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REGULATIONS COMPILER

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Inspector General

3 Division of Health Services

4 (Amended After Comments)

5 902 KAR 20:150. Freestanding Birthing Centers~~[Alternative birth centers]~~.

6 RELATES TO: KRS 211.848, KRS 214.155, KRS 216.530, KRS 216B.010-216B.130,

7 216B.990(1), (2), KRS 216B.198, KRS 304.5-070, 42 U.S.C. 299b-22(a)

8 STATUTORY AUTHORITY: KRS 216B.042, 216B.105, KRS 216B.198

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105
10 mandate that the Kentucky Cabinet for Health and Family Services~~[Human Resources]~~
11 regulate health facilities and health services. This administrative regulation provides for
12 the licensure requirements for the operation and services and facility specifications of
13 freestanding birthing centers~~[alternative birth centers]~~.

14 Section 1. Definitions.

15 (1) "Cabinet" means the Cabinet for Health and Family Services.

16 (2) "Freestanding birthing center" (FSBC) (center) is defined in KRS 216B.198.~~[Center"~~
17 ~~means alternative birth center.]~~

18 (3) "Low risk" means a normal uncomplicated prenatal course as determined by
19 adequate prenatal care and prospects for a normal uncomplicated birth including criteria
20 recognized by the Commission for the Accreditation of Birth Centers (CABC) [the

1 ~~American College Obstetrics and Gynecologists in their Standards for Obstetric-~~
2 ~~Gynecologic Services, as amended].~~

3 Section 2. Scope of Operations and Services. Freestanding birthing centers~~[Alternative~~
4 ~~birth-centers]~~ are establishments with permanent facilities which provide prenatal care to
5 low risk childbearing women. A freestanding birthing center~~[An alternative birth-center]~~
6 provides a homelike environment for pregnancy and childbirth including ~~[prenatal,]~~ labor,
7 delivery, and may include prenatal and postpartum care related to medically
8 uncomplicated pregnancies.

9 Section 3. Administration and Operation.

10 (1) Licensee.

11 (a) The licensee shall be responsible for the management and operation of the center
12 and for compliance with federal, state and local laws and regulations pertaining to its
13 operation.

14 (b) The licensee shall appoint an administrator whose qualifications, responsibilities,
15 authority and accountability shall be defined in writing.

16 ~~(c) Each center shall be accredited and show proof of accreditation by American~~
17 ~~College of Obstetricians and Gynecologists (ACOG).~~

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

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

22 ~~(e)[(f)] Requirement for Service. A center shall not be licensed or relicensed as a center~~
23 ~~unless the facility meets the requirements of this regulation.~~

1 ~~(f)~~(g) Facilities that have ~~[fewer than]~~ four (4) beds or fewer shall be exempt from
2 Certificate of Need.

3 ~~(g)~~(h) Licensed facilities shall follow general licensure and fee regulations as laid out
4 in 902 KAR 20:008.

5 (2) Administrator.

6 (a) The administrator shall be responsible for the daily management and operation of
7 the center.

8 (b) In the absence of the administrator, responsibility shall be delegated to a similarly
9 qualified staff person.

10 (3) Administrative records and reports.

11 (a) Administrative reports shall be established, maintained and utilized as necessary
12 to guide the operation, measure productivity and reflect the program of the center. Such
13 reports shall include financial records and reports, personnel records, inspection reports
14 and other pertinent reports made in the regular course of business.

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

17 (4) Policies.

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

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

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

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

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

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

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

6 7. A policy approved by the medical director which fully identifies the criteria which
7 would exclude a patient~~[pregnant woman or mother]~~ from the center's program;

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

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

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

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

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

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

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

6 (5) Staffing.

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

8 (b) At least one (1) Licensed Certified Professional Midwife (LCPM) or Advanced
9 Practice Registered Nurse designated certified nurse -midwife licensed under KRS
10 314; and;

11 (c) Two people trained in Neonatal Resuscitation Program (NRP), which shall
12 include two nurse midwives or a midwife and a NRP trained birth assistant[and at
13 least one (1) registered nurse. In centers where an obstetrician provides perinatal
14 care, a nurse-midwife is not required]. The center shall employ such other staff or
15 ancillary personnel that are necessary to provide the services essential to the center's
16 operation. Staffing schedules, time worked schedules and on-call records shall be
17 maintained and available in the center at all times. These records shall be maintained for
18 three (3) years.

19 1. Medical director. The center shall have a medical director who is a licensed
20 physician [with experience in obstetrics and newborn care. If the medical director
21 is not a practicing board-eligible or board-certified obstetrician, the center shall
22 have a written agreement with a board-eligible or board-certified obstetrician and
23 pediatrician for consultation, referral, and, if necessary, hospital admission. If the

1 ~~medical director is a practicing obstetrician or a practicing board-eligible or board-~~
2 ~~certified obstetrician, the center shall have a written agreement with a board-~~
3 ~~eligible or board-certified pediatrician. Either the medical director, consultant~~
4 ~~obstetrician or pediatrician shall have admitting privileges in a local hospital which~~
5 ~~offers obstetrics services].~~

6 The medical director position shall:

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

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

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

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

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

1 ~~**3. Nursing services shall be provided by licensed nurses within their respective**~~
2 ~~**scope of practice pursuant to KRS Chapter 314 and any administrative regulations**~~
3 ~~**promulgated**~~

4 ~~**thereunder. Nurses shall have at least one (1) year of experience in perinatal care.**~~

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

10 ~~**(7) [(6)] [(5)] Personnel.**~~

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

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

15 1. ~~**Evidence of compliance with 902 KAR 20:205. [Preemployment and annual**~~
16 ~~**physical examination to include a tuberculin skin test or chest x-ray and rubella**~~
17 ~~**antibody titer. No employee with direct patient contact having an infectious disease**~~
18 ~~**shall appear at work until the infectious disease can no longer be transmitted;]**~~

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

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

23 ~~**[(6)] Staffing.**~~

1 ~~(a) The center shall have a staff that includes a medical director, at least one (1) nurse-~~
2 ~~midwife and at least one (1) registered nurse. In centers where an obstetrician provides~~
3 ~~perinatal care, a nurse midwife is not required. The center shall employ such other staff~~
4 ~~or ancillary personnel that are necessary to provide the services essential to the~~
5 ~~center's operation. Staffing schedules, time worked schedules and on-call records shall~~
6 ~~be maintained and available in the center at all times. These records shall be~~
7 ~~maintained for three (3) years.~~

8 ~~1. Medical director. The center shall have a medical director who is a licensed~~
9 ~~physician with experience in obstetrics and newborn care. If the medical director is~~
10 ~~not a practicing board-eligible or board-certified obstetrician, the center shall have a~~
11 ~~written agreement with a board-eligible or board-certified obstetrician and pediatrician~~
12 ~~for consultation, referral, and, if necessary, hospital admission. If the medical director~~
13 ~~is a practicing obstetrician or a practicing board-eligible or board-certified obstetrician,~~
14 ~~the center shall have a written agreement with a board-eligible or board-certified~~
15 ~~pediatrician. Either the medical director, consultant obstetrician or pediatrician shall~~
16 ~~have admitting privileges in a local hospital which offers obstetrics services.~~

17 ~~2. Nurse midwife. Nurse midwife services shall be provided within the respective~~
18 ~~scope of practice pursuant to KRS Chapter 314 and administrative regulations~~
19 ~~promulgated thereunder. There shall be written protocols developed by the nurse-~~
20 ~~midwife and medical director and approved by the medical director. These protocols~~
21 ~~shall be reviewed, revised, signed and dated on an annual basis.~~

22 ~~3. Nursing services shall be provided by licensed nurses within their respective scope~~
23 ~~of practice pursuant to KRS Chapter 314 and any administrative regulations~~

1 ~~promulgated thereunder. Nurses shall have at least one (1) year of experience in~~
2 ~~perinatal care.~~

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

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

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

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

12 (c) Complete initial physical examination including blood pressure, weight, height,
13 examination of skin, eyes, teeth, throat, neck, thyroid, breasts, heart, lungs, abdomen,
14 height of fundus, fetal position and auscultation, **[pelvic adequacy, including rectum and**
15 **size of uterus,]** fetal heart sounds, edema, and determination of gestational age;

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

22 (e) Nutritional assessment;

23 (f) High risk identification and referral;

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

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

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

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

17 (k) Puerperium-time records ~~[for at least six (6) hours,]~~ including postpartum blood
18 pressure, respirations, pulse, temperature, urine output, ~~[report of breasts and]~~
19 breastfeeding status~~;~~ ~~legs for thrombophlebitis, hemoglobin or hematocrit],~~
20 appropriate RhD immune globin administration at the center; record of follow-up
21 assessment within seventy-two (72) hours; and

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

4 **(9)[(8)]** A health report of the newborn shall be maintained and include the following:

5 (a) Duration of ruptured membranes;

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

8 (c) **[Complete]** Description of the progress of labor and delivery (including
9 complications, if any);

10 (d) Condition of the newborn infant including the Apgar score, resuscitation, time of
11 sustained respirations, (where indicated, details of physical abnormalities, pathological
12 states observed and treatments given before transfer to higher level of care
13 **[appropriate nursery]**);

14 (e) Any abnormalities of placenta and cord vessels;

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

16 (g) Written verification of eye prophylaxis [~~pursuant to 902 KAR 4:020~~ {or
17 documentation of refusal based on religious belief with parent signature{)];

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

19 (i) Discharge-physical examination including weight, head circumference and body
20 length unless previously recorded, recommendations and designation of responsible care
21 **provider[physician]** for care **[immediately]** upon discharge [~~and thereafter; and~~]

1 (j) Progress notes describing ~~[first and subsequent]~~ feedings ~~[type]~~, ~~[time of first]~~
2 voiding, stools passage, body temperature, medication administration; and
3 [Vitamin K prophylaxis,]

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

12 ~~[(9) [In the event emergency hospital care is needed during the pregnancy,~~
13 ~~delivery, or postdelivery period, the pregnant woman or mother's record or a~~
14 ~~complete copy of the record must accompany the pregnant woman or mother or~~
15 ~~newborn at the time of transfer.]~~

16 ~~[(10) All health records shall be safeguarded against loss, destruction or~~
17 ~~unauthorized use.~~

18 (10)~~[(11)]~~ Patient records of mother and newborn shall be maintained at the center for
19 five (5) years or in case of a minor mother, three (3) years after the patient reaches the
20 age of majority under state law, whichever is the longest.

21 (11)~~[(12)]~~ An up-to-date register of all deliveries shall be maintained and contain the
22 following information:

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

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

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

4 (d) Full name of provider~~[attending physician or nurse-midwife]~~.

5 ~~(12)~~**[(13)]** A certificate of birth shall be filed in accordance with the provisions of KRS
6 Chapter 213 and administrative regulations promulgated thereunder.

7 ~~[14] Linkage agreements. The center shall have linkages through written~~
8 ~~agreements with providers of other levels of care which may be medically indicated~~
9 ~~to supplement the services available in the center. These linkages shall include:~~

10 (a) ~~Hospital(s);~~

11 (b) ~~A board-eligible or board-certified obstetrician and pediatrician unless the~~
12 ~~medical director is a practicing board-eligible or board-certified obstetrician;~~

13 (c) ~~A board-eligible or board-certified pediatrician if the medical director is a~~
14 ~~practicing obstetrician or a practicing board-eligible or board-certified obstetrician;~~

15 (d) ~~Registered pharmacist; and~~

16 (e) ~~Licensed emergency medical transportation services with appropriate~~
17 ~~equipment for transporting pregnant [woman/]mother and infant.]~~

18 Section 4. Provision of Services.

19 (1) Medical services.

