CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Services
(Amended After Comments)

902 KAR 20:150. Freestanding Birthing Centers.

RELATES TO: KRS 211.848, 214.155, KRS 216.530, 216B.010-216B.130, 216B.990(1), (2), 216B.198, KRS 304.5-070, 42 U.S.C. 299b-22(a)
STATUTORY AUTHORITY: KRS 216B.042, 216B.105, KRS 216B.198
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 mandate that the Kentucky Cabinet for Health and Family Services regulate health facilities and health services. This administrative regulation provides for the licensure requirements for the operation and services and facility specifications of freestanding birthing centers.

Section 1. Definitions.
(1) "Cabinet" means the Cabinet for Health and Family Services.
(2) "Freestanding birthing center" (FSBC) (center) is defined in KRS 216B.198.
(3) "Low risk" means a normal uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal uncomplicated birth including criteria recognized by the Commission for the Accreditation of Birth Centers (CABC).

Section 2. Scope of Operations and Services. Freestanding birthing centers are establishments with permanent facilities which provide prenatal care to low risk childbearing women. A freestanding birthing center provides a homelike environment for pregnancy and childbirth including labor, delivery, and may include prenatal and postpartum care related to medically uncomplicated pregnancies.

Section 3. Administration and Operation.
(1) Licensee.
(a) The licensee shall be responsible for the management and operation of the center and for compliance with federal, state and local laws and regulations pertaining to its operation.
(b) The licensee shall appoint an administrator whose qualifications, responsibilities, authority and accountability shall be defined in writing.
(c) .Each center shall be accredited and show proof of accreditation by the Commission for the Accreditation of Birth Centers.
(d) The center shall obtain and maintain professional medical malpractice insurance as defined in KRS 304.5-070.
(e) Requirement for Service. A center shall not be licensed or relicensed as a center unless the facility meets the requirements of this regulation.
(f) Facilities that have four (4) beds or fewer shall be exempt from Certificate of Need.
(g) Licensed facilities shall follow general licensure and fee regulations as laid out in 902 KAR 20:008.
(2) Administrator.
(a) The administrator shall be responsible for the daily management and operation of the center.
(b) In the absence of the administrator, responsibility shall be delegated to a similarly qualified staff person.
(3) Administrative records and reports.
(a) Administrative reports shall be established, maintained and utilized as necessary to guide the operation, measure productivity and reflect the program of the center. Such

reports shall include financial records and reports, personnel records, inspection reports and other pertinent reports made in the regular course of business.

(b) Licensure inspection reports and plans of correction shall be made available at the center to the public upon request.

(4) Policies.

(a) Administrative policies. The licensee shall adopt written administrative policies covering all aspects of the center's operation, to include:

1. A description of the organizational structure, staffing and allocation of responsibility and accountability;

2. A description of referral linkages with physician(s), inpatient facilities and other providers;

3. Policies and procedures for the guidance and control of personnel performances;

4. A description of services included in the center's program;

5. A description of the administrative and patient care records and reports;

6. A policy approved by the medical director to specify emergency medical procedures;

7. A policy approved by the medical director which fully identifies the criteria which would exclude a patient from the center's program;

8. A policy approved by the medical director which fully identifies the criteria which would preclude management of newborns at the center.

(b) Patients' rights policies. The licensee shall adopt written policies regarding the rights and responsibilities of patients. These patients' rights policies shall assure that each patient:

1. Is informed of these rights and of all rules and regulations governing patient conduct and responsibilities including a procedure for handling patient grievances;

2. Is fully informed of the services and treatment offered at the center and of related charges, separately identifying those charges not covered by third party payor arrangements;

3. Is encouraged and assisted to understand and exercise her patient rights and to this end may voice grievances and recommend changes in policies and services. Upon the patient's request the grievances and recommendations will be conveyed within a reasonable time to an appropriate decision making level within the organization which has the authority to take corrective action;

4. Is assured confidential treatment of her records and afforded the opportunity to approve or refuse their release to any individual not involved in her care except as required by law or third party payment contract;

5. Is treated with consideration, respect and full recognition of her dignity and individuality including privacy in treatment.

(5) Staffing.

