Legend: (New Rules)

Regular Print = Proposed new language

House Bill 2131 of the 84th Texas Legislature (Regular Session)

§ 133.191 Background and Purpose.

The purpose of this section is to implement Health and Safety Code, Chapter 32, Subchapter D, Centers of Excellence for Fetal Diagnosis and Therapy designation, to achieve healthy fetal outcomes in this state.

§ 133.192 Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Commission--The Health and Human Services Commission.

(2) Department--The Department of State Health Services.

(3) Designation--A formal recognition by the executive commissioner of a facility's neonatal or maternal care capabilities and commitment, for a period of three years.

(4) Facility

(5) Fetal

(6) FCMD—Fetal Center Medical Director

(7) FCPM—Fetal Center Program Manager

(8) Executive commissioner--The executive commissioner of the Health and Human Services Commission.

(9) Level I evidence-based metrics-- Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trial) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results.

(10) Maternal--Pertaining to the mother.

(11) Neonate--An infant from birth through 28 completed days after birth.

(12) Office--Office of Emergency Medical Services (EMS)/Trauma Systems Coordination.

(13) PCR--Perinatal Care Region.

(14) Perinatal--Of, relating to, or being the period around childbirth, especially the five months before and one month after birth.

§ 133.193 General Requirements.

(a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Executive Commissioner of the Health and Human Services Commission (executive commissioner) the designation of an applicant/healthcare facility as a Centers of Excellence for Fetal Diagnosis and Therapy for each location of a facility, which the office deems appropriate.

(b) A healthcare facility is defined under this subchapter as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

(c) Each location shall be considered separately for designation and the office will determine the designation for that location, based on, but not limited to, the location's own resources and level of care capabilities; Perinatal Care Region (PCR) capabilities; compliance with Chapter 133, concerning Hospital Licensing.

(d) Facilities seeking Centers of Excellence for Fetal Diagnosis and Therapy designation shall be surveyed through an organization approved by the office to verify that the facility is meeting office-approved relevant requirements. The facility shall bear the cost of the survey.

(e) Facilities seeking Centers of Excellence for Fetal Diagnosis and Therapy designation shall:

(1) offer fetal diagnosis and therapy through an extensive multi-specialty clinical program that is affiliated and collaborates extensively with a medical school in this state and an associated facility that provides advanced maternal, neonatal and fetal diagnosis and therapy care;

(2) integrate an advanced fetal care program with a program that provides appropriate long-term monitoring and follow-up care for patients;

(3) demonstrate a significant commitment to research in and advancing the field of fetal diagnosis and therapy;

(4) offer advanced training programs in fetal diagnosis and therapy;

(5) hold current verification from the American College of Surgeons (ACS) as a Level I children's surgical center;

(6) hold current verification for maternal-fetal surgical care from an organization approved by the Department of State Health Services;

(7) be designated by the Department of State Health Services as a Level IV Neonatal Level of Care;

(8) be designated by the Department of State Health Services as a Level IV Maternal Level of Care;

(9) meet, as determined by the DSHS, with other designated Centers of Excellence for Fetal Diagnosis and Therapy (CEFDT) for the purposes of mutual collaboration;

(10) All designated centers will be required to meet at an agreed upon site twice yearly to discuss inclusion criteria for fetal intervention and biopsychosocial outcome variables both short-term and long-term.

(11) form a multi-physician performance improvement committee;

(12) have outcomes vetted and approved by the Department of State Health Services for posting; and

(13) post outcomes on the facility website for public access or redirect the public to the facility specific outcomes posted on the DSHS website.

§ 133.194 Designation Process

(a) Designation application packet. The applicant shall submit the packet, inclusive of the following documents to the Office of EMS/Trauma Systems Coordination (office) within 120 days of the facility's verification for maternal-fetal surgical care:

(1) an accurate and complete designation application form for designation; including full payment of the designation fee as listed in subsection (d) of this section;

(2) evidence of current verification from the American College of Surgeons as a Level I Children's Surgical Center; including patient care reviews;

(3) evidence of current verification for maternal-fetal surgical care, including patient care reviews;

(4) a letter of support from the facility's governing board supporting provisions for short and long-term outcomes tracking;

(5) evidence of participation in the CEFDT committee and multi-physician performance improvement committee;

(6) evidence of outcomes posted for public access; and

(7) any subsequent documents submitted by the date requested by the office.

(b) Renewal of designation. The applicant shall submit the documents described in subsection (a)(1) - (6) of this section to the office not more than 180 days prior to the designation expiration date and at least 60 days prior to the designation expiration date.

(c) If a facility seeking designation fails to meet the requirements in subsection (a)(1) - (6) of this section, the application shall be denied.

(d) Non-refundable application fee of $2,500.00 for the three year designation period.

(e) If a facility disagrees with the designation determination by the office for initial designation or re-designation, it may make an appeal in writing not later than 60 days to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation of how the facility meets the requirements for designation.