20 ~~[(a)]~~ Perinatal services shall be available twenty-four (24) hours a day, seven (7) days a
21 week on an on-call basis.

22 ~~[(b) There shall be sufficient staff coverage for all aspects of the center in~~
23 ~~keeping with the size and scope of the operation.]~~

1 (2) ~~[Nursing services.]~~ Staffing.

2 (a) A licensed midwife~~[nurse-midwife]~~ or physician and a member of the FSBC
3 clinical staff~~[registered nurse]~~ shall be on duty at all times when a patient~~[pregnant~~
4 ~~woman]~~ is laboring in the center. A registered nurse shall be present at all times when a
5 patient is~~[woman or mother and newborn are]~~ at the center. The registered nurse shall
6 have at least one (1) year of perinatal experience.

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

11 (3) ~~[Laboratory services.~~

12 ~~(a) The center shall provide laboratory services either directly, through~~
13 ~~arrangement with a laboratory in a licensed hospital or a medical laboratory~~
14 ~~licensed pursuant to KRS Chapter 333. If laboratory services are provided directly,~~
15 ~~the laboratory shall be licensed pursuant to KRS Chapter 333.~~

16 ~~(b) If services are provided through arrangement with other providers, a copy of~~
17 ~~the signed and dated report shall be included in the patient's medical record.~~
18 ~~Laboratory tests conducted at the center shall be entered in the patient's record,~~
19 ~~dated, and signed by the individual performing the test.~~

20 ~~—[(c) Centers shall follow all requirements as set forth in KRS 214.155.~~

21 ~~-(4)] Radiology services. [Radiology services shall be provided directly or through~~
22 ~~arrangement. The radiology service and personnel shall have a current license or~~
23 ~~registration pursuant to KRS 211.848~~[KRS 211.842 and 211.890] and any~~~~

1 ~~administrative regulations promulgated thereunder, as applicable.]~~ A signed and
2 dated report of any radiology examination shall be entered into the patient's~~[pregnant~~
3 ~~woman's or mother's]~~ record.

4 (5) Drug distribution.

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

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

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

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

12 1. Registered nurse;

13 2. Physician;

14 3. Physicians Assistant;

15 4. Advanced Practice Registered Nurse; [or]

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

17 6. Licensed Certified Professional Midwife;

18 ~~(e)[(d)]~~ Drugs and biologicals shall be stored in a locked cabinet and, when refrigeration
19 is necessary, they shall be stored in a locked container in a refrigerator.

20 Section 5. Licensure Inspections.

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

23 (b)

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

3 2. An applicant for licensure or a current licensee shall not deny access to a
4 representative of the Office of Inspector General, after proper identification, to make an
5 inspection for determining compliance with the requirements of each applicable
6 administrative regulation for which the health facility or health service is licensed under
7 902 KAR Chapter 20 or 906 KAR Chapter 1.

8 3.

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

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

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

19 1. The inspection shall be made at any time during the licensee's hours of
20 operation;

21 2. The inspection shall be limited to ensure compliance with the standards set
22 forth in 902 KAR Chapter 20, 906 KAR Chapter 1, KRS Chapter 216, or KRS Chapter
23 216B; and

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

4 Section 6[~~5~~]. Compliance with Building Codes, Ordinances and Regulations.

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

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

10 (a) Requirements for safety pursuant to 815 KAR 10:060[~~815 KAR 10:020~~], as
11 amended;

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

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

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

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

21 Section 7 [~~6~~]. Clinical Facilities.

22 (1) Examination room(s). At least one (1) examination room shall be provided. Each
23 room shall have a minimum clear floor area of eighty (80) square feet excluding such

1 other spaces as vestibule, toilet, closet, and work counter. Arrangement shall permit at
2 least thirty (30) inches of clear space at each side and at the foot of examination table. A
3 lavatory or sink with handwashing facility and counter or shelf space for writing shall be
4 provided.

5 (2) Birthing room(s). There shall be at least two (2) birthing rooms each with a minimum
6 clear floor area of 120 [225] square feet exclusive of fixed and movable cabinets and
7 shelves and with a minimum dimension of fifteen (15) feet.

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

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

10 (b) ~~[Infant warmer with radiant heat source;]~~

11 ~~[(c)]~~ Resuscitation equipment for mother and infant;

12 ~~(c)[(d)]~~ Oxygen with a selection of mask sizes;

13 ~~(d)[(e)]~~ Suction equipment for mother and newborn;

14 ~~[(f) Intubation equipment for mother and newborn; and~~

15 ~~(g) Wall clock with a second hand.]~~

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

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

18 ~~[Sterilizing facilities with high speed autoclave(s) conveniently located to serve~~
19 ~~all birthing rooms];~~

20 (b) Adequate access to sinks for handwashing should be available~~[Scrub~~
21 ~~facilities provided near the birthing room entrance];~~

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

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

3 (5) ~~[Formula room. The following shall be provided unless commercially-~~
4 ~~prepared formula is used:~~

5 ~~(a) Work counter with built-in sink with gooseneck-type spout and knee or foot~~
6 ~~control;~~

7 ~~(b) Lavatory;~~

8 ~~(c) Hot plate;~~

9 ~~(d) Refrigerator;~~

10 ~~(e) Sterilizer (autoclave); and~~

11 ~~(f) Bottle washer.~~

12 ~~(6)]~~ Physical and sanitary environment.

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

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

- 18 1. Plant maintenance;
- 19 2. Housekeeping; and
- 20 3. Laundry operations (if applicable).

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

- 23 1. The sterilization of supplies;

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

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

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

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

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

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

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

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

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

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

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

1 (g) The center shall establish a written policy for the handling and disposal of waste
2 materials. Any incinerator used shall be in compliance with 401 KAR 59:020 or 401 KAR
3 61:010, as applicable.

4 Section 8. Transfer and Transport Agreements~~[Emergency Care]~~.

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

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

11 (3) A transfer agreement between the center and a ~~[Kentucky-]~~ licensed ~~[acute-care]~~
12 hospital shall:

13 (a) Be with a hospital located:

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

15 2. Within~~[No further than]~~ thirty (30) miles~~[normal driving time]~~ from the center;

16 (b) Be a legally binding contractual document;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (a) Be with an ambulance service located:

2 1. In the same county as the center; or

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

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

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

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

11 2. ~~Employ sufficient staff, including paramedics and emergency medical~~
12 ~~technicians, to provide patient care and operate vehicles and equipment in~~
13 ~~accordance with industry standards and applicable laws and administrative~~
14 ~~regulations;~~

15 ~~3.] Require all responding medical personnel to familiarize themselves with the floor~~
16 ~~plan of the facility to minimize the time required to locate the patient in the facility and~~
17 ~~exit the facility with the patient as expeditiously as possible;~~

18 ~~(3)[4-] Acknowledge the existence of, and its familiarity with the terms of, the transfer~~
19 ~~agreement between the facility and an acute care hospital; and~~

20 ~~(4)[5] Transport the patient to the hospital that is party to the transfer agreement,~~
21 ~~unless otherwise directed by the patient.~~

22 (5) A licensed facility applying for a renewal license or an applicant for a provisional
23 license may submit a request in writing for extensions of time to comply with the transfer

1 or transport agreement requirements to the cabinet's Office of Inspector General in
2 accordance with the provisions of this subsection.

3 (a) Any request shall:

4 1. Be in writing;

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

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

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

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

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

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

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

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

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

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

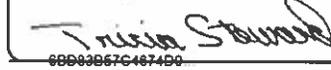
902 KAR 20:150

REVIEWED:

3/6/2026

Date

Signed by:



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Tricia Steward

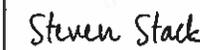
Inspector General, Office of Inspector General

APPROVED:

3/8/2026

Date

Signed by:



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Steven J. Stack, MD, MBA

Secretary, Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

902 KAR 020:150: Freestanding birthing centers

Agency Contact: Valerie Moore

Phone Number: (502) 226-0196

Email: valeriek.moore@ky.gov

Contact Person: Krista Quarles

Phone Number: (502) 564-7476

Email: CHFSregs@ky.gov

Subject Headings: Health and Medical Services; Midwifery; Reproductive Issues

(1) Provide a brief summary of:

(a) What this administrative regulation does: Updates the alternative birthing center regulation to be the freestanding birthing center regulation. Includes accreditation requirements, medical liability insurance, sets timeline for medical director departure, changes all references from "Alternative birthing center" to "Freestanding birthing center".

(b) The necessity of this administrative regulation: Upon passage of 25 RS HB 90, the cabinet was required to promulgate updated administrative regulations.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to KRS 216B.198 by setting rules governing freestanding birthing centers.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The amendment to this administrative regulation sets rules that govern the freestanding birthing center level of care.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Includes accreditation requirements, medical liability insurance, sets timeline for medical director departure, changes all references from "Alternative birthing center" to "Freestanding birthing center". The Amended After Comments (AAC) version of this regulation removed language referencing the American College of Obstetrics and Gynecologists and added language to reference the Commission for the Accreditation of Birth Centers (CABC). In addition, the changes made to the AAC version included clarifications to licensure requirements and considered all public and written comments. Technical changes to the licensure requirements to Freestanding Birthing Centers included requirements for the medical director, the inclusion of Licensed Certified Nurse Midwives, clarifications related to transfer agreements with hospitals and ambulance services, and updated requirements to the minimum standards needed for medical documentation.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to comply with 25 RS HB 90.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment to the regulation conforms to KRS 216B.198 by enhancing licensure standards and procedures for freestanding birthing centers. The proposed amendments are consistent with KRS Chapter 13A by addressing minimum operating standards.

(d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation sets minimum standards that must be met for licensure of freestanding birthing centers.

(3) Does this administrative regulation or amendment implement legislation from the previous five years? Yes, 2025 HB 90; Ky Acts Chapter 121.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect anyone who wishes to open and operate a freestanding birthing center in Kentucky.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment: Regulated entities will have to meet and follow all licensure requirements and comply with this administrative regulation and KRS 216B.198.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4): Facilities will be subject to a yearly licensure fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4): Those who wish to open this level of care will be able to ensure a safer facility and safety provisions that protect their staff and patients.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This amended regulation will have no financial impact on the administrative body. In addition, there is no anticipated financial impact to the Amendment After Comments.

(b) On a continuing basis: This administrative regulation will have no financial impact on the Office of Inspector General.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment: There is not expected to be additional expenditures as a result of this amended regulation.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There is no anticipated budgetary impact on OIG as a result of this amended regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: There is a yearly licensure fee of \$500.

(10) TIERING: Is tiering applied? Tiering does not apply.

FISCAL IMPACT STATEMENT

902 KAR 20:150: Freestanding birthing centers

Contact Person: Valerie Moore

Phone: (502) 226-0196

Email: valeriek.moore@ky.gov

Contact Person: Krista Quarles

Phone Number: (502) 564-7476

Email: CHFSregs@ky.gov

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042, 216B.105, KRS 216B.198

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: Office of Inspector General, Division of Health Care.

(a) Estimate the following for the first year:

Expenditures: There are no anticipated expenditures as a result of this administrative regulation.

Revenues: There is no anticipated revenue generated by the amendment of this administrative regulation.

Cost Savings: No cost savings is expected as a result of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There aren't expected to be any differences in expenditures, revenues or cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): Any person(s) or entities that file for a Freestanding Birthing Center license.

