ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-5-13
BIRTHING CENTERS

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420-5-13-.01 General.

(1) Legal Authority for Adoption of Rules. The following rules for Birthing Centers are adopted by the Alabama State Board of Health pursuant to §22-21-20, et seq., Code of Ala. 1975.

(2) Definitions

(a) "Administrator" means a natural person who is the governing authority of a health care facility or a natural person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor and must be qualified to perform those tasks.

The administrator shall be the addressee of all correspondence and inquiries from the State Board of Health.

(b) "Birthing Center" means a publicly or privately owned health care facility, place, or institution, constructed, renovated, leased, or otherwise established, where nonemergency births are planned to occur away from the mother's usual residence following a documented period of prenatal care for a low risk patient, as defined herein. Such facility, place, or institution must be a freestanding unit, not part of a hospital or other facility licensed for other purposes by the State Board of Health, and hold itself out to the public as a birthing center by advertising by some public means, such as a newspaper, directory, a website, the Internet, etc. The offices of private physicians assisting births strictly on an emergency basis does not constitute birthing centers for the purposes of this rule. Care provided in a birthing center shall be provided by a licensed physician, or by a duly licensed certified nurse midwife and a licensed registered nurse. Certified professional midwives may also provide care as assistive personnel to staff certified nurse midwives and registered nurses in a birthing center, provided that the staffing requirements of these rules are met when patients are present, laboring, and delivering in the birthing center. Nothing in this rule shall be construed to expand the existing scope of practice for a certified professional midwife.

(c) "Board" or "State Board of Health" means the Alabama State Board of Health.

(d) "Certified Nurse Midwife" (CNM) means an advanced practice nurse who is in an active collaborative practice agreement with the licensed physician who is serving as the staff physician or consultant physician for the birthing center, which includes the birthing center as an approved practice site, and who meets the requirements of and is approved by the Alabama Board of Nursing. CNMs in birthing centers shall have at least 1 year of experience in labor and delivery and/or newborn intensive care, be trained and annually certified in adult and infant cardiopulmonary resuscitation (CPR), and possess a Neonatal Resuscitation Program (NRP) certificate or the equivalent thereof.

(e) "Certified Professional Midwife" (CPM) means a person who holds an active license with the Alabama Board of Midwifery. A CPM in a birthing center shall have at least 1 year of documented experience in providing all phases of prenatal, delivery, and postnatal care, be trained and annually certified in adult and infant CPR, and possess an NRP certificate or the equivalent thereof.

(f) "Consultant Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who has a valid agreement to serve as a consultant to the birthing center. In the absence of a staff physician, the consultant physician must also have an approved collaborative practice agreement with the CNM employed by or working at the birthing center. The services of a consultant physician are required for any birthing center which does not have a physician on the medical staff who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama. Consultant physicians must be either (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as family practice physicians with an obstetrical emphasis or fellowship. The consultant physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/ American Heart Association. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A facility is ineligible for licensure as a birthing center unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician to provide consulting and hands-on services as needed.

(g) "Department" means the Alabama Department of Public Health.

(h) "Documented Period of Prenatal Care" means prenatal evaluation and care initiated by an appropriate care provider prior to the third trimester, until 37-42 weeks of gestation.

(i) "Family Centered Care" means a philosophy of care that allows family and significant others to participate in the pregnancy, birth, and postpartum period in a homelike environment.

(j) "Freestanding" means a separate and distinct health care facility, place, or institution, constructed, renovated, leased, or otherwise established, for purposes of these rules, to provide the services of a birthing center. Each freestanding birthing center must obtain its own license and comply with all applicable licensing standards promulgated by the State Board of Health and these rules; provided, however, that a hospital affiliated birthing center located on the hospital's campus does not constitute a freestanding birthing center and is not required to be separately licensed.

(k) "Governing Authority" means the owner or proprietor of the birthing center, or the body, such as a board of directors, which maintains and controls the operation of the birthing center and who is legally responsible for its operation.

(l) "Hospital" means a health care facility duly licensed by the State Board of Health as a general acute care or specialty hospital with an organized obstetrical service, as defined herein, and operating in compliance with the Department's rules in Chapter 420-5-7. The usual service provided in the obstetric gynecology service of an acute care hospital does not constitute or qualify as a birthing center.

(m) "Hospital Affiliated Birthing Center" means a separate and distinct unit of a hospital or a building owned, leased, rented, or utilized by a hospital for the purpose of providing the services of a birthing center. A hospital affiliated birthing center located on the hospital campus may operate under the general acute care or specialty license issued to the hospital. A hospital affiliated birthing center that is not located on the hospital campus is required to be separately licensed and may not operate under the general acute care or specialty license issued to the hospital.

(n) "License" means the legal authority to operate a birthing center, as defined above, to admit patients, and to offer and provide care as permitted under these rules. A license may only be granted by the Board through the actions of its authorized agents.

(o) "Licensed Practical Nurse" (LPN) means a person who holds an active license with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An LPN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(p) "Low Risk Patient" means an individual who does not have any of the listed risk factors for an adverse pregnancy outcome and who is eligible to receive services in a birthing center because the individual:

1. Is in general good health with an uncomplicated prenatal course.

2. Is participating in an ongoing prenatal care and education program that addresses, at a minimum, anticipated changes during pregnancy, the need for prenatal care, nutritional needs during pregnancy, the effects of smoking and substance abuse, the danger signs of preterm labor, what to expect during labor and

delivery, and care and feeding of the newborn, including instruction on lactation (breast feeding).

3. Has no major medical problems, including, but not limited to chronic hypertension, heart disease, pulmonary embolus or congenital heart defects; severe renal disease; medication-controlled diabetes; required use of anticonvulsant drugs; bleeding disorder or hemolytic disease; pyelonephritis; or thrombophlebitis.

4. Has no signs or significant symptoms of preeclampsia, hydramnios, abruptio placenta, chorioamnionitis, malformed fetus, multiple gestation, fetal growth restriction, fetal meconium, fetal distress, alcoholism, substance abuse or misuse, Rh or other blood group antigen sensitization.

5. Has no history of miscarriage or spontaneous abortion or premature delivery.

6. Has no previous significant obstetrical complications likely to recur, nor previous uterine wall surgery or Caesarean section.

7. Has given birth to fewer than five children, unless a justification for a variation is approved in writing by the staff physician or consultant physician.

8. If between 36 and 40 years of age and has never before given birth, has been cleared medically by the staff physician or consultant physician, and has both a normal comprehensive sonogram and normal chromosomal testing.

9. Is not less than 16 years of age at the onset of pregnancy.

10. Is appropriate for a setting where anesthesia is limited to local infiltration of the perineum, or a pudendal block, and analgesia is limited.

11. While in active labor:

(i) Demonstrates no significant signs or symptoms or evidence of anemia, significant hypertension, placenta previa, fetal distress, malformed fetus or breech.

(ii) Is progressing normally.

(iii) Is without prolonged ruptured membranes.

(iv) Is not in premature labor.

12. Is no more than 40 years of age at the outset of pregnancy.

(q) "Nonemergency Births" means those births that are planned to occur away from the mother's usual residence and have been determined to be low risk through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period.

(r) "Organized Obstetrical Service" means a hospital which has an obstetrician (or family practitioner with training and experience in obstetric medicine) and a pediatrician (or family practitioner with training and experience in pediatric medicine) on the active staff, a 24-hour emergency room and Cesarean section capability, and which provides skilled nursing care, facilities, and equipment appropriate for the patient being transferred from the birthing center. The organized obstetrical service must be located no more than 30 minutes driving time by emergency transport vehicle from the birthing center.

(s) "Pediatrician" means a physician who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama, and who is certified in general pediatrics or a pediatric subspecialty by the American Board of Pediatrics. The pediatrician must be trained and annua1ly certified in infant CPR and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart Association and possess an NRP certificate or the equivalent thereof.

(t) "Registered Nurse" (RN) means a person who holds an active license as such with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An RN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(u) "Risk Criteria" means:

1. Birthing center patients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for an adverse pregnancy outcome.

2. Each birthing center shall establish a written risk assessment system which shall be developed by the staff physician or consultant physician in accordance with the parameters set forth herein for low-risk patients and all applicable standards of good medical practice, to be included in the birthing center's policy and procedure

manual. Ongoing written risk assessments from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period shall form part of each patient's clinical record.

3. The general health status and risk assessment shall be conducted by the staff physician or consultant physician, CNM, or CPM by obtaining a detailed medical history, performing a physical examination, and considering family circumstances and other social and psychological factors. The patient's health status and risk assessment shall be reviewed by the staff physician or consultant physician or CNM and initially approved as suitable for delivery in the birthing center.

4. The criteria upon which the risk status of patients is determined under the birthing center's written risk assessment system shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services. Patients presenting with or later developing any of the risk factors listed under the definition of a low-risk patient in these rules shall be ineligible to receive services **in a** birthing center and shall be referred to another qualified physician for continuing maternity care and hospital delivery.

5. Acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited.

(v) "Services Provided in a Birthing Center" shall be defined and limited as follows:

1. Surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or Cesarean sections. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

2. Labor shall not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor (i.e., up to and including vaginal delivery). CPMs

are permitted to administer anti-hemorrhagic medication and oxygen in an emergency circumstance.

3. Systemic analgesia may be administered and local anesthesia for pudenda) block and episiotomy repair may be performed; however, general and conduction anesthesia shall not be administered. CPMs may not order or administer narcotic analgesia.

4. Vacuum extractors and forceps shall not be used in the birthing center.

5. Patients and their newborns shall not routinely remain in the birthing center in excess of24 hours. Exceptional circumstances justifying a stay in excess of24 hours are set forth in Ala. Admin. Coder. 420-5-13-.09(8).

(w) "Staff Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who is (l) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship. The staff physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/ American Heart Association. The staff physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A birthing center is ineligible for licensure unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician.

