

Brian P. Kemp, Governor

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

# PUBLIC NOTICE OF PROPOSED RULE CHANGES

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia (O.C.G.A.) § 50-13-1, et seq., the Georgia Department of Community Health is required to provide public notice of its intent to adopt, amend, or repeal certain rules other than interpretative rules or general statements of policy. Accordingly, the Department hereby provides notice of its intent to transfer and repeal the Rules and Regulations for Birth Centers, from Rules & Regs., R. 290-5-41 to new Chapter 111-8-7. These changes are being proposed pursuant to the authority granted to the Department in O.C.G.A. §§ 33-21A-12 and 49-4-1. An exact copy of the revised rules and a synopsis of the revisions are attached to this public notice.

#### NOTICE OF PUBLIC HEARING

An opportunity for public comment will be held on September 15, 2020 at 10:00 a.m. via WebEx audio. There will be no in-person attendance at the Department of Community Health. The WebEx event number is 127 411 2016 and the event password is "Public". Follow these instructions to join the event:

- 1. Copy the following link to a browser: <a href="https://dchevents.webex.com/dchevents/onstage/g.php?MTID=e44d7dcb">https://dchevents.webex.com/dchevents/onstage/g.php?MTID=e44d7dcb</a> 93755f589ab9c46a6df8e3e06
- 2. Click "Join Now".

Oral comments may be limited to ten (10) minutes per person. Individuals who are disabled and require assistance to participate during this meeting should contact the Office of General Counsel at (404) 657-7195 at least three (3) business days prior to the meeting.

Individuals wishing to comment in writing on any of the proposed changes should do so on or before September 18, 2020. Due to reduced physical staffing at the 2 Peachtree St. location in an attempt to limit the amount of exposure to COVID-19, DCH encourages written public comments submitted in accordance with O.C.G.A. 50-13-4(a)(2) to be submitted via e-mail to the following e-mail address: **PublicComment@dch.ga.gov**.



Any comments not able to be submitted via e-mail may be submitted via regular mail to the following address:

Attention: Mary Peterkin Office of General Counsel Georgia Department of Community Health 2 Peachtree Street, NW, 40<sup>th</sup> Floor Atlanta, GA 30303

Comments from written and public testimony will be provided to the Board of Community Health prior to October 8, 2020. The Board will vote on the proposed changes on October 8, 2020.

NOTICE IS HEREBY GIVEN THIS 13th DAY OF AUGUST, 2020

Frank W. Berry, Commissioner

#### **RULES OF**

## **GEORGIA DEPARTMENT OF COMMUNITY HEALTH**

#### **HEALTHCARE FACILITY REGULATION DIVISION**

#### **REPEAL CHAPTER 290-5-41**

#### AND

#### **REPLACE WITH NEW CHAPTER 111-8-7**

#### **RULES AND REGULATIONS FOR BIRTH CENTERS**

#### **SYNOPSIS OF REVISED RULES**

#### **STATEMENT OF PURPOSE:**

The Department of Community Health proposes to repeal the Rules and Regulations for Birth Centers Chapter 290-5-41 and publish amended Birth Centers Rules under Chapter 111-8-7. This change is necessary to reflect that Birth Centers are subject to regulation by the Department of Community Health rather than the Department of Human Resources, which has since been renamed as the Department of Human Services. These rules are being proposed pursuant to the authority granted to the Department of Community Health in O.C.G.A. §§ 31-2-4, 31-2-5, and 31-7-1 et seq.

#### MAIN FEATURES OF THE PROPOSED RULE:

The proposed Rules and Regulations for Birth Centers, Chapter 111-8-7, update the existing rules by replacing the Chapter number, replacing the name of the Department, and correcting rule numbering and grammatical errors. The proposed Rules and Regulations for Birth Centers, Chapter 111-8-7, do not change any substantive provisions of the existing rule.

