GEORGIA DEPARTMENT OF PUBLIC HEALTH

Kathleen E. Toomey, M.D., M.P.H., Commissioner / Brian Kemp, Governor

2 Peachtree Street, NW, 15th Floor
Atlanta, Georgia 30303-3142

dph.ga.gov

May 12, 2022

NOTICE OF PROPOSED RULEMAKING
Chapter 511-5-13
"Designation of Perinatal Centers"

The Department of Public Health proposes the attached revisions to Chapter 511-5-13, "Designation of Perinatal Centers," pursuant to its authority under Georgia Code Sections 31-2A-6 and 31-2A-52.

The purpose of the proposed rulemaking is to change the criteria for levels of maternal and neonatal care at designated facilities.

The proposed rules have been posted to the Department's website at https://dph.georgia.gov/regulationsrule-making. Interested persons may submit comments on these proposed revisions in writing addressed to:

Melanie Simon
General Counsel
Georgia Department of Public Health
2 Peachtree Street, N.W., 15th Floor
Atlanta, Georgia 20202
melanie.simon@dph.ga.gov

Written comments must be submitted on or before June 9, 2022. Due to the COVID-19 pandemic, there will not be an in-person meeting. However, oral comments may be presented online or via phone at a public meeting scheduled for 10:00 a.m. on June 8, 2022. To join the public meeting:

- To join by computer:
  - https://gapublichealth.webex.com/gapublichealth/j.php?MTID=mb68cd3ca056476ccec5ed32eea3c5e37
  - Meeting Number: 2539 362 2888
  - Password: vaUBghQF946

- To join by phone:
  - 1-415-655-0001 United States Toll
  - Access Code: 2539 362 2888

The Commissioner of Public Health will consider the proposed rules for adoption on or about June 12, 2022, to become effective on or about July 12, 2022.

Melanie Simon

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General Counsel
Georgia Department of Public Health

RULES OF

DEPARTMENT OF PUBLIC HEALTH

CHAPTER 511-5
HEALTH PROMOTION

511-5-13
DESIGNATION OF PERINATAL CENTERS

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Rule 511-5-13-.02 Definitions

~~(1) "Available to be onsite" means available to be physically present onsite within a timeframe that incorporates maternal and fetal risks and benefits with the provision of care, but does not have to be available twenty-four (24) hours a day, seven (7) days a week.~~

~~(2) "Readily available at all times" means available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance and to be physically present onsite within a time frame that incorporates maternal and fetal or neonatal risks and benefits with the provision of care.~~

~~(3) "Physically present at all times" means physically present onsite in the location where perinatal care is provided twenty-four (24) hours a day, seven (7) days a week.~~

(~~4~~1) "Designated facility" means a perinatal facility that has been inspected and approved by the Department pursuant to these regulations as meeting its established criteria for a particular maternal or neonatal level of care.

(~~5~~2) "Perinatal facility" means a hospital, clinic, or birthing center that provides maternal or neonatal health care services.

Authority: O.C.G.A. § 31-2A-50 through -57.

Rule 511-5-13-.04 Designation Criteria for Maternal Centers

~~(1) Level I:~~ A ~~Level I~~ maternal center must meet all standards applicable to the relevant level of care established by The Joint Commission Maternal Levels of Care Verification Program as amended, restated, supplemented or otherwise modified from time to time.~~be able to provide care for low- to moderate-risk pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility at which specialty maternal care is available, and must meet all other requirements of this section (1). Examples of appropriate patients are women with term twin gestation, trial of labor after cesarean, uncomplicated cesarean, or preeclampsia without severe features at term~~.

