

CHAPTER 616. BIRTHING CENTERS REGULATIONS

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[Authority: 63 O.S. Supp. 1991, § 1-701 as amended in 1991]

[Source: Codified 6-11-92]

SUBCHAPTER 1. GENERAL PROVISIONS

Section

310:616-1-1. Purpose

310:616-1-2. Definitions

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-1-1. Purpose

This Chapter establishes the minimum criteria for the issuance and renewal of a birthing center license and the procedures for enforcement thereto.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-1-2. Definitions

The words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise. **"Administrator"** means a person acting in authority and who is responsible for all events and day-to-day operations of the birthing center.

"Applicant" means a person, firm, corporation, organization or association applying for a license to operate a birthing center. **"Birthing center"** means a freestanding facility, place or institution, which is maintained or established primarily for the purpose of providing services of a certified midwife or licensed physician to assist or attend a woman in delivery and birth, and where a woman is scheduled in advance to give birth following a normal, uncomplicated, low-risk pregnancy.

"Birth room" means a home-like room where births are planned to occur with the availability of emergency equipment.

"Board" means the State Board of Health.

"Department" means the Oklahoma State Department of Health.

"License" means a document issued by the Department and renewable annually, provided the institution complies with all requirements of these regulations and the assessed fee.

"Licensed birth attendant" means a doctor of medicine or

osteopathy or a certified nurse-midwife (CNM) licensed in the state of Oklahoma.

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

"Medical director" means a doctor of medicine or osteopathy who is licensed pursuant to the laws of this state with no restrictive sanctions and is commissioned by the birthing center to consult and advise on the medical component of the patient care program of the birthing center.

"Midwife" means a person educated in the discipline of nursing and midwifery, certified by the American College of Nurse-Midwives (ACNM) and licensed by the state to engage in the practice of midwifery and as a registered nurse.

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

"Referral hospital" means a hospital identified by the birthing center to receive mothers and/or infants who are not low risk.

"Transfer agreement" means a formally adopted mutual agreement between the birthing center, a suitable emergency transport system, and a hospital which provides obstetrical services and is located within a thirty minute travel distance.

"The Hospital Licensure Act" also known as **"the Act"** means Title 63 of the Oklahoma Statutes, sections 1-701 through 1-709 inclusive, as amended.

[**Source:** Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

SUBCHAPTER 3. ADMINISTRATION

Section

- 310:616-3-1. Licensure
- 310:616-3-2. Organization
- 310:616-3-3. Reports and records
- 310:616-3-4. Confidentiality

[**Source:** Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-3-1. Licensure

(a) **Applicant.** Any individual, public or private organization desiring to establish a birthing center may apply and obtain a license from the Department. A license is not mandatory to operate a birthing center.

(b) **Application.** The application for a birthing center license shall be filed on a form prescribed by the Department.

(c) **Expiration/renewal.** The birthing center license shall expire one year from the date of issue, unless suspended or revoked. An application for renewal shall be submitted

according to the act.

(d) **Conditions for licensure.**

- (1) The license is valid only for the location indicated on the license.
- (2) The license is not transferable or assignable.
- (3) The Department shall be notified within thirty days of change of administrator.
- (4) The Department shall be notified within thirty days of change in business name and/or address.
- (5) The Department shall be notified in writing when the center closes and the administrator shall return the license to the Department.
- (6) A licensed birth attendant shall be available twenty-four hours a day.
- (7) A transfer agreement shall be in place between the birthing center and a hospital which has obstetrical services where the medical director has obstetrical admitting privileges. The hospital shall be located not more than 30 minutes from the birthing center.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-3-2. Organization

(a) **Policies and procedures.** Each birthing center which falls within the purview of these regulations shall develop and maintain operational policy and procedures which describe the functions, staffing, services available to the patient and other basic information relating to the fulfillment of the facility's objectives.

(b) **Governing body.** A birthing center shall have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the total operations of the center. The governing body must also ensure that all services provided are consistent with accepted standards of practice, including contract services.

