

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

(Amended at ARRS Committee)

902 KAR 20:150. Freestanding Birthing Centers. ~~[Alternative birth centers.]~~

RELATES TO: KRS 211.848, 214.155, KRS 216.530, 216B.010-216B.130, 216B.990(1), (2), 216B.198, 304.5-070, 42 U.S.C. 299b-22(a).

STATUTORY AUTHORITY: KRS 216B.042, ~~[216B.105,]~~ 216B.198

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 ~~requires~~ and 216B.105 mandate ~~that the~~ ~~[Kentucky]~~ Cabinet for Health and Family Services ~~[Human Resources]~~ to promulgate administrative regulations establishing requirements necessary for the proper administration of the licensure function for ~~regulate~~ health facilities and health services. KRS 216B.198 requires the cabinet to promulgate administrative regulations establishing requirements relating to freestanding birthing centers. This administrative regulation ~~establishes~~ provides for the licensure requirements for the operation, ~~and~~ services, and facility specifications of freestanding birthing centers ~~[alternative birth centers]~~.

Section 1. Definitions.

(1) "Cabinet" means the Cabinet for Health and Family Services. ~~[Center" means alternative birth]~~ ~~[center.]~~

(2) "Freestanding birthing center" (FSBC or center) ~~[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). ~~[American College of]~~ ~~[Obstetrics and Gynecologists in their Standards for Obstetric Gynecologic Services, as]~~ ~~[amended.]~~

Section 2. Scope of Operations and Services. Freestanding birthing centers ~~[Alternative birth]~~ ~~[centers]~~ shall be ~~are~~ establishments with permanent facilities, which provide prenatal care to low risk childbearing women. A freestanding birthing center ~~[An alternative birth center]~~ shall provide ~~provides~~ a homelike environment for pregnancy and childbirth and:

(1) Shall include ~~[including]~~ ~~[prenatal]~~ labor and ~~[and]~~ delivery; and

(2) 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 American College]~~ ~~[of Obstetricians and Gynecologists (ACOG)]~~.

~~[(d)]~~ Each center shall be accredited and show proof of accreditation by the Commission for the Accreditation of Birth Centers.

(d) ~~[(e)]~~ The center shall obtain and maintain professional medical malpractice insurance, in accordance with ~~[as defined in]~~ KRS 304.5-070.

~~(e) + (f) +~~ Requirement for Service. A center shall not be licensed or relicensed as a center, unless the facility meets the requirements of this *administrative* regulation.

~~(f) + (g) +~~ Facilities that have ~~+ fewer than +~~ four (4) beds or fewer shall be exempt from Certificate of Need requirements.

~~(g) + (h) +~~ Licensed facilities shall follow general licensure and fee requirements, in accordance with ~~f~~regulations as laid out in~~f~~ 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. ~~These~~f~~Such~~f~~~~ 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, and shall~~to~~ include:

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

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

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 ~~that~~f~~which~~f~~~~ would exclude a patient~~pregnant woman or mother~~ from the center's program; and

8. A policy approved by the medical director, which fully identifies the criteria ~~that~~f~~which~~f~~~~ 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.

1. These~~f~~patients' rights~~f~~ policies shall assure that each patient is:

a. ~~f1~~f~~~~ ~~fIs~~f~~~~ Informed of these rights and of all rules and administrative regulations governing patient conduct and responsibilities, including a procedure for handling patient grievances;

b. ~~f2~~f~~~~ ~~fIs~~f~~~~ 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;

c. ~~f3~~f~~~~ ~~fIs~~f~~~~ Encouraged and assisted to:

(i) Understand and exercise~~f her~~f~~~~ patient rights;

(ii) ~~fand to this end may~~f~~~~ Voice grievances; and

(iii) Recommend changes in policies and services;~~f~~f~~~~

d. ~~fUpon the patient's request the grievances and recommendations will be~~f~~~~
~~fconveyed within a reasonable time to an appropriate decision making level within the~~f~~ organization which has the authority to take corrective action;~~f~~~~

