

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

CHAPTER 420-5-13
BIRTHING CENTERS

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 annually 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 of 24 hours. Exceptional circumstances justifying a stay in excess of 24 hours are set forth in Ala. Admin. Code. 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 (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. 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 10 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

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