~~(a) A Level I maternal center must be able to do and provide documentation that it is able to do the following:~~

~~1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be immediately available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.~~

~~2. Have written policies and procedures in place for the stabilization and resuscitation of the pregnant or postpartum patient in accordance with current standards of medical practice.~~

~~3. Have staff members physically present at all times who have completed Advanced Cardiac Life Support training and who have the skills to perform a complete resuscitation on the mother.~~

~~4. Have resuscitation equipment immediately physically present at all times in the labor and delivery, antepartum, and postpartum areas, including difficult airway management equipment for pregnancy and postpartum patients.~~

~~5. Have the capability to implement the Alliance for Innovation on Maternal Health ("AIM") patient safety bundles for common causes of preventable maternal morbidity, such as management of maternal venous thromboembolism, obstetric hemorrhage, and maternal severe hypertension in pregnancy.~~

~~6. Have laboratory testing readily available at all times.~~

~~7. Have blood bank services readily available at all times, including an ability to initiate massive transfusion protocol, with a process to obtain more blood component therapy as needed.~~

~~8. Provide limited obstetric ultrasonography with interpretation readily available at all times.~~

~~9. Have a written breastfeeding policy that is routinely communicated to all health care staff and train all health care staff in skills necessary to implement this policy.~~

~~10. Provide emergency care and transport for unassigned patients.~~

~~11. Provide perinatal education at frequent intervals concerning high-risk events to medical, nursing and ancillary staff, in order to prepare for such emergencies.~~

~~12. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.~~

~~13. Have guidelines and mechanisms in place for specialty consultations and have an agreement in place with a Regional Perinatal Center or a Level III receiving facility, as designated by the Georgia Department of Community Health Certificate of Need program, for the timely transport of patients who require a higher level of care.~~

~~(b) A Level I maternal center must employ or have available the following personnel:~~

~~1. A director of obstetrical services on staff who is an obstetrician, or who is a board certified family practitioner with obstetrical privileges.~~

~~2. A registered nurse trained in maternal care with level-appropriate competencies as demonstrated by nursing competency documentation and a midwife, family physician, or an obstetrician readily available at all times to attend every birth.~~

~~3. A physician with privileges to perform emergency cesarean delivery readily available at all times.~~

~~4. A perinatal nurse manager on staff who is a registered nurse with level-appropriate formal training and experience in maternal care, and preferably a Bachelor of Science in Nursing.~~

~~5. An anesthesia provider, such as an anesthesiologist, nurse anesthetist, or an anesthesiologist assistant working with an anesthesiologist, for labor analgesia and surgical anesthesia readily available at all times.~~

~~(2) Level II: A Level II maternal center must offer care for moderate- to high-risk antepartum, intrapartum, or postpartum conditions, such as preeclampsia or placenta previa with no prior uterine surgery, and meet all other requirements of this section (2).~~

~~(a) A Level II maternal center must be able to do and provide documentation that it is able to do the following:~~

~~1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.~~

~~2. Have written policies and procedures in place for the stabilization and resuscitation of the pregnant or postpartum patient in accordance with current standards of medical practice.~~

~~3. Have staff members physically present at all times who have completed Advanced Cardiac Life Support training and who have the skills to perform a complete resuscitation on the mother.~~

~~4. Have resuscitation equipment physically present at all times in the labor and delivery, antepartum, and postpartum areas, including difficult airway management equipment for pregnancy and postpartum patients.~~

~~5. Have the capability to implement patient safety bundles for common causes of preventable maternal morbidity, such as management of maternal venous thromboembolism, obstetric hemorrhage, and maternal severe hypertension in pregnancy.~~

~~6. Have laboratory testing readily available at all times.~~

~~7. Have blood bank services readily available at all times, including an ability to initiate massive transfusion protocol, with a process to obtain more blood component therapy as needed.~~

~~8. Provide standard obstetric ultrasound imaging with interpretation readily available at all times.~~

~~9. Provide computed tomography scanning, magnetic resonance imaging, non-obstetric ultrasound imaging, and maternal echocardiography with interpretation available to be onsite or by telemedicine.~~

~~10. Have a written breastfeeding policy that is routinely communicated to all health care staff and train all health care staff in skills necessary to implement this policy.~~

11. Ensure lactation support services are available to be onsite.

12. Provide emergency care and transport for unassigned patients.

13. Provide perinatal education at frequent intervals concerning high-risk events to medical, nursing and ancillary staff, in order to prepare for such emergencies.

14. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.

15. Have guidelines and mechanisms in place for specialty consultations and have an agreement in place with a Regional Perinatal Center or a Level III receiving facility, as designated by the Georgia Department of Community Health Certificate of Need program, for the timely transport of patients who require a higher level of care.

(b) A Level II maternal center must employ or have available the following personnel:

1. A director of obstetric services on staff who is an obstetrician with experience in obstetric care or board certified in another specialty with privileges and expertise in obstetric care including with surgical skill and privileges to perform a cesarean delivery.

2. An obstetrician or a family physician with obstetric fellowship training or equivalent training and skills in obstetrics, and with surgical skill and privileges to perform cesarean delivery readily available at all times.

3. A perinatal nurse manager on staff who is a registered nurse with level-appropriate formal training and experience in maternal care, and preferably a Bachelor of Science in Nursing.

4. Registered nurses trained in maternal care with level-appropriate competencies as demonstrated by nursing competency documentation readily available at all times.

5. A maternal-fetal medicine specialist who is available at all times for consultation onsite or by telephone or telemedicine.

6. Internal or family medicine physicians and general surgeons readily available at all times for obstetric patients.

7. An anesthesiologist readily available at all times.

(3) Level III: A Level III maternal center must be capable of providing care to patients with more complex maternal medical conditions, obstetric conditions, and fetal conditions, such as moderate maternal cardiac disease, suspected placenta accreta or placenta previa and previous uterine surgery, suspected placenta percreta, adult respiratory distress syndrome, acute fatty liver of pregnancy, coagulation disorders, complex hematologic or autoimmune disorders, and expectant management of preeclampsia with severe features remote from term and meet all other requirements of this section (3).

(a) A Level III maternal center must be able to do and provide documentation that it is able to do the following:

1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.

2. Have written policies and procedures in place for the stabilization and resuscitation of the pregnant or postpartum patient in accordance with current standards of medical practice.

3. Have staff members physically present at all times who have completed Advanced Cardiac Life Support training and who have the skills to perform a complete resuscitation on the mother.

4. Have resuscitation equipment physically present at all times in the labor and delivery, antepartum, and postpartum areas, including difficult airway management equipment for pregnancy and postpartum patients.

5. Have the capability to implement patient safety bundles for common causes of preventable maternal morbidity, such as management of maternal venous thromboembolism, obstetric hemorrhage, and maternal severe hypertension in pregnancy.

6. Have laboratory testing readily available at all times.

7. Have blood bank services readily available at all times, including an ability to initiate massive transfusion protocol and in-house availability of all blood components.

8. Provide onsite medical and surgical intensive care units that accept pregnant women and women in the postpartum period, have adult critical care providers physically present at all times, and have a maternal-fetal medicine specialist readily available at all times to actively communicate or consult for all obstetric patients in the intensive care unit.

9. Have appropriate equipment and personnel physically present at all times to ventilate and monitor women in labor and delivery until they can be transferred safely to the intensive care unit.

10. Provide standard obstetric ultrasound imaging with interpretation readily available at all times.

11. Provide computed tomography scanning, magnetic resonance imaging, non-obstetric ultrasound imaging, and maternal echocardiography with interpretation readily available at all times.

12. Provide specialized obstetric ultrasound and fetal assessment, including Doppler studies, with interpretation readily available remotely, but does not have to be available twenty-four (24) hours a day, seven (7) days a week.

13. Provide basic interventional radiology capable of performing uterine artery embolization readily available at all times.