## **RULES OF**

# GEORGIA DEPARTMENT OF HUMAN SERVICES COMMUNITY HEALTH DIVISION OF PUBLIC HEALTH HEALTHCARE FACILITY REGULATION

## CHAPTER <del>290-5-41</del> 111-8-7

## **RULES AND REGULATIONS FOR BIRTH CENTERS**

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#### Rule 290-5-41 111-8-7-.01 Definitions

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

- (a) "Administrator" means the individual who is responsible for the day to day management of the center.
- (b) "Birth Center", "Birthing Center" or "Center" means a facility, other than the laboring woman's legal residence, which admits persons for the purpose of childbearing and which facility has not been classified and licensed by the Department as a hospital.
- (c) "Birth Room" means any room within a center which is provided as an area where births take place.
- (d) "Certified Nurse Midwife" means an individual who is a Registered Nurse currently licensed in the State of Georgia and who is also certified by the American College of Nurse Midwives.
- (e) "Department" means the Georgia Department of Human Resources Community Health.
- (f) "General Anesthesia" means any drug, element or other material which is administered to eliminate all sensation and which, when administered, is accompanied by a state of unconsciousness.
- (g) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, or person or group of persons who maintain and control the operation of the center and who are legally responsible for its operation.
- (h) "Hospital" means any facility which meets the requirements of and is currently licensed as a hospital under the provisions of OCGA Chapter 31-7, Article 1, and is in compliance with all rules and regulation of the Department pertaining to Maternity, Obstetrics and Newborn services.
- (i) "Local Anesthesia" means any drug which, when administered, provides localized temporary loss of sensation, but not accompanied by a state of unconsciousness.
- (j) "Low Risk Patient" means an individual who:
  - 1. is in general good health with uncomplicated prenatal course;

- 2. is participating in an ongoing prenatal care and education program;
- 3. has no major medical problems;
- has no significant signs or symptoms of hypertension, toxemia, hydramnios, abruptio placenta, chorioamnionitis, malformed fetus, multiple gestation, intrauterine growth retardation, fetal meconium, fetal distress, alcoholism, or drug addiction, Rh or other blood group antigen sensitization;
- 5. has no history of fetal wastage or premature delivery;
- has no previous significant obstetrical complications likely to recur, nor previous uterine wall surgery or Caesarean section;
- 7. has parity under six unless a justification for a variation is documented by clinical staff;
- 8. is not a nullipara of greater than thirty six years of age;
- 9. is not less than sixteen years of age at onset of pregnancy;
- is appropriate for a setting where anesthesia is limited to local infiltration of the perineum, or a pudendal block, and analgesia is limited;
- 11. while in active labor:
  - demonstrates no significant signs, or symptoms, or evidence of anemia, significant hypertension, placenta previa, malpositioned fetus or breech;
  - (ii) is progressing normally;
  - (iii) is without prolonged ruptured membranes; and
  - (iv) is not in premature labor.
- 12. is not postmature.
- (k) "Patient" means any woman who receives antepartum, intrapartum and postpartum care, or any newborn who receives medical care, in facilities governed by these regulations.

- (I) "Permit" or "License" means an authorization granted by the Department to the Governing Board to operate a birth center.
  (m) "Physician" means an individual who is currently licensed to practice medicine in the State of Georgia and is board certified or board eligible in obstetrics, family practice or pediatrics.
- (n) "Plan of Correction" means an acceptable written plan submitted to the Department by the person or persons responsible for the center and which states proposed procedures and methods to correct the areas of non-compliance within an acceptable time frame.
- (o) "Practitioner" means a physician or a certified nurse midwife.
- (p) "Professional Staff" means the group of physicians, certified nurse midwives, other registered nurses, licensed practical nurses and other health professionals who require special licensure, certification or registration, who provide patient services at the center.
- (q) "Provisional Permit" means an authorization granted by the Department to operate a birth center on a conditional basis in order to allow a newly established center a reasonable but limited period of time, as determined by the Department, to demonstrate that operational procedures are in satisfactory compliance with these rules and regulations, or to allow an established and operating center a specific length of time to comply with these regulations, provided said center shall first present an acceptable plan of correction.
- (r) "Regional Anesthesia" means any drug, element or other material which, when administered, is accompanied by temporary sectional loss of sensation.
- (s) "Special Care Capability" means availability of on-site equipment for use in providing emergency care to adult and newborn patients.

#### Rule 290-5-41 111-8-7-.02 Application for Permits

(1) The governing body shall submit an application to the Department for a permit using forms provided by the Department. No center shall be operated in Georgia without a valid permit which shall be displayed in a conspicuous place within the center. Failure or

refusal by the governing body of any facility existing at the time these rules become effective to file an application for a permit within ninety (90) days shall constitute a violation of law and shall be dealt with as provided by law.