~~4.4~~ ~~Assured confidential treatment of the patient's~~ records and afforded the opportunity to approve or refuse ~~their~~ release ~~of these records~~ to any individual not involved in ~~the patient's~~ care, except as required by law or third party payment contract; and

~~e. 5.4~~ Treated with consideration, respect, and full ~~recognition~~ ~~recognition~~ of ~~the patient's~~ dignity, ~~and~~ individuality, ~~and including~~ privacy in treatment.

2. Upon the patient's request, grievances and recommendations shall be conveyed within a reasonable time to an appropriate decision making level within the organization, which has the authority to take corrective action.

(5) Staffing.

(a) The center shall have a staff that includes :

1. A medical director ~~;~~ ~~and~~ ~~;~~

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

3. ~~Two (2) people certified~~ ~~trained~~ ~~in the Neonatal Resuscitation Program (NRP), which shall include at minimum two (2) licensed midwives~~ ~~two (2) nurse-midwives~~ ~~or a licensed midwife and an~~ ~~an~~ ~~NRP certified~~ ~~trained~~ ~~birth~~ ~~assistant~~ ~~and at least one (1) registered nurse. In centers where an obstetrician provides~~ ~~perinatal care, a nurse-midwife is not required~~ ~~;~~ ~~and~~

4. ~~The center shall employ such~~ Other staff or ancillary personnel ~~that are~~ necessary to provide the services essential to the center's operation.

(b) Staffing schedules, time worked schedules, and on-call records shall be maintained for three (3) years and shall be available in the center at all times during that period. ~~These records shall be maintained for three (3) years.~~

(c)

1. Medical director.

a. The center shall have a medical director who is a licensed physician and who meets the statutory requirements delineated in KRS 216B.198(3)(a) ~~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~~.

b.

(i) The medical director position shall ~~not~~ not be vacant for a time period in excess of ninety (90) days. ~~and~~

(ii) ~~If the birth center is unable to fill the vacancy within ninety (90) days, the birth center may submit a written request for an extension to the Inspector General. The Inspector General may grant an extension of up to ninety (90) days after considering all relevant factors, included those listed in Section 8(5). The birth center may file an appeal pursuant to Section 5~~ ~~(b)3.b~~ ~~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).}~~

2. ~~{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, within their scope of practice.

3. ~~{2.}~~ Licensed Certified Professional Midwife (LCPM) or Advanced Practice Registered Nurse designated certified nurse midwife (APRN CNM).~~{Nurse} : {Midwife} . {Nurse}~~

a. Midwife services shall be provided within the respective scope of practice pursuant to KRS Chapter 314 and 201 KAR Chapter 20 ~~{administrative regulations promulgated thereunder}~~.

b. There shall be written policies of the birthing center ~~{protocols}~~ :

(i) Developed by the ~~{nurse-midwife and}~~ medical director and licensed midwives ; and

(ii) Approved by the medical director.

c. These policies ~~{protocols}~~ shall be reviewed annually. {,} and revised, signed , and dated as necessary. ~~{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.

(6) ~~{(b)}~~ In-service training. The licensee shall provide proof of ongoing in-service training programs ~~{for all personnel relating to their respective job activities}~~ required by their respective professional licensure boards ~~{These programs shall emphasize professional competence and the human relationship necessary for effective health care}~~.