(x) "Transfer Agreement" means a birthing center's written agreement with a hospital located no more than 30 minutes driving time by emergency transport vehicle from the birthing center, which has an organized obstetrical service, as defined in these rules. The Transfer Agreement shall provide for the hospital's acceptance of referrals from the birthing center and phone consultations as needed to address emergency situations; the agreement shall address financial responsibility for services rendered. A birthing center is ineligible for licensure unless it has a Transfer Agreement with a licensed, qualified hospital. A written agreement with at least one currently licensed emergency medical service (EMS) is also required for the rapid response and transport of a patient or infant to the hospital named in the Transfer Agreement.

(3) Type of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the Board has determined that the birthing center is in substantial compliance with these rules.

(b) Probational License. At its discretion, the Board may grant a probational license when it determines that both of the following conditions exist:

1. The birthing center has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the birthing center has failed to correct.

2. The birthing center's current governing authority has demonstrated the capability and willingness to correct cited problems and to maintain compliance.

(c) A probational license shall be granted for a specific period which may be extended, but which shall in no case exceed 1 year.

(4) Licensing.

(a) Application. Application for an initial license or renewal of a license shall be made on forms provided by the State Board of Health, including all information required by law, these rules, and the policies and procedures of the Department. An applicant shall submit such additional information as shall be required by the Department in its discretion to demonstrate that the applicant has the ability and the willingness to comply with these rules. Each application shall be signed by a person authorized to bind the applicant to the representations in the application and shall include any supporting documentation with the application.

(b) Fee. An initial license application, an application for license renewal, or an application for a change in ownership shall be accompanied by the application fee specified in §22-21-24, Code of Ala. 1975. An application for a name change is not subject to a license application fee. An application fee is non-refundable. Any application fee submitted in the incorrect amount shall nevertheless be deposited. If the fee submitted is too large, a refund for the difference shall be processed using the Department's usual procedures. If the fee submitted is too small, the applicant shall be notified, and the application shall not be considered until the difference is received. Any application submitted without any fee shall be returned to the applicant. If an incomplete application is submitted, the application fee shall be deposited, and the applicant shall be notified in writing of the defects in the application. If the applicant fails to submit all required

additional information within IO working days of the date of the notice, the application shall be denied. The Department may, in its discretion, extend the deadline for submitting additional information. Denial of an application as incomplete shall not prejudice the applicant from submitting a new application, accompanied by the requisite fee, at a future date.

(c) Renewal. A license, unless suspended or revoked, shall be renewable annually as a matter of course upon submission of a completed renewal application and payment of the required fee. When the Department has served written notice on a birthing center of its intent to revoke or downgrade the license, a renewal application shall be filed, but does not affect the proposed adverse licensure action.

(d) Name. Every birthing center shall be designated by a permanent and distinctive name which shall be used in applying for a license, which shall include the words "birthing center." No birthing center shall change its name without first applying for a change of name approval, nor shall it change its name until such approval is granted. The Department may, in its discretion, deny an initial birthing center application or an application for a change of name if the Department determines that the proposed name is misleading to the public or that the name is overly similar to the name of an already licensed birthing center. Separately licensed birthing centers owned by the same governing authority may have names that are similar to one another and distinguished from one another in some other manner, such as a geographic description. If an initial birthing center application is denied under this rule, the applicant shall be provided a reasonable period of time to submit a revised application with a different name. No freestanding birthing center shall include the word "hospital" in its name.

(e) Issuance of License. All licenses issued by the State Board of Health shall set forth the name of the birthing center, the physical address, the name of the licensee, and the license number.

(f) Separate License. A hospital-affiliated birthing center or facility that is not located on the hospital campus is required to be licensed separately and may not operate under the license issued to the hospital.

(g) Posting of License. Licenses shall be posted in a conspicuous place on the licensed premises.

(h) License Not Transferable. The license shall not be transferable or assignable and shall be issued for the premises named in the application.

(i) Expiration of License. Each license shall expire on December 31 following the date of issuance.

(j) Condition of Licensure. It is a condition of licensure that the licensee must continuously occupy the licensed premises, remain open to the public as a birthing center, fully staffed, and otherwise capable of admitting and treating patients. If a birthing center fails to remain open and staffed as required for 30 days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void. If the facility subsequently wishes to reopen as a birthing center, it shall be required to file an initial licensure application, to include plan review and building inspection, and obtain a certificate of completion before the application can be processed by the Department.

(k) The following changes in the status of the birthing center will require issuance of a new license.

1. Change in facility ownership or operating entity (application fee required).

2. Change in facility name (no application fee required).

3. Relocation.

The governing authority shall file with the State Board of Health an application for license and application fee (if applicable) 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(l) The Department shall be notified in writing within 30 days prior to the effective date of any change in the birthing center's administrator or staff physician and of the birthing center's intent to cease operation.

(m) Denial and Revocation of a License.

1. The Board may deny a license to any applicant or suspend or revoke the license to operate a birthing center in any case in which it finds that there has been a substantial failure to comply with the requirements established under these rules or on grounds of insufficient evidence of the willingness or ability to comply with §§22-21-20 through 22-21-34, Code of Ala. 1975, or these rules. Each license shall be returned to the Board immediately upon its revocation or after the birthing center voluntarily ceases operation.

2. Hearing procedures concerning the denial, suspension, or revocation of a license shall be governed by the

provisions of the Alabama Administrative Procedure Act, §41-22-1, et seq., Code of Ala. 1975, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(5) Failure to Renew a License. Any licensee who fails to renew a license on or before the close of business on the last business day in December shall be assessed a late fee equal to the amount of the original license fee. A license may only be renewed with the payment of a late fee before the close of business on the last business day in January of any calendar year. A license which has not been renewed by the end of January has expired and shall be void.

(6) Compliance with Federal, State, and Local Laws. The birthing center shall be in compliance with applicable federal, state, and local laws, including all applicable zoning ordinances. A birthing center may not be operated in a private residence.

(a) Licensing of Staff. Staff of the birthing center shall be currently licensed, certified, or registered in accordance with applicable laws.

(b) Compliance with Other Laws. The birthing center shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements. If a birthing center utilizes the services of a clinical laboratory located outside the state of Alabama, the birthing center shall ensure that, in connection with any work performed for the birthing center, the laboratory complies with the requirements for the reporting of notifiable diseases to the Department, as set forth in state law and the rules of the Board.

(7) A birthing center shall promptly notify the Department in writing when there is any change in its accrediting organization or its status with the accrediting organization.

(8) Waiver and Variance. At its discretion, the State Board of Health may grant an exception to, or modify the application of, one or more provisions of these rules or reference codes for a period and under conditions, if any, determined by the Board. The exceptions or modifications shall be based on hardship, impracticality, or economic infeasibility in complying with the rules. The birthing center's request shall be in writing and meet the requirements of Rule 420-1-2-.09, including a statement regarding the specific provisions for which the exception or modification is requested and the reasons for each requested exception or modification.

(9) Disclosure of information. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the birthing center's license or proceedings involving the license of another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.

Author: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq., §22-21-28, et seq.
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420-5-13-.02 Administration.

(1) Governing Authority.

(a) Responsibility. The governing authority is the person or persons responsible for the management, maintenance, control, and operation of the birthing center, including the provision of personnel, facilities, equipment, supplies, and services to mothers and families, as well as appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the birthing center is organized, equipped, staffed, and administered in a manner to provide adequate care for each patient.

(b) The governing body shall be formally organized in accordance with a written constitution, bylaws, rules, or regulations. In the event the governing authority consists of one person, this requirement shall still be met. The written constitution, bylaws, rules, or regulations of the birthing center shall:

1. Specify by name the person to whom responsibility for operation and maintenance of the birthing center is delegated and methods established by the governing authority for holding such individuals responsible.

2. Provide for at least annual meetings of the governing authority. Minutes shall be maintained of such meetings.

3. Require policies and procedures consistent with professionally recognized standards of practice to

include provisions for administration and use of the birthing center, compliance, personnel, medical records, patient rights, emergency care/transfers, emergency preparedness, policy reviews, quality assurance, infection control, procurement of outside services and consultations, patient care policies, and services offered.

4. Provide for annual reviews and evaluations of the birthing center's policies and services offered.

(c) Contracted Services. The governing authority shall be responsible for services furnished in the birthing center, whether or not they are furnished under contracts. The governing authority shall ensure that a contractor of services furnishes services that permit the birthing center to maintain compliance with the requirements of these rules.

1. The governing authority shall ensure that the services performed under a contract are provided in a safe and effective manner.

2. The birthing center shall maintain a list of all contracted services, including the scope and nature of the services provided.

(d) The governing authority shall provide for the selection and appointment of the medical or nurse midwifery and nursing staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(2) Administrator.

(a) Responsibility. The governing authority shall appoint a qualified person as administrator of the birthing center to represent the governing authority and shall define the administrator's authority and duties in writing. The administrator shall be responsible for the management of the birthing center, implementation of the policies of the governing authority, and shall be authorized and empowered to carry out the provisions of these rules. Appropriate procedures to enforce these policies, assure proper patient care and safety, and meet requirements of these rules shall be developed in writing by an appropriate committee of professionals and shall be reviewed at least annually.

(b) The governing authority of the birthing center shall notify the Department in writing of any change in the birthing center's administrator within 30 days of the effective date of such change.

(3) Personnel Records. The birthing center shall maintain a personnel record of each employee. At a minimum, the personnel

record shall include a copy of the application for employment that contains information regarding education, certification, experience, and if applicable, registration and/or licensure information of the applicant, a current job description, all physical examinations, and evidence of continuing education or in service training and education. Personnel records shall be confidential. Representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.
Author: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.03 Medical Staff.

(1) Organization. There shall be an organized medical staff consisting of a minimum of one staff physician or consultant physician, and CNMs and RNs. CPMs may also provide assistive care to the medical staff of a birthing center while a patient is laboring, during birth, and throughout the postpartum period when in the birthing center. The staff physician shall have overall responsibility for the quality of a11 clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. In the event the birthing center does not have a qualified staff physician on the medical staff, the consultant physician shall have overall responsibility for the quality of all clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. The staff physician and consultant physician shall maintain independent medical judgment related to the practice of medicine at all times.