(1) If the office upholds its original determination, the director of the office will give written notice of such to the facility not later than 30 days of its receipt of the applicant's complete written appeal.

(2)The facility may, not later than 30 days of the office sending written notification of its denial, submit a written request for further review. Such written appeal shall be submitted to the Associate Commissioner of the Division for Consumer Protection (associate commissioner).

(f) The survey agency shall provide the facility with a written, signed survey report regarding their evaluation of the facility's compliance with neonatal program requirements. This survey report shall be forwarded to the facility no later than 30 days of the completion date of the survey. The facility is responsible for forwarding a copy of this report to the office if it intends to continue the designation process.

(g) The office shall review the application packet documents submitted by the facility, to determine compliance with the centers of excellence for fetal diagnosis and therapy program requirements.

(1) A recommendation for designation shall be made to the commissioner based on compliance with the requirements.

(2) A centers of excellence for fetal diagnosis and therapy designation shall not be denied to a facility that meets the minimum requirements for designation.

(A) If a facility disagrees with the office's decision regarding its designation application or status, it may request a secondary review by a designation review committee. Membership on a designation review committee will:

(i) be voluntary;

(ii) be appointed by the office director;

(iii) be representative of fetal diagnosis and therapy providers and the highest levels of neonatal and maternal care designated facilities; and

(iv) include representation from the office.

(B) If a designation review committee disagrees with the office's recommendation, the records shall be referred to the associate commissioner for recommendation to the commissioner.

(C) If a facility disagrees with the office's recommendation at the end of the secondary review, the facility has a right to a hearing, in accordance with a hearing request referenced in §133.121(9) of this title (relating to Enforcement Action), and Government Code, Chapter 2001.

§ 133.195 Program Requirements.

The designated Centers of Excellence for Fetal Diagnosis and Therapy Centers shall provide patient-centered and family-centered health care. The facility environment for perinatal care shall comprehensively meet the

physiologic and psychosocial needs of the pregnant women, their infants, and families.

(b)Program Plan. The facility shall develop a written plan of an organized program to implement and maintain a multidisciplinary health care team, and to focus the scope of services to the highest-level fetal center, capable of treating the most complex fetal conditions. A facility shall provide, at a minimum, all fetal therapies proven effective based on level I evidence-based metrics.

(1) The written plan and the program policies and procedures shall be reviewed and approved by the facility's governing body. The governing body shall ensure that the requirements of this section are implemented and enforced.

(2) The written Fetal Center program plan shall include, at a minimum:

(A) standards of fetal diagnosis and therapy practice that the program policies and procedures are based upon that are adopted, implements and enforced for the maternal-fetal services it provides;

(B) a periodic review and revision schedule for all maternal-fetal care policies and procedures;

(C) a QAPI Program as described in §133.41(r) of this title (relating to Hospital Functions and Services). The facility shall demonstrate that the Fetal Center program evaluates the provision of maternal-fetal care on an ongoing basis, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until a resolution is achieved. The Fetal Center program shall measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and is outcome based. Evidence shall support that aggregate patient data is continuously reviewed for trends and data is submitted to the department as requested;

(D) requirements for minimal credentials for all staff participating in the care of maternal-fetal patients;

(E) Provisions for providing continuing staff education; including annual competency and skills assessment that is appropriate for the patient population served;

(F) The availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served.

(c) Medical Staff. The facility shall have an organized, effective maternal-fetal program that is recognized by the medical staff and approved by the facility's governing body. The credentialing of the medical staff shall include a process for the delineation of privileges for maternal-fetal care.

(d) Medical Director. There shall be an identified Fetal Center Medical Director (FCMD) responsible for the provision of maternal-fetal care services and credentialed by the facility for the treatment of maternal-fetal patients.

(1) The FCMD shall be a physician who:

(A) is a board certified maternal fetal medicine physician with additional experience and/or training in fetal interventions;

(B) demonstrates administrative skills and oversight of the Fetal Center QAPI Program;

(C) completed annual continuing medical education specific to maternal-fetal care;

(D) frequently and actively participates in maternal-fetal care at the facility where medical director services are provided; and

(E) maintains active staff privileges as defined in the facility's medical staff bylaws.

(2) The Fetal Center Medical Director shall have the authority and responsibility to monitor maternal-fetal patient care from admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program.

(3) The responsibilities and authority of the FCMD shall include but are not limited to:

(A) examining qualifications of medical staff requesting fetal care privileges and makes recommendations to the appropriate committee for such privileges;

(B) collaborates with the FCPM in areas to include, but not limited to: developing and/or revising policies, procedures and guidelines, assuring medical staff competency, education and training; the QAPI Program; and frequently participates in the fetal QAPI meeting; and

(C) ensuring that the QAPI Program is specific to maternal-fetal care, is ongoing, data driven and outcome based; and

(D) collaborates with the FCPM to lead the Fetal Center QAPI meeting.

(e) Fetal Center Program Manager (FCPM). There shall be an identified Fetal Center Program Manager (FCPM) responsible for the provision of maternal-fetal care services.

