Center of Excellence for Fetal Diagnosis and Therapy
Subcommittee (HB 2131) Proposed Rules

Amended after Apr 4, 2017 PAC Meeting v. 11.1 May 1, 2017

1. Program Requirements and Plan

a. The designated Center of Excellence For Fetal Diagnosis and Therapy (CoEFDT or Center) will provide patient-centered and family-centered health care. The hospital environment for perinatal care shall comprehensively meet the physiologic and psychosocial needs of the pregnant women, their infants, and families.

b. The CoEFDT will develop a written plan of an organized program to implement and maintain a multidisciplinary health care team, including maternal fetal medicine specialists, pediatric and pediatric surgical specialists, neonatologists, nurses with specialized maternal and neonatal training, and other ancillary and support staff as appropriate to provide maternal, fetal, and neonatal services, and is considered as the highest-level fetal center, treating the full continuum from the least to most complex fetal conditions. A facility will provide, at a minimum, all fetal therapies proven effective antenatally based on level I evidence-based metrics (5-6,17). The program and the scope of practice shall be reviewed every 3 years to maintain designation.

2. Personnel Requirements

A. Medical directorship - The Fetal Medical Directorship (FMD) shall include at least one board-certified Maternal-Fetal Medicine (MFM) specialist or board-certified Pediatric Surgeon; FMD shall have additional training and expertise in fetal interventions, and active involvement in fetal intervention.

1. The Fetal Medical Director (FMD) shall be responsible for the provision of fetal medical care services and credentialed by the facility and/or program for the treatment of fetal patients.
2. The FMD shall have the authority and responsibility to monitor fetal care from admission, stabilization, peri-operative intervention(s) as applicable, through discharge, inclusive of the QAPI Program.
3. The responsibilities and authority of the FMD shall include but are not limited to:

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

(B) assuring staff competency in managing emergencies;

(C) participating in ongoing staff education and training in the care of the fetal patient;

(D) participating in the development, review and assurance of the implementation of the policies, procedures and guidelines of fetal care in the facility including criteria for transfer if needed;

(E) regular and active participation in fetal care at the facility and program where medical director services are provided;

(F) maintaining active staff privileges as defined in the facility's medical staff by-laws;

(G) ensuring that the QAPI Program is specific to fetal care, is ongoing, data driven and outcome based; and regularly participates in the fetal center QAPI meetings including the biannual CoEFDT meetings; and

(H) providing to the department of annual report containing aggregate short-term and long-term outcomes data as requested or required by the department and makes those reports available to the public.

B. Medical Staff -

1. A board-certified/eligible Maternal-Fetal Medicine specialist should have primary responsibility for the direct, comprehensive, and

coordinated medical care of patients undergoing fetal interventions. A MFM will be available at all times to the bedside commensurate to the patient's condition.

2. A Board-certified/eligible Pediatric Surgeon with training and expertise in fetal intervention.
3. A Board-certified/eligible Pediatric Neurosurgeon with training and expertise in fetal intervention.
4. A Board-certified/eligible Neonatologist .
5. A Board-certified/eligible pediatric radiologist with expertise in the interpretation of fetal MRI should be part of the Center, and be available with interpretation within 24 hours.
6. A Board-certified/eligible pediatric cardiologist with expertise in the performance and interpretation of fetal echocardiography will be part of the Center, and be available with interpretation within 24 hours, and within 2 hours of an urgent request.
7. A Board-certified/eligible anesthesiologist with expertise in maternal-fetal physiology and uterine relaxation methods will provide consultation and be available 24/7 to administer anesthesia as required.
8. A Board-certified/eligible Pediatric Urologist.
9. A Board-certified/eligible Pediatric Nephrologist.
10. A Board-certified/eligible Pediatric Palliative Care Medicine specialist.
11. A Medical Ethicist with a terminal degree (MD, DO, JD, PhD) and expertise in clinical perinatal medical ethics shall be an active member of the Center. Duties include, but are not limited to, regular participation of fetal program conferences, providing ethical consultations, and participation with research team as needed.