(a) The medical staff shall be accountable to the governing authority and organized in a manner consistent with the birthing center's documented staff organization and bylaws, rules, and regulations, provided that only a physician may conduct an annual appraisal or evaluation of another physician.

(b) The medical staff shall conduct annual appraisals of its members, examine the credentials of candidates for medical staff membership, and make recommendations to the governing authority on the appointment of the candidates.

(2) The staff physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. In the event the birthing center does not have a qualified staff physician on

the medical staff, the consultant physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. Each policy and protocol shall be signed by the staff physician or consultant physician who is a member of the medical staff. The organization and policies and protocols of the medical staff shall be approved by the birthing center's governing authority. The policies and protocols shall require that patients are admitted to the birthing center only when they have been prescheduled to deliver there following a documented period of prenatal care for a patient who has been determined to be low risk, as defined herein, through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period, and upon immediate evaluation by the medical staff to be low risk.

(a) Consultant Physician.

1. Services of a consultant physician are required in those birthing centers which do not have an Alabama licensed physician on the medical staff who serves as the staff physician. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called.

2. The responsibilities and functions of the consultant physician shall be specifically described in the policy and procedure manual and the patient care protocols.

3. The governing body shall maintain a written agreement with each consultant physician who agrees to provide advice and services to the birthing center as requested.

4. If a birthing center does not have a staff physician and is unable to enter into an agreement with a consultant physician, the license of the birthing center shall be denied or suspended, and no patient services may be rendered until an agreement with a consultant physician is formalized.

(b) The initial appointment and continued medical staff membership shall be dependent upon professional competence and ethical practice in keeping with the qualifications, standards, and requirements set forth in the medical staff policies and protocols and governing authority bylaws, rules, and regulations.

(c) Hospital Privileges. The staff physician and/or consultant physician shall have full active privileges in obstetrics at

the hospital that is a party to the birthing center's Transfer Agreement.

(d) Staffing. There shall *be* a minimum of two licensed RNs at the birthing center at all times when patients are present, with a staffing ratio of one licensed RN for every two patients. There shall be a staff physician or consultant physician or CNM at the birthing center when a patient is laboring, during delivery, and for a minimum of 2 hours post-delivery. When the patient census exceeds the above, additional medical staff are to be called in or the patients are to be transferred to a hospital. There shall be an adequate number of medical and support staff on duty and on call to meet demands for services routinely provided and periods of high demand or emergency, to assure that no mother in active labor shall remain unattended.

(e) Licensure. All birthing center personnel shall be currently licensed to perform the services they render when such services require licensure under the laws of the state of Alabama.

(f) Health Examinations. At a minimum, each employee coming in contact with patients shall have a pre-employment health examination by a physician, certified registered nurse practitioner, or physician assistant. The examination is to be repeated annually and more frequently if indicated to ascertain freedom from communicable diseases. The extent of such examinations shall be determined by the governing authority in consultation with the staff physician and documentation made in the employee's personnel folder. The examination shall include a chest x-ray or a tuberculin test. Each employee must be offered a Hepatitis B vaccine and sign a written declination if the vaccination is refused. Documentation of immunization status for vaccine preventable diseases in pregnancy may be required.

(g) Staff Development. All medical staff will participate in an orientation and training program developed by the birthing center upon hire and at least annually in staff development, including, but not limited to, recertification of adult and infant CPR training and education programs to maintain knowledge and skills used in birthing center practice.

(h) Nursing Service.

1. Staffing Pattern. There shall be 24-hour availability of qualified RNs and CNMs as defined in these rules. A minimum of two RNs shall be in the birthing center whenever a patient is in labor, during birth, and throughout the postpartum period while a patient is in the center.

2. Nursing Care Plan. An RN must plan, supervise, and evaluate the nursing care of each patient from admission to discharge. Prior to discharge, each patient shall be given a referral with a specific time, date, and place for postpartum, family planning, and infant care. A 2-week health status of the baby shall be documented on the patient's record following review of records evidencing the pediatric or neonatal care provided at the birthing center or other facility.

3. LPNs who are currently licensed to practice within the state may provide nursing care that does not require the skill and judgment of an RN, under the supervision of an RN. LPNs providing such care shall maintain current certification in both adult and infant CPR.

(i) Certified Nurse Midwifery and Physician Service.

1. A CNM or the staff physician or consultant physician shall be in the birthing center when a patient is in labor, during birth, and for a minimum of 2 hours postpartum, or longer if necessary. A physician obstetrician and pediatrician shall be available 24 hours a day for phone consultation pursuant to a written agreement with the birthing center.

2. There shall be a minimum of one CNM or physician for every two patients in the birthing center, to ensure that every patient in labor is attended.

3. Care policies and procedures shall be consistent with professionally recognized standards and shall be in accordance with the Nurse Practice Act and Medical Practice Act of the State of Alabama. Policies shall, at a minimum, include the following:

(i) Diagnostic and therapeutic orders.

(ii) Assignment of care of patients.

(iii) Medication orders.

(iv) Charting.

(v) Infection control.

(vi) Patient and personnel safety.

(vii) Family centered maternity care.

(j) Inservice and Continuing Education. An inservice education program shall be provided for all staff members of the birthing center to improve existing practices, obtain new

knowledge and skills, keep personnel informed of changes in policies and procedures, and discuss problems in the birthing center.

1. The inservice program shall be planned, scheduled, documented, and held monthly.

2. All medical staff shall participate annually in appropriate training programs for the safe and effective use of diagnostic and therapeutic equipment, for CPR, and infant resuscitation and transport.

3. All personnel shall have training that meets state and federal guidelines, as applicable, including, but not limited to, regulations of the Occupational Safety and Health Administration (OSHA), the Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA).

Author: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.04 Informed Consent.

(1) Before admission to services, a patient shall be informed of:

(a) The qualifications of the birthing center medical staff

(b) The risks related to out-of-hospital childbirth.

(c) The possibility of referral or transfer if complications arise during pregnancy or labor, with additional costs for services rendered by any hospital to which the patient may be transferred.

(2) The birthing center medical staff shall obtain the patient's written consent for birthing center services using the form, "Consent to Deliver in a Birthing Center," as provided by the Department.

(3) The signed consent form shall be included with the patient's individual clinical record.

Author: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6). et seq.; §22-21-20, et seq.
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420-5-13-.05 Patient Orientation And Preparation For Childbirth.

(1) Prior to admission for services, patients shall be fully informed of:

(a) The criteria adopted by the birthing center for the selection and admission of patients.

(b) The philosophy of the birthing center's governing body and medical staff regarding childbirth care and management, including the limited use of analgesics and anesthetics.

(c) The scope of services to be provided.

(d) Th expectation that the patient and family will be responsible for self-care to the extent and feasible and safe. Birthing centers shall not provide the level of care offered in an acute care hospital.

(e) The customary length of stay following delivery.

(f) The policies of the birthing center regarding transfer to hospitals with whom the birthing center has a written agreement.

(g) The qualifications of the medical staff.

(2) During the course of prenatal care, the patient and family, to the extent necessary, shall be counseled or instructed to prepare them for childbirth. At a minimum, the educational topics shall include:

(a) Anticipated changes during pregnancy.

(b) Need for prenatal care.

(c) Nutritional needs during pregnancy.

(d) Effects of smoking and substance abuse.

(e) Danger signs of preterm labor.

(f) What to expect during labor and delivery.

(g) Care and feeding of the newborn, including instruction on lactation (breast feeding).

Author: Dana Billingsley, Diane Milledge
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420-5-13-.06 Prenatal Visits.

(1) The birthing center's medical practitioners shall follow the guidelines set forth by the American College of Obstetricians and Gynecologists for testing pregnant women for sexually transmitted diseases.

(2) Initial Visit.

(a) The birthing center shall at a minimum conduct one prenatal visit in which a comprehensive health history of the patient shall be completed, which includes medical, emotional, dietary, and obstetrical data, including a preterm delivery risk assessment.

(b) A physical examination of the patient shall be completed by qualified staff, within their scope of practice, including height and weight measurements; vital signs, including blood pressure; and examination of the skin, head and neck, heart and lungs, breasts, abdomen, pelvis, and neurologic reactions.

(c) The following tests are also required to be performed by a staff member or by other of the birthing center's qualified personnel:

1. Hemoglobin and hematocrit.

2. Urinalysis by dipstick for protein, sugar, and ketones.

3. Cervical cytology. Recommendation by The American Society of Colposcopy and Cervical Pathology (ASCCP) is for pap smears every 3 years (age 21-30) and every 5 years with co-testing (age 31-64).

4. Rh determination and blood type.

5. Prenatal screening recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, HIV, syphilis, and Hepatitis B surface antigen screening.

(2) At a minimum, return visits to the birthing center shall include the following measurements and testing:

(a) Weight, blood pressure, fundal height, and fetal heart rate, as applicable.

(b) Urinalysis by dipstick for protein and sugar.

(c) Hemoglobin and hematocrit should be repeated at least twice and more often if indicated during the course of the pregnancy.

(d) Review of signs and symptoms of complications of pregnancy and risk status.

(e) Examination to determine the estimated weeks of gestation, fetal position, and presentation.

(3) If prenatal visits subsequent to an initial visit are offered at the birthing center, they should be scheduled at least every 4 weeks until the 28th week, every 2 weeks until the 36th week, and then every week until delivery, unless more frequent monitoring is required. Patients must be evaluated by qualified medical staff at the birthing center at their initial prenatal visit and regularly throughout their pregnancy, with a copy of each performed risk assessment retained in their file, to assure that they remain at low risk for an adverse pregnancy outcome. If prenatal visits subsequent to the initial visit are conducted at a location other than the birthing center, visit summaries must be obtained by the birthing center and reviewed as part of the continuing risk assessment for that patient. Prenatal visits conducted by a provider other than the birthing center must be scheduled and conducted with the same frequency as the visits conducted by the birthing center under these rules and must meet the same evaluation and risk assessment requirements for each visit in order for the patient to remain eligible for delivery in the birthing center.

