

902 KAR 20:150. Alternative birth centers.

RELATES TO: KRS 216B.010-216B.130, 216B.990(1), (2)

STATUTORY AUTHORITY: KRS 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 mandate that the Kentucky Cabinet for Human Resources regulate health facilities and health services. This administrative regulation provides for the licensure requirements for the operation and services and facility specifications of alternative birth centers.

Section 1. Definitions.

- (1) "Center" means alternative birth center.
- (2) "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 American College of Obstetrics and Gynecologists in their Standards for Obstetric-Gynecologic Services, as amended.

Section 2. Scope of Operations and Services. Alternative birth centers are establishments with permanent facilities which provide prenatal care to low risk childbearing women. An alternative birth center provides a homelike environment for pregnancy and childbirth including prenatal, labor, delivery, 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.
- (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 pregnant woman or mother 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) 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. Preemployment and annual physical examination to include a tuberculin skin test or chest x-ray and rubella antibody titer. No employee with direct patient contact having an infectious disease shall appear at work until the infectious disease can no longer be transmitted;
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.

(6) Staffing.

(a) The center shall have a staff that includes a medical director, at least one (1) nurse-midwife and at least one (1) registered nurse. In centers where an obstetrician provides perinatal care, a nurse-midwife is not required. 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 with experience in obstetrics and newborn care. If the medical director is not a practicing board-eligible or board-certified obstetrician, the center shall have a written agreement with a board-eligible or board-certified obstetrician and pediatrician for consultation, referral, and, if necessary, hospital admission. If the medical director is a practicing obstetrician or a practicing board-eligible or board-certified obstetrician, the center shall have a written agreement with a board-eligible or board-certified pediatrician. Either the medical director, consultant obstetrician or

pediatrician shall have admitting privileges in a local hospital which offers obstetrics services.

2. Nurse-midwife. Nurse-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 nurse-midwife and medical director and approved by the medical director. These protocols shall be reviewed, revised, signed and dated on an annual basis.

3. Nursing services shall be provided by licensed nurses within their respective scope of practice pursuant to KRS Chapter 314 and any administrative regulations promulgated thereunder. Nurses shall have at least one (1) year of experience in perinatal care.

(b) In-service training. The licensee shall provide ongoing in-service training programs for all personnel relating to their respective job activities. These programs shall emphasize professional competence and the human relationship necessary for effective health care.

(7) 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, pelvic adequacy, including rectum and size of uterus, fetal heart sounds, edema, and determination of gestational age;

(d) Initial laboratory tests to include hemoglobin or hematocrit and white blood count, urinalysis for sugar and protein determination, pap smear, serologic tests for syphilis and rubella antibody titer, blood type, Rh factors and screen for Rh and irregular antibodies, when indicated, tuberculin skin test and chest x-ray or evidence of physician follow-up when skin test is positive, sickle cell test when indicated and gonorrhea culture;

(e) Nutritional assessment;

(f) High risk identification and referral;

(g) Records of subsequent visits with recorded weight, blood pressure, urinalysis for protein, sugar, height of fundus, abdominal findings on palpation; rate and location of fetal heart tones, estimation of gestational age, edema, unusual signs, symptoms or quickening, third trimester hemoglobin or hematocrit, repeat venereal disease test, Rh and irregular antibody screen for Rh negative unsensitized women; and repeat antibody titers at twenty-six (26) weeks, thirty-two (32) weeks, and thirty-six (36) weeks;

(h) Parturient initial record of intercurrent problems, physical examination, temperature, pulse, respiration, blood pressure, head, heart, lungs, abdomen for lie and presentation position, fundal height and engagement, reevaluation of pelvic adequacy, recording of time of ruptured membranes, record of hemoglobin or hematocrit and urine for protein and sugar;

(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, episiotomy, placenta delivery time, medications given, abnormalities, and any complications along with actions taken;