- (2) The applicant for a permit to operate a birth center shall submit a completed application and a certification that the applicant is able and willing to comply with the minimum standards for a birth center and with the rules and regulations lawfully promulgated. Each applicant shall be responsible for complying with applicable fire safety laws and shall present evidence of such compliance, prior to receiving a permit.
- (3) The application shall include complete information concerning the name and address of the applicant and the services to be provided; the ownership of the property and operation; if organized as a corporation, the names and addresses of each officer and members of the board of directors of the corporation; if organized as a partnership, the names and addresses of each partner; the identity of the medical director of the facility; and any other information which the Department may require.
- (4) The applicant shall submit evidence of approval from the State Health Planning and Development Agency, as a part of the application to the Department for a permit.
- (5) Plans for birth centers shall be submitted to the Department for review and approval in two stages of development:
  - (a) schematic drawings; and
  - (b) final working drawings and specifications.
- (6) A permit shall be issued to the person or persons named only for the premises listed on the application for licensure.
- (7) Permits are not transferable or assignable.
- (8) Changes in ownership shall be subject to prior review and approval as required by the State Health Planning and Development Agency Department. Each planned change of ownership or lease shall be reported to the Department and to the State Health Planning and Development Agency at least sixty (60) days prior to such change along with an application from the proposed new owners for a new permit.

- (9) The Center shall file a new application, prior to change in ownership or location. A written amendment to the current application shall be filed when there is a change in management or operational objectives.
- (10) Separate applications and permits are required for centers maintained in separate premises, even though they are owned or operated by the same person(s), business or corporation, and may be doing business under the same title.

#### Rule 290-5-41 111-8-7-.03 Permits

- (1) Following inspection and evidence of compliance with these regulations, the Department may issue a permit. Each permit shall indicate the classifications of services to be provided and patient capacity of the center.
- (2) Permits issued shall remain in force and effect until revoked or suspended for failure to comply with these rules and regulations.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule 290-5-41 111-8-7-.04 Provisional Permits

Provisional permits may be issued by the Department for a time specific period based on an acceptable written plan for correcting deficiencies (plan of correction) found during an inspection. Provisional permits may be revoked by the Department due to prevailing circumstances which are not acceptable to the Department. Centers which are established and operating prior to adoption of these rules and regulations may be issued provisional permits when additional time is needed to meet physical plant standards.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule <del>290-5-41-111-8-7-.05</del> Inspections

(1) The center shall be open at all reasonable hours for observation and examination by properly identified representatives of the Department.

- (2) The governing body shall notify the Department of the anticipated opening date of a newly constructed center in order that a preopening licensure inspection of the center may be conducted to determine compliance with these rules and regulations.
- (3) The administrator (or a designated representative) shall accompany the Department representative on all tours of inspection and shall sign the completed inspection report.
- (4) The center may be inspected at the discretion of the Department to determine whether it is continuing to meet these requirements or is making satisfactory progress in accordance with approved plans of correction.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-5-21; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule 290-5-41 111-8-7-.06 Organization and Administration

- (1) The birth center shall be organized with an identifiable governing body which is responsible for establishing objectives and policies and which assumes full legal responsibilities for the overall conduct of the center, including compliance with laws and regulations pertaining to the center. The governing body and its membership shall be identified in the application for licensure.
- (2) The ownership of the center shall be fully disclosed in the application. This disclosure shall include the names and addresses of all corporate officers and any person(s) having a five percent (5.0%) or more financial interest in the center.
- (3) The governing body shall be responsible for professional staff appointments, shall establish effective mechanisms for quality assurance, and shall ensure the accountability of the professional staff.
- (4) The organizational objectives of the center shall be clearly stated in the policies and procedures of the center.
- (5) The governing body shall appoint an administrator and shall notify the Department of such person's name.
- (6) The center shall be at all times under the personal and daily supervision and control of the administrator (or a designated