(c) **Personnel requirements.** Policies shall be developed concerning the following and placed in personnel records:

- (1) Job descriptions for all personnel.
- (2) A requirement for orientation of all employees.
- (3) Inservice education.
- (4) Evidence that all birth attendants are currently certified by the American Heart Association or the American Red Cross in infant and adult cardiopulmonary resuscitation.
- (5) Verification that all staff meet state licensure requirements.
- (6) Certification of the midwife by the American College of Nurse-Midwives (ACNM), and a certificate of recognition from the Oklahoma Board of Nursing permitting the use of the title of Certified Nurse-Midwife (CNM).

(d) **Food service**

- (1) Birthing centers with three or fewer birth rooms which provide meals to patients shall use one of the following methods:

- (A) Food catered from a licensed food service using vendor's utensils.
- (B) Prepackaged complete meals or snacks.
- (C) For meals prepared on the premises:
 - (i) Kitchen shall be equipped for sanitary preparation of food and snacks.
 - (ii) There shall be a sink to wash, sanitize and air dry dishes or there shall be a mechanical dishwasher.
 - (iii) Mechanical refrigeration shall be provided.
- (2) Birthing centers with four or more birth rooms which provide meals to patients shall comply with the requirements for food services in Chapter 665 of this Title.
- (3) Commercially prepared food products may be brought to the birth center by the family for patient use.
- (4) Prepackaged disposable formula units shall be used for other than breast feeding for infants.
- (e) **Medical director.** The medical director shall be a doctor of medicine or osteopathy licensed to practice in the state of Oklahoma, free of restrictive sanctions and shall assume overall responsibility for the medical component of the patient care program of the center.
[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-3-3. Reports and records

- (a) **Reports.** Reports shall be made by the birthing center to the appropriate agency, including but not limited to the following:
 - (1) Communicable diseases.
 - (2) Births and deaths.
 - (3) Periodic reports to the Department on forms supplied for this purpose.
 - (4) Newborn hearing screening report.
 - (5) Newborn metabolic screening.
 - (6) Birth defects.
- (b) **Retention and preservation of records.**
 - (1) **State retention requirements.** Medical records will be retained a minimum of five years beyond the date the patient was last seen or a minimum of three years beyond the date of the patient's death.
 - (2) **Preservation of records.** Birthing centers generating medical records may microfilm the medical records and destroy the original record in order to conserve space.
- (c) **Record of care.**
 - (1) The birthing center shall establish and maintain a medical record for each mother and infant receiving care and services. The record shall be complete, timely and accurately documented, and readily accessible.
 - (2) The medical record shall contain sufficient information to justify the diagnosis and treatment and warrant the services provided. Entries are made and signed by the person providing the services. The record shall include all care and services whether furnished directly or under

arrangement made by the center. Each record shall contain at least, but not limited to, the following:

- (A) Identification data.
- (B) Initial and subsequent assessments.
- (C) Record of prenatal care.
- (D) Medical history and physical exam.
- (E) Risk assessment.
- (F) Allergies and medication reactions.
- (G) A disclosure statement signed by the patient explaining the principles of midwifery, benefits, limitations, and risks available to them at the birthing center and describing the arrangements the center has with physicians and the referral hospitals.
- (H) Plan of care.
- (I) Laboratory reports.
- (J) X-Ray reports.
- (K) Intrapartum care.
- (L) Postpartum care.
- (M) Newborn care.
- (N) Patient's compliance to advice and/or treatment.
- (O) Discharge Summary.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-3-4. Confidentiality

(a) Medical records shall be kept confidential. Only authorized personnel shall have access to the record. Written consent of the patient, the court appointed guardian, or a court order must be presented as authority for release of medical information.

(b) Patient access to medical records. Any person who is or has been a patient of a physician, hospital, or other medical facility, except psychiatric, shall be entitled to access information contained in his/her medical records upon request.

Request for minors may be made by parents or legal guardian.

A copy of the medical record pertaining to his/her case shall be furnished upon tender of the expense of such copy or copies. The cost of each copy shall not exceed the statutory fee.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

SUBCHAPTER 5. MINIMUM STANDARDS

Section

- 310:616-5-1. Admission
- 310:616-5-2. Quality assurance
- 310:616-5-3. Life Safety Code
- 310:616-5-4. Construction

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-5-1. Admission

(a) Admission to the birthing center shall be limited to low risk, uncomplicated pregnancies, with an anticipated spontaneous vaginal delivery, which, determined by history of prenatal care and risk criteria, predicts a normal, uncomplicated birth. Regional or general anesthesia shall not be utilized in the birthing center.