(a) Estimate the following for the first year:

Expenditures: There are no anticipated expenditures as a result of this administrative regulation.

Revenues: There is no anticipated revenue generated by the amendment of this administrative regulation.

Cost Savings: No cost savings is expected as a result of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There aren't expected to be any differences in expenditures, revenues or cost savings in subsequent years.

(4) Identify additional regulated entities not listed in questions (2) or (3): There are no additional regulated entities.

(a) Estimate the following for the first year:

Expenditures: N/A

Revenues: N/A

Cost Savings: N/A

(b) How will expenditures, revenues, or cost savings differ in subsequent years? N/A

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: There is no anticipated fiscal impact from this amendment.

(b) Methodology and resources used to determine the fiscal impact: There have been no financial changes made in this regulation and this amendment has no fiscal impact.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate) There is no economic impact expected from this amendment. There is no anticipated negative or adverse fiscal impact to the Amendment After Comments.

(b) The methodology and resources used to reach this conclusion: No additional monies coming in or going out means no fiscal impact.

STATEMENT OF CONSIDERATION
RELATING TO 902 KAR 20:150

Cabinet for Health and Family Services
Office of Inspector General
Division of Health Care

Amended after Comments

- I. A public hearing on 902 KAR 20:150 was held on January 30, 2026, at 12:00 p.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period.
- II. The following individuals submitted comments or attended the public hearing.

Name and Title	Agency/Organization/Entity/Other
Rep. Jason Nemes	State Representative, 33 rd District
Alexa Scisney, Executive Director	Granny's Birth Initiative
Christine Peterson	Clarksville Midwifery
Jennifer Fardink	Clarksville Midwifery
Maria Carr	
Dolores Polito	KY Affiliate of A.C.N.M.
Ellen Hunt, RN	
Kelly Jenkins, Executive Director	KY Board of Nursing
Jill York, Executive Director	KY Association of Nurse Practitioners and Nurse-Midwives (KANPNM)
Kaeli Riley	
Kate Bauer, Executive Director	American Association of Birth Centers
Kelli Perkinson	
Kelly Taulbee, Policy Director	KY Voices for Health (KVH)
Liz McQuillen, Chief Policy Officer	Metro United Way
Mary Kathryn DeLodder	KY Birth Coalition
Melissa Halte	
Michael Rasche	
Nancy Rasche	
Robin Centner	KY Association of Nurse Practitioners and Nurse-Midwives
Robin Elise Weiss	

III. The following people from the promulgating administrative body responded to the comments:

Name and Title	Agency/Organization/Entity/Other
Tricia Steward, Inspector General	Office of the Inspector General
Carrie Storms, Director	OIG Division of Health Care
Andrea Wilhite, Assistant Director	OIG Division of Health Care
Marissia Izlar, Assistant Director	OIG Division of Health Care
Kevin Byrd, Assistant Director	OIG Division of Health Care
Melanie Poynter, Staff Assistant	OIG Division of Health Care
Rose Thompson, Branch Manager	OIG Division of Health Care, Operations Branch

IV. SUMMARY OF COMMENTS AND AGENCY RESPONSES

(1) Subject: Correcting responsible accreditation organization.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, "ACOG does not accredit birth centers, and a requirement for ACOG accreditation was not part of HB 90. So, any references to ACOG definitions, I don't think would be appropriate for birth center regulations since ACOG is a professional organization for obstetricians and gynecologists and not birth centers."

(a) Comment: Robin Centner from the Kentucky Association of Nurse Practitioners and Nurse-Midwives stated, "ACOG is not an accrediting body, and any mention of them should be removed from the language and regulations. The CABC is what is written in the legislation as being the accrediting body for birth centers, and that's what we should adhere to."

(a) Comment: Jennifer Fardink of Clarksville Midwifery and the President of the Tennessee Midwives Association, urged the adoption of CABC standards for accreditation.

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated, "ACOG does not accredit birth centers, so we're recommending that that gets removed and require only CABC accreditation or equivalent National Birth Center accrediting body."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM strongly recommends deletion of Section 3(1)(c) requiring accreditation by the American College of Obstetricians and Gynecologists (ACOG). ACOG does not accredit freestanding birthing centers. HB 90 contemplates accreditation through the Commission for the Accreditation of Birth Centers (CABC), which is the nationally recognized accrediting body for these facilities."

(a) Comment: Liz McQuillen, Chief Policy Officer for Metro United Way, stated, "The primary concerns raised by these proposed regulations include: Regulations that exceed the threshold necessary to ensure patient safety; Regulations that specifically conflict with the text of the statute; Regulations that are legally impossible, such as requiring accreditation that does not currently exist from Academy of Obstetrics and Gynecology (ACOG); and Regulations that are duplicative of other standards."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "consider deleting the definition of 'low risk' since it is only used in Section 2 'Scope of Operations and Services.' At a minimum, the words "including criteria recognized by the American College of Obstetrics and Gynecologists in their Standards for Obstetric-Gynecologic Services, as amended" should be deleted. ACOG definitions are not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation."

(a) Comment: Ellen Hunt, Registered Nurse, stated "A major change from HB90 is the requirement of accreditation by CABC. This accreditation covers MANY of the details outlined in the regulations. In some cases, the info in the regulations is not consistent with the requirements for accreditation. The accreditation requirements should be carefully reviewed by staff to ensure consistency, and many items can be deleted from the regulations and allowed to rely on the accreditation requirements."

(a) Comment: Christine Peterson of Clarksville Midwifery, stated "[ACOG] recommends CABC accreditation of birth centers" and urged the adoption of CABC accreditation within the regulation.

(a) Comment: Nancy Rasche stated, "ACOG does not accredit birth centers. This simply does not exist."

(a) Comment: Michael Rasche stated, "ACOG does not accredit birth centers. This simply does not exist."

(a) Comment: Kaeli Riley stated, "ACOG does not accredit birth centers. This simply does not exist."

(a) Comment: Melissa Halte stated, "ACOG does not accredit birth centers. This simply does not exist."

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated, "ACOG supports birth centers, but does not accredit them. Accreditation of birth centers is issued by the Commission for the Accreditation of Birth Centers (CABC)."

(a) Comment: Robin Elise Weiss stated, "ACOG is a professional membership organization for obstetrician-gynecologists; it does not accredit birth centers. The Commission for the Accreditation of Birth Centers (CABC) is the only national accrediting body dedicated exclusively to the quality of operation and services of birth centers."

(a) Comment: Dolores J. Polito, President of the Kentucky Affiliate of the American College of Nurse-Midwives, stated, "The American College of Obstetricians and Gynecologists (ACOG) does not accredit freestanding birth centers, and its inclusion in the regulation as an accrediting entity is inaccurate and misleading. Recognition of birth centers by ACOG occurs only when centers meet nationally accepted accreditation standards through the Commission for the Accreditation of Birth Centers (CABC). We suggest aligning the regulation with this distinction and correcting the stated role of

ACOG. The Affiliate strongly supports the proposed requirement for CABC Accreditation.”

(b) Response: The Office of Inspector General appreciates the feedback on this issue and the changes have been made to 902 KAR 20:150 accordingly.

(2) Subject: The removal of the ACOG definition for “low risk” from the regulations for FSBCs.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “in Section 1.3, we recommend deleting the definition of low risk since it is only used in Section 2 in the scope of operations and services. At a minimum, the words, “including criteria recognized by the American College of Obstetrics and Gynecologists in their standards for obstetric gynecologic services as amended” should be deleted.”

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated, the “[d]efinition of low risk should be set by CABC, not ACOG.”

(a) Comment: Robin Centner from the Kentucky Association of Nurse Practitioners and Nurse-Midwives stated the Cabinet should not include the definition of low risk as defined by the American College of Obstetrics and Gynecologists because it is not an acceptable standard to use. She further stated, “We should be going by a definition that is recognized by the American College of Nurse Midwives and the American College of Birth Centers, as amended, and the CABC guidelines.”

(a) Comment: Maria Carr, a certified nurse midwife and labor and delivery nurse stated, “I want to underscore the importance of not using the term ‘low-risk’ as defined by ACOG because that would exclude many potential clients that would be appropriate and who might benefit from birth center care.” Ms. Carr then provided several examples of potential patients who would qualify under the definition of low risk as defined by ACOG and would lose the opportunity to receive care from a Birth Center. Ms. Carr urged the adoption of the guidelines promulgated by the CABC.”

(a) Comment: Ellen Hunt, Registered Nurse, stated “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation.”

(a) Comment: Nancy Rasche stated, “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation.”

(a) Comment: Michael Rasche stated, “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation.”

(a) Comment: Kaeli Riley stated, “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation.”

(a) Comment: Melissa Halte stated, “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model, per the requirement for CABC accreditation.”

(a) Comment: Kate Bauer, Executive Director of the American Association of Birth Centers, stated, “An ACOG definition for “low risk” is not appropriate for a freestanding birth center, which operates in the Midwifery Model of Care and not the obstetric model,

per the requirement for CABC accreditation. The ACOG and SM FM document titled Levels of Maternal Care, states that AABC Standards are the acceptable guide for operations of the freestanding birth center. The CABC accreditation indicators use the AABC Standards and are the evidence-based resource for the appropriate risk level for the freestanding birth center."

(a) Comment: Robin Elise Weiss stated, "If the regulations use an ACOG definition for 'low risk' pregnancy, this should be reconsidered. Freestanding birth centers operate within the Midwifery Model of Care, not the obstetric model. Per CABC accreditation requirements, birth centers use the American Association of Birth Centers (AABC) Standards for Birth Centers, which include appropriate criteria for risk screening specific to the birth center setting. The regulations should either reference the CABC/AABC standards for risk criteria or allow birth centers to establish risk criteria consistent with their required accreditation. Using obstetric-model definitions may inappropriately exclude women who are appropriate candidates for birth center care or impose criteria that do not align with evidence-based midwifery practice."

(b) Response: The Office of Inspector General appreciates the feedback on this issue and the changes have been made to 902 KAR 20:150 accordingly.

(3) Subject: Inclusion of Licensed Certified Professional Midwives in the FSBC regulations.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, "Kentucky has two types of licensed midwives: APRN-certified nurse midwives, which are referenced in these regulations, and licensed certified professional midwives." "LCPMs must be included as providers who can own, operate, and work in freestanding birth centers."

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "one major omission in these regulations is the absence of licensed certified professional midwives, or LCPMs. This provider type was authorized in Kentucky through legislation passed in 2019, and they consist of the majority of the providers of out-of-hospital maternity care in Kentucky. I believe this omission was an oversight that occurred as a part of updating old regulations given that LCPMs were not authorized to practice in Kentucky when these regulations were first created. There are numerous places throughout the proposed regulations where updates need to be made to reflect all licensed midwives in Kentucky. While the Kentucky Birth Coalition does believe this was a simple oversight, I cannot emphasize enough that this is a major issue, and it must be corrected for these regulations to be acceptable."

(a) Comment: Kelly Jenkins, Executive Director, Kentucky Board of Nursing, submitted written comments stating, "The Council respectfully requests LCPMs be added to the Section 3(5) of the amended regulation".

(a) Comment: Robin Centner from the Kentucky Association of Nurse Practitioners and Nurse-Midwives stated the Licensed Certified Professional Midwives should be included in the regulation.

(a) Comment: Ellen Hunt, Registered Nurse, stated "Licensed Certified Professional Midwives MUST be included. Their omission is presumed to be an oversight, since LCPMs were not licensed in KY prior to 2020, and these regulations pre-date that. Their exclusion is completely unacceptable."