(a) The center shall have a staff that includes a medical director and;

(b) At least one (1) Licensed Certified Professional Midwife (LCPM) or Advanced Practice Registered Nurse designated certified nurse -midwife licensed under KRS 314; and;

(c) Two people trained in Neonatal Resuscitation Program (NRP), which shall include two nurse midwives or a midwife and a NRP trained birth assistant. The center shall employ such other staff or ancillary personnel that are necessary to provide the services essential to the center's operation. Staffing schedules, time worked schedules and on-call records shall be maintained and available in the center at all times. These records shall be maintained for three (3) years.

1. Medical director. The center shall have a medical director who is a licensed physician. The medical director position shall:

a. Not be vacant for a time period in excess of ninety (90) days; and

b. If the birth center can document that it has been making a good faith attempt to fill the medical director vacancy, an extension may be given to the facility by the Inspector General on a case by case basis.

c. Meet statutory requirements delineated in KRS 216B.198(3)(a).

d. In the interim absence of a medical director, a Certified Nurse Midwife (APRN CNM) licensed by KRS 314.042 and within their scope of practice may temporarily fulfill the duties of the medical director.

2. Licensed Certified Professional Midwife (LCPM) or Advanced Practice Registered Nurse designated certified nurse midwife (APRN CNM) -.Midwife services shall be provided within the respective scope of practice pursuant to KRS Chapter 314 and administrative regulations promulgated thereunder. There shall be written protocols developed by the medical director and licensed midwives and approved by the medical director. These protocols shall be reviewed annually and revised, signed and dated as necessary.

(6) In-service training. The licensee shall provide proof of ongoing in-service training programs required by their respective professional licensure boards .

(7) Personnel.

(a) The licensee shall establish personnel policies for the center. These policies shall be reviewed, revised and approved on an annual basis.

(b) There shall be an individual personnel record for each person employed by the center which shall include the following:

1. Evidence of compliance with 902 KAR 20:205.

2. Evidence of education, training and experience of the individual along with a copy of the current license or certification credentials if applicable; and

3. Evidence that employees have received orientation to the center's personnel policies and emergency medical procedures during the first week of employment.

(8) Medical records. The center shall maintain a medical record for pregnant women and mothers to include at least the following:

(a) Prenatal history to include any physical or health problems;

(b) Past medical, menstrual, obstetric, contraceptive and immunization history including progress of current pregnancy;

(c) Complete initial physical examination including blood pressure, weight, height, examination of skin, eyes, teeth, throat, neck, thyroid, breasts, heart, lungs, abdomen, height of fundus, fetal position and auscultation, fetal heart sounds, edema, and determination of gestational age;

(d) Initial laboratory tests to include hemoglobin or hematocrit and white blood count, serologic tests for syphilis and rubella antibody titer, blood type, Rh factors and screen for Rh and irregular antibodies, and gonorrhea culture;

(e) Nutritional assessment;

(f) High risk identification and referral;

(g) Records of subsequent visits with recorded weight, blood pressure, height of fundus, abdominal findings on palpation; rate and location of fetal heart tones, estimation of gestational age, edema, unusual signs, symptoms or quickening, follow-up hemoglobin or hematocrit, Rh and irregular antibody screen for Rh negative unsensitized women;

(h) Physical examination, temperature, pulse, respiration, blood pressure, and presentation position, and engagement recording of time of ruptured membranes;

(i) Progress of labor, monitoring of contractions and fetal heart rate, dilation, effacement, station, urinary output, medications, complications and action taken;

(j) Delivery time, newborn's Apgar score, laceration, placenta delivery time, medications given, abnormalities, and any complications along with actions taken;

(k) Puerperium-time records including postpartum blood pressure, respirations, pulse, temperature, urine output, breastfeeding status, appropriate RhD immune globin administration at the center; record of follow-up assessment within seventy-two (72) hours; and

(l) A four (4) to six (6) week follow-up examination to include record of weight, blood pressure, breast, abdominal, appropriate cervico vaginal cytologic study.

