documented with previously positive reactions shall be given a chest x-ray to determine whether tuberculin disease is present. If tuberculosis is diagnosed, appropriate treatment should be given.

(2) Employees who complete treatment, either for disease or infection, may be exempt from further screening unless they have symptoms of tuberculosis.

(3) Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest x-ray. These individuals shall be informed of their lifelong risk of developing and transmitting tuberculosis to individuals in the agency and in the community. They shall be informed of symptoms which may suggest the onset of tuberculosis, and of the procedure to follow in reporting suspect symptoms to a designated member of the agency staff.

(4) Employees with negative tuberculin skin tests shall have an annual tuberculin skin test.

b. Personnel Records: A personnel record folder shall be maintained for each employee. The folder shall contain history and physicals, laboratory test results, resumes of training and experience, current job description that reflects the employee's responsibilities and work assignments, orientation and periodic evaluations. (II)

c. Job Descriptions:

(1) Written job descriptions which adequately describe the duties of every position shall be maintained.

(2) Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.

(3) Job descriptions shall be reviewed at least annually, kept current and given to each employee when assigned to the position and when revised.

d. Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibility.

e. Continuing education must be provided to all non-clerical employees at least once a year. Inservice training may be provided by qualified facility staff.

f. All professional personnel and clinical staff shall be certified in adult and neonatal American Red Cross CPR training.

6. Emergency:

a. All practicing and/or consulting physicians shall have admitting privileges at one or more hospitals with appropriate obstetrical services, or other arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary. (I)

b. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital for both mother and infant. (I)

c. The center shall enter into a signed written agreement with an ambulance service licensed in this state to ensure the immediate transfer of mothers and/or newborns in emergencies, where appropriate. (I)

7. Client's Rights:

a. The birthing center shall have written policies and procedures to assure the individual client the right to dignity, privacy, and safety. The policies and procedures shall be developed by the Director of Midwifery Services and the Director of Medical Affairs, if appropriate, and approved by the governing body.

b. Each center shall display in a conspicuous place on the premises, a copy of the "Rights of Patients."

D. Professional Care

1. Limitation of Services Offered by Birthing Center: (l) In order to be delivered in a birthing center, the woman and/or her infant shall exhibit no evidence of:

- a. Severe anemia;
- b. Diabetes mellitus;
- c. Symptomatic heart disease;
- d. Severe hypertension or preeclampsia;
- e. Renal disease;
- f. Thrombophlebitis;
- g. Multiple gestation;
- h. Active herpes (within one week of delivery), syphilis, or HIV positive;
- i. Placental abnormalities;
- j. Premature labor;
- k. Intrauterine growth retardation;
- l. Fetal disease;
- m. Previous caesarean delivery with classical incision;
- n. Desire for transfer;
- o. Anticipated macrosomia;
- p. Breech birth;
- q. Six or more (nonmiscarriage or nonabortion) pregnancies;
- r. Polyhydramnios or oligohydramnios, or chorionitis;

- s. Malformed fetus;
- t. Any other high risk condition.

2. Birthing Center Policies and Procedures: The facility shall formulate written policies and procedures which shall include, but not be limited to: (II)

a. Informed consent which shall be obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the birthing service offered and potential risks. Documentation of the informed consent must be filed in the patient's chart.

b. Registration of birth and fetal death or death certificates.

c. Infection control committee duties and responsibilities shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility.

d. 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 time of delivery in order to determine the need for Anti D Immune Globulin (Human) to prevent sensitization by the postpartum mother. There shall be evidence of a plan for the appropriate use of Rh immune globulin.

e. The physician or midwife shall, upon the birth of a child, instill or cause to be instilled in each eye of such newborn antibiotics of currently proven efficacy in preventing development of ophthalmia neonatorum. A maximum delay of one hour shall be allowed between the time of birth and the administration of an approved prophylactic agent.

3. Pharmaceutical Services: (I)

a. Written policies shall be established addressing the type and intended use of any drug to be used within the facility.

b. There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

c. There shall be written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant within the birthing center.

d. Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs.

e. Drugs, medications, and chemicals kept anywhere in the center shall be clearly labeled with drug name, strength, and expiration date.

f. Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons.

g. Drugs requiring refrigeration shall be kept secure in a refrigerator under proper temperature. Each refrigerator shall be provided with a thermometer.