(b) Each birthing center shall have sufficient space to accommodate participating family members and support personnel of the patient's choice and shall provide care for childbearing women during pregnancy, birth and puerperium with public service standards accessible to acute care obstetrical and newborn services.

(c) A woman who develops any condition that causes her to deviate from having a low-risk birth shall be referred and transferred to the appropriate referral hospital when the abnormal condition is recognized.

(d) Infants who are born with or develop problems following birth shall also be referred to the appropriate hospital or physician.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-5-2. Quality assurance

The birthing center shall have a quality assurance program to monitor and assure that all requirements are met, including but not limited to:

(1) **Sanitation.**

(A) A safe and sanitary environment shall be properly constructed, equipped and maintained according to established policies and procedures to protect the health and safety of the patient.

(B) An infection control program shall be developed which includes the utilization of universal precautions.

(C) Properly functioning equipment shall be available to sterilize instruments, equipment and supplies prior to use in the center using current standards and principles of sterilization in processing sterile supplies.

(D) All waste, including biomedical waste, shall be disposed of by a state approved method. Placentas shall not be placed in the trash or dumpster for disposal. Infectious or pathological waste shall be double-bagged in plastic bags not less than 1.5 mil thick each and conspicuously marked. Biomedical waste shall not be commingled with routine solid waste.

(2) **Emergency equipment.**

(A) Properly functioning emergency equipment shall include oxygen, respiratory support equipment including airways, manual breathing bag and mask and laryngoscope and endotracheal tubes for adults and infants.

(B) Emergency medications as specified by the medical director shall be maintained.

(3) **Evaluation of care.**

(A) Acceptable quality of care shall be provided to

patients both directly and under arrangements.

(B) The governing board shall annually review and revise, as needed, the birthing center's quality assurance program. Goals shall be established and problems identified with documented solutions.

(C) Policies and procedures shall be reviewed, revised as needed, and approved by the governing board, annually.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency);
Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-5-3. Life Safety Code

(a) This section establishes life safety requirements for free standing birthing centers that are permitted to operate twenty-four hours per day.

(b) Each floor occupied by patients shall have not less than two remote exits, one of which shall discharge directly to the outside.

(c) Travel distance to an exit shall be limited to 150 feet.

(d) Doors in means of egress shall be not less than thirty-four inches wide.

(e) Corridors and ways of exit shall be provided with emergency lighting. Emergency lights shall operate, without manual intervention, on failure of normal electric service with power supplied by battery packs or emergency generator.

(f) Construction standards shall be in accordance with applicable building codes for group use and occupancy. In locations where no building code exists, construction shall conform to the state adopted building code. New and existing buildings to be occupied by a birthing center may be of NFPA construction Type V-000, unprotected wood frame or any code complying residential construction type providing that fire and safety features are in practice. Buildings three stories in height shall be of at least one hour fire resistive construction. Plans of construction of a new building, addition to or major alterations of existing buildings, shall be submitted to the Department and the State Fire Marshall. All structures shall be equipped with an approved sprinkler system.

(g) Interior finishes in exit ways shall be class "A" (flame spread 0 - 25).

(h) A manual fire alarm interconnected with a corridor smoke detection system shall be installed with direct connection with the local fire department of a manned central station.

(i) Electrical wiring in new construction shall be in compliance with national electrical code N.F.P.A. #70. Major electrical appliances shall be grounded in accordance with manufacturers recommendations.

(j) The use of extension cords or temporary wiring is prohibited. (k) A floor plan of the building shall be posted in a conspicuous place showing the evacuation route of the exit ways.

(l) Fire drills shall be conducted quarterly and will be

documented.

(m) The birthing center shall have at least one fire extinguisher for each floor and one extinguisher for the kitchen area. The kitchen extinguisher shall be at least a five pound dry chemical or carbon dioxide type. All others shall be either a five pound ABC or two and one-half gallon pressurized water type.

(n) Emergency telephone numbers shall be posted at the telephone.

(o) Air conditioning, heating and ventilation equipment shall be installed and maintained in accordance with N.F.P.A. 90A.

(p) Corridors shall not be used as return air plenums.

(q) Air handling units in excess of 2500 cubic feet per minute (cfm) used for heat, exhaust and air conditioning systems, shall be controlled by all phases for the fire alarm system to cease air movement.