(9) A health report of the newborn shall be maintained and include the following:

(a) Duration of ruptured membranes;

(b) Maternal antenatal blood serology, rubella titer, blood type, Rh factors and when indicated, a Coombs Test;

(c) Description of the progress of labor and delivery (including complications, if any);

(d) Condition of the newborn infant including the Apgar score, resuscitation, time of sustained respirations, (where indicated, details of physical abnormalities, pathological states observed and treatments given before transfer to higher level of care);

(e) Any abnormalities of placenta and cord vessels;

(f) Date and hour of birth, birth weight, sex, and period of gestation;

(g) Written verification of eye prophylaxis or documentation of refusal based on religious belief with parent signature;

(h) Report of initial physical examination including any abnormalities;

(i) Discharge-physical examination including weight, head circumference and body length unless previously recorded, recommendations and designation of responsible care provider for care upon discharge

(j) Progress notes describing feedings, voiding, stools passage, body temperature, medication administration; and

(k) Newborn screening in accordance with KRS 214.155 and 902 KAR 4:030 (documentation of parental refusal for religious reasons including parent signature in record), notations of abnormal respiratory rate, dyspnea, color, cyanosis, periodic pallor, lethargy, vomiting, condition of eyes, umbilical cord and other relevant factors as indicated by the condition of the newborn. If postnatal care is not provided at the FSBC, the FSBC must document the coordination of postnatal care with qualified staff. Postnatal care coordination is expected to be in place within 48 hours.

(10) Patient records of mother and newborn shall be maintained at the center for five (5) years or in case of a minor mother, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(11) An up-to-date register of all deliveries shall be maintained and contain the following information:

(a) Infant's full name, sex, date, time of birth and weight;

(b) Mother's full name, including maiden name, address, birthplace and age at time of this birth;

(c) Father's full name, birthplace, and age at time of this birth, if provided; and

(d) Full name of provider.

(12) A certificate of birth shall be filed in accordance with the provisions of KRS Chapter 213 and administrative regulations promulgated thereunder.

Section 4. Provision of Services.

(1) Medical services.Perinatal services shall be available twenty-four (24) hours a day, seven (7) days a week on an on-call basis.

(2) Staffing.

(a) A licensed midwife or physician and a member of the FSBC clinical staff shall be on duty at all times when a patient is laboring in the center. A registered nurse shall be present at all times when a patient is at the center. The registered nurse shall have at least one (1) year of perinatal experience.

(b) The center shall ensure that a mechanism is in place to receive calls twenty-four (24) hours a day, seven (7) days a week, in order to alert the on-call staff. Telephone numbers of emergency services and staff shall be posted by all telephones in large legible print.

(3) Radiology services. A signed and dated report of any radiology examination shall be entered into the patient's record.

(4) Drug distribution.

(a) There shall be a list approved by the medical director of all drugs and biologicals including intravenous solutions which are retained for use in the center.

(b) The list of drugs and biologicals shall include the identity of center staff authorized to administer the drugs, biologicals and intravenous solutions. Oxytocic drugs shall not be used to induce or augment labor.

(c) Drugs and biologicals shall be administered only by persons legally authorized.

(d) A medication shall only be administered by a:

1. Registered nurse;
2. Physician;
3. Physicians Assistant;
4. Advanced Practice Registered Nurse;
5. Licensed Practical Nurse under the supervision of a registered nurse; or
6. Licensed Certified Professional Midwife;

(e) Drugs and biologicals shall be stored in a locked cabinet and, when refrigeration is necessary, they shall be stored in a locked container in a refrigerator.

Section 5. Licensure Inspections.

(1) Except for a health facility subject to KRS 216.530, a licensure inspection may be unannounced.

(2)

(a) A representative of the Office of Inspector General shall have access to the health facility pursuant to KRS 216B.042(2).

(b) An applicant for licensure or a current licensee shall not deny access to a representative of the Office of Inspector General, after proper identification, to make an inspection for determining compliance with the requirements of each applicable administrative regulation for which the health facility or health service is licensed under 902 KAR Chapter 20 or 906 KAR Chapter 1.

(c)

1. Denial of access, including any effort to delay, interfere with, or obstruct an effort by a representative of the Office of Inspector General to enter the health facility or health service, or deny access to records relevant to the inspection, unless deemed confidential by 42 U.S.C. 299b-22(a), shall result in disciplinary action, including denial, revocation, modification, or suspension of the license of the health facility or health service.

2. Denial, revocation, modification, or suspension of a health facility's or health service's license shall be subject to appeal pursuant to KRS 216B.105.

(3) An inspection of a health facility or health service licensed under 902 KAR Chapter 20 or 906 KAR Chapter 1 shall comply as follows:

(a) The inspection shall be made at any time during the licensee's hours of operation;

(b) The inspection shall be limited to ensure compliance with the standards set forth in 902 KAR Chapter 20, 906 KAR Chapter 1, KRS Chapter 216, or KRS Chapter 216B; and

(c) The inspection of a health facility or health service based on a complaint or a follow-up visit shall not limit the scope of the inspection to the basis of the complaint or the implementation of a plan of correction.