4. Laboratory Services:

The center shall enter into a signed written agreement with a certified clinical laboratory to ensure accessibility to a full range of clinical laboratory testing, as may be required.

5. Birthing Center Equipment and Supplies: There shall be appropriate equipment and supplies maintained for the mother and the newborn to include but not limited to:
(II)

a. A bed suitable for labor, birth, and recovery;

b. Oxygen with flow meters and masks or equivalent;

c. Mechanical suction and bulb suction (immediately available);

d. Resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for the mother and newborn;

e. Firm surfaces suitable for resuscitation;

f. Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;

g. Fetal monitoring equipment;

h. A means of monitoring and maintaining the optimum body temperature of the newborn;

i. A clock with a sweep second hand;

j. Sterile suturing equipment and supplies;

k. Adjustable examination light;

l. Containers for soiled linen and waste materials which shall be closed;

m. Refrigeration unit or units;

n. Matching identification for the baby to the mother shall be provided.

6. Clinical Staff:

a. All clinical staff who practice in a facility shall be organized as a clinical staff with appropriate bylaws approved by the governing body. The clinical staff shall meet at least quarterly and minutes shall be maintained of such meetings.

(1) A physician must be on call and available to provide medical assistance at the birthing center at all times that it is serving the public. (I)

(2) A physician shall make a written determination that the planned birth is low risk. (I)

(3) The center shall enter into a signed written agreement with an obstetrician(s) and a pediatrician(s) to ensure their availability to the staff and mother at all times that it is serving the public. (I)

b. The facility shall have an organized midwifery department under the supervision of a Director of Midwifery. (II)

(1) The Director of Midwifery shall be a certified nurse-midwife and be responsible and accountable for all midwifery service to include:

(a) Delivery of midwifery services to patients;

(b) Development and maintenance of midwifery service objectives, standards of midwifery practice, midwifery policy and procedure manuals (reviewed annually), written job descriptions for each type of midwifery personnel;

(c) Coordination of midwifery services with other patient services;

(d) Establishment of a means of assessing the midwifery care needs of patients and staffing to meet those needs;

(e) Staff development.

c. An adequate number of licensed and ancillary midwifery personnel shall be on duty to meet the total midwifery needs of patients. Midwifery personnel shall be assigned to duties consistent with their training and experience. (I)

d. At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's

delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. (l)

7. Medical Records: An accurate complete medical record shall be maintained for each patient.

a. A legible medical record in ink shall include at least the following:

(1) Admitting identification data including patient history and physical examination;

(2) Signed consent;

(3) Orders of physician or certified practitioner;

(4) Laboratory tests;

(5) Prenatal care record containing at least prenatal blood serology, Rh factor determination and obstetrical history and physical examination;

(6) Labor and delivery record;

(7) Records of anesthesia and analgesia and medication given in the course of labor, delivery and postpartum;

(8) Recovery and other progress notes;

(9) Record of all medications and treatments ordered and administered;

(10) Condition and referral on discharge.

b. Records of newborn infants shall include in addition to the requirements for medical records the following information:

(1) Date and hour of birth, birth weight and length, period of gestation, sex, condition of infant on delivery and APGAR rating;

(2) Mother's name and patient number, and/or similar identification;

(3) Record of ophthalmic prophylaxis;

(4) Record of administration of Rh immune globulin if any;

(5) Appropriate physical examination at birth and at discharge;

(6) Test results and date specimen was collected for PKU and hypothyroid newborn screening test. (Exempt only when parents object because of religious convictions; then file copy of executed "Statement of Religious Objection Form," DHEC #1804 with newborn record.)

c. Provisions shall be made by the facility for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of under 10 years. Records may be destroyed after 10 years provided that:

(1) Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute.

(2) The facility retains an index, register, or summary cards providing such basic information as dates of admission and discharge, name of responsible clinical staff, and record of diagnoses for all records so destroyed.

d. Facilities that microfilm before 10 years have expired must film the entire record.

e. In the event of change of ownership, all medical records shall be transferred to the new owners.

f. Prior to the closing of a facility for any reason, the facility shall arrange for preservation of records to insure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

g. Information to be Provided to Other Health Care Providers. In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

E. Functional Safety

1. General:

a. The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.

b. The policies and procedures shall include: (II)

(1) Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;

(2) Provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;

(3) Provisions for disseminating safety-related information to employees and users of the facility;

(4) Provision of syringe and needle storage, handling and disposal.