- representative) whose authority, duties and responsibilities shall be defined in writing. This information shall be available to the Department on request.
- (7) The center shall be available for occupancy <u>twenty-four (24)</u> hours per day, with professional staff on call at all times.
- (8) Criteria for admission to the center shall be clearly identified in the center's policies. The admission policy shall be submitted with the application for licensure. At a minimum, admission criteria shall include a provision that only low-risk patients will be admitted and that there will be no discrimination according to race.
- (9) Each patient shall be provided with a copy of the fee schedule and policy regarding payment.
- (10) Admissions to the center shall be restricted to low-risk patients who have received antepartum care in accordance with the facility's policies. The center's policies and procedures regarding management of complications shall be explained by a staff physician or certified nurse midwife.
- (11) The center shall have written policies and procedures for antepartum, intrapartum, postpartum and newborn care including physician consultation, referral, transfer and transport to the hospital and registration of vital records. A written procedure shall be established to maintain these policies.
- (12) The center shall have a written policy regarding visitation or attendance during the birth process.
- (13) The mother and newborn shall be discharged within twenty-four (24) hours after delivery, in a condition which will not endanger the well-being of either the mother or newborn, or shall be transferred to a licensed hospital. The mother and newborn will be discharged in the care of another responsible adult who will assist in their transport from the birth center.
- (14) The center shall have an organized professional staff which is responsible for the development of patient care policies and procedures and for maintaining the level of professional performance through a continuing program of staff education, and

- review and evaluation of care. Records of staff attendance at educational programs shall be maintained.
- (15) The center shall have a medical director who is a physician, designated by the governing body, who shall be responsible for the direction and coordination of all professional aspects of the center's program.
- (16) Practitioners applying for center privileges shall sign an agreement to abide by the center's policies and procedures.
- (17) The center shall have specific policies and procedures for infection control, which include a mechanism for reporting to the Department those infections which develop within <a href="six (6">six (6)</a> weeks after discharge of the patient from the center, using forms provided by the Department.
- (18) The center shall submit annually to the Department a statistical summary of morbidity and mortality data on forms supplied by the Department.
- (19) Nothing in these rules and regulations shall prevent a licensed hospital from organizing and providing a birth center as an integral part of its facility, so long as the provided services are included in the application under which the hospital license is granted.

## Rule 290-5-41 111-8-7-.07 Transfer and Transport Capability

- (1) Each birth center shall have a written agreement with a hospital(s) which is licensed to provide obstetrical services, for emergency care. Each physician practicing in the birth center shall have admitting privileges at the back-up hospital.
- (2) Each birth center shall have a written agreement with the emergency back-up hospital for acceptance and examination of laboratory specimens to expedite treatment, prior to formal admission procedures.
- (3) The center shall have the capability to transfer and transport the adult and/or newborn patients to the contract hospital within

thirty (30) minutes of initiation of transfer procedure to the arrival on the obstetric/newborn service of the hospital. Documentation of each transfer shall be maintained by the center to substantiate to the Department that it has met this requirement.

(4) The center shall have a written contract with a licensed ambulance service which will assure timely response.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule 290-5-41 111-8-7-.08 Professional Services

- (1) All services provided by or in the center shall be performed by persons who are appropriately licensed or certified to perform such services in accordance with the laws of the State of Georgia. There shall be qualified staff members to provide for patient needs. At least one physician, certified nurse midwife or registered nurse shall be present at all times that the facility is open whenever a patient (mother or new-born) is in the facility.
- (2) All services shall occur within a health care system which provides for medical consultation, collaborative management or referral.
- (3) All intrapartal services shall be under the direct supervision of a physician or a certified nurse midwife. At least one other member of the professional staff shall also be present at each delivery.
- (4) The center shall establish written policies and procedures for emergency services to patients and shall require each professional staff member to receive instruction in emergency treatment of adult and infant patients, upon employment and at least annually thereafter.
- (5) Each medical staff member shall have admitting privileges or a written agreement with a staff physician to provide services at the contract hospital. Documentation to show compliance with this requirement shall be maintained in the center.
- (6) Definite means of identification shall be applied to every infant immediately after birth. Such identification shall remain on the infant until discharged. The permanent records of each newborn shall include footprints.