(4) All patients shall receive specific instruction regarding preterm labor, including the potential hazards, preventive measures, symptoms, detection and timing of contractions, and the need for prompt notification of the health provider.

(5) At least one prenatal visit in the second trimester of pregnancy shall be overseen by the staff physician or consultant physician, to certify that the patient remains eligible for delivery in the birthing center. All patients found to be at obstetrical risk pursuant to the criteria set forth in these rules shall be referred to a qualified local physician, certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists, for continued care.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.07 Intrapartum Care.

(1) A member of the medical staff shall be present or available to the patient at all times throughout her stay in the birthing center.

(2) The medical staff shall monitor the progress oflabor and condition of the mother and fetus at sufficiently frequent intervals to identify abnormalities or complications as soon as possible.

(3) The patient shall be transferred to a hospital if complications requiring medical or surgical intervention occur, as set forth in the criteria established in these rules.

(4) The birthing center shall be able to respond to medical emergencies that may arise during the provision of services to patients, including adult basic life support, neonatal resuscitation, and initial management of postpartum complications.

(5) The patient's family or persons offering her support shall be instructed as needed to assist the patient during labor and delivery.

(6) Labor shall not be inhibited, stimulated, or augmented with drugs administered in the birthing center except when the patient is to be transported immediately to the hospital and the drug is prescribed by the medical consultant or physician who will receive the patient and manage her continued care. All such drugs shall be administered solely by appropriate, qualified staff within each staff member's permissible scope of practice.
Author: Dana Billingsley, Diane Milledge
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420-5-13-.08 Surgical Services And Use Of Analgesics And Anesthetics.

(1) No surgical procedures shall be performed in the birthing center except episiotomy, repair of episiotomy or laceration, or circumcision. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or

consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

(2) Systemic analgesics and local anesthetics may be administered under the following conditions:

(a) The medical staff member who administers the systemic analgesic is legally authorized to do so and shall be present in the birthing center during the use of intravenous analgesics. CPMs may not order or administer narcotic analgesia.

(b) The dosage and drugs are specifically noted in the protocols for clinical services.

(c) The use of such drugs is in conformance with the policies and procedures of the birthing center.

(3) General and conduction anesthesia shall not be administered at birthing centers.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.09 Postpartum Care.

(1) Immediate postpartum care shall be provided to the mother at the birthing center by qualified members of the medical staff.

(2) The condition of the mother shall be monitored frequently to detect signs of hemorrhage or other complications requiring prompt transfer to a hospital.

(3) Adequate nutrition must be provided to the mother during her stay at the birthing center, as evidenced by written dietary requirements on file at the birthing center.

(4) Qualified members of the birthing center's staff shall perform a postpartum examination on the mother, as permitted within the staff member's legal scope of practice, prior to discharge and within 72 hours after delivery, and an additional examination of the mother shall be performed at approximately 4 to 6 weeks after delivery by the birthing center, a referral facility, or a qualified medical professional.

(a) The patient examination prior to discharge and within 72 hours shall include, at a minimum:

1. Interval history.

2. Blood pressure measurement.

3. Observation of the breasts, perineum, and abdomen.

(b) The patient examination at 4 t o6 weeks shall include all of the above and:

1. Weight.

2. Hemoglobin and hematocrit.

3. Bi-manual pelvic examination.

(5) Immediate postpartum care shall be provided to the newborn at the birthing center by qualified members of the medical staff as permitted within the staff member's legal scope of practice.

(a) A prophylaxis shall be instilled into each eye of the newborn.

(b) A cord blood sample shall be secured for laboratory testing for type, Rh determination, and direct Coombs test when the mother is Rh negative. The newborn shall also receive umbilical cord care.

(c) Newborn screening monitoring as recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, testing for Group B Streptococcal infection, HIV, syphilis, and metabolic screening, to include newborn hearing screening and congenital cardiac screening, as required by state law.

(d) The newborn shall be weighed, measured, and examined for abnormalities and complications, and an Apgar score shall be obtained and recorded at 1 and 5 minutes. An identification tape shall be placed on all newborns.

(e) One-half milligram of Vitamin K shall be administered to the newborn within 24 hours after birth.

(f) The newborn must be examined by a qualified medical staff member, pursuant to each one's scope of practice, prior to discharge and shall be immediately referred to a qualified physician or hospital care if any of the following conditions occur:

1. Low birth weight (under 2,500 grams).

2. Apgar score of 7 or less at 5 minutes.

3. Signs of pre- or post-maturity.

4. Jaundice.

5. Persistent hypothermia consisting of a body temperature of less than 97°F for more than 2 hours after birth.

6. Respiratory difficulties.

7. Major congenital anomalies.

8. Exaggerated tremors.

9. Any other condition requiring medical care.

(6) Discharge Criteria.

(a) Prior to discharge of the newborn, recommendations and care consistent with the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department must be followed, to include, but not be limited to, any required treatment for congenital syphilis, post-exposure prophylaxis for HIV, Hepatitis B immune globulin, and Hepatitis B vaccination. The newborn should also be evaluated for the risk for hyperbilirubinemia by either blood or transcutaneous measurement, with a written plan for medical follow up.

(b) The mother and newborn shall be discharged from the birthing center within 24 hours after the birth occurs, except under the following conditions:

1. The mother is in a deep sleep when the 24-hour period is completed. In this case, the mother shall be discharged as soon after waking as is feasible; or

2. The 24-hour period is completed between the hours of 10 p.m. and 6 a.m.

(7) If the mother or newborn is retained at the birthing center longer than 24 hours after the birth, a report shall be filed with the Department's Division of Licensure and Certification within 48 hours after the birth, describing the circumstances and reasons for retention.

(8) The mother shall be counseled and receive written information regarding breastfeeding, perineal care, family planning, signs of

common complications, activities and exercises, sex relations, care and feeding of the newborn, and changing family relationships prior to discharge from the birthing center.

(9) Prior to discharge, the parents shall be instructed by the birthing center in the importance of immunization and a 2-week screening for the newborn in accordance with the American Academy of Pediatrics schedule of visits. Parents shall also be instructed in the importance of repeat metabolic screening starting at several weeks of age. The parents shall be referred to providers of pediatric care if not provided on site.

(10) Observation of the Newborn at 72 Hours and 4 to 6 Weeks. A metabolic screening test shall be performed on the newborn by the birthing center, a referral facility, or a qualified medical professional between 24-72 hours and shall include, at a minimum, hypothyroidism and phenylketonuria. Sickle cell testing should be included if indicated. An examination of the newborn should also be made at 4 to 6 weeks by qualified members of the birthing center's medical staff, pursuant to each staff member's legal scope of practice, or a licensed pediatrician, family medicine practitioner, or pediatric nurse practitioner.

(11) If complications in the mother or newborn occur during the postpartum period, a consultation or referral shall be made to the appropriate source of secondary or tertiary care.

(12) If the mother refuses to permit eye prophylaxis, Vitamin K injections, or a metabolic screening test prophylaxis for the newborn due to religious beliefs, a waiver indicating this decision shall be signed by the mother, witnessed by a medical staff member, and filed with the clinical record.
Author: Dana Billingsley, Diane Milledge
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420-5-13-.10 Management Of Emergencies.

(1) When necessary, patients shall be transferred from the birthing center to a hospital with which a written Transfer Agreement is in effect. A complete copy of the health record of both the mother and newborn, maintained up to and including the time of transfer, shall be provided to the referred provider or facility upon transfer.

If the mother is unable to ride in an upright position, or the mother's condition is such that she needs observation or treatment by EMS personnel, or the mother requires transportation on a

stretcher, gurney, or cot, the birthing center shall arrange or request transportation services only from providers who are ambulance service operators licensed by the Alabama State Board of Health and with whom the birthing center has a written agreement for the transport of a patient to the hospital named in the Transfer Agreement. For the purposes of this rule, an upright position means no more than 20° from vertical.

(2) The birthing center shall have a written protocol for emergency situations, which shall include:

(a) The name, address, telephone numbers, and contact persons of the licensed ambulance service; identify the hospital under written agreement with the birthing center to provide emergency obstetrical and neonatal services; and list other hospitals in the vicinity.

(b) The conditions specified in the arrangements between the birthing center, the ambulance service, and the hospital, including financial responsibility for services rendered.

(c) The criteria requiring medical consultation with a qualified physician who is (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship, or transfer to the hospital under written agreement with the birthing center, including, but not limited to:

1. Premature labor, meaning labor occurring at less than 37 weeks gestation.

2. Estimated fetal weight less than 2,500 grams. Newborns weighing more than 4,000 grams may require referral in the clinical judgment of the staff physician or consultant physician.

3. Hypertension.

4. Preeclampsia.

5. Failure to progress in labor.

6. Evidence of an infectious process.

7. Premature rupture of the membranes, meaning rupture occurring more than 24 hours before onset of active labor, provided there is no evidence of infection.

8. Suspected placenta previa or abruption.

9. Non-vertex presentation.

10. Hemorrhage of greater than 500 cc of blood.

11. Anemia, consisting of less than 10 grams of hemoglobin per 100 milliliters of blooc or 30 percent hematocrit.

12. Persistent fetal tachycardia (heart rate more than 160 beats per minute), repetitive fetal bradycardia (heartbeat less than 110 beats per minute for more than 10 minutes), or undiagnosed abnormalities of the fetal heart tones.

13. Persistent hypothermia in the newborn.

(d) Criteria to determine risk status which requires immediate emergency transfer include, but are not limited to:

1. Prolapsed cord.

2. Uncontrolled hemorrhage.

3. Placental abruption.

4. Convulsions.

5. Major anomaly of the newborn.

6. Apgar score of 7 or less at 5 minutes.

7. Fetal heart rate of 90 or less beats each minute for 3 minutes.

8. Thick meconium staining at the time of membrane rupture.

9. Respiratory distress in the newborn.

10. Weight less than 2,500 grams.

(e) The criteria and protocols for transfer shall be readily accessible to medical staff members at all times.