12. Other Board-certified/eligible pediatric subspecialists will be identified and be available for both prenatal and/or neonatal face-to-face consultation as appropriate for specific fetal condition(s). These could include, but are not limited to, pediatric cardiovascular surgery, pediatric craniofacial surgery, pediatric plastic surgery, pediatric rehabilitative medicine, and pediatric orthopedics.

d. Fetal Program Manager

A Fetal Program Manager (FPM) is responsible for the provision of clinical care services for the patients in the fetal center, and shall be identified by the program and:

1. is a registered nurse,
2. has experience in perinatal or neonatal care,
3. has the authority and responsibility to monitor the provision of coordinated family-centered care services in areas to include, but not limited to, outpatient navigation, admission, stabilization, operative intervention(s) if applicable, discharge, and ensuring collection of outcomes measures as appropriate,
4. collaborates with the medical director(s) in areas to include, but not limited to developing and/or revising policies, procedures and guidelines, assuring staff competency, education and training of staff, and regular participation in quality assurance programs.

e. Clinical Coordinators

1. At least one registered nurse with experience in perinatal or neonatal care.
2. Clinical coordinators engaged in research must have completed the research ethics training/human subjects protection training as appropriate according to the Center's Intuitional Review Board (IRB).

f. Genetic Counseling

Board-certified/eligible genetic counselor(s) or a board-certified/eligible physician with specialized training in prenatal genetics must be available for face-to-face prenatal consultation at the Center.

g. Research Support and Personnel

1. Must have appropriate personnel and infrastructure to collect, analyze, and abstract data as needed for research and follow-up of perinatal outcomes.
2. Personnel must have experience with clinical trials and be familiar with institutional review board processes.
3. Research coordinators must have completed the research ethics training/human subjects' protection training as approved by the IRB with jurisdiction.
4. Research coordinators must have Certified Clinical Research Professional (CCRP) or Certified Clinical Research Associate (CCRA) credential, or equivalent.

h. Mental Health Services

1. Consultation for mental health must be available for onsite visit upon-request at all times for prenatal, peri-operative, and postnatal needs of the patient.
2. Qualifications must include at least one of the following: Clinical Psychologist, Psychiatrist, Licensed Clinical Social Worker (LCSW), Licensed Professional Counselor (LPC) or Licensed Mental Health Counselor (LMHC).

3. At least one member of the team must have experience in a perinatal or neonatal setting.
4. Consultation for mental health evaluation must be available onsite, commensurate to the patient's condition, by a board-certified/eligible psychiatrist as needed.

i. Social Support Personnel

1. Social services shall be provided as appropriate to the patient population served.
2. Must have a minimum of a Baccalaureate or advanced degree in social service, such as a LBSW.
3. At least one member of this team must have experience in perinatal or neonatal care.

j. Financial Counseling Services

The program will ensure that financial counseling is provided to patients and their families, which includes but not limited to, examining the healthcare costs associated with the proposed fetal procedure(s) as compared to postnatal procedure(s), identifying resources that are available for financial support for evaluation and therapy of fetal condition(s), as well as options of returning to the community hospitals near families' homes when appropriate.

k. High-Risk Perinatal Sonographer

1. Must have graduated from an accredited ultrasound-training program, such as The American Registry for Diagnostic Medical Sonography, Cardiovascular Credentialing International, American Registry for Radiologic Technologists, or equivalent approved by the Department.

2. Must have documented continuing education as appropriate for the certifications, and demonstrate competence in mainstream fetal diagnostic ultrasounds, and new diagnostic modalities as they become available.

l. Child Life Specialist

1. A child life specialist should be available for onsite consultation as needed.
2. Must have a Bachelor's degree.
3. Must have licensure as a Certified Child Life Specialist (CCLS).

m. Pastoral Care

1. Pastoral care and/or spiritual counseling shall be provided as needed.
2. Must meet minimum standard to serve as pastoral care as outlined in the hospital policy.

n. Palliative Care

1. A team including at least one board-certified/eligible Pediatric Palliative care physician shall be available for both prenatal and postnatal counseling of families onsite.
2. Must have individuals trained in palliative care who organize clinical protocols, birth plans, staff education and work with hospital palliative care team~~.~~
3. At least one or more members of the team must have training or experience in the support of the perinatal maternal and neonatal patients and families. The program may be part of a larger institutional palliative care team.

o. Institutional Review Board (IRB)

An IRB that fulfills the guidelines of the Food and Drug Administration will be available for the prospective review and approval of all research studies involving human subjects. An Institutional Animal Care and Use Committee (IACUC) that fulfills the requirements of the U.S. Department of Agriculture will be available to prospectively review and approve all studies involving animal research. The IRB and IACUC of a research study may be part of the organization of the Center's affiliated medical school, or an independent governing body with oversight over the research study or protocol. The Center's local IRB shall have the final jurisdiction of a study protocol.