(r) The use of non-vented fuel burning space heaters and portable electric heaters are prohibited.

(s) All hot water heaters shall be equipped with temperature and pressure relief valves designed for relieving capacity.

(t) Combustion, exhaust and ventilation air shall be taken from and discharged directly to outside air.

(u) If parts of a birthing center, already in operation prior to the date a standard is issued, fail to meet a particular standard, compliance with the standard will be waived if patient care and safety are not deemed to be in jeopardy.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-5-4. Construction

(a) **Location.** The facility shall be serviced by all weather roads and available to private and emergency vehicles at all times.

(b) **Parking.** Parking shall be made available for patients, staff and visitors. (See Uniform Federal Accessibility Standards [UFAS] and American National Standards Institute Standard A117.1 [ANSI], American Standard Specification for Making Buildings and Facilities Accessible to and Useable by the Physically Handicapped).

(c) **Building plans and specifications.** Before the start of construction, plans and specifications covering the construction of new buildings or major alterations to existing buildings, shall be submitted to the Department for review and approval.

(d) **Staged submission.** Prepared plans and specifications shall be submitted in two stages.

(1) Stage one shall contain sufficient information to establish the scope of the project, project location, required fire safety and exiting criteria, building construction type, bed count and services, and assignment of all spaces for all floors.

(2) Stage two shall be the final drawings and

specifications. This submittal shall be complete and adequate for proposed contract purposes. All final plans and specifications shall be sealed and signed by an architect registered by the State of Oklahoma. All construction modifications of approved documents are subject to review and approval by the Department and shall be submitted as is timely.

(e) **Construction start.** Construction, other than minor alterations, shall not commence until the stage two plan-review has been approved.

(f) **Special submittal.** Fast-Tract projects must have prior approval and shall be submitted in a maximum of four separate packages:

- (1) Foundation, structural, underslab, mechanical, electrical and plumbing work, and related specifications.
- (2) Complete architectural plans and specifications.
- (3) All mechanical, electrical, and plumbing plans and specifications.
- (4) Equipment and furnishings.
- (5) Automatic sprinkler systems. A minimum of two sets of sprinkler system show drawings, specifications and calculations (if applicable) prepared by the installer, shall be submitted to the office of the State Fire Marshall for review and approval prior to the installation of the proposed system in the project.

(g) **Construction.** The completed construction shall be in compliance with the approved drawings and specifications, including all addenda or modifications to the project.

(h) **Final inspection.** A final inspection, prior to occupancy, will be scheduled for the purpose of verifying compliance with the licensing standards, plans and specifications.

[**Source:** Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

SUBCHAPTER 7. ENFORCEMENT

Section

- 310:616-7-1. Inspections
- 310:616-7-2. Complaints and investigations
- 310:616-7-3. Penalties
- 310:616-7-4. Appeals

[**Source:** Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-7-1. Inspections

(a) Any duly authorized representative of the Department shall have the right to conduct inspections as necessary in order to determine compliance with the provisions of the Act and this Chapter in force pursuant thereto.

(b) Inspections shall be conducted by authorized representatives of the Department at least annually, but more frequently if there is a reasonable basis

for such action. [Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-7-2. Complaints and investigations

(a) A complaint may be registered with the Department by any person who believes the birthing center is operating contrary to the Act or is posing a serious threat to the health and welfare of a patient in its care. The complaint may be registered verbally or in writing.

(b) An investigation will be conducted by the Department to determine the validity of the complaint and instigate necessary action applicable to the situation. The complainant will be notified, in writing, of the findings, if a name and address is furnished.

(c) If the Department determines there are reasonable grounds to believe the birthing center is operating in violation of the regulations, the Department shall follow the notice and hearing procedure established by the Act and as contained in the Procedure of the State Department of Health, Chapter 2 of this Title.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-7-3. Penalties

After notice and hearing pursuant to the Act, the Department may use any and all the remedies provided by the Act and by the general statutory authority of the Commissioner of Health.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]

310:616-7-4. Appeals

Final orders of the Department may be appealed to the District Court by any party directly affected or aggrieved by the order.

[Source: Added at 9 Ok Reg 1715, eff 4-23-92 (emergency); Added at 9 Ok Reg 1979, eff 6-11-92]