(a) Comment: Christine Peterson of Clarksville Midwifery stated, Licensed Certified Professional Midwives needed to be added to the regulation, because all licensed midwives should be able to practice within birth centers.

(a) Comment: Nancy Rasche stated, "Licensed Certified Professional Midwives MUST be included, this is non-negotiable. Their omission is presumed to be an oversight, since LCPMs were not licensed in KY prior to 2020, and these regulations pre-date that. Their exclusion is completely unacceptable. Certified Professional Midwives are the only professionals who are specifically trained to manage healthy, low risk pregnancies and births in out of hospital settings. These professionals are already regulated by the state and should be welcomed to bring their specific expertise to the table, therefore ensuring the best outcomes for moms and babies."

(a) Comment: Michael Rasche stated, "Licensed Certified Professional Midwives MUST be included. Their omission is presumed to be an oversight, since LCPMs were not licensed in KY prior to 2020, and these regulations pre-date that. Their exclusion is completely unacceptable."

(a) Comment: Kaeli Riley stated, "Licensed Certified Professional Midwives MUST be included. Their omission is presumed to be an oversight, since LCPMs were not licensed in KY prior to 2020, and these regulations pre-date that. Their exclusion is completely unacceptable."

(a) Comment: Melissa Halte stated, "Licensed Certified Professional Midwives MUST be included. Their omission is presumed to be an oversight, since LCPMs were not licensed in KY prior to 2020, and these regulations pre-date that. Their exclusion is completely unacceptable."

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated "The regulations omit Certified Professional Midwives (CPMs) from birth center practice. We understand this omission may have been an oversight given that the original birth center regulations predated CPM licensure in Kentucky, therefore we request that CPMs be added to the regulatory update."

(a) Comment: Kate Bauer, Executive Director of the American Association of Birth Centers, stated, "Licensed Certified Professional Midwives MUST be included as birth center providers. In the 37 states that license CPMs, the birth settings included in their licensure are the home and the Freestanding Birth Center."

(a) Comment: Robin Elise Weiss stated, "Licensed Certified Professional Midwives (LCPMs) must be explicitly included in the regulations as qualified providers who may practice in freestanding birth centers."

(a) Comment: Dolores Polito stated, "LCPMs are licensed maternity care providers in Kentucky and should be included wherever licensed midwives are referenced to ensure internal consistency and appropriate recognition of the full midwifery workforce authorized under Kentucky law per KRS Chapter 314."

(b) Response: The Office of Inspector General apologizes for this oversight. The regulation has been updated to include Licensed Certified Professional Midwife (LCPM) to 902 KAR 20:150.

(4) Subject: Requirement for facilities to have contractual/written agreements with obstetricians and/or pediatricians having admitting privileges to a hospital. Requirement that Medical Director be a physician should be enough regulation.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, "This requirement was seen by the General Assembly to be sufficient for the operations of a freestanding birth center, and additional written agreements with other physicians, such as an obstetrician or pediatrician with hospital admitting privileges is not necessary and likely will create another barrier for many birth centers."

(a) Comment: Ellen Hunt, Registered Nurse, stated "There should NOT be a requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. This does not mean there will not be relationships with these providers."

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated "Right now, our bill currently states that there's a requirement for written agreements with board-eligible, certified obstetricians and pediatricians, and that one has admitting privileges. The recommendation is to require written transfer agreements with hospitals and consulting physicians but not require admitting privileges for a person or staff."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends revising this subsection to read: 'The center shall have a medical director who is a licensed physician with experience in obstetrics and newborn care.' All remaining language in this subsection should be deleted. This revision would appropriately allow a family physician with obstetric training to serve as medical director. The medical director's role is to support policy development, standards, and safety oversight for the birth center—not to provide direct care at the receiving hospital during transfers. Accordingly, hospital admitting privileges should not be required." "KANPNM further recommends specifying that the medical director be limited to an obstetrician-gynecologist or a family physician with obstetric experience. While obstetricians do provide limited newborn care (including neonatal resuscitation and circumcision), and family physicians may provide broader maternal-newborn care, other physician specialties lack the clinical background necessary for this role. Clear standards are needed to ensure appropriate expertise without unnecessarily restricting qualified providers."

(a) Comment: Kate Bauer, Executive Director of the American Association of Birth Centers, stated, "There should be NO requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. Standards and accreditation require that written plans be in place for consultation, collaboration, and transfer of patients can be accomplished when needed. Midwife staff of the birth center will develop consultative relationships with providers at nearby acute care facilities. Requiring a written agreement with various consultant physicians places another barrier to operations for the birth center."

(a) Comment: Robin Elise Weiss stated, "The medical director requirement already ensures physician involvement in birth center operations. Birth centers will naturally develop professional relationships and communication channels with obstetricians and pediatricians in their communities through the medical director, transfer relationships, and standard care coordination. Requiring formal written agreements beyond what the

statute mandates may create unnecessary barriers, particularly in communities where hospitals have historically been unwilling to enter into agreements with birth centers.”

(a) Comment: Melissa Halte stated, “There should NOT be a requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. This does not mean there will not be relationships with these providers.”

(a) Comment: Nancy Rache stated, “There should NOT be a requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. These supposed experts are the very professionals whose practices have dropped the standing of American maternal and fetal outcomes from 19th globally in 1997 to ~59 globally currently. The American obstetric model manages to lose more moms and babies than all the developed nations combined. These experts should step away from the table and welcome the wisdom of out-of-hospital CPMs who are the only professionals trained for the 85% of the population who experience healthy, low-risk pregnancies. This does not mean there will not be relationships with these providers. As people currently in the field were able to attest during the Zoom hearing on 1-30-2026, the best transfers come from the facilities and providers who willingly enter into these agreements and arrangements rather than from facilities who are avoiding signing such contracts and are hostile, therefore risking the lives of moms and babies.”

(a) Comment: Michael Rasche stated, “There should NOT be a requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. This does not mean there will not be relationships with these providers.”

(a) Comment: Kaeli Riley stated, “There should NOT be a requirement to have a written agreement with an OB and pediatrician in addition to having a medical director. This does not mean there will not be relationships with these providers.”

(b) Response: OIG appreciates the comment, and the regulation has been updated to clarify the qualifications of the Medical Director.

(5) Subject: Transfer agreements within range of a hospital.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, “HB 90 was very intentionally written over many years to require a freestanding birth center to be located within 30 miles of a hospital. This can be any hospital, any hospital. We also made sure that -- to state that a hospital closing would not necessitate the closure of the birthing center that was already open. HB 90 also calls for the birth center to have a transfer agreement with a hospital that provides obstetric services. The legislation does not have any proximity requirements for the hospital for the transfer agreement. These two things have combined -- have been combined in these regulations, and this is not the intent of HB 90.”

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated “We also want to remove a requirement for written agreements and collaboration of physicians and hospitals for emergencies. Much like Mr. Nemes said, it's more likely that that will not happen if providers or facilities are non-collaborative.”

(a) Comment: Nancy Rache stated, “The provisions in the regulations to ‘defer’ the requirements for a transfer agreement with a hospital or ambulance service do not meet the statutory requirements of KRS 216B.198, which says there must be a process to waive these requirements. You cannot calculate ‘30 miles normal drive time.’ The transfer agreement does not need to be with a hospital within 30 miles, the birth center

simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services."

(a) Comment: Michael Rasche stated, "The provisions in the regulations to "defer" the requirements for a transfer agreement with a hospital or ambulance service do not meet the statutory requirements of KRS 216B.198, which says there must be a process to waive these requirements. You cannot calculate '30 miles normal drive time.' The transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services."

(a) Comment: Kaeli Riley stated, "The provisions in the regulations to "defer" the requirements for a transfer agreement with a hospital or ambulance service do not meet the statutory requirements of KRS 216B.198, which says there must be a process to waive these requirements. You cannot calculate '30 miles normal drive time.' The transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services."

(a) Comment: Ellen Hunt, Registered Nurse, stated "The transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services." Ms. Hunt further stated, "You cannot calculate 30 miles normal drive time."

(a) Comment: Robin Elise Weiss stated, "The phrase '30 miles normal drive time' is not a meaningful or enforceable metric. Drive time varies dramatically based on traffic, weather, time of day, county, and route. The regulations should use a straightforward distance measurement. It is also important to distinguish between two separate requirements in the statute. First, KRS 216B.198(2)(c) requires the birth center to be located within 30 miles of a hospital. This is a general hospital, not necessarily a hospital with obstetric services. This makes sense because emergencies at a birth center may require non-obstetric care (e.g., cardiac emergency, trauma from a fall), and the closest hospital, regardless of whether it has labor and delivery services, may be the

appropriate destination. Second, KRS 216B.198(5) requires a written patient transfer agreement with a hospital that provides obstetric services. This statute does not specify geographic proximity for the hospital with which the transfer agreement is held. The agreement ensures a receiving hospital for planned obstetric transfers, but the closest hospital may not be the hospital with obstetric services. The regulations should clearly distinguish these requirements: location within 30 miles of any hospital (which may or may not have obstetric services), and a transfer agreement with a hospital that provides obstetric services (with no geographic limitation specified in statute)."

(a) Comment: Melissa Halte stated, "You cannot calculate '30 miles normal drive time.' The transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services."

(a) Comment: Kelli Perkinson stated, "The transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services."

(a) Comment: Dolores Polito stated, "The Affiliate suggests removing the county-based requirement as county boundaries do not reliably reflect transportation time, particularly in rural areas. Distance or travel time are more appropriate measures of patient safety and may more accurately reflect safe and timely access to emergency services. The Affiliate recommends that thirty (30) minutes normal driving time is an appropriate standard to access to emergency services, ensuring timely and effective care in urgent situations."

(b) Response: OIG appreciates the comment, and the regulation has been updated.

(6) Subject: Certificate of Need (CON) requirements are not necessary for facilities with four beds or fewer.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, "The main barrier to small birth centers was the Certificate of Need requirement. While HB 90 removed the CON requirement for birth centers with few -- with 4 or fewer beds, we have to be sure that other artificial and unnecessary barriers are not created in the regulations."

(a) Comment: Robin Centner from the Kentucky Association of Nurse Practitioners and Nurse-Midwives stated, "the regulation currently states that the facility that has fewer than four beds shall be exempt from a Certificate of Need, so the language needs to be changed to align with the statute."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "This subsection should be revised to clearly state that facilities with four (4) or fewer beds are exempt from certificate of need (CON) requirements. As currently written, the provision could be interpreted to apply only to facilities with three (3) beds. KANPNM is concerned that the term "beds" may be interpreted to include exam rooms or exam tables in addition to labor rooms, which could unintentionally subject most freestanding birthing centers to CON requirements. If the bed threshold was established in statute and cannot be increased through regulation, revising the language to explicitly state 'four (4) or fewer labor room beds' would still provide needed clarity and reduce unintended regulatory burden."

(a) Comment: Dolores Polito stated, "Kentucky statute KRS Chapter 216B explicitly exempts freestanding birth centers with limited bed capacity from the requirement of certificate of need. The proposed regulation currently states: "Facilities that have fewer than four (4) beds shall be exempt from Certificate of Need" The Affiliate suggests maintaining consistency between statutory language and legislative intent and revising this provision to state "no more than four (4) beds."