14. Have a process for providing perinatal pathology services.

~~15. Provide a program for genetic diagnosis and counseling for genetic disorders or a policy and process for referral to an appropriate provider for genetic consultation.~~

~~16. Have a written breastfeeding policy that is routinely communicated to all health care staff and train all health care staff in skills necessary to implement this policy.~~

~~17. Ensure lactation support services are available to be onsite.~~

~~18. Provide emergency care for unassigned patients.~~

~~19. Provide perinatal education at frequent intervals concerning high-risk events to medical, nursing and ancillary staff, in order to prepare for such emergencies.~~

~~20. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.~~

~~21. Have a documented mechanism to facilitate and accept maternal transfers and transports.~~

~~(b) A Level III maternal center must employ or have available the following personnel:~~

~~1. A director of obstetric services on staff who is a board certified obstetrician.~~

~~2. An obstetrician physically present at all times.~~

~~3. A perinatal nurse manager on staff who is a registered nurse with a Bachelor of Science in Nursing and adequate numbers of registered nurses who have special training and experience in the management of women with complex and critical maternal illnesses and obstetric complications.~~

~~4. A maternal-fetal medicine specialist with inpatient privileges readily available at all times onsite or by telephone or telemedicine. The maternal-fetal medicine specialist must be able to be physically present to provide direct care within twenty-four (24) hours of a request.~~

~~5. Subspecialists, such as specialists in critical care, general surgery, infectious disease, hematology, cardiology, nephrology, neurology, gastroenterology, internal medicine, behavioral health, and neonatology, readily available at all times for inpatient consultation.~~

~~6. An anesthesiologist physically present at all times.~~

~~7. A director of obstetric anesthesia services who is a board certified anesthesiologist with obstetric anesthesia fellowship training or experience in obstetric anesthesia.~~

~~8. A pharmacist who is physically present at all times.~~

Authority: O.C.G.A. § 31-2A-50 through -57.

Rule 511-5-13-.05 Designation Criteria for Neonatal Centers

~~(1) Level I:~~ A ~~Level I~~ neonatal center must meet all standards applicable to the relevant level of care established by the American Academy of Pediatrics Standards for Neonatal Levels of Care as amended, restated, supplemented or otherwise modified from time to time.~~be able to~~

~~provide comprehensive care for women with low-risk pregnancies, anticipated uncomplicated deliveries, and apparently normal fetuses; stabilize and provide care for infants who are at least thirty-five (35) weeks gestation, greater than 2000 grams birthweight, and physiologically stable; and meet all other requirements of this subsection (1)~~.

~~(a) A Level I neonatal center must be able to do and provide documentation that it is able to do the following:~~

~~1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.~~

~~2. Have diagnostic support services available to be onsite, such as X-ray and ultrasound imaging, with the capability to perform studies as needed for maternal and newborn care.~~

~~3. Provide anesthesia, laboratory services, and access to emergency drugs onsite at all times.~~

~~4. Have social services available to be onsite.~~

~~5. Have a written breastfeeding policy that is routinely communicated to all health care staff, and train all health care staff in skills necessary to implement this policy.~~

~~6. Provide perinatal education at frequent intervals concerning high-risk events to medical, nursing, and ancillary staff, in order to prepare for such emergencies.~~

~~7. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.~~

~~8. Have guidelines and mechanisms in place for specialty consultations and have an agreement in place with a Regional Perinatal Center or a Level III receiving facility, as designated by the Georgia Department of Community Health Certificate of Need program, for the timely transport of patients who require a higher level of care.~~

~~(b) A Level I neonatal center must employ or have available the following personnel:~~

~~1. A director of neonatal services on staff who is a board certified family practitioner, a pediatrician, or a neonatologist.~~

~~2. A perinatal nurse manager on staff who is a registered nurse with education in and demonstrated knowledge and experience in perinatal nursing, and preferably a Bachelor of Science in Nursing.~~

~~3. A staff member trained in providing newborn services who is physically present at all times in the newborn nursery when it is occupied by one or more newborns.~~

~~4. A nurse who is physically present at all times to provide routine newborn care in the newborn nursery when it is occupied by one or more newborns.~~

5. A pharmacist with neonatal pharmacology resources must be available for consultation onsite or by telephone or telemedicine at all times.