- (7) The center shall have written policies and procedures to ensure (a) metabolic screening of all newborns within one week of age, (b) assessment of newborn status, including Apgar score at one and five minutes, (c) prevention of eye infection, (d) umbilical cord care, and (e) periodic observation and assessment after birth until the infant's condition is stable. These policies shall be developed in consultation with a pediatrician.
- (8) Policies, procedures and facilities shall be provided for proper collection, storage and laboratory testing of cord blood for necessary studies on Rh Negative and O Positive mothers and a supply of Rhogam or other appropriate treatment material shall be readily available for use when needed.
- (9) Prior to discharge, each newborn shall be examined by a physician.
- (10) Verbal and written instructions shall be provided for observation and care of both the mother and newborn after discharge.
- (11) A joint conference involving physicians, nurses, representatives of administration and other health personnel responsible for obstetric and newborn care shall be conducted at least quarterly to discuss morbidity and mortality. All fetal and newborn deaths and transfers occurring within the interval since the previous conference shall be reviewed. Minutes shall be kept of the meetings and shall be available to the Department.

#### Rule 290-5-41 111-8-7-.09 Personnel

- (1) The center shall require that each employee receives a health examination up on employment. The examination shall be in sufficient detail, including pertinent laboratory and tuberculosis screening, to assure that the employee is able to perform assigned tasks. The center shall have a policy for monitoring the health status of employees.
- (2) There shall be a separate personnel folder maintained for each employee. This personnel file shall contain all pertinent information concerning the employee, including the application for

- employment and qualifications for employment, verifications of physical examinations, job description and a copy of current Georgia license for those required to be licensed.
- (3) There shall be an on-going program of continuing education for all personnel. This shall include aspects of fire safety and the disaster plan for moving personnel and patients to safety and for handling patient emergencies.

#### Rule 290-5-41 111-8-7-.10 Health Services Information System

- (1) The birth center shall establish and maintain an organized health services information system for the collection, processing, maintenance, storage and retrieval of information concerning health services received by the patient.
- (2) An individual medical record shall be maintained within the system for each patient, and shall include the following data:
  - (a) Identification-name, address, identifying number, date of first visit, age or birth date, sex, marital status, occupation, telephone number, and name and telephone number of <u>a</u> person to contact in event of an emergency;
  - (b) An initial health evaluation including a chronological record of past medical history, drug use profile, personal and family history and results of physical examinations, including laboratory and x-ray reports;
  - (c) A health care plan which includes information regarding each visit;
  - (d) Clinical diagnosis or impression, studies ordered, treatment given, disposition, recommendations, and instructions to patient, complete with a progress note for each follow-up visit.
- (3) The system shall be kept current and available to staff or agencies authorized to use the system.

- (4) Medical records shall be preserved as original records, microfilms or other usable forms and shall be such as to afford a basis for complete audit of professional information. Centers shall retain all medical records or shall assure that they are maintained in a manner acceptable to the Department at least until the sixth anniversary of the patient's discharge. In the case of patients who have not attained majority at the time of the discharge, centers shall retain such records for at least six (6) years after the patient reaches age of majority. In the event a center shall cease operation, the Department shall be advised of the location of said records.
- (5) Sufficient space and equipment for record processing, storage and retrieval shall be provided.
- (6) Policies and procedures shall be written and implemented to assure organization and continuous maintenance of the health information system.

#### Rule 290-5-41 111-8-7-.11 Clinical Laboratory Services

If laboratory services are provided on site, the laboratory shall be licensed under the provisions of the Georgia Laboratory Licensure Law of 1970, O.C.G.A. Chapter 31-22, and applicable rules and regulations.

Authority: Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1; O.C.G.A. Chapter 31-22.

#### Rule 290-5-41 111-8-7-.12 Drug Storage and Administration

- (1) Each center shall provide adequate space and equipment and staff to assure that drugs are stored and administered in compliance with State and Federal laws and regulations.
- (2) No drugs shall be dispensed at the facility unless pharmacy regulations are met.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

## Rule 290-5-41 111-8-7-.13 Food Service

If food services are provided, the facility must comply with Georgia Laws and Food Services Rules and Regulations of the Department.