(b) Response: The relevant portion of the regulation has been updated to reflect that facilities with four (4) or fewer beds are exempt from the Certificate of Need (CON) requirements in accordance with KRS 216B.198(7).

(7) Subject: Limiting the proximity of an ambulance provider could limit the places that facilities could operate.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District stated, "HB 90 also had no limiting factors for the ambulance service, but the proximity requirements of 5 miles or 10 minutes for the ambulance service proposed in the regulation -- in these regulations significantly limit where a birth center could be located. You can be in the same county and be a lot more than 10 minutes away."

(b) Response: OIG appreciates the comment, and the regulation has been updated.

(8) Subject: Waiving Transfer Agreements with Hospitals and Ambulance Services.

(a) Comment: Rep. Jason Nemes, State Representative, 33rd District, stated, "Cabinet shall establish a process and criteria by which the requirement of a transfer agreement or the hospital with the obstetric services may be waived if a freestanding birth center submits to the cabinet evidence of failure by a hospital that provides obstetrics services to enter into a written patient transfer agreement with the freestanding birthing center." KRS 216.198(6)b mirrors this language for the ambulance agreement. Current regulation to grant an extension does not comply with the statutory requirement. Must have a process to be waived, not amended. Granting an extension is not the same as waiving the requirement.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "Section 8(4)A, regarding the transport agreement with the ambulance service, these requirements significantly limit where a birth center can be located since they would have to locate the center in a county where an ambulance service is willing to enter into an agreement or the service is within 5 miles or 10 minutes of the center. You could be in the same county and be a lot more than 10 minutes away, so we would ask, why define this at all? If the ambulance service feels they are too far away from the center to provide

service, they will not and should not enter into the agreement.” “Regarding Section 8.5, KRS 216B.198, Subsection 5B says, ‘The cabinet shall establish a process and criteria by which the requirement of a transfer agreement with the hospital with obstetric services may be waived if a freestanding birthing center submits to the cabinet evidence of a failure by the hospital that provides obstetric services to enter into a written patient transfer agreement with the freestanding birthing center.’ Similar language is in the statute regarding the ambulance transport agreement. The current proposal in the regulations to grant an extension does not comply with the statutory requirements. Everything else in this section should be amended to comply with the statute. The proposed regulations provide a mechanism to receive an extension or to defer the requirement of transfer and transport agreements. This process for an extension does not comply with the statutory requirement of waiving. The other items in Section 8.5 regarding documentation are very appropriate, but the outcome is required to be a waiving of the requirement for the agreement, rather than an extension or a deferral. And we believe that this would cause these regulations to be deficient if this section was not amended to conform to the statute.”

(a) Comment: Ellen Hunt, Registered Nurse, stated “The provisions in the regulations to “defer” the requirements for a transfer agreement with a hospital or ambulance service do not meet the statutory requirements of KRS 216B.198, which says there must be a process to waive these requirements.”

(a) Comment: Melissa Halte stated “The provisions in the regulations to “defer” the requirements for a transfer agreement with a hospital or ambulance service do not meet the statutory requirements of KRS 216B.198, which says there must be a process to waive these requirements.”

(a) Comment: Robin Elise Weiss stated, “KRS 216B.198(5)(b) and (6)(b) require the Cabinet to establish a process and criteria by which transfer agreement requirements “may be waived” if a birth center submits evidence of a failure by a hospital or emergency medical transportation service to enter into an agreement. If the proposed regulations provide a process to “defer” rather than “waive” these requirements, the language must be corrected to match the statutory requirement. The statute specifically uses the term “waived,” and the regulations must provide an actual waiver process as the General Assembly intended.”

(b) Response: OIG appreciates the comment, and the regulation has been updated to clarify the processes for transfer and transportation agreements.

(9) Subject: Outdated language carried over from old regulations when these types of facilities did not exist.

(a) Comment: Nancy Rasche stated, “No freestanding birth centers have been operational in KY since the 1980s, and therefore, this is the first major update to these regulations in decades. Attempting to update the existing regulations is not a good approach, and these proposed regulations must be revised to reflect modern standards of care. Many of the items in these regulations are outdated.”

(a) Comment: Michael Rasche stated, “No freestanding birth centers have been operational in KY since the 1980s, and therefore, this is the first major update to these regulations in decades. Attempting to update the existing regulations is not a good

approach, and these proposed regulations must be revised to reflect modern standards of care. Many of the items in these regulations are outdated.”

(a) Comment: Kaeli Riley stated, “No freestanding birth centers have been operational in KY since the 1980s, and therefore, this is the first major update to these regulations in decades. Attempting to update the existing regulations is not a good approach, and these proposed regulations must be revised to reflect modern standards of care. Many of the items in these regulations are outdated.”

(a) Comment: Robin Elise Weiss, stated, “It is important to note that no freestanding birth centers have been operational in Kentucky since the 1980s. The existing regulations in 902 KAR 20:150 are therefore decades old and do not reflect modern standards of care, current evidence, or the healthcare landscape in Kentucky today. Rather than attempting to update outdated regulations, I strongly encourage the Cabinet to develop new regulations that reflect contemporary evidence-based practice and align with the accreditation standards required by HB90.”

(a) Comment: Melissa Halte stated, “No freestanding birth centers have been operational in KY since the 1980s, and therefore, this is the first major update to these regulations in decades. Attempting to update the existing regulations is not a good approach, and these proposed regulations must be revised to reflect modern standards of care. Many of the items in these regulations are outdated.”

(b) Response: The cabinet has taken the recommendations of those who commented on this outdated language into consideration and made changes to update language as has been requested to fall in line with modern standards of care.

(10) Subject: Regulation should govern facilities, not providers.

(a) Comment: Chrstine Peterson of Clarksville Midwifery, stated “These regulations should be regulating the facility and not putting additional restrictions on the providers themselves[.]” Ms. Peterson urged the Cabinet to ensure the regulation does not conflict with the requirements of the individual licensing boards.

(a) Comment: Nancy Rasche stated, “There is a difference between the birth center (the facility) and the licensed healthcare providers who work at the facility. The providers (midwives and physicians) are already governed by their own professional practice standards, licensure requirements, scope of practice, etc. They are accountable their credentialing agency i.e. KBML or KBN. The regulations for birth centers as a facility should focus on regulating the facility and not re-creating requirements for the providers. This is redundant and often unnecessary.”

(a) Comment: Michael Rasche stated, “There is a difference between the birth center (the facility) and the licensed healthcare providers who work at the facility. The providers (midwives and physicians) are already governed by their own professional practice standards, licensure requirements, scope of practice, etc. They are accountable their credentialing agency i.e. KBML or KBN. The regulations for birth centers as a facility should focus on regulating the facility and not re-creating requirements for the providers. This is redundant and often unnecessary.”

(a) Comment: Kaeli Riley stated, “There is a difference between the birth center (the facility) and the licensed healthcare providers who work at the facility. The providers (midwives and physicians) are already governed by their own professional practice standards, licensure requirements, scope of practice, etc. They are accountable their

credentialing agency i.e. KBML or KBN. The regulations for birth centers as a facility should focus on regulating the facility and not re-creating requirements for the providers. This is redundant and often unnecessary.”

(a) Comment: Robin Elise Weiss stated, “There is an important distinction between the birth center as a facility and the licensed healthcare providers who work at the facility. Midwives (both Certified Nurse-Midwives and Licensed Certified Professional Midwives) and physicians are already governed by their own professional practice standards, licensure requirements, and scope of practice. They are accountable to their respective credentialing agencies: the Kentucky Board of Medical Licensure (KBML) for physicians, the Kentucky Board of Nursing (KBN) for Certified Nurse-Midwives and Licensed Certified Professional Midwives. The regulations for birth centers as facilities should focus on regulating the facility itself, not recreating requirements for individual providers. Duplicating provider requirements in facility regulations is redundant, potentially creates conflicting standards, and adds unnecessary administrative complexity. Provider qualifications and practice standards should remain under the purview of the appropriate licensing boards.”

(a) Comment: Melissa Halte stated, “There is a difference between the birth center (the facility) and the licensed healthcare providers who work at the facility. The providers (midwives and physicians) are already governed by their own professional practice standards, licensure requirements, scope of practice, etc. They are accountable their credentialing agency i.e. KBML or KBN. The regulations for birth centers as a facility should focus on regulating the facility and not re-creating requirements for the providers. This is redundant and often unnecessary.”

(b) Response: The Cabinet appreciates these comments, but the regulation will remain unchanged.

(11) Subject: Duplication of state regulations with Commission of the Accreditations of Birth Centers (CABC).

(a) Comment: Nancy Rasche stated, “A major change from HB90 is the requirement of accreditation by CABC. This accreditation covers MANY of the details outlined in the regulations. In some cases, the info in the regulations is not consistent with the requirements for accreditation. The accreditation requirements should be carefully reviewed by staff to ensure consistency, and many items can be deleted from the regulations and allowed to rely on the accreditation requirements.”

(a) Comment: Michael Rasche stated, “A major change from HB90 is the requirement of accreditation by CABC. This accreditation covers MANY of the details outlined in the regulations. In some cases the info in the regulations is not consistent with the requirements for accreditation. The accreditation requirements should be carefully reviewed by staff to ensure consistency, and many items can be deleted from the regulations and allowed to rely on the accreditation requirements.”

(a) Comment: Kaeli Riley stated, “A major change from HB90 is the requirement of accreditation by CABC. This accreditation covers MANY of the details outlined in the regulations. In some cases the info in the regulations is not consistent with the requirements for accreditation. The accreditation requirements should be carefully reviewed by staff to ensure consistency, and many items can be deleted from the regulations and allowed to rely on the accreditation requirements.”

(a) Comment: Robin Elise Weiss stated, "A major provision of HB90 is the requirement for accreditation by the Commission for the Accreditation of Birth Centers (CABC). This accreditation is comprehensive and addresses many of the operational, clinical, and quality assurance details that regulations typically cover. I recommend that Cabinet staff carefully review the CABC Indicators for Compliance with the Standards for Birth Centers to identify areas where the proposed regulations duplicate, conflict with, or are inconsistent with accreditation requirements. Where CABC accreditation already addresses a particular requirement, the regulations can defer to accreditation standards rather than creating redundant or potentially conflicting requirements. This approach streamlines compliance for birth centers while maintaining high standards, recognizes that CABC accreditation is itself a rigorous quality assurance mechanism, and reduces administrative burden without compromising safety or quality."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM has significant concerns with the level of prescriptive clinical detail in Sections 3(7) and (8). Many of these requirements are already addressed through CABC accreditation standards and are subject to frequent change by CDC, WHO, and ACOG guidance. Embedding such detailed clinical standards in regulation risks rapid obsolescence and limits patient-centered care, including informed refusal."

(a) Comment: Melissa Halte stated, "A major change from HB90 is the requirement of accreditation by CABC. This accreditation covers MANY of the details outlined in the regulations. In some cases, the info in the regulations is not consistent with the requirements for accreditation. The accreditation requirements should be carefully reviewed by staff to ensure consistency, and many items can be deleted from the regulations and allowed to rely on the accreditation requirements."

(b) Response: OIG appreciates this suggestion. While we understand that CABC does maintain the most up-to-date standards in this industry, KRS 216B.198(2) establishes licensure standards for FSBCs.