6. A respiratory therapist on staff who is trained in the Neonatal Resuscitation Program.

(2) Level II: A Level II neonatal center must be able to provide care for infants of greater than thirty-two (32) weeks gestation and weighing greater than 1500 grams who have physiologic immaturity, or who are moderately ill with problems that are expected to resolve rapidly and who are not expected to require subspecialty services; and must be able to stabilize infants born before thirty-two (32) weeks gestation and weighing less than 1500 grams until they can be transferred to a neonatal intensive care facility; and meet all other requirements of this subsection (2).

(a) A Level II neonatal center must be able to do and provide documentation that it is able to do the following:

1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.

2. Provide conventional mechanical ventilation for up to twenty-four (24) hours and have Continuous Positive Airway Pressure equipment physically present at all times. Specialized personnel necessary to manage respiratory emergencies for an infant being maintained on a ventilator, such as a pediatrician, neonatologist, pediatric hospitalist, nurse practitioner, or physician assistant must be physically present at all times until the neonate is transferred or extubated and stabilized.

3. Transfer an intubated infant as soon as possible if a neonatologist is not available, and contact a Level III facility, as designated by the Georgia Department of Community Health Certificate of Need program, if the length of intubation is approaching twenty-four (24) hours and extubation is not anticipated.

4. With respect to high-risk patients or neonates on mechanical ventilation, ensure that a respiratory therapist, certified lab technician or blood gas technician, and x-ray technician are physically present at all times and available to the maternal and newborn services area.

5. Have diagnostic support services available to be onsite, such as x-ray and ultrasound imaging, with the capability to perform studies as needed for maternal and newborn care.

6. Have anesthesia, laboratory services, and access to emergency drugs available onsite at all times.

7. Have social services and pastoral care available to be onsite.

8. Ensure follow-up care at discharge for infants who are at high risk for neurodevelopmental, medical, or psychosocial complications.

9. Have a written breastfeeding policy that is routinely communicated to all health care staff, and train all health care staff in skills necessary to implement this policy.

10. Provide perinatal education at frequent intervals concerning high-risk events to medical, nursing, and ancillary staff, in order to prepare for such emergencies.

11. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.

12. Have guidelines and mechanisms in place for specialty consultations and have an agreement in place with a Regional Perinatal Center or a Level III receiving facility, as designated by the Georgia Department of Community Health Certificate of Need program, receiving hospital for the timely transport of patients who require a higher level of care.

(b) A Level II neonatal center must employ or have available the following personnel:

1. A director of neonatal services on staff who is a pediatrician or neonatologist.

2. A perinatal nurse manager on staff who is a registered nurse, preferably with a Bachelor of Science in Nursing, with training and demonstrated knowledge and experience in the care of high-risk and moderately ill newborns.

3. A nurse educator on staff.

4. A neonatologist who is available for consultation onsite or by telephone or telemedicine at all times.

5. A pharmacist with neonatal pharmacology resources who is onsite or available for consultation by telephone at all times.

6. If the facility offers care for newborns requiring parenteral support, then a dietitian or a pharmacist with parenteral experience shall be on staff.

7. Respiratory therapists who are physically present at all times.

8. Radiology technicians who are physically present at all times to provide ongoing care and to address emergencies.

9. An International Board Certified Lactation Consultant who is available to be onsite to provide lactation support services.

(3) Level III: A Level III neonatal center must be able to provide comprehensive care for infants born before thirty-two (32) weeks gestation and weighing less than 1500 grams, and infants born at any age and birth weight who have a critical illness; and meet all other requirements of this subsection (3).

(a) A Level III neonatal center must be able to do and provide documentation that it is able to do the following:

1. Provide at least one caregiver to be present at every delivery whose primary responsibility is for the newborn infant, and a person who has successfully completed the Neonatal Resuscitation Program and can be available to be onsite to perform neonatal resuscitation, including endotracheal intubation and administration of medications.