(7) ~~{(6)}~~ ~~{(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. Evidence of:

1. ~~{Evidence of}~~ Compliance with 902 KAR 20:205 ; ~~{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. Completion of new employee ~~{Evidence that employees have received}~~ orientation ~~about 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.]~~

~~(8) [(7)]~~ Medical records. The center shall maintain a medical record for pregnant women and mothers ~~and shall~~**to** include at least the following:

- (a) Prenatal history, ~~including~~**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:

- 1. Blood pressure, weight, ~~and~~ height **measurements; and**
- 2. ~~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~~

- 3. Determination of gestational age;

- (d) Initial laboratory tests, **including:**

- 1. ~~to include~~ Hemoglobin or hematocrit and white blood count;
- 2. ~~urinalysis for sugar and protein determination, pap smear,~~ Serologic tests for syphilis and rubella antibody titer;
- 3. ~~Blood type;~~
- 4. ~~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
- 5. Gonorrhea culture;

- (e) Nutritional assessment;

- (f) High risk identification and referral;

- (g) Records of subsequent visits with recorded:

- 1. Weight ~~and~~ blood pressure;
- 2. ~~urinalysis for protein, sugar,~~ Height of fundus;
- 3. ~~Abdominal findings on palpation;~~
- 4. Rate and location of fetal heart tones;
- 5. ~~Estimation of gestational age;~~
- 6. ~~Edema;~~
- 7. ~~Unusual signs;~~
- 8. ~~Symptoms of~~ quickening;
- 9. ~~Follow-up third trimester~~ hemoglobin or hematocrit; **and**

~~10. f/ 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) Physical ~~Parturient initial record of intercurrent problems, physical~~ examination including:

~~1. f/~~ Temperature, pulse, respiration, and blood pressure measurements;

~~2. f, and/ head, heart, lungs, abdomen for lie~~ Presentation position;

~~3. f, and/ fundal height~~ Engagement; and

~~4. f, 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, laceration~~[episiotomy]~~, placenta delivery time, medications given, abnormalities, and any complications and~~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 globin administration at the center, and~~f/~~ record of follow-up assessment within seventy-two (72) hours; and

(l) A four (4) to six (6) week follow-up examination, including~~to include~~ record of weight, blood pressure, breast, abdominal, and~~pelvic including rectal examination,~~ appropriate cervico vaginal cytologic study~~, hematoctrit or hemoglobin, and urinalysis.~~

(2) ~~(8)~~

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

~~1. f(a)~~ Duration of ruptured membranes;

~~2. f(b)~~ Maternal antenatal blood serology, rubella titer, blood type, Rh factors and ~~if/when~~ indicated, a Coombs Test;

~~3. f(c)~~ ~~Complete~~ Description of the progress of labor and delivery, ~~f/~~ including complications, if any~~f/~~;

~~4. f(d)~~ Condition of the newborn infant, including the Apgar score, resuscitation, time of sustained respirations, ~~if/where~~ indicated, details of physical abnormalities, pathological states observed, and treatments given before transfer to higher level of care~~appropriate nursery~~~~f/~~;

~~5. f(e)~~ Any abnormalities of placenta and cord vessels;

~~6. f(f)~~ Date and hour of birth, birth weight, sex, and period of gestation;

~~7. f(g)~~ Written verification of eye prophylaxis ~~pursuant to 902 KAR 4:020~~ (or documentation of refusal based on religious belief with parent signature~~f/~~);

~~8. f(h)~~ Report of initial physical examination, including any abnormalities;

~~9. f(i)~~ Discharge-physical examination including weight, head circumference and body length, unless previously recorded, recommendations and designation of responsible care provider~~physician~~ for care ~~immediately~~ upon discharge;~~and thereafter; and~~

~~10. f(j)~~ Progress notes describing~~first and subsequent~~ feedings~~type~~, ~~time~~~~of first~~ voiding, stools passage, body temperature, medication administration; and Vitamin K prophylaxis;

~~11. f(k)~~ Newborn screening in accordance with KRS 214.155 and 902 KAR 4:030, ~~blood metabolic screen for phenylketonuria and hypothyroidism, galactosemia~~ ~~f/~~ documentation of parental refusal for religious reasons, including parent signature in record~~f/~~, 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.