2. Maintenance:

a. Facility Maintenance: A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. (II)

b. Equipment Maintenance: A written preventive maintenance program for all patient monitoring equipment shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (II)

3. Disaster Preparedness:

a. General:

(1) The facility shall have a posted plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (II)

(2) A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

b. Fire Drills: At least one drill shall be held every three months to familiarize all employees with the drill procedure. Reports of the drills shall be maintained. (II)

F. Infection Control and Sanitation

1. General: The governing authority shall provide adequate space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection. (II)

2. Sterilization Procedures:

a. Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment. (II)

b. Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled. (I)

c. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be checked at least quarterly by an approved method; periodic calibration and/or preventive maintenance shall be provided as necessary, and a log maintained. (II)

d. The date of expiration shall be marked on all supplies sterilized in the facility. (I)

3. Linen and Laundry:

a. An adequate supply of clean linen or disposable materials shall be maintained. (II)

b. Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers. (II)

c. A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

4. Sanitation:

a. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused. (II)

b. All contaminated dressings, pathological and/or similar waste shall be properly disposed of by incineration or other approved means. (I)

5. Housekeeping: (II)

a. General: A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.

b. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

c. Dry sweeping and dusting of walls and floors are prohibited.

6. Refuse and Waste Disposal: (II)

a. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

b. Immediately after emptying, containers for garbage shall be cleaned.

7. Outside Areas: All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for roaches, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

G. Dietary Services (II)

1. General: When the birthing center policy provides for allowing the preparation and/or storage of food, there shall be adequate means for maintaining cold foods at a temperature of 45 degrees Fahrenheit or lower; a microwave oven; and a dishwashing machine provided with hot water at a temperature of not less than 160 degrees Fahrenheit.

2. Food Storage:

a. Food shall not be stored together with medicines requiring refrigeration.

b. All refrigerated food items shall be labeled and dated.

H. Design and Construction

1. General: Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

2. Local and State Codes and Standards: Facilities shall substantially comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. Birthing Centers are a "business occupancy" as defined in the Standard Building Code. No facility will be licensed unless the Department has assurance that responsible local officials sanction the licensing of the facility. The Department uses as its basic codes the Standard Building Code, the Standard Plumbing Code, the Standard Mechanical Code, and the National Electrical Code.

Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the minimum requirements set forth in these standards are met. (II)

3. Submission of Plans and Specifications:

a. New Buildings, Additions or Major Alterations to Existing Buildings: When construction is contemplated either for new buildings, additions or major alterations to existing buildings, plans and specifications shall be submitted to the Department for review. Such plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal. These submissions shall be made in at least two stages: preliminary and final. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents require approval by the Department. (II)

b. Preliminary submission shall include the following:

(1) Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection.

(2) Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys.

(3) Outline specifications listing a general description of construction including interior finishes and mechanical systems.

c. Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout.

d. In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

e. One complete set of as built drawings shall be filed with DHEC.

4. Licensure of Existing Structures: When an existing structure is contemplated for licensure as a new facility or as an expansion to an existing facility, the following

submittals shall be made to the Department: (II) (All plans shall be neatly prepared and drawn to scale with the title and date shown thereon.)

a. Plot plan in accordance with H.3.b.(1).

b. Floor plan(s) in accordance with H.3.b.(2).

c. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

5. Minor Alterations in Licensed Facilities: When alterations are contemplated that may affect life safety, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards.

6. Location:

a. Environment: The facility shall be located in an environment that is conducive to the type of care and services provided.

b. Transportation: The facility must be served by roads which are passable at all times and are adequate for the volume of expected traffic.

c. Parking: The facility shall have parking space to satisfy the minimum needs of patients, employees, staff and visitors.

d. Communications: A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

7. Physical Facilities:

a. Birthing rooms shall have at least a gross floor space of 120 square feet with a minimum room dimension of 10 feet.

b. Birthing rooms shall be located to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment.

c. Adequate fixed or portable work surface areas shall be maintained for use in each birthing room.

d. Toilet and bathing facilities:

(1) A toilet and lavatory shall be provided in the immediate vicinity of the birthing room.