(k) Puerperium-time records for at least six (6) hours, including postpartum blood pressure, respirations, pulse, temperature, urine output, report of breasts and breastfeeding status, legs for thrombophlebitis, hemoglobin or hematocrit, appropriate RhD immune globulin 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, pelvic including rectal examination, appropriate cervico vaginal cytologic study, hematocrit or hemoglobin, and urinalysis.
- (8) 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) Complete 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 appropriate nursery);
 - (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 pursuant to 902 KAR 4:020 (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 physician for care immediately upon discharge and thereafter; and
 - (j) Progress notes describing first and subsequent feedings type, time of first voiding, stools passage, body temperature, Vitamin K prophylaxis, blood metabolic screen for phenylketonuria and hypothyroidism, galactosemia (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.
- (9) In the event emergency hospital care is needed during the pregnancy, delivery, or postdelivery period, the pregnant woman or mother's record or a complete copy of the record must accompany the pregnant woman or mother or newborn at the time of transfer.
- (10) All health records shall be safeguarded against loss, destruction or unauthorized use.
- (11) 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.
- (12) 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 attending physician or nurse-midwife.
- (13) A certificate of birth shall be filed in accordance with the provisions of KRS Chapter 213 and administrative regulations promulgated thereunder.
- (14) Linkage agreements. The center shall have linkages through written agreements with providers of other levels of care which may be medically indicated to supplement the services available in the center. These linkages shall include:
- (a) Hospital(s);
 - (b) A board-eligible or board-certified obstetrician and pediatrician unless the medical director is a practicing board-eligible or board-certified obstetrician;
 - (c) A board-eligible or board-certified pediatrician if the medical director is a practicing obstetrician or a practicing board-eligible or board-certified obstetrician;

- (d) Registered pharmacist; and
- (e) Licensed emergency medical transportation services with appropriate equipment for transporting pregnant woman/mother and infant.

Section 4. Provision of Services.

- (1) Medical services.
 - (a) Perinatal services shall be available twenty-four (24) hours a day, seven (7) days a week on an on-call basis.
 - (b) There shall be sufficient staff coverage for all aspects of the center in keeping with the size and scope of the operation.
- (2) Nursing services.
 - (a) A nurse-midwife or physician and a registered nurse shall be on duty at all times when a pregnant woman is laboring in the center. A registered nurse shall be present at all times when a woman or mother and newborn are at the center. The registered nurse shall have at least one (1) year of perinatal experience.
 - (b) The center shall insure that phones are answered 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) Laboratory services.
 - (a) The center shall provide laboratory services either directly, through arrangement with a laboratory in a licensed hospital or a medical laboratory licensed pursuant to KRS Chapter 333. If laboratory services are provided directly, the laboratory shall be licensed pursuant to KRS Chapter 333.
 - (b) If services are provided through arrangement with other providers, a copy of the signed and dated report shall be included in the patient's medical record. Laboratory tests conducted at the center shall be entered in the patient's record, dated, and signed by the individual performing the test.
- (4) Radiology services. Radiology services shall be provided directly or through arrangement. The radiology service and personnel shall have a current license or registration pursuant to KRS 211.842 and 211.890 and any administrative regulations promulgated thereunder, as applicable. A signed and dated report of any radiology examination shall be entered into the pregnant woman's or mother's record.
- (5) 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) 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. 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 10:020, 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 6. 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 225 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) Infant warmer with radiant heat source;
 - (c) Resuscitation equipment for mother and infant;
 - (d) Oxygen with a selection of mask sizes;
 - (e) Suction equipment for mother and newborn;
 - (f) Intubation equipment for mother and newborn; and
 - (g) Wall clock with a second hand.
- (4) The service areas for the birthing room shall include:
 - (a) Sterilizing facilities with high speed autoclave(s) conveniently located to serve all birthing rooms;
 - (b) Scrub facilities provided near the birthing room entrance;
 - (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) Formula room. The following shall be provided unless commercially-prepared formula is used:
 - (a) Work counter with built-in sink with gooseneck-type spout and knee or foot control;
 - (b) Lavatory;
 - (c) Hot plate;
 - (d) Refrigerator;
 - (e) Sterilizer (autoclave); and
 - (f) Bottle washer.
- (6) 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.
- (9 Ky.R. 95; eff. 8-11-1982; 16 Ky.R. 1012; eff. 1-12-1990; Crt eff. 4-30-2019.)