(1) The FCPM shall be a registered nurse who:

(A) has experience and/or training in maternal-fetal care and interventions;

(B) demonstrates administrative skills and oversight of the Fetal Center QAPI Program;

(C) completed annual continuing education specific to maternal-fetal care; and

(D) frequently and actively participates in maternal-fetal care at the facility where program manager services are provided.

(2)The Fetal Center Program Manager shall have the authority and responsibility to monitor maternal-fetal patient care from admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program.

(3)The responsibilities and authority of the FCPM shall include but are not limited to:

(A) examining qualifications of nursing and ancillary staff providing maternal-fetal care services;

(B) collaborates with the FCMD in areas to include, but not limited to: developing and/or revising policies, procedures and guidelines, assuring staff competency, education and training; the QAPI Program; and frequently participates in the Fetal Center QAPI meeting; and

(C) ensuring that the QAPI Program is specific to maternal-fetal care, is ongoing, data driven and outcome based; and

(D) collaborates with the FCMD to lead the Fetal Center QAPI meeting.

(E) develops collaborative relationships with other FCPM(s) of designated facilities.

(f) Medical Staff. There shall be identified medical staff responsible for the provision of maternal-fetal care services and credentialed by the facility for the treatment of maternal-fetal patients.

(1) board-certified Maternal Fetal Medicine (MFM) physician, shall:

(A) have primary responsibility for the direct, comprehensive, and coordinated medical care of patients undergoing fetal interventions and

(B) be available to the bedside as requested, related to the patient's condition.

(2) Pediatric Surgery specialists with additional experience and/or training in fetal interventions and care;

(3) Neonatal/Perinatal Medicine specialists with additional experience and/or training in fetal interventions and care;

(4) The identified medical staff responsible for the provision of maternal-fetal care services shall:

(A) have completed annual continuing medical education specific to the maternal-fetal care;

(B) have frequent and active participation in maternal-fetal care at the facility; and

(C) maintain active staff privileges as defined in the facility's medical staff bylaws.

(5) An anesthesiologist with expertise in maternal-fetal physiology and uterine relaxation methods shall be available for consultation and available at all times if anesthesia is required for fetal interventions.

(6) Pediatric subspecialists shall be available for prenatal and neonatal face-to-face consultation including: cardiologist, cardiovascular surgery, craniofacial surgery, nephrology, neurosurgery, orthopedics, plastic surgery, radiologist, rehabilitative medicine, and urology.

(7) An anesthesiologist with expertise in maternal-fetal physiology and uterine relaxation methods shall be available for consultation and available at all times if anesthesia is required for fetal interventions.

(g) Medical Ethicist. A medical ethicist shall be facility staff and an active member of the fetal diagnosis and therapy program.

(h) Clinical Coordinator(s) shall be identified and be the primary point of contact for the family as evidenced through documentation in the electronic medical record (EMR). Coordinator(s) delineation includes:

(1) predominance of inpatient or outpatient care of patients referred to the center;

(2) at least one Clinical Coordinator shall be a registered nurse with experience in perinatal or neonatal care; and

(3) clinical coordinators engaged in research shall have completed the research ethics training/human subjects' protection.

(i) Genetic Counseling. Board certified genetic counselor(s) or a board certified physician with specialized training in prenatal genetic counseling shall be available for onsite prenatal consultation as requested.

(j) High-Risk Perinatal Sonographer.

(1) Shall be registered through the American Registry for Diagnostic Medical Sonography, Cardiovascular Credentialing International, American Registry for Radiologic Technologists, or an office approved equivalent.

(2) Shall have documented continuing education as required for the certifications, and demonstrate competence in mainstream fetal diagnostic ultrasounds, and new diagnostic modalities as available.

(k) Child Life Specialist. A child life specialist shall be available for onsite consultation as requested and be licensed as a Certified Child Life Specialist (CCLS).

(l) Fetal Center Committee. A multidisciplinary, objective committee will review fetal interventions that are innovative, but not mainstream medicine or research. The committee shall include medical personnel with fetal and/or neonatal knowledge, and non-medical patient advocates, as

appropriate for the proposed study. The chair of the committee shall have an independent objective view of the proposed intervention. The members of the committee may or may not be directly involved with the Fetal Center, but shall not be directly involved in the proposed innovation. The committee has the final authority to approve or disapprove the innovative intervention.

(m) Laboratory Services.

(1) Perinatal pathology services shall be available onsite.

(2) Reference lab capabilities, or agreements with specialized testing centers, shall be available for complete karyotype, fluorescent in-situ hybridization, computerized microarray, free fetal DNA testing for red cell typing and polymerase chain reaction testing for perinatal viruses.

(n) Medical Imaging Services.

(1) A pediatric radiologist with expertise in the interpretation of fetal MRI available and provide interpretation available within 24 hours upon completion of study.

(2) A pediatric cardiologist with expertise in the performance and interpretation of fetal echocardiography shall be available and provide interpretation available within 24 hours upon completion of study.