

1 Legend: (New Rules)

2 Regular Print = Proposed new language

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

4 § 133.191 Background and Purpose.

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

8 § 133.192 Definitions.

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

- 11 (1) Commission--The Health and Human Services Commission.
- 12 (2) Department--The Department of State Health Services.
- 13 (3) Designation--A formal recognition by the executive
14 commissioner of a facility's neonatal or maternal care
15 capabilities and commitment, for a period of three years.
- 16 (4) Facility
- 17 (5) Fetal
- 18 (6) FCMD—Fetal Center Medical Director
- 19 (7) FCPM—Fetal Center Program Manager
- 20 (8) Executive commissioner--The executive commissioner of the
21 Health and Human Services Commission.
- 22 (9) Level I evidence-based metrics-- Evidence from a systematic
23 review or meta-analysis of all relevant RCTs (randomized
24 controlled trial) or evidence-based clinical practice guidelines
25 based on systematic reviews of RCTs or three or more RCTs of
26 good quality that have similar results.
- 27 (10) Maternal--Pertaining to the mother.
- 28 (11) Neonate--An infant from birth through 28 completed days after
29 birth.
- 30 (12) Office--Office of Emergency Medical Services (EMS)/Trauma
31 Systems Coordination.

32 (13) PCR--Perinatal Care Region.

33 (14) Perinatal--Of, relating to, or being the period around childbirth,
34 especially the five months before and one month after birth.
35

36 § 133.193 General Requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

87 § 133.194 Designation Process

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

92
93 (1) an accurate and complete designation application form for
94 designation; including full payment of the designation fee as listed in
95 subsection (d) of this section;

96
97 (2) evidence of current verification from the American College of
98 Surgeons as a Level I Children’s Surgical Center; including patient care
99 reviews;

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

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

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

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

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

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

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

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

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

122

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

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

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

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

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

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

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

152

153 (i) be voluntary;

154 (ii) be appointed by the office director;

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

158 (iv) include representation from the office.

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

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

167

168 § 133.195 Program Requirements.

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

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

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

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

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

186 (A) standards of fetal diagnosis and therapy practice that the
187 program policies and procedures are based upon that are adopted,
188 implements and enforced for the maternal-fetal services it provides;
189

190 (B) a periodic review and revision schedule for all maternal-fetal
191 care policies and procedures;
192

193 (C) a QAPI Program as described in §133.41(r) of this title
194 (relating to Hospital Functions and Services). The facility shall
195 demonstrate that the Fetal Center program evaluates the provision
196 of maternal-fetal care on an ongoing basis, identify opportunities
197 for improvement, develop and implement improvement plans, and
198 evaluate the implementation until a resolution is achieved. The
199 Fetal Center program shall measure, analyze, and track quality
200 indicators or other aspects of performance that the facility adopts
201 or develops that reflect processes of care and is outcome based.
202 Evidence shall support that aggregate patient data is continuously
203 reviewed for trends and data is submitted to the department as
204 requested;
205

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

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

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

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

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

221 (1) The FCMD shall be a physician who:

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

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

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

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

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

233
234 (2) The Fetal Center Medical Director shall have the authority
235 and responsibility to monitor maternal-fetal patient care
236 from admission, stabilization, operative intervention(s) if
237 applicable, through discharge, inclusive of the QAPI
238 Program.

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

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

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

249
250 (C) ensuring that the QAPI Program is specific to
251 maternal-fetal care, is ongoing, data driven and outcome based;
252 and

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

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

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

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

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

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

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

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

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

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

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

281
282 (C) ensuring that the QAPI Program is specific to
283 maternal-fetal care, is ongoing, data driven and outcome based;
284 and

285
286 (D) collaborates with the FCMD to lead the Fetal Center
287 QAPI meeting.

288 (E) develops collaborative relationships with other
289 FCPM(s) of designated facilities.
290

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

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

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

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

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

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

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

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

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

310 (C) maintain active staff privileges as defined in the facility's
311 medical staff bylaws.
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313 (5) An anesthesiologist with expertise in maternal-fetal physiology
314 and uterine relaxation methods shall be available for consultation and
315 available at all times if anesthesia is required for fetal interventions.

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

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

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

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

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

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

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

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

337 (j) High-Risk Perinatal Sonographer.

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

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

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

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

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

357 (m) Laboratory Services.

358 (1) Perinatal pathology services shall be available onsite.

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

363 (n) Medical Imaging Services.

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

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

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