Authority: O.C.G.A. Chapter 26-2, Article 13; O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule 290-5-41 111-8-7-.14 Anesthesia

General or regional anesthesia shall not be utilized in a birth center. Local or pudendal anesthesia is permitted.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

## Rule 290-5-41 111-8-7-.15 Physical Plant and Operational Standards

The following minimum physical plant and operational standards shall be met:

- (a) The center shall provide sufficient space and equipment for patient and visitor waiting area, examination and treatment rooms, birth rooms, special care capability, and for staff and administrative areas. Birth\_rooms shall each have at least 100 square feet of area, exclusive of bathroom, toilet or entry way, and be designed and located to prevent traffic through them to any other part of the center.
- (b) The Department may deny the center a permit if it does not comply with Federal, State and local laws, codes, ordinances, and regulations which apply to its location, construction, maintenance and operation.
- (c) It shall be the responsibility of the governing body to assure that the center is in a safe condition at all times, and that a fire inspection record is maintained on equipment, systems, and areas that may present a hazard to occupants.
- (d) Fire and internal disaster drills shall be conducted at least quarterly and the time of the drill and results documented.
- (e) In addition to requirements specified herein, and those required by local ordinances or regulations, the construction of a birth center

shall meet the requirements of the Georgia Safety Fire Commissioner, Chapter 120-3-3,\* March 1, 1979, and subsequent revisions thereto. Applications for licensure shall be accompanied by written evidence that these requirements have been met.

- (f) Entrances for patients shall be connected to the public right-of-way by a hard-surfaced, unobstructed walkway in good rapair repair. Access for handicapped individuals shall be provided at a minimum of one entrance. A hard-surfaced, unobstructed road or driveway for use by ambulances or other emergency vehicles shall run from at least one entrance of the building to the public right-of-way. The doorway of such entrance shall be immediately adjacent to the road or driveway. If such doorway is not on the same level as the road, a ramp shall provide a continuous, unobstructed plane to the entrance.
- (g) Services provided in multi-story buildings shall be accessible by an elevator of adequate size to accommodate a standard wheeled litter patient and two attendants. Multi-story buildings will be considered to have met this requirement when patients are located only on ground level floors with outside exits. A stairway or ramp of adequate dimensions shall be available for transfer of patients in case of power failure.

\*EDITORIAL NOTE: A copy of said Chapter 120-3-3, Rules and Regulations of the Safety Fire Commissioner, was filed with this former Chapter 290-5-41 and is on file with same in the Office of Secretary of State.

- (h) The birth center shall be constructed, equipped, and maintained to assure the safety of patients and personnel. The following requirements shall apply within the center:
  - 1. Birth rooms shall be designed and located to prevent traffic through them to any other part of the center.
  - The walls and floors of birth rooms, examination rooms and staff dressing and scrub areas shall be of material that will permit frequent washing and cleaning.
  - 3. Staff dressing rooms and scrub facilities shall be convenient to the birth rooms, and shall include a knee, elbow, wrist or foot operated sink soap dispenser and brushes.

- 4. Toilet and handwashing facilities shall be accessible to patients from the birth room. Convenient handwashing facilities shall be provided for both staff and patient and shall be provided with soap dispenser and individual or disposable towels. The use of common towels is prohibited
- 5. The center shall be arranged and organized in such a manner as to ensure the comfort, safety, hygiene, privacy and dignity of patients treated therein.
- 6. A clean up room for equipment shall be provided.
- The center shall have an audible alarm system with control switches in all birth rooms which can be activated during an emergency.
- 8. The center shall have special care capability which includes but is not necessarily limited to the following, for both adults and infants: resuscitation equipment, intravenous solutions, drugs, oxygen, suction, infant stethoscope and transfer isolette. Such emergency equipment shall be provided on each floor on which patients are served.
- Each birth\_room shall have an infant resuscitation tray with a laryngoscope, positive pressure bag and mask and endotracheal tubes.
- The center shall provide space and facilities for administrative activities, including offices, medical records and other files and storage of supplies.
- (j) A waiting room and patient admissions area(s) shall be provided. There shall also be space for storage of personal belongings of staff, patients and visitors.
- (k) The center shall have adequate and conveniently located toilets and handwashing facilities for its staff, employees, patients and visitors.