(12) Subject: FSBCs may not be the place where a patient receives prenatal/postnatal care, they may choose to receive this care from an outside provider.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "In Section 2, the scope of operations and services, this should match the definition in KRS 216B.198. Birth centers are ultimately for the purpose of giving birth. Prenatal care may or may not be provided in that same location. It may be provided in a separate office where the providers see patients, such as when people go to the hospital to have a baby, that's generally not the same location where they received their prenatal care. This may or may not be the case for a birth center. The definition from KRS 216B.198 reads "freestanding birthing center means any health facility, place, or institution which is not a hospital, is not in a hospital or a private residence, and is established to provide care for labor, delivery, the immediate postpartum period, and the newborn immediately following delivery."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "Section 2- Scope of Operations and Services should match the definitions in 216B.198. Birth centers are ultimately for the purpose of giving birth. Prenatal care may or may not be provided there. It may be provided in a separate office where the provider(s) sees patients."

(a) Comment: Christine Peterson, of Clarksville Midwifery stated, “And so just like someone could have a hospital birth and they didn’t get their prenatal care at the hospital, they had it at their doctor’s office, the same thing can happen in a birth center setting. Ms. Peterson urged amending the regulation to better reflect the reality of practice within a birth center.

(b) Response: The cabinet appreciates bringing this matter to our attention and this has been amended in the regulation.

(13) Subject: Delete the requirement for an RN to be on staff in section 3.5A to be more aligned with CABC and Neonatal Resuscitation Program guidelines.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “In section 3.5A, under staffing, this section needs to be changed to reflect at least one midwife licensed under KRS 314, as both type of midwives licensed in Kentucky are licensed under this chapter. And we also suggest deleting the requirement for an RN to be on staff. CABC accreditation standards and Neonatal Resuscitation Program guidelines, or NRP, call for two people trained in NRP to be present, but there is no requirement for an RN. Two midwives can be present, or a midwife and an NRP-trained birth assistant would be sufficient, and that’s referenced in the CABC Standard 3.5. While I’m sure many birth centers will choose to employ RNs, we don’t think that that needs to be mandated.”

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated, “RNs can be valuable members of birth center teams, however birth assistants can be RNs, CPMs, Certified Midwives (CMs), CNMs, and other non-nurse birth assistants who receive specialized training in community birth settings and are supervised by midwives. RN shortages contribute to birth center staffing shortages when RNs are required by regulation.”

(a) Comment: Robin Elise Weiss stated, “If the regulations require that a Registered Nurse (RN) be a mandatory staff member of a birth center, this requirement should be removed or modified to be permissive rather than mandatory. Many birth centers choose to employ RNs, and this should certainly be permitted. Many birth centers across the country operate safely and effectively with midwifery staff (CNMs or CPMs) who are trained and qualified to provide the care appropriate to the birth center setting. CABC accreditation does not require RN staffing. Mandating RN staffing would add costs without corresponding safety benefits, may create staffing challenges, particularly in rural areas, and does not align with how birth centers typically operate nationally.”

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, “KANPNM recommends that each freestanding birthing center be required to have a certified nurse-midwife (CNM) as part of its clinical leadership structure. A CNM should be permitted to serve as the clinical or clinic director of the birthing center, consistent with licensure, education, and scope of practice under KRS Chapter 314.”

“Further, we recommend that a CNM, as part of the leadership team, may serve as an interim medical director, if the physician medical director position should become vacant. Requiring CNM leadership provides an important safeguard for patient safety and quality of care in a setting designed for low-risk births. CNMs are uniquely trained in the full continuum of prenatal, intrapartum, postpartum, and newborn care, including care of newborns up to twenty-eight (28) days of life—training that is not universally shared by physicians providing obstetric services.” “KANPNM strongly urges the

Cabinet to adopt the revisions proposed below in Section 3(5)(a)(1) to broaden eligibility for the medical director role to include both obstetrician/gynecologists and family physicians with obstetric experience. In the absence of a required CNM, such clarification becomes critically important to ensure appropriate clinical oversight. KANPNM strongly agrees with the proposed regulation that at least one (1) registered nurse be included in center staff."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "CABC accreditation standards and NRP guidelines call for two people trained in NRP to be present, but there is no requirement for an RN. Two midwives present, or a midwife and an NRP birth assistant is sufficient. (CABC standard 3.5) This section could also specify the medical director and nothing else. If multiple physicians wanted to open a birth center on their own, they could do so as long as they followed all criteria to obtain CABC accreditation."

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated "Our recommendation is allow flexibility in staffing, requiring at least one licensed midwife present for all births with appropriate supporting staff, including non-RN birth assistants."

(a) Comment: Kate Bauer, Executive Director of the American Association of Birth Centers, stated, "Staffing should include at least one "licensed midwife" rather than "1 nurse-midwife." Licensed and accredited Birth centers frequently operate without nurse-midwives on staff when Certified Professional Midwives staff the birth center."

(a) Comment: Ellen Hunt, Registered Nurse, stated "An RN is not a necessary mandatory staff member of a birth center. Many birth centers may choose to hire an RN, though."

(a) Comment: Kelli Perkinson stated, "An RN is not a necessary mandatory staff member of a birth center. Many birth centers may choose to hire an RN, though."

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(a) Comment: Kaeli Riley stated, "An RN is not a necessary mandatory staff member of a birth center. Many birth centers may choose to hire an RN, though."

(b) Response: The cabinet appreciates this suggestion, and the requested amendment has been made.

(14) Subject: Delete the following from Section 5 A.1. "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 the board-eligible or board-certified pediatrician. Either the medical director, consultant, obstetrician, or pediatrician shall have admitting privileges in a local hospital which offers obstetric services."

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "Our rationale for this is that with the passage of HB 90, the requirement for a medical director is codified in statute, and this was a major point of negotiation in the legislation. The medical director requirement is sufficient to cover the required physician oversight for a birth center. Retaining the requirements of this section from the previous antiquated regulations is unnecessary, imposes an unreasonable burden to a birth center. CBAC Standard 2C9 covers these requirements and allows for "agreements and/or written policies and procedures for collaboration with other agencies, institutions, or individuals for services to clients, including, but not limited to, obstetric consultation services, pediatric services, and transport services." It is important to know that written agreements with these other providers is not mandated by the statute or the accreditation requirements. It is highly likely that obstetricians and pediatricians, many of whom are employed by hospital systems, particularly if they have admitting privileges, are unlikely to be permitted to enter into such written agreements with birth centers due to perceived concerns for liability. This, however, does not mean that the providers of the birth center will not have professional relationships for consultation and collaboration. Certified Nurse Midwives and Licensed Certified Professional Midwives are already practicing in Kentucky attending out-of-hospital births without such written agreements with OBs and pediatricians."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends deleting subsections (b) and (c). The qualifications of the medical director are already addressed elsewhere in the regulation, making these provisions redundant."

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, recommended the addition of inclusive language for midwives. Ms. Scisney stated the regulation, "currently states that the staff must include medical director or physician, at least one nurse midwife, and at least one registered nurse. The nurse midwife is specified, but the CPM is not included, and that is a strong non-negotiable. That is something that we really want to make sure that the amendments recognize all licensed midwives as primary providers."

(b) Response: The cabinet appreciates these comments, and the provision will be removed.

(15) Subject: Transfer Agreements are not needed for FSBCs.

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "No provision has been made in the regulation so far for a timeline for when the agreement is required. Above it says that the agreement must be filed with the Cabinet within 10 days of finalization. For scenarios where an agreement is never finalized, please note that KRS 216B.198(5)(b) says "The cabinet shall establish a process and criteria by which the requirement [of a transfer agreement with a hospital with obstetric services] may be waived if a freestanding birthing center submits to the cabinet evidence of a failure by a hospital that provides obstetric services to enter into a written patient transfer agreement with the freestanding birthing center."

(b) Response: KRS 216B.198 requires the cabinet to establish licensure standards for levels of care including FSBCs. Additionally, KRS216B.198(5)(a) and (6)(b) requires the

FSBC to have a written patient transfer agreement with a hospital and a licensed emergency medical transportation service. Written agreements are a requirement for other licensed healthcare entities. Additionally, CABC standards also require agreements with transportation services, hospitals, laboratories, obstetrics, and home health care services.

(16) Subject: Recommendations for a waiver process for obtaining a Medical Director for a FSBC.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "Section 3(5)A1(a), we suggest adding language to defer the acquisition of a new medical director if the birth center can document that it has been making an attempt. It could likely be a very lengthy process to secure a new medical director if the center suddenly loses its current medical director. We do not want to see a situation where a birth center must close while it is actively seeking to fill the position."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "Suggest adding language to defer the acquisition of a new medical director if the birth center can document that it has been making an attempt. It could likely be a very lengthy process to secure a new medical director if a center abruptly loses its current medical director to unforeseen circumstances. Forcing a facility to prematurely shutter its doors fractures community confidence and is economically unsustainable. Ninety-days is a fair start, but there is simply not enough providers as it stands and so long as substantial efforts are being made, birthing centers should have some sort of state partnership agreement opportunity or more accommodating timeframe. Identifying medical directors should be given thoughtful consideration and not be hastily acted on in ways that stifles the economic viability of birthing centers."

(b) Response: in accordance with KRS 216B.198(3)(a) a FSBC must have a medical director who is a licensed physician and according to KRS 216B (b) the cabinet shall establish a timeline for an FSBC to fill the position of medical director if a position becomes vacant. The cabinet has updated the regulation with a timeframe. If the birth center can document that it has been making a good faith attempt to fill the medical director vacancy, a time limited extension may be given to the facility by the Inspector General on a case-by-case basis.

(17) Subject: Deleting requirements for CEUs related to "the human relationship necessary for effective healthcare".

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "In section 3(5)B, we had some questions about why was this specific language included, and how would one obtain CEUs related to "the human relationship necessary for effective healthcare." This is inherent in the midwifery model of care."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends deleting this subsection. Licensed professionals are already subject to continuing education requirements established by their respective licensure boards, rendering this provision redundant."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "Some of the language in this section is confusing to the Midwifery Model of Care core

competencies, specifically this part: 'the human relationship necessary for effective health care'. This is inherent in the Midwifery Model of Care, and Kentucky LCPMs indicate they have never seen CEUs for this topic."

(b) Response: Specific requirements for CEUs were removed. However, FSBCs shall maintain proof of continuing education and keep on file in the facility.

(18) Subject: Update of modern hiring practices and Tuberculosis (TB) testing for health care workers.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "Section 3(6)B1 should be updated to reflect modern hiring and testing practices."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends deleting requirements for routine physical examinations and tuberculosis skin testing. These requirements are no longer standard practice in hospitals or licensed health facilities and impose unnecessary administrative burden without demonstrated patient safety benefit."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "Even hospitals, birthing or otherwise, do not require this annually, and this is in fact is contradictory in application based on what Kentucky facilities are allowed to have as public health rules in place."

(b) Response: The cabinet appreciates the suggestion, and the requested updates have been made to 902 KAR 20:150 to include compliance with 902 KAR 20:205 Tuberculosis (TB) testing for health care workers.

(19) Subject: Delete the requirement for a pharmacist.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "there is no logical reason to keep the requirement for a pharmacist."

(b) Response: While the FSBC may not need a pharmacist, it is still expected that a FBMC drugs and biologicals are received from a pharmacy. Any contraindications of possible adverse actions are monitored by the practitioner. Consultation with a pharmacist at the pharmacy may be necessary.

(20) Subject: Recommendation for rewording to reflect that the center shall have a mechanism in place to receive calls 24 hours a day, 7 days a week, to alert on-call staff.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "In Section 4.2.B, we recommend rewording that to reflect that the center shall have -- shall ensure that a mechanism is in place to receive calls 24 hours a day, 7 days of week, in order to alert the on-call staff."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "Sections 4 should be revised" Ms. York further stated, "This structure provides flexibility while ensuring patient safety and accounts for circumstances in which a patient may arrive before a provider."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "The building itself isn't staffed 24/7 if someone is not admitted. But there will always be some mechanism to reach someone, whether it be a pager, etc. 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."