(b) If postnatal care is not provided at the FSBC, the FSBC shall ~~must~~ document the coordination of postnatal care with qualified staff. Postnatal care coordination is expected to be in place within *forty-eight (48)* hours.

~~{(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.}~~

(10) {(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.

(11) {(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 ~~the~~**this** birth;
- (c) Father's full name, birthplace, and age at time of ~~the~~**this** birth, if provided; and
- (d) Full name of ~~provider~~**attending physician or nurse-midwife**.

(12) {(13)} A certificate of birth shall be filed in accordance with ~~the provisions of~~ KRS Chapter 213 and **901 KAR Chapter 5**~~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) Staffing. ~~{Nursing services.}~~

(a) A **licensed midwife**~~{nurse-midwife}~~ or physician and a **member of the FSBC clinical staff**~~{registered nurse}~~ shall be on duty at all times ~~if~~**when** a **patient**~~{pregnant woman}~~ is laboring in the center. A **member of the center's clinical staff**~~{registered nurse}~~ shall be present at all times ~~if~~**when** a **patient is**~~{woman or mother and newborn are}~~ at the center. The **clinical staff member**~~{registered nurse}~~ shall have at least one (1) year of perinatal experience.

(b) The center shall ~~ensure~~insure that a mechanism is in place to receive calls~~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.}~~

~~{(c)} {Centers shall follow all requirements as set forth in KRS 214.155.}~~

~~{(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 211.848} {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 patient's~~pregnant woman's or mother's~~ record.~~

~~(4)~~ ~~{(5)}~~ Drug distribution.

(a) There shall be a list approved by the medical director of all drugs and biologicals, including intravenous solutions ~~that~~*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. Physician ~~{Physicians}~~ Assistant;

4. Advanced Practice Registered Nurse; ~~{or}~~

5. Licensed Practical Nurse under the supervision of a registered nurse; or

6. Licensed Certified Professional Midwife;

(e) ~~{(d)}~~ Drugs and biologicals shall be stored in a locked cabinet and, ~~if~~*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, for ~~to~~ make an inspection to determine ~~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 to the following shall result in disciplinary action, including denial, revocation, modification, or suspension of the license of the health facility

or health service:

a. ~~f, 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 ; ~~f~~ or

b. Denial of ~~deny~~ access to records relevant to the inspection, unless deemed confidential by 42 U.S.C. 299b-22(a). ~~f, shall result in disciplinary action, including denial, f revocation, modification, or suspension of the license of the health facility or health f 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. ~~[Section 5.]~~ Compliance with Building Codes, Ordinances and Regulations.

(1) ~~fNothing stated herein shall relieve~~ The licensee ~~shall comply from compliance~~ with building codes, ordinances, and administrative regulations ~~thatfwhich~~ are enforced by city, county, or state jurisdiction.

(2) The following requirements shall apply, ~~if~~ applicable and as adopted by the respective agency authority. Requirements for:

(a) ~~fRequirements for~~ Safety, pursuant to 815 KAR 10:060~~[815 KAR 10:020]~~, ~~as amended~~;

(b) ~~fRequirements for~~ Plumbing, pursuant to 815 KAR 20:010 through 191~~f, as amended~~; and

(c) ~~fRequirements for~~ Making buildings and facilities accessible to and usable by a person with a disability~~fthe physically handicapped~~, pursuant to KRS 198B.260 and 815 KAR Chapter 7~~fadministrative 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. ~~[Section 6.]~~ Clinical Facilities.

(1) ~~fExamination 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.~~

~~f(2) Patient fBirthing rooms froom(s)~~. Each patient room shall be private,~~fThere shall be at least two (2) birthing rooms each~~ with a minimum clear floor area of 120~~[225]~~ square feet, ~~excluding~~~~fexclusive of~~ fixed and movable cabinets and shelves and with a minimum dimension of fifteen (15) feet.