Section 6. Compliance with Building Codes, Ordinances and Regulations.

(1) Nothing stated herein shall relieve the licensee from compliance with building codes, ordinances, and regulations which are enforced by city, county, or state jurisdiction.

(2) The following requirements shall apply where applicable and as adopted by the respective agency authority:

(a) Requirements for safety pursuant to 815 KAR 10:060, as amended;

(b) Requirements for plumbing pursuant to 815 KAR 20:010 through 191, as amended;

(c) Requirements for making buildings and facilities accessible to and usable by the physically handicapped pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(3) The facility shall be currently approved by the Fire Marshal's Office in accordance with the Life Safety Code before licensing or relicensure is granted by the licensing agency.

(4) All facilities shall receive any necessary approval from appropriate agencies prior to occupancy and licensure.

Section 7. Clinical Facilities.

(1) Examination room(s). At least one (1) examination room shall be provided. Each room shall have a minimum clear floor area of eighty (80) square feet excluding such other spaces as vestibule, toilet, closet, and work counter. Arrangement shall permit at least thirty (30) inches of clear space at each side and at the foot of examination table. A lavatory or sink with handwashing facility and counter or shelf space for writing shall be provided.

(2) Birthing room(s). There shall be at least two (2) birthing rooms each with a minimum clear floor area of 120 square feet exclusive of fixed and movable cabinets and shelves and with a minimum dimension of fifteen (15) feet.

(3) Each birthing room shall be equipped with the following:

(a) Adequate lighting, including a spotlight suitable for use during delivery;

(b) Resuscitation equipment for mother and infant;

(c) Oxygen with a selection of mask sizes;

(d) Suction equipment for mother and newborn;

(4) The service areas for the birthing room shall include:

(a) Proper sterilization equipment used for the sterilization of birth instruments;

(b) Adequate access to sinks for handwashing should be available;

(c) A clean holding room for storage and distribution of clean supply materials; and

(d) A soiled holding room as part of a system for the collection and disposal of soiled materials.

(5) Physical and sanitary environment.

(a) The condition of the physical plant and the overall center environment shall be maintained in such a manner that the safety and well being of patients, personnel and visitors are assured.

(b) A person or persons shall be designated as responsible for each of the following areas:

1. Plant maintenance;

2. Housekeeping; and

3. Laundry operations (if applicable).

(c) The center shall develop written infection control policies and procedures to minimize and control possibilities of infection which shall include:

1. The sterilization of supplies;

2. Policies for the protection of patients from employees who have a communicable disease; and

3. Infection control measures including birth room cleaning and waste disposal.

(d) The center building, equipment and surroundings shall be kept in a condition of good repair, neat, clean, free from all accumulations of dirt and rubbish, and free from foul, stale or musty odors.

1. Written housekeeping procedures shall be established for cleaning of all areas and copies shall be made available to personnel.

2. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe sanitary condition.

3. Hazardous cleaning solutions, compounds and substances shall be labeled, stored in proper containers and kept separate from other cleaning materials.

(e) The center shall have available at all times a quantity of linen essential to the proper care and comfort of patients.

1. Linens shall be handled, stored, and processed so as to control the spread of infection.

2. Clean linen and clothing shall be stored in clean, dry, dust-free areas designated exclusively for this purpose.

3. Soiled linen and clothing shall be placed in suitable bags or closed containers and stored in an area designated exclusively for this purpose.

(f) The center shall have an emergency source of lighting for exam, labor, and birthing room(s) to protect the health and safety of the pregnant woman or mother in the event the normal supply is interrupted.

(g) The center shall establish a written policy for the handling and disposal of waste materials. Any incinerator used shall be in compliance with 401 KAR 59:020 or 401 KAR 61:010, as applicable.

Section 8. Transfer and Transport Agreements.

(1) As required by KRS 216B.198, a center shall enter into a written agreement with a licensed hospital that provides obstetrics services and a local, Kentucky-licensed Class I ambulance service for the transport and treatment of a patient with unforeseen complications related to labor and delivery.

(2) Each written agreement shall be filed with the cabinet pursuant to KRS 216B.198 within ten (10) calendar days of finalization.