(3) The name and telephone numbers of the licensed ambulance services providing transport for the birthing center, the Children's Hospital Critical Care Transport Team, and the hospital accepting transfer shall be clearly posted at each telephone in the birthing center.

(4) A written report of the transfer shall be provided and retained for quality assurance review and Departmental inspection. The report shall include:

(a) The Patient's name.

(b) The date of the event.

(c) The reason for transfer.

(d) The provider and mode of transportation to the hospital.

(e) The exact time of the initial call and of any subsequent calls.

(f) Time of arrival of the emergency personnel.

(g) Time of the patient's departure from the birthing center.

(h) Time of arrival at the hospital.

(i) Name of the receiving hospital.

(j) Details concerning the initiation of EMS.

(k) The condition of the patient at the time of transfer.

(l) Any information regarding the medical care of the patient and outcome.

(5) The medical staff, consultants, and governing authority shall review and evaluate the criteria, protocols, and emergency transfer reports on a monthly basis. The results of the evaluation shall be documented.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.11 Patient Records.

(1) Medical Records to be Kept. A birthing center shall keep comprehensive, organized, and readily accessible records for each patient (mother and newborn), including, but not limited to, admission and discharge notes, histories, physical examinations, nurses notes, procedure schedules, anesthesia/analgesic records, informed consent, follow-up care, and records of tests performed. The patients' records shall be current and kept with sufficient detail, consistent with good medical and professional practice, based on the services provided to each patient.

(2) Authentication of Records. All records shall be written, dated, and signed in an indelible manner, with the identity of the writer indicated, and made part of the patient's permanent record.

(3) Indexes. All health records should be indexed according to the patient's name.

(4) Facilities. A room or area shall be designated for maintaining paper copies of patient health records within the birthing center if a paper record is prepared. The area shall be sufficiently large and adequately equipped to permit the proper processing and storing of records and to protect them from fire or water damage. Access to electronic health records shall be properly secured and restricted to the birthing center's medical staff. All health records must be easily retrievable and readily accessible to the medical staff.

(5) Ownership. Health records shall be property of the facility and must be protected against loss, destruction, and unauthorized use; responsibility for the control of all such records shall rest with the administrator and the governing authority.

(6) Preservation of Records. Health records shall be preserved either in the original form, by microfilm, or in electronic form for a period of not less than 6 years following the most recent discharge of the patient. In the case of a minor, records shall be kept for 6 years after obtaining legal age. Mother and newborn records shall be kept together.

(7) Records are Confidential. Records and information regarding patients shall be confidential; however, patients may access and request copies of their own and their newborn's medical records, consistent with the provisions of HIPAA. The clinical record shall not be released without the written consent of the patient except under the following conditions:

(a) When the patient is transferred to another source of care. A complete patient record shall accompany the mother or newborn in the event of an emergent or non-emergent transfer of care.

(b) For audit by the Department during licensure inspection.

(c) In response to a lawfully issued subpoena or court order.

(d) As otherwise provided or required by HIPAA or other applicable state of federal law.

(8) Individual Patient Records. Each patient's health record shall include, but is not limited to, at least the following information:

(a) Demographic information and patient identification.

(b) Orientation to program and informed consent.

(c) Complete social, family, medical, reproductive, nutrition, and behavioral history.

(d) Initial physical examination, laboratory tests, and evaluation of risk status.

(e) Appropriate referral of at risk patients with report of findings on risk assessment.

(f) Development of a plan for care.

(g) Continuous periodic prenatal examination and evaluation of risk factors including documentation of prenatal care provided outside the center at related practitioner or clinic sites.

(h) Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care, and feeding and medical evaluation.

(i) History, physical examination, and risk assessment on admission to the birthing center in labor (labor graph).

(j) Ongoing assessment of maternal and fetal status after admission to care and during the intrapartum period.

(k) Evaluation of progress in labor with ongoing assessment of maternal and newborn reaction to the process of labor.

(l) Consultation, referral, and transfer for maternal or neonatal problems that elevate risk status.

(m) Physical assessment of newborn, including apgar scores, gestational age, maternal newborn interaction, feeding, prophylactic procedures, postpartum monitoring of vital signs, and accommodation to extrauterine life. The birthing center must perform an ongoing postpartum assessment of both mother and newborn.

(n) Labor summary.

(o) Discharge summary for mother and newborn.

(p) Plan for newborn health supervision and required screening tests.

(q) Plan for newborn health supervision and required screening tests.

(r) Late postpartum evaluation of mother, counseling for family planning and other services, and evaluation of mother-child relationships.

(s) Eye care, vitamin K.

(t) All entries shall be dated and signed by the attending professional staff members.

(9) Completion of records. All health records shall be completed promptly. Reports of laboratory tests, treatments, and consultations shall be entered promptly on the health record.

(10) Vital Statistics Report. A record shall be kept of all births, deaths, and stillbirths that occur within the birthing center.

(a) A certificate of birth for each live birth shall be filed with the Department's Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the birth, in accordance with Code of Ala. 1975, §22-9A-7 and Ala. Admin. Code r. 420-7-1-.03.

(b) A report of fetal death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the occurrence is known if the fetus has advanced to, or beyond, the 20th week of uterogestation, in accordance with Code of Ala. 1975, § 22-9A-13 and Ala. Admin. Coder. 420-7-1-.03.

(c) A certificate of death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days of the death, in accordance with Code of Ala. 1975 § 22-9A-14 and Ala. Admin. Coder. 420-7-1-.03 and -.10.

(d) If a record of death or fetal death has not been created in the state's electronic registration system, the administrator or his/her designee must report to the Center for Health Statistics, or as otherwise directed by the State Registrar, any dead body or fetal death no later than the fifth day of the following month of which the body was handled by the birthing center.

(e) All records and reports registered by the birthing center with the Center for Health Statistics shall be in a format prescribed by the State Registrar.

(11) Disposition of Records. When a birthing center ceases to operate either voluntarily or by revocation of its license, the governing body shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the proper

storage, safeguarding, and confidential transfer and/or disposal of patient medical records and x-ray files. Any birthing center that fails to develop a plan for disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(12) System of Periodic Review. There shall be a system for periodic record review and documentation of issues and outcomes.
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420-5-13-.12 Rights And Responsibility Of The Patient And Family.

(1) The rights and responsibilities of the patient and family, however defined, shall be clearly delineated in the birthing center's policies and procedures and communicated on the patient's admission for care. All patients have a right to:

(a) Be treated with respect, dignity, and consideration.

(b) Be assured of confidentiality.

(c) Be informed of the benefits, risks, and eligibility requirements for care in the birthing center.

(d) Be informed of the services provided by the birthing center and those provided by contract, consultation, and referral.

(e) Be informed of the identity and qualifications of care providers, consultants, and related services and institutions.

(f) Have access to their medical records and all results of screening or diagnostic studies.

(g) Be informed of all diagnostic procedures and reports, recommendations, and treatments.

(h) Participate in decisions relating to the plan for management of the patient's care and all changes in that plan, once established, including referral or transfer to other practitioners or other levels of care.

(i) Receive a written statement of fees for services and responsibilities for payment.

(j) Be informed of the birthing center's plan for the provision of emergency and nonemergency care in the event of complications to mother or newborn.

(k) Receive a written statement of the birthing center's plan and the family's responsibility to ensure adequate supportive home care and follow-up health supervision of the mother and infant.

(l) Be informed of, and reserve the right to refuse, participation in research or student education programs.

(m) Be informed of the birthing center's policy for hearing grievances. The telephone number to register complaints with the Alabama Department of Public Health, Division of Health Care Facilities, shall be posted in a prominent location and shall be included in the written material given to the patient upon discharge. A grievance log, including the nature of the complaint and its resolution, shall be maintained by the birthing center and made available for inspection by the Department on its request.

(n) Be informed of the liability insurance status of the birthing center and medical staff.

(2) The birthing center shall provide or demonstrate its availability to provide a range of services to meet the physical, emotional, socio-economic, informational, and medical needs of the individual patient while under care, including, but not limited to:

(a) An orientation to the facility fees and services of the birthing center.

(b) Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birthing center's program of care.

(c) Prenatal care (may be provided at a related practitioner or clinic site).

(d) A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self-care/self-help, and sibling preparation.

(e) Laboratory services.

(f) Twenty-four (34) hour telephone consultation services.

(g) Intrapartum care.

(h) Light nourishment during labor and postpartum.

1. When patients remain in the birthing center for 24 hours, food must be provided to meet the dietary needs of those patients. If meals are prepared in the birthing center, the facility shall have organized dietary services that are directed and staffed by adequate qualified personnel, including a qualified food service manager and consultation by a licensed registered dietician as required to meet the dietary needs of the patients. However, a birthing center that has a contract with an outside food management company may meet the requirements of this rule if the company has a dietitian who serves the birthing center on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this rule and provides for constant liaison with the birthing center medical staff for recommendations on dietetic policies affecting patient treatment.

2. Food prepared outside the facility shall be performed only by facilities which meet the requirements of Alabama Administrative Code, Chapter 420-3-14, Food Service Sanitation. In addition, the birthing center must provide a food preparation area with:

• Double sink, if disposable are not utilized at all times.

• Microwave oven.

• Refrigerator.

• Hand-washing sink.

• Counter space.

• Towel cabinet.

• Soap dispenser.

• Garbage cans with cover.

• Coffee maker.

• Storage area for silverware and cutlery, if disposables are not utilized at all times.

(i) Immediate post partum care.

(j) Home or office follow-up for mother and newborn.