(b) Response: The cabinet appreciates this recommendation and has made the requested amendment to 902 KAR 20:150.

(21) Subject: Recommendation regarding deleting the use of ultrasound in a FSBC.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "In Section 4.4, patients will have an ultrasound coordinated with the provider practice. No one should need an ultrasound once they are admitted to a birth center. CABC accreditation does not permit ultrasound to be used during labor in the birth center, as that would indicate that the person is high-risk and not appropriate for care at the birth center."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends deleting radiologic services. X-ray are not required at a birthing center. Ultrasound capability may be available for prenatal care and point-of-care assessment. Ultrasound should not be mandated but should be permitted when clinically appropriate."

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, "Patients will have ultrasound coordinated with the provider practice. No one should need U/S once they are admitted to the birth center. Accreditation does not allow U/S to be used during labor in the birth center-- that would indicate the person is high-risk."

(b) Response: The cabinet appreciates this recommendation, and the regulation has been amended to reflect this change.

(22) Subject: Removal of duplicative language related to the administration of medication.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "In Section 4.5, CABC accreditation includes a list of required medications, and that's in their accreditation standard 4B.1. Section 4.5D, this section is unnecessary and duplicates Section C above it. Anyone who is legally allowed to administer drugs should be able to do so, and LCPMs are authorized under KRS 314.404 Subsection 8, and 201 KAR 20:650 to obtain, transport, and administer specific drugs. There is a specific formulary of medications for LCPMs that are in that regulation. This is another important area were LCPMs were omitted."

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, "KANPNM recommends: Deleting subsections (b) and (c) as redundant; Adding the sentence: 'Oxytocic drugs shall not be used to induce or augment labor.'; Removing physician assistants from the list of medication administrators; Adding licensed certified professional midwives if CHFS elects to include them elsewhere in the regulation."

(b) Response: Duplicative language within Sections 4 and 5 have been updated. However, drug distribution and storage requirements will remain within 902 KAR 20:150.

(23) Subject: Recommendation to delete provisions in Section 7.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, "Section 7, most, if not all, of these clinical facility requirements are contained in the CABC accreditation requirements. We suggest considering deleting this section and deferring the

accreditation requirements. However, I will highlight some changes that should be made if this section is kept.”

(a) Comment: Dolores Polito stated, “The requirement for a dedicated infant formula preparation room is unnecessary and unsupported by national birth center standards. Birth centers use commercially available infant formula only when breastfeeding is not possible and a separate formula room does not enhance safety. In fact, this requirement creates unnecessary regulatory burden, and the Affiliate recommends removing this requirement.”

(b) Response: Dimensions of the exam rooms in Section 7(1) will remain unchanged. The formula room requirements have been removed in Section 7.

(24) Subject: Prenatal and post-natal exams may or may not happen at the same location as the birth center, such as if the provider has a separate office.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “In Section 7.1, examination rooms are unnecessary to be specified. Prenatal and postpartum exams may or may not happen at the same location as the birth center, such as if the providers have a separate office.”

(b) Response: The cabinet appreciates the recommendation, and the regulation has been amended to incorporate the changes.

(25) Subject: Recommendation to change size of birthing rooms to follow Facility Guidelines Institute (FGI) guidelines.

(a) Comment: Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “In Section 7.2, this needs to follow the Facility Guidelines Institute guidelines, or the FGI. For birth centers, the 2022 FGI guidelines reduced the minimum size for birthing rooms from 200 to 120 square feet of clear floor area aligning them with the more homelike settings while still allowing space for care with many existing rooms already smaller than the previous standard. This change reflects a trend towards more flexible, patient-centered spaces, reducing requirements in favor of clearances and functionality.”

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, “the 2022 FGI Guidelines reduced the minimum size for birthing rooms from 200 to 120 square feet of Clear Floor Area (CFA), aligning them more with home-like settings, while still allowing space for care, with many existing rooms already smaller than the previous standard. This change reflects a trend toward more flexible, patient-centered spaces, reducing requirements in favor of clearances and functionality.”

(b) Response: The cabinet appreciates the feedback, and the regulation has been amended to incorporate these changes.

(26) Subject: Recommendation to change the wording of “Emergency Care” to “Transfer and Transport Agreements”.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “In Section 8, we suggest changing the title of this section from ‘Emergency Care’ to something such as ‘Transfer and Transport Agreements.’”

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, “Section 8 (1) should be revised to require a written agreement with a Class I Advanced Life Support (ALS) ambulance service. Emergency transfers involving

laboring patients or newborns require paramedic-level care and equipment, and the regulation should reflect this standard.”

(a) Comment: Kate Bauer, Executive Director of the American Association of Birth Centers, stated, “According to the recently passed legislation, the transfer agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because a patient may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be a hospital with obstetric services.”

(b) Response: The cabinet appreciates the feedback, and the regulation has been amended to incorporate these changes.

(27) Subject: Request for consideration related to agreements with out-of-state hospitals.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “Section 8.1 specifies that the transfer agreement must be with a Kentucky licensed hospital; however, what if the birth center is geographically closest to an out-of-state hospital? Would that be acceptable to have an agreement with that out-of-state hospital? So, we suggest that being reviewed. Section 8.2 specifies that the agreement must be filed within 10 days. This needs clarification. Can the center open before the agreement is obtained, or must it simply be filed within 10 days of finalization? Section 8(3)A, a statute does not require the transfer agreement to be with a hospital located within 30 miles. The statute simply requires that a birth center be located within 30 miles of a hospital per KRS 216B.198, Subsection 2C. The statute also clarifies that the birth center can continue to operate in the event of the closure of the hospital that would be within 30 miles. The Hospital Transfer Agreement, however, specified in KRS 216B.198, Subsection 5, does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it is with a hospital providing obstetric services. This was all very intentionally written into the language. The closest obstetric hospital may not be the actual closest hospitals, and as we know, many hospitals do not provide obstetric services. And so, these things have been combined in the proposed regulations, and so that needs to be separated and clearly defined.”

(a) Comment: Jill York, Executive Director, KANPNM, submitted written comments stating, “Section 8 (3)(a)(2) The Birthing center should be 30 miles from the nearest hospital. The center does not need to have an agreement with this hospital. 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The transfer agreement should be with a hospital that provides obstetrical care.”

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, “The agreement does not need to be with a hospital within 30 miles, the birth center simply needs to be located within 30 miles of any hospital per KRS 216B.198(2)(c). This is because you may need emergency care and need to go to the closest hospital, which may or may not have L&D, depending on the nature of the emergency. The transfer agreement, however, specified in 216B.198(5) does not specify geographic proximity to the hospital with which the transfer agreement is held. The only requirement is that it be

a hospital with obstetric services. The closest obstetric hospital may not be the actual closest hospital.”

(b) Response: The cabinet appreciates the feedback, and the regulation has been amended to incorporate these changes.

(28) Subject: Recommendation to delete Section 8(3) e.2.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “Section 8(3)E2, suggest deleting or revise “receive confirmation of the availability of appropriate facility, services, and staff necessary for the care of the patient.” This would seem to imply that the hospital can reject the transfer, which may violate federal EMTALA laws.”

(b) Response: While the cabinet appreciates the comment, notifying the hospital of an impending emergency is essential for patient safety and appropriate care. The regulatory language will remain unchanged.

(29) Subject: Recommendation to add language requiring the hospital to submit patient records of care provided at the hospital back to the birth center.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “Section 8.3, we suggest adding another item here requiring the hospital to submit patient records of care provided at the hospital back to the birth center, so this is a two-way street of communication.”

(b) Response: 902 KAR 20:150 regulates FSBCs, not hospitals. Patient records returning from hospitals may be addressed with each hospital transfer agreement.

(30) Subject: Recommendation to delete Section 8(4)c.2. Regarding staff training in the ambulance service.

(a) Comment: Mary Kathryn DeLodder, KY Birth Coalition, stated, “Section 8(4)C2 speaks to staffing and training for the ambulance service. We ask if this is appropriate to include in regulations about birth centers. This isn't a regulation for ambulance services, and I would question the appropriateness of dictating these things here. It would seem to be the purview of the Kentucky Board of Emergency Medical Services.”

(b) Response: The cabinet appreciates the feedback, and the regulation has been amended to incorporate these changes.

(31) Subject: Permitting Certified Nurse Midwives and Certified Professional Midwife to serve as Clinical Director.

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated, “Certified Nurse Midwives and Certified Professional Midwives should be permitted to act as clinical directors, consistent with national standards set by AABC and CABC.”

(a) Comment: Jill York stated, “Further, we recommend that a CNM, as part of the leadership team, may serve as an interim medical director, if the physician medical director position should become vacant.”

(a) Comment: Dolores Polito stated, “The regulation currently limits transfer decision-making authority to physicians. This does not reflect Kentucky licensure law or the scope of practice of midwives. The Affiliate recommends the following revision: “Require transfer of a patient if deemed medically necessary by the physician, certified nurse-

midwife (CNM), or licensed certified professional midwife (LCPM) attending the patient, consistent with licensure authority under KRS Chapter 314.”

(b) Response: KRS 216B.198 mandates that the Medical Director be a licensed physician. The regulatory language will remain unchanged for the Medical Director. However, the regulation has been updated to clarify who may be designated in the rare event of a search for a new medical director should the position become vacant. The cabinet believes decisions regarding transfer are most appropriately made by the Medical Director of the facility.

(32) Subject: Scope of practice and exclusion criteria.

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated “Currently, it excludes criteria and emergency policies must be approved by the medical director, which is a physician. The AABC model recommends that we want to allow the clinical director to be a licensed midwife and to be able to approve those policies, and they should be able to refer to the CABC standards for the risk assessment and exclusion criteria to build those policies.”

(a) Comment: Kelly Taulbee, Policy Director for KY Voices for Health (KVH), stated, “This section needs to be reworded to include all licensed midwives. Change the last sentence to delete ‘revised, signed, and dated.’ While protocols will be reviewed annually, they may not need to be revised annually.”

(a) Comment: Cassaundra Jah, Executive Director of the National Association of Certified Professional Midwives, stated, “Certified Nurse Midwives and Certified Professional Midwives should be permitted to act as clinical directors, consistent with national standards set by AABC and CABC.”

(b) Response: Current KRS 216B.198 mandates that the Medical Director be a licensed physician. The FSBC will develop policies and procedures. While the regulation addresses that certain ones will be reviewed and approved by the Medical Director, it indicates that the written protocols will be developed by the Medical Director and licensed midwives. The regulation has been clarified that the written protocols will be annually reviewed but may or may not need to be revised annually.

(33) Subject: Use of certain gendered language.

(a) Comment: Maria Carr, a certified nurse midwife and labor and delivery nurse, stated, “I also suggest amending lanugage to update woman to person to be more inclusive with language, because it is physically possible for a transgender man to carry a pregnancy.”

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative stated, “Our section 6 is about inclusive person-centered language. Currently, right now, it uses “pregnant woman” and “mother” throughout. The recommendation is to update inclusive language for everybody to also be included.”

(a) Comment: Kelli Perkinson stated, “Maintain the terms ‘woman/women’ and ‘mother(s)’ in the regulation language rather than erase women and our uniquely honored place in society with the ‘inclusive’ term ‘birthing person’ that negates the creative power belonging only to women.”