p. Oversight Committee

1. The program shall have a formal multidisciplinary objective oversight committee to review fetal interventions that are innovative but not considered mainstream medicine or research. The responsibilities include ensuring adequate education and informed consent of patients and their families, the ethical use of procedures or surgeries, evaluating the risk of proposed procedures to the fetus and/or pregnant woman, and evaluating the healthcare costs associated with the procedure as compared to post-natal procedures.
2. An authoritative board of the facility, such as the hospital governing board, shall identify the committee members.
3. The committee members shall have:
    a. sufficient knowledge with perinatal and fetal interventions, independent objective view of the proposed intervention(s), and are without conflict of interest with the Center, or the proposed intervention(s),

b. medical personnel including at a minimum, but not limited to, MFM specialist, neonatologist, nurse, medical ethicist, genetic counselor, with perinatal knowledge who are affiliated, and not affiliated, with the Fetal Center,

c. pertinent specialists with expertise in the proposed procedure, and

d. patient advocates, as appropriate for the proposed intervention.

4. The decisions made by the committee will be independent and without conflict of interest, either due to direct care of the patient or by affiliation or financial gain.

5. The meetings must be formal with appropriate documentation of the discussions and actions taken.

6. All non-standard fetal procedures must have formal approval by the oversight committee prior to the intervention. The committee has the final authority to approve or disapprove the innovative intervention.

3. Performance Improvements and Patient Safety Program

A Center must measure short-term and long-term patient diagnostic and therapeutic outcomes. The Center must participate in Quality Assessment and Performance Improvement (QAPI) and patient safety programs. A committee structure will be instituted to follow outcomes, QAPI and patient safety programs; such a committee shall meet at least quarterly.

4. Facility requirements

a. Maternal Care

The maternity facility affiliated with the Center will be designated as a Level IV unit based on the guidelines from the American Congress of Obstetricians and Gynecologists (ACOG). Supportive and emergent care shall be delivered

by appropriately trained personnel and be immediately available for emergent maternal care including, but not limited to, ultrasound and radiology diagnostic procedures as appropriate. If the Center cannot meet these guidelines, a written agreement with a level IV Center, in a contiguous facility that is willing to accept these patients by maternal transport, must be in place. Once approved, the rules for a Level IV maternity center, approved by the Texas Department of State Health Services, will supersede the ACOG guidelines.

b. Pediatric Surgical Care

The pediatric surgery facility associated with the Center will be designated by the American College of Surgeons as a Level I Center through the Children's Surgery Verification Program.

c. Neonatal Care

The neonatal facility affiliated with the Center will be designated as a Level IV unit according to the Texas Department of State Health Services. Supportive and emergent care shall be delivered by appropriately trained personnel and be immediately available for emergent deliveries.

d. Ultrasound Imaging

The program's ultrasound unit shall be accredited by the American Institute of Ultrasound in Medicine or the American College of Radiology, or another entity approved by the Department.

e. Fetal Echocardiography

The program's fetal echocardiography unit shall be accredited by the American Institute of Ultrasound in Medicine or the Intersocietal Accreditation Commission (IAC), or another entity approved by the Department.

f. Other Radiology Services

The program's fetal MRI unit shall be accredited by the American College of Radiology, or another entity approved by the Department.

g. Support Services

1) Appropriately trained and qualified laboratory personnel must be onsite at all times.

2) Perinatal pathology service must be available onsite.

3) Reference lab capabilities, or agreements with specialized testing centers, must be available for specialized testing for perinatal genetic testing, fetal conditions, and infections.

4) Pharmacy service, with a registered pharmacist trained and experienced in neonatal/pediatric and maternal pharmacology, must be available onsite at all times.

5. Other Program Requirements

a. Database

The Center shall collect ongoing data into a computerized repository of data that meets HIPPA requirements.

b. Multidisciplinary Approach to Care

The Center shall implement a multidisciplinary conference, involving fetal center medical staff and appropriate nursing, ethicist(s), ancillary personnel to discuss the options of prenatal and postnatal management for fetal anomalies and other conditions. Fetal intervention(s) performed emergently prior to the conference will be discussed after the procedure as appropriate. There must be appropriate documentation of regular meetings and group discussions of the plan and management for all fetal therapy patients. At a minimum, these meetings will occur on a monthly basis.

c. Medical School Affiliation

The Center offers 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 hospital facility that provides advanced maternal and neonatal care.

d. Formal advanced training program in fetal diagnosis and therapy shall be offered at the Center through an accredited Texas medical school's Graduate Medical Education Office.

e. Commitment to Research

A Center will demonstrate a significant commitment to research in and advancing the field of fetal diagnosis and therapy.

f. Outcomes

1. The Center must provide follow-up of infants through an established institutional or affiliated High Risk Follow-Up Clinic. After specific fetal interventions, short- and long-term outcomes of the pregnant patient and her fetus(es) will be monitored by the Center. These data will be updated on a regular basis with a minimum frequency of annually. A Center's annual report containing aggregate data on short-term and long-term diagnostic and therapeutic outcomes will be provided to the department as requested or required by the department and makes those reports available to the public.
2. All designated Centers must meet at an agreed-upon site twice yearly to discuss and establish inclusion criteria for fetal intervention and bio-psychosocial outcome variables, both short- and long-term. The annual report shall reflect the effectiveness of the fetal interventions and demonstrate risks and benefits of fetal

interventions, including but not limited to the financial burden to the families as reflected in the hospital charges.