# Rule 290-5-41 111-8-7-.16 Housekeeping, Laundry, Maintenance and Sterile Supplies

- (1) The center shall ensure that housekeeping and maintenance is adequate to maintain the center and equipment in a clean condition and state of good repair. An equipment clean-up area with adequate plumbing, including a sink with counter, shall be provided within the center.
- (2) Laundry service shall be provided either in house or by contractual arrangement. Separate space and facilities shall be provided for receiving, sorting and storing soiled laundry and for the sorting, storing and issuing of clean laundry, if reusable items are utilized.
- (3) There shall be adequate space and facilities for receiving, packaging and proper sterilization end storage of supplies and equipment consistent with the services to be provided.
- (4) Special precaution shall be taken to ensure that sterile instruments and supplies are kept separate from nonsterile instruments and supplies. Equipment for sterilization of instruments and supplies shall be conveniently located and of adequate capacity for the work-load. Records shall be maintained to assure quality control, including, date, time and temperature of each batch of sterilized supplies and equipment. Sterilization performance shall be checked and records shall be kept. Sterile items shall be dated and utilized, based on established procedures.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule <del>290-5-41</del> 111-8-7-.17 Electrical Power

- (1) All electrical work and equipment shall be designed and installed in accordance with State and local laws and ordinances.
- (2) All areas of the center shall have sufficient artificial lighting, for designated purposes.
- (3) All centers shall have an alternative lighting source for emergency use in the event of a power failure.

#### Rule 290-5-41 111-8-7-.18 Sanitation and Waste Disposal

- (1) The center shall maintain sanitary conditions throughout the premises. This shall include the water supply, sewerage, and solid waste disposal systems. Such facilities shall meet local and State regulations.
- (2) All garbage, trash and waste shall be stored and disposed of in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents.
- (3) Obstetrical wastes and contaminated materials shall be disposed of by incineration or other means acceptable to the Department.
- (4) Effective means shall be provided at all outside doors, windows and other openings to the center to prevent the entrance and harborage of flies, other insects and rodents.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

#### Rule 290-5-41 111-8-7-.19 Advertising

Any advertising of the services provided in or by a birth center shall be truthful and shall include the full name of the center and its Georgia license number, as shown on the face of the permit.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

## Rule 290-5-41 111-8-7-.20 Waivers and Variances

- (1) The Department upon application may grant variances or waivers of specific rules and regulations as provided for in O.C.G.A. Section 31-2-4 31-2-7(b), when it has been shown that the rule or regulation is not applicable or to allow experimentation and demonstration of new and innovative approaches to delivery of services.
- (2) The Department may exempt classes of facilities from regulation as provided for in O.C.G.A. Section 31-2-4-31-2-7(c), when regulation Proposed Rule Changes in Chapter 290-5-41 Presented to the BCH for Initial Adoption on 8/13/2020

would not permit the purpose intended or the class of facilities is subject to similar requirements under other rules and regulations.

Authority: O.C.G.A. § <del>31-2-4</del> <u>31-2-7</u>; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

## Rule 290-5-41 111-8-7-.21 Enforcement

A birth center which fails to comply with these rules and regulations shall be subject to denial of a permit, revocation of its permit or provisional permit and other sanctions provided by law. The enforcement and administration of the rules and regulations: shall be as prescribed in O.C.G.A. Chapter 31-5 31-7, Enforcement and Administrative Procedure, which includes provision for:

- the misdemeanor penalty for violation of rules and regulations promulgated under this Title;
- (b) injunctive relief under appropriate circumstances;
- (c) the Inspection Warrant; and
- (d) the due process requirements of notice, hearing and appeals.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. Chapter 31-5; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1; O.C.G.A. Chapter 50-13.

#### Rule 290-5-41 111-8-7-.22 Applicability of Regulations

These regulations are applicable to any building or facility which is or shall be classified by the Department of Human Resources Community Health as a birth center and the services provided there in, and expressly do not modify or revoke any of the provisions of the published rules of the Department of Human Resources Community Health, Chapter 290-5-6 111-8-40 (Rules and Regulations for Hospitals), or of Chapter 290-5-32 111-8-3 (Rules and Regulations for Performance of Abortions After the First Trimester of Pregnancy and Reporting Requirements for all Abortions), or of revisions which may be made to said regulations.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.

## Rule 290-5-41 111-8-7-.23 Severability

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions there-of and such remaining rules or portions there of shall remain of full force and effect, as if such rule or portions there-of so determined, declared or adjudged invalid or unconstitutional were not originally a part here-of. It is the intent of the Board of Human Resources to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.