(2) ~~f(3)~~ Each private patient~~fbirthing~~ room shall be equipped with the following:

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

(b) ~~fInfant warmer with radiant heat source~~;

- ~~{(e)}~~ Resuscitation equipment for mother and infant;
- ~~(c)~~ ~~{(d)}~~ Oxygen with a selection of mask sizes; and
- ~~(d)~~ ~~{(e)}~~ Suction equipment for mother and newborn.~~;~~
- ~~{(f)}~~ ~~{Intubation equipment for mother and newborn; and}~~
- ~~{(g)}~~ ~~{Wall clock with a second hand.}~~
- ~~(3)~~ ~~{(4)}~~ The service areas for the birthing room shall include:
 - (a) Proper sterilization equipment used for the sterilization of birth instruments ~~{Sterilizing facilities with high speed autoclave(s) conveniently located to}~~ ~~{serve all birthing rooms};~~
 - (b) A lavatory or a sink for handwashing shall be included in every patient's room. ~~{Adequate access to sinks for handwashing should be available}~~ ~~{Scrub facilities}~~ ~~{provided near the birthing room entrance};~~
 - (c) A separate and enclosed area dedicated only~~{clean holding room}~~ for storage and distribution of clean supply materials; and
 - (d) A separate and enclosed area dedicated only~~{soiled holding room as part of a system}~~ for the collection and disposal of soiled materials.
- ~~(4)~~ ~~{(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 so~~in such a manner~~ that the safety and well being of patients, personnel, and visitors are assured~~{assure}~~.
 - (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~~ if applicable~~if~~.
 - (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. This~~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 a separate and enclosed, 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 a separate and enclosed area designated exclusively for this purpose.
- (f) The center shall have an emergency source of lighting for exam, labor, and birthing ~~rooms~~room(s) to protect the health and safety of the pregnant woman or mother ~~if~~in the event that 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. ~~Emergency Care.~~

- (1) As required by KRS 216B.198, a center shall enter into a written agreement with a ~~Kentucky~~ licensed ~~acute-care~~ 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) business ~~calendar~~ days of finalization.
- (3) A transfer agreement between the center and a ~~Kentucky~~ licensed ~~acute-care~~ hospital shall:
- (a) ~~Be with a hospital located:~~
 - ~~1. In the same or contiguous county as the facility; or~~
 - ~~2. Within No further than thirty (30) miles normal driving time from the center;~~Be a legally binding contractual document;
 - (b) ~~Be signed by individuals authorized to execute the agreement on behalf of the center and hospital, who shall certify they have this~~ such ~~authority;~~
 - (c) ~~Require transfer of a patient, if deemed medically necessary by the provider~~ physician attending to the patient;
 - (d) ~~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
 - (e) ~~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 *or contiguous* 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 *this [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. ~~Employ sufficient staff, including paramedics and emergency medical technicians, to provide patient care and operate vehicles and equipment in accordance with industry standards and applicable laws and administrative regulations;~~
 - 3. ~~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;~~
 - 4. ~~Acknowledge the existence of, and its familiarity with, the terms of the transfer agreement between the facility and an acute care hospital; and~~
 - 5. ~~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 an ~~transfer or transport~~ agreement for a continuous ninety (90) ~~business~~ *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* ~~inspector general~~ shall consider all *relevant* factors ~~the inspector general deems relevant~~ under the circumstances, *including at a minimum* ~~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 *through* ~~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) ~~business~~ *calendar* days from the date of issuance.
 - (d) If the request is granted for a transfer agreement, the transport agreement *shall need* ~~not be required to~~ comply with subsection (4)(c)3. and 4. ~~(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 at the end of the ninety (90) day extension, the center is unable to secure an agreement with a hospital or ambulance provider, the Inspector General shall determine if a waiver will be granted by considering all relevant factors including those listed in Section 8(5).*

(g) If a request for an extension *or* waiver is denied, an applicant or licensee shall have ten (10) ~~business featendarf~~ 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.

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