3. The application for designation as a Fetal Center of Excellence requires a letter of support from the applying institution's appropriate governing board or the hospital CEO stating that the Center will provide material and personnel support for short- and long-term outcome tracking.
4. An outcome database at a minimum includes:
    a. Demographics:
        i. Number of contacts for possible advanced fetal treatment, and the maternal county of origin in Texas, or state if not Texas, or country of origin.
        ii. Number of patients seen onsite for evaluation.
        iii. Number of maternal patients eligible for a procedure
        iv. Number of maternal patients eligible for a procedure and voluntarily refused procedure.
        v. Number of maternal patients eligible for procedure and underwent procedure.
    b. Short Term Maternal Outcomes (by fetal diagnosis):
        i. Maternal readmission post procedure (except for delivery)
        ii. Maternal blood transfusion (any)
        iii. Maternal ICU admission
        iv. Maternal Death
    c. Long Term Maternal Outcomes (by fetal diagnosis):
        i. Registry of mother's undergoing fetal intervention to be cross-referenced by state health departments against future birth certificates assigned to said mother. This subsequent post-fetal intervention birth rate could be compared to the overall age-specific birthrate in Texas.
    d. Short Term Fetal and Neonatal Outcomes (by fetal diagnosis):
        i. Gestational age at procedure

ii. Gestational age at delivery
iii. Fetal demise pre-procedure
iv. Fetal demise post-procedure
v. Number of days in NICU
vi. Neonatal survival in NICU
vii. Neonatal survival at 30 days after NICU discharge
viii. Complications specific to fetal procedures, related directly or indirectly to the use of advanced fetal interventions

e. Long Term Neonatal Outcome using standardized validated neurodevelopmental-testing assessments will be performed at a minimum of age 2 and 5 years. This includes measures of cognitive, behavioral, language and sensory motor outcomes, as well as measures of growth and long-term survival.

g. Outreach and Collaboration with Other Centers and Practitioners

The Center will demonstrate education and outreach to referring practitioners, other Texas fetal centers or hospitals, by means such as but not limited to, the use of webinars, newsletters, on-line videos, direct mentoring of procedure(s) at the Center, or telemedicine as appropriate and as available.

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Definitions

1. Available at all times - without delay.
2. Center - Center of Excellence For Fetal Diagnosis and Therapy
3. Department - Department of State Health Services.
4. Experiment - is defined as a clinical intervention the outcome of which cannot be reliably predicted.
5. Fetal Medical Care – medical care of the pregnant mother and her fetus(s).
6. Fetal patient – both the pregnant mother and her fetus(s).
7. Innovation - is an experiment undertaken to benefit an individual patient.
8. Level I evidence-based metrics - evidence from a systematic review of all relevant randomized controlled trials (RCT's), or evidence-based clinical practice guidelines based on systematic reviews of RCT's, or of best available consensus of the major national perinatal organizations.
9. Onsite - at the facility.
10. Research - is an experiment undertaken to create generalized knowledge.

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House Bill 2131, 86th Legislature Subcommittee Members

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Program Plan

The facility of the Center of Excellence For Fetal Diagnosis and Therapy Centers program shall develop a written plan that includes a detailed description of the scope of services available to all maternal and neonatal patients, defines the patient population evaluated and/or treated, transferred, or transported by the facility, that is consistent with accepted professional standards of practice for maternal, fetal, and neonatal care, and ensures the health and safety of patients.

(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 Center of Excellence For Fetal Diagnosis and Therapy Centers written program plan shall include, at a minimum:

(A) standards of practice that the program policies and procedures are based upon that are adopted, implemented and enforced for the services it provides;

(B) a periodic review and revision schedule for all policies and procedures;

(C) ensure appropriate follow-up for all pregnant women and their families treated at the Center;

(D) provisions for disaster response to include evacuation of mothers and infants to appropriate levels of care;

(E) a commitment to the highest quality collection, analysis, and regular reporting of outcomes in the field of advanced fetal intervention;

(F) requirements for minimal credentials for all staff participating in the care of all patients at the Center;

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

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