(a) Comment: Nancy Rasche, stated the Cabinet should, “Maintain the terms ‘woman/women’ and ‘mother(s)’ in the regulation language rather than erase women

and our uniquely honored place in society with the 'inclusive' term 'birthing person' that negates the creative power belonging only to women."

(a) Comment: Melissa Halte stated, "We are females, women, ladies not persons giving birth!!"

(b) Response: While the cabinet appreciates these comments, the regulation will remain unchanged.

(34) Subject: Addition of Quality Assurance and Data Collection.

(a) Comment: Alexa Scisney, Executive Director of Granny's Birth Initiative, stated "Section 8 is about quality assurance and data collection. Right now, there's nothing explicitly addressed, so we want to make sure that our birth centers are collecting data and that they are up to quality. So, we want to add a requirement for a quality assurance program and participation in national data collection and reporting. Heavy on the reporting, because being a part of collection does not mean that people then are required to then put it out there so that birthing people can actually assess if this is the best facility for them."

(b) Response: The cabinet may consider this for a future amendment to the regulation if data collection and national reporting are deemed useful.

Summary of Statement of Consideration Action Taken by Promulgating Administrative Body

A public hearing on 902 KAR 20:150 was held on January 30, 2026, at 12:00 p.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period. The Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care responded to the comments and amends the administrative regulation as follows:

Page 1

Section 1(2)

Line 16

After "Freestanding birthing center" insert "(FSBC)"

Page 1

Section 1(3)

Line 19

After "recognized by", insert the following:

the Commission for the Accreditation of Birth Centers (CABC)

Delete the following:

The American College Obstetrics and Gynecologists in their Standards for Obstetric-Gynecologic Services, as amended

Page 2
Section 2
Line 4

After "childbirth including", delete "prenatal".
After "labor, delivery," , insert "and may include prenatal".

Page 2
Section 3 (1) (c)
Line 12 -14

Delete the following:
Each center shall be accredited and show proof of accreditation by
American College of Obstetricians and Gynecologists (ACOG).(d)

Re-letter paragraphs (e) – (h)

Page 2
Section 3(1)(g)
Line 20

After "four (4) beds" insert: "or fewer".

After "that have" Delete: "fewer than".

Page 3
Section 3 (4)(a)7.
Line 23

After "exclude a" insert: "patient".

Delete "pregnant woman or mother".

Page 4
Section 3 (5)(a)
Line 20

After "medical director" insert "and; (b)".

Delete: " ,"

Page 4
Section 3 (5)(a)
Line 21

After "at least one (1)" delete "nurse midwife"

After "at least one (1)" insert the following:
Licensed Certified Professional Midwife (LCPM) or Advanced Practice
Registered Nurse designated certified nurse midwife licensed under

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

Delete the following:

and at least one (1) registered nurse. In centers where an obstetrician provides perinatal care, a nurse-midwife is not required

Page 5

Section 3 (5)(a)1.

Lines 3-10

After "a licensed physician", delete the following:

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

Page 5

Section 3 (5)(a)1.b.

Line 13

After "b." insert the following"

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.

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.

Page 5

Section 3(5)(a)2.

Line 14

After "2." Insert the following:

Licensed Certified Professional Midwife (LCPM) or Advanced Practice Registered Nurse designated certified nurse midwife (APRN CNM).

After "2" delete "Nurse Midwife. Nurse"

Page 5

Section 3 (5)(a)2.

Lines 16

After “developed by the”, delete: “nurse-midwife and”.

Page 5

Section 3 (5)(a)2.

Lines 17

After “medical director” insert “and licensed midwives” .

Page 5

Section 3 (5)(a)2.

Line 17

After “shall be reviewed” insert “annually and” .

Delete “,”

After “dated” insert “as necessary” .

Page 5

Section 3 (5)(a)2.

Line 18

Delete “on an annual basis”.

Page 5

Section 3 (5)3.

Line 19

Delete the following:

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.

Page 5

Section 3 3.(b)

Lines 22

insert “(6)”

Delete (“b”)

Renumber the remainder of Section 3. (7) – (12)

After “shall provide” insert: “proof of”.

Delete the following:

for all personnel relating to their respective job activities

After “programs” insert the following:

required by their respective professional licensure board(s)

Delete: These programs shall emphasize professional competence and the human relationship necessary for effective health care

Page 6

Section 3 (6)(b)1.

Line 6

After "1." insert the following:

Evidence of compliance with 902 KAR 20:205.

Delete the following:

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;

Page 7

Section 3 (7)(c)

Line 23

After "position and auscultation", delete the following:

pelvic adequacy, including rectum and size of uterus,

Page 8

Section 3 (7)(d)

Line 2

Delete the following:

urinalysis for sugar and protein determination, pap smear,

Page 8

Section 3 (7)(d)

Lines 3-5

After "irregular antibodies," delete the following:

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

Page 8

Section 3 (7)(g)

Lines 8 - 9

After "blood pressure," delete "urinalysis for protein, sugar,".

Page 8

Section 3 (7)(g)

Line 10

After "or quickening," insert "follow-up".

Delete "third trimester".

Page 8
Section 3 (7)(g)
Line 11

After "or hematocrit," delete "repeat venereal disease test,".

Page 8
Section 3 (7)(g)
Line 12 -13

After "unsensitized women;" delete the following:
and repeat antibody titers at twenty-six (26) weeks, thirty-two (32) weeks, and
thirty-six (36) weeks;

Page 8
Section 3 (7)(h)
Line 14

After "(h)" insert "Physical"
After "(h)", delete the following:
Parturient initial record of intercurrent problems,

Page 8
Section 3 (7)(h)
Line 15

After "blood pressure," delete the following:
head, heart, lungs, abdomen for lie

Page 8
Section 3 (7)(h)
Line 15 -16

After "presentation position," delete "fundal height".

Page 8
Section 3 (7)(h)
Line 16

After "and engagement," delete "reevaluation of pelvic adequacy,".

Page 8
Section 3 (7)(h)
Line 17

After "membranes," delete the following:
record of hemoglobin or hematocrit and urine for protein and sugar

Page 8
Section 3 (7)(j)
Line 20

After "Apgar score, insert "laceration".
Delete "episiotomy".

Page 8

Section 3 (7)(k)

Line 22

After "Puerperium-time records", delete the following:
for at least six (6) hours,

Page 8

Section 3 (7)(k)

Line 23

After "urine output," delete "report of breasts and".

Page 8-9

Section 3 (7)(k)

Lines 23-1

After "breastfeeding status," delete the following:
legs for thrombophlebitis, hemoglobin or hematocrit,

Page 9

Section 3

Line 4

After "breast, abdominal," delete "pelvic including rectal examination,".

Page 9

Section 3 (7)(l)

Line 5

After "study," delete the following:
hematocrit or hemoglobin, and urinalysis

Page 9

Section 3 (8)(c)

Line 10

After "(c)", delete "Complete".

Page 9

Section 3 (8)(d)

Line 13

After "transfer to" insert "higher level of care".
Delete "appropriate nursery".

Page 9

Section 3 (8)(i)

Line 20

After "designation of responsible" insert "care provider".
Delete "physician".

Page 9

Section 3 (8)(i)

Line 21

Before "upon discharge" delete "immediately".
After "upon discharge", delete "and thereafter"
After "," delete "and"

Page 9
Section 3 (8)(j)
Line 22

After "notes describing", delete "first and subsequent".
After "feedings", delete "type".
Before "voiding", delete "time of first".

Page 9
Section 3 (8)(j)
Line 23

After "body temperature" insert "medication administration; and (k) Newborn

Delete "Vitamin K prophylaxis,".

Page 10
Section 3 (8)(j)
Line 4

After "the newborn." insert the following:
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.

Page 10
Section 3 (9)
Line 5- 8

After (9), delete the following:
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.

Page 10
Section 3 (12)(d)
Line 18

After "name of" insert "provider".

Delete the following:
attending physician or nurse-midwife

Page 10 and 11

Section 3 (14)

Lines 21-7

Delete (14) in its entirety.

Page 11

Section 4 (1)

Line 10

Delete "(a)"

Page 11

Section 4 (1)(b)

Line 12

Delete the following:

(b) There shall be sufficient staff coverage for all aspects of the center in keeping with the size and scope of the operation.

Page 11

Section 4 (2)

Line 14

After (2), insert "Staffing"

Page 11

Section 4 (2)(a)

Line 15

After "A" insert "licensed midwife".

Delete "nurse-midwife".

After "physician and a" insert the following:
member of the FSBC clinical staff

Delete "registered nurse".

Page 11

Section 4 (2)(a)

Line 15-16

After "when a" insert "patient".

Delete "pregnant woman".

Page 11

Section 4 (2)(a)

Line 16-17

After "when a" insert "patient is".

Delete the following:

woman or mother and newborn are

Page 11

Section 4 (2)(b)

Line 19

After "center shall" insert the following: "ensure"

Delete the following: "insure"

After "that" insert the following:

a mechanism is in place to receive calls

Delete the following: "phones are answered"

Page 11

Section 4 (3)

Line 5-14

Delete the following:

"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."

Page 12

Section 4 (3)(c)

Line 7-8

Delete the following:

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

(4)

Page 12

Section 4 (4)

Line 8 - 11

Delete the following:

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.

Page 12
Section 4 (4)
Line 11-12

After "entered into the" insert: "patient's".
Delete the following:
"pregnant woman's or mother's"

Page 12
Section 4 (5)(d)4.
Line 24

Delete the following: "or"

Page 13
Section 4 (5)(d)5.
Line 1

After "registered nurse" Insert the following:
:or
6. Licensed Certified Professional Midwife;

Page 15
Section 7 (2)
Line 5

After "floor area of "insert "120".

Delete "225".

Page 15
Section 7 (3)(b)
Line 9

After "(b)", delete the following:
Infant warmer with radiant heat source;

Renumber the remainder of the section

Page 15
Section 7 (3)
Line 13-14

Delete the following:
(f) Intubation equipment for mother and newborn; and
(g) Wall clock with a second hand.

Page 15
Section 7(4)(a)
Line 16

After "(a)" insert the following:

Proper sterilization equipment used for the sterilization of birth instruments

Delete the following:

Sterilizing facilities with high speed autoclave(s) conveniently located to serve all birthing rooms

Page 15

Section 7 (4)(b)

Line 18

After "(b)" insert the following:

Adequate access to sinks for handwashing should be available

Delete the following:

Scrub facilities provided near the birthing room entrance

Page 15

Section 7 (5)

Line 21

After "(5)", delete the following:

"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)

Page 16

Section 7 (6)(a)

Line 7

After "and visitors are" insert "assured".

Delete "assure".

Page 17

Section 8

Line 16

After "Section 8" insert "Transfer and Transport Agreements."

Delete "Emergency Care".

Page 17
Section 8 (1)
Line 18

Delete "Kentucky-".
After "licensed", delete "acute-care".
After "hospital" insert "that provides obstetrics services".

Page 17
Section 8 (3)
Line 23

Delete "Kentucky-".
Delete "acute-care".

Page 18
Section 8 (3)(a)1.
Line 2

After "In the same" insert "or contiguous".

Page 18
Section 8 (3)(a)2.
Line 3

After "2." insert "Within".

Delete "No further than".

After "thirty (30) miles", delete "normal driving time".

Page 19
Section 8 (4)(c)2.
Line 15-17

Delete the following:

"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;"

Re-number the remaining subsections.