(k) Additional options:

1. Exercise p0rograms.

2. Parent support groups.

3. Postpartum classes.

4. Family planning.

5. Well baby care.

6. Circumcision.

7. Nursing mother support programs.

8. Well woman gynecologic care.

9. Public education.

10. Professional education.

11. Clinical investigation and/or research.

(3) The birthing center shall inform patients that drugs for induction or augmentation of labor, vacuum extractors, and forceps are not necessary during normal labor and are not appropriate for use in birthing centers. Patients must be provided with and consent to this policy.

(4) The birthing center's policy and procedure manual shall include all aspects of birthing center practice and care and shall be made available to practitioners and support staff at all times.

(5) The birthing center's practice protocols must be approved by the staff physician or consultant physician and made available to the hospital receiving transfers upon request.
Author: Dana Billingsley, Denise Milledge
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420-5-13-.13 Quality Assurance.

(1) There shall be a written quality assurance program consisting of an interdisciplinary committee which shall perform quality assurance reviews for maternal and newborn care provided in the birthing center, including, but not limited to:

(a) At least annual review of protocols, policies, and procedures relating to the maternal and newborn care provided during the prenatal, intrapartum, and postpartum periods.

(b) The appropriateness of the criteria for determining eligibility for admission to and continuation in the birthing center's program of care.

(c) The appropriateness of diagnostic and screening procedures, including laboratory studies, sonography, and nonstress tests, and their impact on quality of care and patient cost.

(d) The appropriateness of medications prescribed, dispensed, or administered in the birthing center.

(e) Performance evaluations of medical and support staff employed by the birthing center (peer review - self evaluation).

(f) Quarterly meetings of medical staff to review the management of care of individual patients (medical chart reviews) and make recommendations for improving the plan for care.

(g) Quarterly review of all transfers of mothers and neonates to hospital care, to determine the appropriateness and quality of the transfer.

(h) Immediate review and evaluation of all complications of pregnancy, labor, and postpartum periods arising in the birthing center and the appropriateness of medical staffs consultation and treatment of the same.

(i) Evaluation of staff's ability to manage emergency situations via unannounced periodic drills for fire, maternal/ newborn emergencies, power failures, etc.

(j) The birthing center's responses to patient grievances and feedback.

(2) Patient records shall be audited by the medical staff at least every 3 months and a sample audited by the quality assurance committee at least every 6 months. The audit shall evaluate the following for accuracy and completeness:

(a) Initial history, physical examination, risk assessments, and laboratory tests.

(b) Documentation of clinical observations, examinations, and treatments.

(c) Evidence that appropriate actions have been taken in response to clinical findings.

(d) Counseling, education, consultation, and referral activities are recorded.

(e) Consent forms are signed.

(f) All entries are legible, dated, and signed in ink or typed.

(3) The quality assurance committee shall analyze the incidence of maternal and perinatal morbidity and mortality, obstetrical risk assessments, pre-term labor risk assessments, consultant referrals and outcomes, and transfers of care and outcomes.

(4) The quality assurance program ensures quality of care to patients and the community through an effective system for collection and analysis of data, which includes, but is not limited to, utilization of information obtained through the following:

(a) Orientation sessions.

(b) Patient registrations.

(c) Women attending educational programs at the birthing center.

(d) Total number of encounters/visits antepartum.

(e) Number of and reasons for antepartum transfers.

(f) Intrapartum care admissions.

(g) Number of and reasons for intrapartum transfers.

(h) Time in the birthing center before delivery.

(i) Births occurring in the birthing center.

(j) Births occurring en route to the birthing center.

(k) Time in birthing center after delivery.

(l) Number of and reasons for maternal postpartum transfers.

(m) Number of and reasons for newborn transfers

(n) Postpartum home visits.

(o) Follow-up maternal postpartum office visits.

(p) Follow-up newborn office visits.

(q) Total classes conducted antepartum.

(r) Total classes conducted postpartum.

(s) Outcomes of care provided.

1. Loss of pregnancy before 20 weeks gestation.

2. Type of anesthesia/analgesia used.

3. Type of delivery.

4. Place of delivery.

5. Complications of delivery, including postpartum hemorrhages of more than 1,000 cc.

6. Episiotomies, lacerations.

7. Infants with birth weight below 2,500 grams or over 4,000 grams.

8. Apgar scores.

9. Neonatal morbidity/mortality.

10. Maternal morbidity/mortality.

11. Maternal or newborn admissions from home to hospital in a 4-week postpartum period.

(t) Deviations from written protocols.

(5) The birthing center's quality assurance plan should, at a minimum, address any issues related to the following:

(a) Administrative or supervisory action.

(b) Continuing education or simulation.

(c) Modification of policies and procedures.

(d) Revision of risk criteria.

(e) Revision of health record or other forms.

(f) Utilization of outside consultation and expertise.

(g) Changes to facility, equipment, or supplies.

(6) Professional Accreditation. The birthing center must apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license.

(7) Yearly Evaluation. The birthing center shall assess the needs of the childbearing community and continue to develop services and programs to address the following:

(a) The general geographical area to be served.

(b) Demographic data and vital statistics of the community to be served.

(c) Availability of and access to maternal and newborn services, including practitioners, hospital obstetrical and newborn services, home birth services, family-centered maternity care programs, birthing rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education, and parental support programs.

(d) Periodic market surveys to determine the impact of the birthing center on the community and to assess the needs of childbearing families in the population served, for purposes of program planning and development.

(e) Changes in population, environment, regulations, legislation, reimbursement, and access to and availability of maternal and newborn services in the community.

(8) Reports of the quality assurance committee shall be given to the governing body.

(9) The governing body shall examine the reports of the quality assurance committee and shall make such reports available for inspection by the licensing authorities for the facility and the providers.

Author: Dana Billingsley, Denise Milledge
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420-5-13-.14 Reports.

(1) An annual report shall be created by the birthing center no later than the 30th day of the month following the end of the calendar year and kept on file by the facility. At a minimum, the report shall contain the following information and shall be made available for inspection by the Department upon its request:

(a) Name and address of the birthing center.

(b) Number of patients accepted for care during the reporting year.

(c) Number of deliveries and number of deliveries of newborns less than 2, 500 grams.

(d) Number of transfers to hospitals, the reasons for transfer, and outcomes.

(e) Number of maternal and newborn deaths and stillborns associated with birthing center patients.

(f) Range and average length of stay in hours.

(g) Range and average length of stay after birth in hours.

(h) The nature and number of surgical procedures performed in the birthing center.

(i) Any other additional information the Department may require.

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420-5-13-.15 Pharmaceutical Services.

(1) The birthing center shall develop, implement, and enforce written policies and procedures governing the provision of pharmaceutical services.

(2) Administering Drugs and Medicines.

(a) Drugs and medicines shall not be administered to patients unless ordered by a physician duly licensed to prescribe such drugs, or, by a licensed CNM, as authorized by the CNM's collaborative practice protocol or formulary pursuant to the rules of the Alabama Board of Nursing and the Alabama State Board of Medical Examiners, as applicable, and approved protocols. Such orders shall be in writing and signed personally by the prescriber.

(b) All verbal or telephone orders for medication shall be received by an RN, LPN, CNM, physician, or registered pharmacist and shall be placed in writing into the patient's permanent medical record. The order shall include the name of the prescribing physician or CNM, accompanied by the time, date, name, and title of the person making the entry into the record. All verbal or telephone orders shall be countersigned by the prescriber within 48 hours of the order.

(c) All treatments and medications provided to patients shall be recorded in the medical record by the nurse administering the treatment or medication. CPMs may not administer drugs and medicines to patients or handle drugs or medicines for administration to patients, other than anti-hemorrhagic medication and oxygen in an emergency.

(d) Preparation and administration of medications shall be under the supervision of a physician or CNM. Pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(e) The birthing center shall not dispense any medications to outpatients. The birthing center may procure medications for its patients from community pharmacists through contractual agreements with those pharmacies. Individual medication containers shall be properly stored in individual patient bins/trays within a lockable area, room or cabinet; or the birthing center may procure medications via the staff physician's or CNM's registration. Medical staff shall administer or order medications to be administered to patients solely while in the birthing center. Medications for patients to take home shall be provided only via written prescription by the attending physician or CNM.

(f) An individual qualified by licensure and experience to meet the requirements of subsections (d) and (g) of this section shall be responsible for the overall supervision of the handling, administration, storage, record-keeping, and final disposition of medications and controlled substances stocked within the birthing center.

(g) Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the Alabama State Board of Medical Examiners, the Alabama State Board of Pharmacy, and the Alabama Board of Nursing.

(3) Medical Storage.

(a) Medicines and drugs maintained in the birthing center shall be stored in a drug room of sufficient size for orderly storage and accurate identification. The room shall be adequately illuminated and maintained at a temperature for safe storage of drugs.

(b) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable federal and state laws.

(c) Only authorized personnel shall have access to the drug/ medicine room, as defined by the birthing center.

(d) The drug/medicine room shall be provided with a counter and sink.

(4) Emergency Kit. The birthing center, upon the written advice and written approval of its staff physician or consultant physician, shall provide an emergency kit or stock supply of drugs and medicines for the exclusive use of the physician or CNM in treating the emergency needs of patients.
Author: Dana Billingsley, Diane Milledge
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420-5-13-.16 Laboratory Services.

(1) The birthing center may provide a clinical laboratory or make contractual arrangements with a certified laboratory to perform services commensurate with the needs of the birthing center and the laboratory's level of certification.

(a) Outside Laboratory.

1. Qualifications. An approved outside laboratory may be a state licensed hospital laboratory or state licensed independent clinical laboratory and must have all necessary current federal CLIA numbers and waivers.

2. A contractual arrangement shall be deemed as meeting the requirements of this rule so long as the arrangement includes written policies, procedures, and individual chart documentation evidencing that the policies of the birthing center are met and the needs of the patients are being provided, including the processing of specimens and reporting of test results to the birthing center on a 24/7 basis, as the demands of labor and delivery require.

(b) In-House Laboratory.

1. In-house laboratory services shall be licensed by the state as required and have all necessary federal CLIA certificates and waivers. The laboratory shall be under the direction and supervision of an individual meeting the qualifications set forth in the Department's Rules and Regulations for Independent Clinical Laboratories and CLIA regulations, based on the level of laboratory testing performed.