(3) A transfer agreement between the center and a licensed hospital shall:

(a) Be with a hospital located:

1. In the same or contiguous county as the facility; or

2. Within thirty (30) milesfrom the center;

(b) Be a legally binding contractual document;

(c) Be signed by individuals authorized to execute the agreement on behalf of the center and hospital, who shall certify they have such authority;

(d) Require transfer of a patient if deemed medically necessary by the physician attending to the patient;

(e) Identify responsibilities of the center in which the center shall, at a minimum:

1. At the time of transfer, provide the hospital with complete and accurate information regarding the patient being transferred to the hospital;

2. Notify the hospital of the impending transfer of a patient and receive confirmation of the availability of appropriate facilities, services, and staff necessary for the care of the patient;

3. At the time of transfer, provide the hospital with copies of relevant portions of the patient's clinical record;

4. Transfer with the patient, the patient's medical records, demographic information, insurance information, and other information deemed necessary or otherwise required by law to facilitate the provision of medical care when the patient arrives at the hospital; and

5. Arrange for the immediate transfer of the patient's personal effects, including a document listing of the effects; and

(f) Identify responsibilities of the hospital in which the hospital shall, at a minimum:

1. Provide prompt and appropriate evaluation and treatment of a patient transferred to the hospital pursuant to the transfer agreement;

2. Accept responsibility for the patient's care when the patient is received by the hospital;

3. Direct charges performed by the hospital to the patient or patient's third-party payer; and

4. Acknowledge receipt of the patient's personal effects in writing signed by an authorized representative of the hospital and deliver the receipt to the facility.

(4) A transport agreement between the center and a Kentucky-licensed Class I ambulance service capable of responding immediately to a call for emergency transport shall:

(a) Be with an ambulance service located:

1. In the same county as the center; or

2. No further than five (5) miles or ten (10) minutes normal driving time from the center;

(b) Be signed by individuals authorized to execute the agreement on behalf of the center and ambulance service, who shall certify they have such authority; and

(c) Identify responsibilities of the ambulance service in which the ambulance service shall agree, at a minimum to:

1. Provide services in accordance with all federal and state laws and administrative regulations applicable to emergency service entities;

2. Require all responding medical personnel to familiarize themselves with the floor plan of the facility to minimize the time required to locate the patient in the facility and exit the facility with the patient as expeditiously as possible;

3. Acknowledge the existence of, and its familiarity with the terms of, the transfer agreement between the facility and an acute care hospital; and

4. Transport the patient to the hospital that is party to the transfer agreement, unless otherwise directed by the patient.

(5) A licensed facility applying for a renewal license or an applicant for a provisional license may submit a request in writing for extensions of time to comply with the transfer or transport agreement requirements to the cabinet's Office of Inspector General in accordance with the provisions of this subsection.

(a) Any request shall:

1. Be in writing;

2. Contain a certification under oath that the party seeking the extension of time has exhausted all reasonable efforts to obtain a transfer or transport agreement for a continuous ninety (90) calendar day period prior to the request; and

3. Contain a detailed description of the efforts taken to secure the agreements.

(b) In deciding to grant or deny the request for an extension of time, the inspector general shall consider all factors the inspector general deems relevant under the circumstances, but at least the following factors:

1. Whether the facility or applicant made, and continues to make, a good faith effort to obtain a transfer or transport agreement;

2. Whether the facility or applicant can provide the same level of patient care and safety via alternative health services during any extension period; and

3. Regulatory compliance history at the facility and at any other health care facility owned, in whole or in part, by the applicant or any other individual or entity having an ownership interest with the facility.

(c) If the request is granted, the extension of time shall be effective for a time-period of ninety (90) calendar days from the date of issuance.

(d) If the request is granted for a transfer agreement, the transport agreement need not comply with subsection (4)(c)4. and 5. of this section for the duration of the extension of time.

(e) The inspector general may rescind a previously granted extension of time at any time upon determining that the applicant or facility has not met, or is not meeting, the conditions of paragraph (b) of this subsection.

(f) If a request for an extension is denied, an applicant or licensee shall have ten (10) calendar days to submit a written request for reconsideration to the inspector general, whose decision shall be final. The licensee or applicant for provisional license may appeal a denial in accordance with Section 5 of this administrative regulation.

TRICIA STEWARD, Inspector General
STEVEN J. STACK, MD, MBA, Secretary

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