2. Provide a full range of respiratory support onsite at all times.

3. Provide total parenteral nutrition onsite at all times.

4. Provide a process for the monitoring, treatment, and follow-up of retinopathy of prematurity.

5. Provide advanced imaging onsite at all times, with interpretation readily available at all times, including computed tomography, magnetic resonance imaging, and echocardiography.

6. Provide anesthesia, laboratory services, and access to emergency drugs onsite at all times.

7. Ensure the availability of a blood bank capable of providing blood and blood component therapy, and neonatal blood gas monitoring onsite at all times.

8. Have a process for providing perinatal pathology services.

9. Provide social work services with social workers assigned specifically to the neonatal units and have pastoral care available to be onsite.

10. Have developmental follow-up care available to be onsite, or provide a referral to a facility that provides developmental follow-up care.

11. Have a written breastfeeding policy that is routinely communicated to all health care staff, and train all health care staff in skills necessary to implement this policy.

12. Provide perinatal education at frequent intervals concerning high risk events to medical, nursing, and ancillary staff, in order to prepare for such emergencies.

13. Participate in the Georgia Perinatal Quality Collaborative or a comparable state, regional, or national quality improvement collaborative.

14. Enroll in and provide data to the Vermont Oxford Network.

15. Provide a transport team, or have a prearranged agreement with another facility or provider for neonatal transports. If geographic constraints for land exist, the facility should ensure availability of rotor and fixed-wing transport services to quickly and safely transfer infants requiring subspecialty intervention.

(b) A Level III neonatal center must employ or have available the following personnel:

1. A director of neonatal services on staff who is a neonatologist.

2. A perinatal nurse manager on staff who is a registered nurse with a Bachelor of Science in Nursing and has demonstrated knowledge and experience in neonatal intensive care nursing and who has a dedicated assignment to the intensive care nursery.

3. A nurse educator on staff.

4. For perinatal facilities with an average of less than thirty (30) very low birth weight admissions per year over a three-year period, a nurse practitioner or physician assistant with neonatal or acute care experience must be physically present at all times with a neonatologist readily available at all times but no later than within thirty (30) minutes of a request. For perinatal facilities with an average of thirty (30) or more very low birth weight admissions per year over a three-year period, a neonatologist must be readily available at all times but no later than within thirty (30) minutes of a request.

5. Pediatric subspecialists must either be on staff or available for consultation onsite or by telephone or telemedicine at all times. The center must have access to a pediatric ophthalmologist and a pediatric cardiologist by telemedicine.

6. If therapeutic hypothermia is provided onsite, then the center must have access to a pediatric neurologist by telephone or telemedicine.

7. If complex surgery is provided onsite, then a pediatric surgeon and a pediatric anesthesiologist must be available to be onsite. If complex surgery is not provided onsite, a pediatric surgeon must be available for consultation by telephone at all times.

8. A registered dietitian or nutritionist on staff to serve only the neonatal intensive care unit who has special training in perinatal nutrition and can plan diets that meet the special needs of both women and newborn infants at high risk as well as expertise in the storage and preparation of human milk for medically fragile infants.

9. Pharmacy personnel on staff with pediatric expertise who can work to continually review the perinatal facility's systems and processes of medication administration to ensure that patient care policies are maintained.

10. Respiratory therapists who are physically present at all times.

11. Radiology technicians who are physically present at all times to provide ongoing care and to address emergencies.

12. An occupational or physical therapist on staff with neonatal expertise.

13. An individual on staff skilled in evaluation and management of neonatal feeding and swallowing disorders, such as a speech-language pathologist.

14. An International Board Certified Lactation Consultant on staff to assist mothers of neonatal intensive care unit infants with establishing and maintaining lactation.

Authority: O.C.G.A. § 31-2A-50 through -57.