2. The laboratory must be of sufficient size and adequately equipped to perform the necessary services of the birthing center.

3. Provisions shall be made for a preventive maintenance and an acceptable quality control program covering all types of analyses performed by the laboratory. Documentation must be maintained for both programs.

4. Written policies and procedures shall be developed and approved for all services provided by the laboratory.

5. Documentation of patient laboratory values shall be recorded on appropriate laboratory report forms and duplicate copies of these reports retained for a minimum of2 years in the laboratory. A record must be maintained to reflect the apparent condition of the specimen collected, time and date collected, and name of the patient. All personnel collecting specimens shall be adequately and appropriately trained and, where otherwise required by law shall be licensed, and their personnel files shall reflect such training and licensure.

6. Contractual arrangements for referral laboratory testing shall be made in accordance with subsection (l) (a) above for laboratory testing procedures not provided by the in house laboratory.

7. If medical laboratory technologists are employed on the staff of the birthing center, such technologists must meet one of the following requirements.

(i) Successful completion of2 years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university, with an associate degree as a medical laboratory technologist; or

(ii) Graduation from high school, and subsequent to graduation, 2 years of documented, hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health; or

(iii) Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study, with at least 1 year of hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory

providing equivalent hands-on training accepted by the Alabama Department of Public Health.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.17 Physical Environment.

(1) Safety. The governing authority shall develop written policies and procedures designed to safeguard patients, staff, and visitors while in the birthing center and on its grounds. The policies and procedures shall include the following:

(a) Safety rules and practices pertaining to personnel, equipment, liquids, and drugs, with particular attention to hazards of children, such as uncovered electrical outlets, unsafe toys, unprotected stairs, and unlocked storage cabinets, as well as walkways, parking lots, and outside play areas.

(b) Provisions for reporting and investigation of accidental events regarding patients, visitors, and personnel (incidents), and corrective actions taken.

(c) Provision for dissemination of safety-related information to employees and users of the facility.

(d) Provision for syringe and needle storage, handling, and disposal.

(e) Provide a security alarm and camera service to ensure controlled/limited access to the facility; activate protocols to screen family members and visitors; restrict public entry to the birthing center during certain hours and all general access to patient areas; provide panic buttons for staff and alarm bracelets for mothers and infants; and develop Code Pink plans to be approved by the Department.

(2) Housekeeping/Sanitation. The birthing center shall provide a safe and sanitary environment, properly constructed and maintained to protect the health of patients.

(a) The birthing center shall be maintained in a clean condition and have written policies and procedures for housekeeping and sanitation. The birthing rooms shall be appropriately cleaned after each birth, using appropriate disinfectants to assure asepsis between each use, as approved by the Infection Control Committee.

(b) The premises and equipment shall be kept clean and free of insects, rodents, litter, and rubbish.

(c) There shall be strict adherence to regulations of OSHA for handling of medical waste, regulations of the Alabama Department of Environmental Management (ADEM), and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to, disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers).

(d) Adequate arrangements for housekeeping staff shall be made, or housekeeping staff shall be employed to fulfill the above requirements. Primary patient care personnel shall not perform routine decontamination and housekeeping duties during periods in which they are caring for patients.

(3) Linen and Laundry.

(a) An adequate supply of clean linen or disposable materials shall be available at all times for the proper care and comfort of patients.

(b) Provisions for proper laundering oflinen and washable goods shall be made. Linens used for draping must be sterilized. All reusable linens, including those used as sterilizing wrappers, must be laundered before reuse. Linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection. Soiled and clean linen must be handled and stored separately.

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

(4) Disaster Preparedness.

(a) The birthing center shall have a posted plan for evacuation of patients, staff, and visitors in case of fire, severe weather, natural disasters or other emergencies, or threats to the personal safety of patients or staff.

(b) Disaster Drills.

1. At least one fire or emergency drill shall be held every 3 months to familiarize employees with the drill procedure. Reports of the drills shall be maintained with records of attendance.

2. Records shall show that action has been taken to correct any identified problems with fire drills.

(c) The birthing center shall develop a plan or methods to communicate with patients in the event of a disaster-related temporary closure of the facility. The birthing center shall advise the Department in writing of any such closure within 24 hours thereof.

(5) Infection Control.

(a) An Infection Control Committee, or comparable group, comprised of the staff physician or consultant physician and members of the nurse-midwifery staff, nursing staff, administration, and other services of the birthing center, shall be established and shall be responsible for investigating, controlling, and preventing infections in the birthing center. The Infection Control Committee shall meet quarterly and maintain written documentation and an attendance roster for all such meetings.

(b) There shall be written procedures to govern the use of aseptic techniques and procedures in all areas of the birthing center.

(c) To keep infections at a minimum, such procedures and techniques shall be reviewed on an annual basis by the Infection Control Committee.

(d) Continuing education shall be provided on an annual basis to all birthing center personnel on the causes, effects, transmission, prevention, and elimination of infection.

(e) Reports of infections observed during any follow-up or return visit of the patient shall be made and kept as a part of the patient's medical record. The birthing center shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least once quarterly by the birthing center's staff physician or consultant physician.

(f) Efforts shall be made to determine the origin of any infection, and if the birthing process was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

1. In the event of sustained numbers of infections (three or more patients in 1 week), the Department shall be immediately notified. Upon order of the Department, operation of the birthing center shall be discontinued until approval for continuation of operation is granted by the Department.

2. If the birthing center wishes to contest such closure, the Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedure Act. Such hearing shall be held not more than 2 working days after notice of appeal is given to the Department, unless the birthing center agrees otherwise. The birthing center shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, in accordance with state law.

(g) Written policies and procedures shall be developed to ensure that employees with any communicable disease in an infectious stage shall not be on duty in the birthing center.

(h) Call Records. In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the RN, CNM, CPM, or physician. The call record should include the patient's name, time and date of call, a brief description of the reason for the call, date of the procedure, location of any emergency department the patient is presenting to, if known and applicable, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient's medical record.

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420-5-13-.18 Service Facilities, Equipment And Supplies.

(1) The birthing center shall establish and maintain a safe environment for healthy women anticipating an uncomplicated labor and birth, with adequate space for furnishings, equipment, and supplies necessary to ensure comfortable and private accommodations for the mother and family, and adequate space for personnel, including but not limited to:

(a) Admissions Office. There shall be a room designated as the admissions office, where patients may discuss personal matters in private. The admissions office may be combined with the business office and medical record room if privacy can be maintained when confidential matters are being discussed. This space shall be separated from the treatment area by walls.

(b) Business Office. This space shall be adequate for the number of birthing center personnel.

(c) Reception and Waiting Area. A waiting room shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time. Public toilets, telephones, and drinking fountains, accessible to the handicapped, shall be available.

(d) Staff/Employee Locker Rooms and Toilets. The birthing center shall provide male and female toilet and locker rooms, which are centrally located.

(e) Family Room and Play Area for Children. The size and number of family rooms shall be adequate for the patient caseload. A couch, chairs, end table, reading lights, and toy storage area shall be included. Sufficient precautions for child safety shall be observed. Depending on the size of the caseload, the family area may double as a conference room and/or classroom. Toilet facilities shall be available.

(f) Conference/Educational Facilities/Library Area. These areas may be one room or separate rooms; however, each area shall be of sufficient size for the number of personnel in the birthing center and the patient caseload. The conference area may be used for childbirth classes, staff inservice education, meetings, etc.

(g) Clean Utility. A clean workroom for storage and assembly of supplies shall contain storage cabinets or storage carts, a work counter, and a sink.

(h) Soiled Utility. The soiled utility room shall contain a deep sink, work counter, waste receptacle, and soiled linen receptacle.

(i) Medicine Room. The medicine room shall include a sink, small refrigerator, locked storage, narcotic locker, and work counter. The medicine area may be combined with the clean utility room.

(j) Clean Linen Storage. The clean linen storage shall contain a closet large enough to hold an adequate supply of clean linen. This can be combined with the clean utility room.

(k) Kitchen Facilities. The kitchen/nourishment centers shall have sufficient storage for patients' prepared food and beverages. A centralized kitchen/nourishment center may be shared or individual nourishment centers may be present in each birthing room.

(l) Janitor's closet.

(m) Laundry. A laundry room with a residential washer and dryer shall be provided if an outside laundry contract is not used.

(n) Laboratory. The laboratory area shall contain a counter, sink, and storage area for supplies.

(o) Emergency cart storage.

(p) Examination Rooms. The number of examination rooms shall be adequate for the patient caseload. When used for prenatal care, the examination rooms shall be situated away from the birthing rooms. Each examination room shall contain at least I 00 square feet. At least one examination room shall be provided for admission evaluation, containing an examining table with stirrups, stool, goose neck light, equipment table, sink, and supply storage area.

(q) Central Sterile Supply. Written policies and procedures shall be maintained for the sterilization of supplies and water and reprocessing of sterile supplies at specific time periods. The following areas shall be separated:

1. The receiving and clean-up area shall include a two-compartment sink with two drainboards.

2. The area for instrument pack assembly shall have a sterilizer or approved alternate source of sterilization, work counter, and a lavatory or sink. A sterile storage area shall also be provided.

3. When sterilization services are provided via contract outside of the birthing center, there shall be a separately designated area in the facility for dirty, clean, and sterile supplies.

(r) Birthing Rooms.

1. Birthing rooms shall have sufficient space for a double bed, cradle, nightstand, rocking chair, cabinet for supplies, and a sink, with a minimum of 120 square feet. A counter area for infant resuscitation should be lighted in such a manner as to provide at least l00 foot candles at the infant's body surface, and should include an overhead source of radiant heat, a heating pad overlying a thin mattress on which the neonate is placed, and a large wall clock with a clearly visible second hand.