(2) A bathing facility shall be available for the mother's use.

e. Doors providing access into the birthing center and birthing room(s) shall be at least 44 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. Hallways shall be at least 48 inches wide.

f. Heating and ventilation:

(1) Lighting, heating, and ventilation systems shall comply with the local and state codes. There shall be approved equipment capable for maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.

(2) Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces which are not provided with operable windows or outside doors.

g. The entrance shall be at grade level or above, be sheltered from the weather and accommodate wheelchairs.

h. Multipurpose room(s) shall be available for interviews, education, training, and other purposes.

i. There shall be adequate general storage space for office, sterile supplies and other storage. There shall be a work counter for charting purposes.

j. Sufficient janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

k. A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

l. There shall be at least two exits remote from each other.

m. Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

n. Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.

o. All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.

p. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

q. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

r. Wall bases in soiled equipment and material workrooms and other areas which are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

s. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

t. Interior finish materials shall comply with these flame spread limitations:

(1) Floor, walls, and ceilings in exit ways and storage rooms containing flammable storage materials and in other rooms of unusual fire hazard such as furnace rooms shall have a flame spread rating of 75 or less (ASTM Standard E84) and a smoke production rating of .45 watts or less.

(2) Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less.

u. A special unit or area for transitional care shall be provided for increased observation of the infant while stabilizing vital signs, i.e., respiration, temperature, and body weight, or for acute supportive care prior to transfer to referral facilities.

v. Adequate space for the storage, handling and/or preparation of formulas.

8. Water Supply and Plumbing:

a. Water Supply: Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting. (II)

b. Plumbing:

(1) All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code.

(2) All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. (II)

(3) There shall be access to a sink with hot and cold running water with elbow/wrist controls.

I. Fire Protection and Prevention

1. Fire Extinguishers, Standpipes, and Automatic Sprinklers: Fire-fighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the Standard Building Code. Extinguishers shall be sized, located, installed and maintained in accordance with NFPA No. 10. Suitable fire extinguishers shall also be installed in all hazardous areas. Each facility shall conform with all state and local fire and safety provisions. (II)

2. Alarms: Where required, a manual fire alarm system in accordance with provisions of "Local Protective Signaling System," NFPA No. 72A, shall be provided. (II)

3. Gases: Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes. (II)

J. Mechanical Requirements

1. Emergency Electrical Power: The facility shall be equipped with an emergency power source. The emergency electrical power system shall be adequate to maintain the operation of lighting for egress, fire detection equipment, and alarms. (I)

2. Lighting and Electrical Services: There shall be sufficient safe lighting for individual activities, including suitable lighting for corridors and baths. Lighting in work area shall not be less than 50 foot candles. (II)

K. General

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

L. Prerequisites for Initial Licensure

Prior to admission of patients to, and issuance of a license for new facilities or additional stations, the following actions must be accomplished and documentation furnished at the final inspection:

1. Plans and construction must be approved by the Division of Health Facilities Construction, DHEC.

2. The facility shall submit a completed Application for License on forms which shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:

a. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of DHEC. (Includes satisfactory laboratory reports of water samples taken by the local office of Environmental Quality Control.)

b. Approval from appropriate building official stating that all applicable local codes and ordinances have been complied with.

(1) If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or

(2) If the facility is located outside town or city limits, a written agreement with the nearest fire department that will provide protection and respond in case of fire at the facility.

c. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility has been tested under

(1) ASTM E-84 and has a flame spread rating of not more than 75, or

(2) ASTM E-648 or NFPA No. 253 with a rating of not less than .45 watts/sq. cm.

d. Certification by the contractor that only the carpeting described in (c) above was installed in the facility.

e. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.

f. Certification by the owner or contractor that only materials described in (e) above were installed.

g. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.

h. Certification by the contractor that only the materials described in (g) above were installed.

i. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.

j. Certification by the contractor that the automatic sprinkler system has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.

k. Certification that all medical gas systems have been properly installed and tested.

l. For corporation-owned facilities, a list of all officers and their corporate titles.

3. Resumes for the persons in charge of the day to day operation of the facility and midwifery services.

4. Required personnel must be employed, available, trained and capable of performing their duties.

5. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.

6. The facility must pay the required licensing fee.

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