2. Ceiling height of the birthing rooms shall be a minimum of 8 feet.

3. Each birthing room will have immediate access to a bathroom. Tubs are recommended.

4. Birthing rooms shall be designed to provide privacy for the mother and family.

5. All walls and floors shall be suitable for washing.

6. A nurse call outlet or emergency call system shall exist with control switches in all birthing rooms that can be activated during an emergency.

7. Portable oxygen and suction shall be available. All outlets shall be grounded.

(2) Equipment.

(a) The birthing center shall have properly maintained equipment for routine care of women and neonates, including, but not limited to:

1. A readiant heat source for newborn examination.

2. Transfer incubator or isolete.

3. Sterilizer or an approved alternate source of sterilization.

4. Blood pressure equipment, thermometers, fetoscope/ doptone.

5. Intravenous equipment.

6. Oxygen equipment for mother and newborn.

7. Instruments for delivery, episiotomy, and repair.

(b) Testing and Diagnostic Equipment. All testing and diagnostic equipment, including equipment that is readily available to perform ongoing assessments of the mother and fetus/infant, shall be maintained in good working order at all times and tested on a routine basis.

1. If equipment is obsolete or permanently unusable because of irreparable damage, malfunction, or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible.

2. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be

returned to use until repaired and tested to ensure proper operation.

(c) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the birthing center integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment and shall be retained by the birthing center for a minimum of 2 years:

1. Ultrasound. All ultrasound machines must be tested and calibrated by a trained, qualified technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually.

2. Autoclave. All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged.

3. A readily accessible emergency cart or tray for the mother shall be equipped to carry out the birthing center's written emergency procedures. A written log of routine equipment maintenance shall be maintained for the emergency cart. The emergency cart or tray for the mother shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, intravenous equipment, an automatic external defibrillator (AED), blood expanders, and postpartum hemorrhagic equipment.

4. A readily accessible emergency cart or tray for the newborn shall be equipped to carry out the birthing center's written emergency procedures and shall be securely placed with a written log of routine maintenance. The emergency cart or tray for the newborn shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, and intravenous equipment and shall be available in each birthing room.

(d) The birthing center must maintain a record for all equipment containing the following information:

1. Manufacturer, make, and model of the equipment.

2. Date of purchase.

3. Any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service.

4. Date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by medical staff.

5. Names and qualifications of the company and technician performing the tests, maintenance, or repairs.

6. Results of any tests, maintenance, or repairs.

7. All manufacturer literature and information. Any missing information shall be noted in the equipment record, and if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.

(e) The birthing center shall have properly maintained accessory equipment, which incudes, but is not limited to:

1. A conveniently placed telephone and emergency call system.

2. Portable lighting, including an emergency light source.

3. Kitchen equipment usually found in home for light refreshment.

4. Laundry area for residential washer and dryer if an outside laundry contract ids not used.

(3) Supplies.

(a) The inventory of supplies shall be sufficient to care for the number of childbearing women and families registered for care.

(b) Shelf life of all medications and intravenous fluids shall be monitored. Medications and supplies which have

deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. The birthing center shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The birthing center shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for removal.

Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.19 Physical Plant.

(1) General.

(a) Location. The birthing center shall be in a location that is free from undue noise, smoke, dust, or foul odors and shall have sufficient parking spaces to accommodate patients and their families.

(b) Local Requirements. The birthing center shall comply with all local zoning, building, and fire ordinances. A birthing center may not be operated in a private residence.

(c) Accessibility. The birthing center shall be located on streets or roads which can be kept passable at all times.

(d) Communication. The birthing center shall have telephones to summon help in case of fire or other emergency.

(e) Occupancy. No part of the birthing center may be rented, leased, or used for any commercial purpose or for any purpose not necessary or in conjunction with the operation of the birthing center. Food and drink machines may be maintained or a diet kitchen provided for prepared foods.

(2) Submission of Plans and Specifications.

(a) Scope. A facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy and shall comply with the codes and standards adopted by the State Board of Health and in effect at the time of plan submission, including, but not limited to, the

specific requirements for freestanding birth centers set forth in the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, applicable Life Safety Codes, and the National Fire Protection Association (NFPA) International Building Code (IBC).

(b) New Construction, Additions, and Major Alterations. When construction is contemplated for new buildings, conversions, or additions to existing buildings coming within the scope of these rules, plans and specifications shall be submitted for review by the Department in accordance with Alabama Administrative Code Rule 420-5-22, "Submission of Plans and Specifications for Health Care Facilities)".

(c) Minor Alterations and Remodeling. Minor alterations and remodeling which do not affect the structural integrity of the building, change functional operation, affect fire safety, and add services to those for which the birthing center is licensed need not be submitted for review.

(d) Water Supply, Plumbing, and Drainage. No system of water supply, plumbing, sewage, garbage, or refuse disposal shall be installed, nor shall any such existing system be materially altered or extended until complete plans and specifications for the installation, alteration, or extension have been submitted to the Department for review.

(e) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation or progress.

(3) Building Requirements.

(a) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(b) Temperature to be Maintained. The mechanical system shall be capable of maintaining a temperature of 70° F to 75° F throughout the birthing center.

(c) Lighting. There shall be general lighting and provision for adequate examination lights in the birthing room.

(d) Screens. All screen doors and non-stationary windows (except in air-conditioned areas) shall be equipped with tight fitting, full length 16 mesh screens. Screen doors shall swing out and shall be equipped with self-closing devices.

(e) Emergency Lighting System. Emergency lighting systems shall be provided to adequately light corridors, exit signs,

stairways, and lights at the exterior of each exit in case of electrical power failure.

(f) Emergency Power. An emergency generator shall be provided to operate the emergency lighting system and make life sustaining equipment operable in case of power failure. Emergency outlets shall be provided in all patient care areas.

(g) Floors. All floors in birthing rooms shall be smooth resilient tile, free from cracks, and finished for easy cleaning. All other floors shall be covered with hard tile, resilient tile, carpet, or the equivalent. Carpeting is prohibited as a floor covering in birthing rooms.

(h) Interior Finish and Decorative Materials. All combustible decorative and acoustical material, to include wall paneling, shall be as follows:

1. Materials on wall and ceiling in corridors and rooms occupied by four or more persons shall carry a flame spread rating of 25 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

2. Rooms occupied by less than four persons shal1 have a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

(i) Ramps. Ramps shall not be steeper than 1 foot of rise in 12 feet of run, shall be finished with a nonslip surface, and shall be provided with handrails on both sides. Exterior ramps, where installed, shall be provided with handrails on open sides.

(j) Doors.

1. The minimum width of doors to all rooms needing access for stretchers shall be 3 feet 8 inches.

2. Hardware on all toilet and bathroom doors shall be operable from outside the room.

3. Birthing doors shall not be equipped with hardware that will permit a patient to lock herself within the room.

(k) Floor Levels. All differences in floor levels or step-downs within the building shall be accomplished by stairs of not less than three 6-inch risers or ramps and shall be equipped with handrails on both sides.

(l) Ventilation. The building shall be well ventilated at all times. Birthing rooms shall be ventilated in such a manner as to supply fresh air and to prevent accumulation of

objectionable odors. Kitchens, laundries, service rooms, toilets, bathrooms, and all inside rooms shall be ventilated by louvers, wall vents, or undercut in doors and by windows, gravity vents, or mechanical means so as to prevent offensive odors from entering other parts of the building.

(m) Fire Extinguisher. An all purpose fire extinguisher shall be provided at each exit and special hazard area and located so a person would not have to travel more than 75 feet to reach an extinguisher. Fire extinguishers shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected at least annually. An attached tag shall bear the initials or name of the inspector and the date inspected.

(n) Elevators. Multi-story facilities shall be equipped with at least one automatic elevator of a size sufficient to carry a patient on a stretcher.

(o) Multi-Story Buildings. All multi-story buildings shall be of fire resistive construction in accordance with NFPA 220, Standard Types of Building Construction.

(p) Exits. Each floor of a facility shall have two or more exit ways remote from each other, leading directly to the outside or to a 2-hour fire resistive passage to the outside. Exits shall be so located that the maximum distance from any point in a floor area, room, or space to an exit doorway shall not exceed 100 feet, except that when a sprinkler system is installed, the distance of travel shall not exceed 150 feet.

(q) Exit Door. Exit doors shall meet the following criteria:

1. Shall be no less than 44 inches wide.

2. Shall swing in the direction of the exit and shall not obstruct the travel along any required fire exit route.

3. One exit door shall be easily accessible to ambulances in the event of an emergency transport.

(r) Exit Signs. Exits shall be equipped with approved illuminated signs bearing the word "Exit" in letters at least 4 1/2 inches high. Exit signs shall be placed in corridors and passageways to indicate the direction of exit.

(s) Carpet. All carpet or pad shall carry a flame spread rating of 75 or less or a radiant flux greater than 0.45 watts per square centimeter and a smoke density rating of 450 or less.

(t) Curtains. All draperies shall be rendered and maintained flame retardant.

(u) Handicapped Facilities. The facility shall be accessible to the physically handicapped and shall comply with ANSI 117.1, "Making Buildings and Facilities Accessible and Useable by the Physically Handicapped."

(v) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization, removal, or by a combination of these techniques. Infectious waste materials shall be rendered noninfectious on the premises by appropriate measures.

(w) Corridors. Corridors shall comply with the following:

1. All rooms shall open onto a corridor leading to an exit.

2. Corridors used by patients shall be a minimum of 6 feet wide.

3. Service corridors may be a minimum of 4 feet wide.

(x) Water Temperature. Water temperature shall be as follows:

1. Hot water at handwashing facilities shall not exceed 120° F.

2. Hot water at bathing facilities shall not exceed 110° F.

Author: Dana Billingsley, Diane Milledge
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420-5-13-AA **Appendix A (Repealed 5/21/10).**
Author:
Statutory Authority:
History:

420-5-13-AB **Appendix B (Repealed 5/21/10).**

CODE OF ALA. 1975, SECTIONS 22-21-20, ET SEQ.
Author:
Statutory Authority:
History: