

- 1 Legend: (Proposed New Rules)
- 2 Regular Print = Proposed new language
- 3 Subchapter J

4

5 **§133.181 Purpose**

6 The purpose of this section is to implement Health and Safety Code, Chapter
7 241, Subchapter H, Hospital Level of Care Designations for Maternal and
8 Maternal Care, which requires a level of care designation of maternal
9 services to be eligible to receive reimbursement through the Medicaid
10 program for maternal services.

11

12 **§133.182 Definitions**

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

- 15 (1) ACLS – Advanced Cardiac Life Support –
- 16 (2) Antepartum -
- 17 (3) Attestation--A written statement, signed by the Chief Executive
18 Officer of the facility, verifying the results of a self-survey represent a
19 true and accurate assessment of the facility's capabilities required in
20 this subchapter.

21 (2) Birth weight--The weight of the neonate recorded at time of birth.

22 (A) Low birth weight--Birth weight less than 2500 grams (5 lbs., 8 oz.);

23 (B) Very low birth weight (VLBW)--Birth weight less than 1500 grams (3
24 lbs., 5 oz.); and

25 (C) Extremely low birth weight (ELBW)--Birth weight less than 1000grams
26 (2 lbs., 3 oz.).

27 (3) CAP--Corrective Action(s) Plan. A plan for the facility developed by the
28 Office of EMS/Trauma Systems Coordination that describes the actions
29 required of the facility to correct identified deficiencies to ensure compliance
30 with the applicable designation requirements.

- 31 (4) Commission--The Health and Human Services Commission.
- 32 (5) Department--The Department of State Health Services.
- 33 (6) Designation--A formal recognition by the executive commissioner of a
34 facility's neonatal or maternal care capabilities and commitment, for a period
35 of three years.
- 36 (7) EMS--Emergency medical services used to respond to an individual's
37 perceived need for immediate medical care.
- 38 (8) Executive commissioner--The executive commissioner of the Health and
39 Human Services Commission.
- 40 (9) Gestational age--The age of a fetus or embryo at a specific point during
41 a woman's pregnancy.
- 42 (10) High-risk Infant--A newborn that has a greater chance of
43 complications because of conditions that occur during fetal development,
44 pregnancy conditions of the mother, or problems that may occur during
45 labor and/or birth.
- 46 (11) Immediate supervision--The supervisor is actually observing the task
47 or activity as it is performed.
- 48 (12) Immediately--Without delay.
- 49 (13) Infant--A child from birth to 1 year of age.
- 50 (14) Intrapartum -
- 51 (14) Lactation consultant--A health care professional who specializes in the
52 clinical management of breastfeeding.
- 53 (15) Maternal--Pertaining to the mother.
- 54 (16) NCPAP--Nasal continuous positive airway pressure.
- 55 (17) Neonate--An infant from birth through 28 completed days after.
- 56 (18) NMD--Neonatal Medical Director.
- 57 (19) NPM--Neonatal Program Manager.

- 58 (20) Neonatal Resuscitation Program (NRP)--A resuscitation course that
59 was developed and is administered jointly by the American Heart
60 Association/American Academy of Pediatrics.
- 61 (21) MFM – Maternal Fetal Medicine
- 62 (22) MMD – Maternal Medical Director
- 63 (23) MPM – Maternal Program Manager
- 64 (24) Obstetrical -
- 65 (21) Office--Office of Emergency Medical Services (EMS)/Trauma Systems
66 Coordination.
- 67 (22) PCR--Perinatal Care Region.
- 68 (23) Perinatal--Of, relating to, or being the period around childbirth,
69 especially the five months before and one month after birth.
- 70 (24) POC--Plan of Correction. A report submitted to the office by the facility
71 detailing how the facility will correct any deficiencies cited in the survey
72 report or documented in the self-attestation.
- 73 (25) Premature/prematurity--Birth at less than 37 weeks of gestation.
- 74 (26) Postpartum--The six-week period following delivery.
- 75 (27) QAPI Program--Quality Assessment and Performance Improvement
76 Program.
- 77 (28) RAC--Regional Advisory Council as described in §157.123 of this title
78 (relating to Regional Emergency Medical Services/Trauma Systems).
- 79 (29) Supervision--Authoritative procedural guidance by a qualified person
80 for the accomplishment of a function or activity with initial direction and
81 periodic inspection of the actual act of accomplishing the function or activity.
- 82 (30) TSA--Trauma Service Area as described in §157.122 of this title
83 relating to (Trauma Service Areas).
- 84 (31) Urgent--Requiring immediate action or attention.

85

86 **§133.183 General Requirements**

87 (a) The Office of Emergency Medical Services (EMS)/Trauma Systems
88 Coordination (office) shall recommend to the Executive Commissioner of the
89 Health and Human Services Commission (executive commissioner) the
90 designation of an applicant/healthcare facility as a maternal facility at the
91 level for each location of a facility, which the office deems appropriate.

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

96 (c) Each location shall be considered separately for designation and the
97 office will determine the designation level for that location, based on, but not
98 limited to, the location's own resources and level of care capabilities;
99 Perinatal Care Region (PCR) capabilities; and compliance with Chapter 133
100 of this title, concerning Hospital Licensing. The final determination of the
101 level of designation may not be the level requested by the facility.

102 (1) Level I (Basic Care). The Level I maternal designated facility will:

103 (A) provide care of pregnant and postpartum women who are
104 generally healthy, and do not have medical, surgical, or
105 obstetrical conditions that present a significant risk of maternal
106 morbidity or mortality; and

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108 (B) have skilled personnel with documented training,
109 competencies and continuing education annually specific for the
110 patient population served.

111 (2) Level II (Specialty Care). The Level II maternal designated facility
112 will:

113 (A) provide care for pregnant women and postpartum women
114 with medical, surgical, and/or obstetrical conditions that present a low
115 to moderate risk of maternal morbidity or mortality; and

116 (B) have skilled personnel with documented training,
117 competencies and continuing education annually specific for the
118 patient population served.

119 (3) Level III (Subspecialty Care). The Level III maternal designated facility
120 will:

121 (A) provide care for pregnant and postpartum women with low
122 risk conditions to significant complex medical, surgical and/or
123 obstetrical conditions that present a high risk of maternal
124 morbidity or mortality;

125 (B) Ensure access to consultation to a full range of medical
126 and maternal subspecialists and surgical specialists, and the capability
127 to perform major surgery on-site.

128 (C) have physicians with critical care training onsite to
129 actively collaborate with Maternal Fetal Medicine and
130 Obstetrical physicians at all times;

131 (D) have skilled personnel with documented training,
132 competencies and continuing education annually, specific
133 for the population served;

134 (E) facilitate transports; and

135 (F) provide outreach education to lower level designated
136 facilities including the Quality Assessment and
137 Performance Improvement (QAPI) process.

138 (4) Level IV (Comprehensive Care). The Level IV maternal
139 designated facility will:

140 (A) provide perinatal women with comprehensive care for low
141 risk conditions to the most complex medical, surgical and/or
142 obstetrical conditions and their fetuses, that present a high risk
143 of maternal morbidity or mortality;

144 (B) Ensure access to on site consultation to a full range of
145 medical and maternal subspecialists and surgical

150 specialists, and the capability to perform major surgery
151 on-site.

152 (C) have skilled personnel with documented training,
153 competencies and continuing education annually, specific
154 for the patient population served;

155 (D) facilitate transports; and

156 (E) provide outreach education to lower level designated
157 facilities including the Quality Assessment and Performance
158 Improvement (QAPI) process.

159 (e) Facilities seeking maternal facility designation shall be surveyed through
160 an organization approved by the office to verify that the facility is meeting
161 office-approved relevant maternal facility requirements. The facility shall
162 bear the cost of the survey.

163 (e) PCR's

164 (1) The PCRs are established for descriptive and regional planning
165 purposes and not for the purpose of restricting patient referral.

166 (2) The PCR will consider and facilitate transfer agreements through
167 regional coordination.

168 (3) A written plan identifies all resources available in the PCRs for
169 perinatal care including resources for emergency and disaster
170 preparedness.

171 (4) The PCRs are geographically divided by counties and are integrated
172 into the existing 22 TSAs and the applicable Regional Advisory Council
173 (RAC) of the TSA provided in §157.122 and §157.123 of this title; will
174 be administratively supported by the RAC; and will have fair and
175 equitable representation on the board of the applicable RAC.

176 (5) Multiple PCRs can meet together for the purposes of mutual
177 collaboration.

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179 **§133.184 Designation Process.**

180 (a) Designation application packet. The applicant shall submit the packet,
181 inclusive of the following documents to the Office of EMS/Trauma Systems
182 Coordination (office) within 120 days of the facility's survey date:

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

186 (2) any subsequent documents submitted by the date requested by the
187 office;

188 (3) a completed maternal attestation and self-survey report for Level I
189 applicants or a designation survey report, including patient care reviews if
190 required by the office, for Level II, III and IV applicants;

191 (4) a plan of correction (POC), detailing how the facility will correct any
192 deficiencies cited in the survey report, to include: the corrective action; the
193 title of the person responsible for ensuring the correction(s) is implemented;
194 how the corrective action will be monitored; and the date by which the POC
195 will be completed; and

196 (5) evidence of participation in the applicable Perinatal Care Region (PCR).

197 (b) Renewal of designation. The applicant shall submit the documents
198 described in subsection (a)(1) - (5) of this section to the office not more
199 than 180 days prior to the designation expiration date and at least 60 days
200 prior to the designation expiration date.

201 (c) If a facility seeking designation fails to meet the requirements in
202 subsection (a)(1) - (5) of this section, the application shall be denied.

203 (d) Non-refundable application fees for the three year designation period are
204 as follows:

205 (1) Level I maternal facility applicants, the fees are as follows:

206 (A) ≤ 100 licensed beds, the fee is \$250.00; or

207 (B) > 100 licensed beds, the fee is \$750.00.

208 (2) Level II maternal facility applicants, the fee is \$1,500.00.

209 (3) Level III maternal facility applicants, the fee is \$2,000.00.

210 (4) Level IV maternal facility applicants, the fee is \$2,500.00.

211 (A) All completed applications, received on or before July 1, 2020,
212 including the application fee, evidence of participation in the PCR, an
213 appropriate attestation if required, survey report, and that meet the
214 requirements of the requested designation level, will be issued a designation
215 for the full three-year term.

216 (B) Any facility that has not completed an on-site survey to verify
217 compliance with the requirements for a Level II, III or IV designation at the
218 time of application must provide a self-survey and attestation and will
219 receive a Level I designation. The office, at its sole discretion may
220 recommend a designation for less than the full three-year term. A
221 designation for less than the full three-year term will have a pro-rated
222 application fee consistent with the one, two or three-year term length.

223 (C) A facility applying for Level I designation requiring an attestation may
224 receive a shorter term designation at the discretion of the office. A
225 designation for less than the full three-year term will have a pro-rated
226 application fee.

227 (D) The office, at its discretion, may designate a facility for a shorter term
228 designation for any application received prior to September 1, 2020.

229 (E) An application for a higher or lower level designation may be
230 submitted at any time.

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

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

240 (2) The facility may, not later than 30 days of the office's sending written
241 notification of its denial, submit a written request for further review. Such
242 written appeal shall then go to the Director of EMS / Trauma Systems
243 Coordination of the Division for Consumer Protection.

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

250 (g) The office shall review the findings of the survey report and any POC
251 submitted by the facility, to determine compliance with the maternal
252 program requirements.

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

255 (2) A maternal level of care designation shall not be denied to a facility that
256 meets the minimum requirements for that level of care designation.

257 (3) If a facility does not meet the requirements for the level of designation
258 requested, the office shall recommend designation for the facility at the
259 highest level for which it qualifies and notify the facility of the requirements
260 it must meet to achieve the requested level of designation.

261 (4) If a facility does not comply with requirements, the office shall notify
262 the facility of deficiencies and required corrective action(s) plan (CAP).

263 (A) The facility shall submit to the office reports as required and outlined
264 in the CAP. The office may require a second survey to ensure compliance
265 with the requirements. The cost of the survey will be at the expense of the
266 facility.

267 (B) If the office substantiates action that brings the facility into
268 compliance with the requirements, the office shall recommend designation to
269 the executive commissioner.

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

- 274 (i) be voluntary;
- 275 (ii) be appointed by the office director;
- 276 (iii) be representative of maternal care providers and appropriate levels
277 of designated maternal facilities; and
- 278 (iv) include representation from the office and the Perinatal Advisory
279 Council.

280 (D) If a designation review committee disagrees with the office's
281 recommendation for corrective action, the records shall be referred to the
282 assistant commissioner for recommendation to the executive commissioner.

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

287 **§133.185 Program Requirements.**

288
289 (a) Designated facilities shall have a family centered philosophy. The
290 facility environment for perinatal care shall meet the physiologic and
291 psychosocial needs of the mothers, infants, and families. Parents shall
292 have reasonable access to their infants at all times and be encouraged
293 to participate in the care of their infants.

294
295 (b) Program Plan. The facility shall develop a written plan of the
296 maternal program that includes a detailed description of the scope of
297 services available to all maternal patients, defines the maternal patient
298 population evaluated and/or treated, transferred, or transported by
299 the facility, that is consistent with accepted professional standards of
300 practice for maternal care, and ensures the health and safety of
301 patients.

302
303 (1) The written plan and the program policies and procedures shall
304 be reviewed and approved by the facility's governing body. The
305 governing body shall ensure that the requirements of this section
306 are implemented and enforced.

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308 (2) The written maternal program plan shall include, at a minimum:

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

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

(C) written triage, stabilization, and transfer guidelines for pregnant and postpartum women that include consultation and transport services;

(D) written guidelines or protocols for prevention, early identification, early diagnosis, and therapy for various conditions that place the pregnant or postpartum woman at risk for morbidity and/or mortality.

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

(F) a Quality Assessment and Performance Improvement (QAPI) Program as described in §133.41(r) of this title (relating to Hospital Functions and Services). The facility shall demonstrate that the maternal program evaluates the provision of maternal care on an ongoing basis, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until a resolution is achieved. The Maternal program shall measure, analyze, and track quality indicators and 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;

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

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

350 (I) a perinatal staff registered nurse as a representative on the
351 nurse staffing committee under §133.41(o)(2)(F) of this title; and

352
353 (J) the availability of all necessary equipment and services to
354 provide the appropriate level of care and support of the patient
355 population served;
356

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

361 (d) Medical Director. There shall be an identified Maternal Medical Director
362 (MMD) and/or Transport Medical Director (TMD) as appropriate, responsible
363 for the provision of maternal care services and credentialed by the facility for
364 the treatment of maternal patients.

365
366 (1) The MMD and/or TMD shall have the authority and responsibility
367 to monitor maternal patient care from admission, stabilization,
368 operative intervention(s) if applicable, through discharge, and inclu-
369 sive of the QAPI Program.

370
371 (2) The responsibilities and authority of the MMD and/or TMD shall
372 include but are not limited to:

373 (3)

374 (A) examining qualifications of medical staff requesting maternal
375 privileges and makes recommendations to the appropriate
376 committee for such privileges;

377
378 (B) assuring staff competency in managing obstetrical
379 emergencies, complications and resuscitation techniques;

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381 (C) participating in ongoing staff education and training in the
382 care of the maternal patient;

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384 (D) oversight of the inter-facility maternal transport;

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386 (E) participating in the development, review and assurance of
387 the implementation of the policies, procedures and guidelines of
388 maternal care in the facility including written criteria for transfer,
389 consultation or higher level of care;

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391 (F) regular and active participation in maternal care at the facility
392 where medical director services are provided;

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394 (G) ensuring that the QAPI Program is specific to maternal and
395 fetal care, is ongoing, data driven and outcome based; and
396 regularly participates in the maternal QAPI meeting; and

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398 (H) maintaining active staff privileges as defined in the facility's
399 medical staff bylaws.

400
401 (e) Maternal Program Manager (MPM). The MPM responsible for the provision
402 of maternal care services shall be identified by the facility and:

- 403
404 (1) be a registered nurse;
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406 (2) have the authority and responsibility to monitor the provision of
407 maternal patient care services from admission, stabilization, operative
408 intervention(s) if applicable, through discharge, and inclusive of the
409 QAPI Program as defined in subsection (b)(2)(E) of this section;
- 410
411 (3) collaborate with the MMD in areas to include, but not limited to:
412 developing and/or revising policies, procedures and guidelines; assuring staff
413 competency, education, and training; the QAPI Program; and regularly
414 participates in the maternal QAPI meeting; and
- 415
416 (4) develops collaborative relationships with other MPM(s) of
417 designated facilities within the applicable Perinatal Care Region.

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419 **§133.186 Maternal Designation Level I.**

420 (a) Level I (Basic Care). The Level I maternal designated facility will:

421 (A) provide care of pregnant and postpartum women who are
422 generally healthy, and do not have medical, surgical, or
423 obstetrical conditions that present a significant risk of maternal
424 morbidity or mortality; and

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426 (B) have skilled personnel with documented training,
427 competencies and continuing education annually specific for the
428 patient population served.

429 (b) Maternal Medical Director (MMD). The MMD shall be a physician who is:

430 (1) a family medicine physician or an obstetrician;

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432 (2) demonstrates effective administrative skills and oversight of the
433 Quality Assessment and Performance Improvement (QAPI) Program;

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435 (3) has completed continuing medical education annually specific to
436 maternal care;

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438 (4) has regular and active participation in maternal care at the facility
439 where medical director services are provided; and

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

443

444 (c) Program Function and Services

445 (1) Triage and assessment of all patients admitted to the
446 perinatal service with:

447 (A) identification of pregnant women who are at high risk of
448 delivering a neonate that requires a higher level of neonatal
449 care than the scope of their neonatal facility shall be
450 transferred to a higher level neonatal designated facility prior
451 to delivery unless the transfer is unsafe.

452 (B) identification of pregnant or postpartum women with
453 conditions or complications that will likely require a higher
454 level of care will be transferred to a higher level maternal
455 designated facility unless the transfer will be unsafe.

456 (2) the capability care for women with uncomplicated
457 pregnancies and to stabilize and initiate management of
458 unanticipated maternal-fetal or maternal problems that occur
459 during the antepartum, intrapartum, or postpartum period until
460 the patient can be transferred to a higher level of neonatal
461 and/or maternal care;

462 (3) a board certified obstetrician available at all times and
463 specialists available for consultation appropriate to the patient
464 population served.

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(4) The ability to begin an emergency cesarean delivery and ensure the availability of a physician with the training, skills, and privileges to perform the surgery within a time period consistent with current standards of professional practice and maternal care.

(5) Ensure that a qualified physician or certified nurse midwife with appropriate physician back-up is available to attend all deliveries or other obstetrical emergencies.

(6) The primary physician or Certified Nurse Midwife with competence in the care of pregnant women, whose credentials have been reviewed by the MMD and is on call:

(A) Shall arrive at the patient’s bedside within 30 minutes of an urgent request;

(B) If not immediately available to respond or is covering more than one facility, be provided appropriate backup coverage who shall be available, documented in an on call schedule and readily available to facility staff;

(C) the physician providing backup coverage shall arrive at the patient’s bedside within 30 minutes of an urgent request; and

(D) Has completed continuing education annually, specific to the care of the pregnant and postpartum woman, including complicated conditions.

(7) Certified nurse midwives who attend patients:

(A) Shall operate under guidelines reviewed and approved by the MMD; and

(B) Shall have a formal arrangement with a physician who will:

1. provide back-up and consultation;
2. arrive at the patient’s bedside within 30 minutes of an urgent request; and
3. have credentials reviewed by the MMD.

(8) An on-call schedule of providers, back-up providers, and provision for patients without a physician will be posted on the labor and delivery unit.

(9) Availability of appropriate anesthesia, laboratory, pharmacy, radiology, ultrasonography and blood bank services on a 24 hour basis as described in § 133.41(a), (h), and (s) of this title respectively.

506 (A) have anesthesia personnel with obstetrical experience or
507 training available at all times and arrive to the patient's bedside within
508 30 minutes of an urgent request.

509
510 (B) Laboratory and blood bank services shall have guidelines or
511 protocols for:

- 512 (i) massive blood product transfusion;
- 513 (ii) emergency release of blood products; and
- 514 (iii) management of multiple blood component therapy.

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516 (C) A pharmacist shall be available for consultation at all times.

517
518 (D) If preliminary reading of imaging studies pending formal
519 interpretation is performed, the preliminary findings must be
520 documented in the medical record.

521 (E) There must be regular monitoring of the preliminary versus
522 final reading in the QAPI Program.

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524
525 (10) Obstetrical Services.

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527 (A) Ensure the availability and interpretation of non-stress
528 testing, and electronic fetal monitoring; and

529
530 (B) A trial of labor for patients with prior cesarean delivery must
531 have the immediate availability of anesthesia, cesarean delivery, and
532 maternal resuscitation capability during the trial of labor.

533
534 (11) Resuscitation. Written policies and procedures shall be specific to
535 the facility for the stabilization and resuscitation of pregnant or postpartum
536 women based on current standards of professional practice.

537
538 (12) At least one person must be immediately available on site at all
539 times who demonstrates current status of successful completion of ACLS and
540 the skills to perform a complete resuscitation.

541
542 (13) Ensure that resuscitation equipment including fiber optic scopes
543 for awake intubation for pregnant and postpartum women is readily available
544 in the labor and delivery, antepartum and postpartum areas.

545
546 (14) The facility shall have written guidelines or protocols for
547 various conditions that place the pregnant or postpartum woman at risk for
548 morbidity and/or mortality, including promoting prevention, early
549

550 identification, early diagnosis, therapy, stabilization, and transfer. The
551 guidelines or protocols must address a minimum of:

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553 (A) Massive hemorrhage and transfusion of the pregnant or
554 postpartum patient in coordination of the blood bank, including
555 management of unanticipated hemorrhage and/or coagulopathy;
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557 (B) Obstetrical hemorrhage including promoting the identification
558 of patients at risk, early diagnosis, and therapy to reduce morbidity
559 and mortality;
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561 (C) Hypertensive disorders in pregnancy including eclampsia and
562 the postpartum patient to promote early diagnosis and treatment to
563 reduce morbidity and mortality;
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565 (B) Sepsis and/or systemic infection in the pregnant or
566 postpartum woman;
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568 (E) Venous thromboembolism in pregnant and postpartum
569 women, and to assessment of risk factors, prevention, early diagnosis
570 and treatment;
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572 (F) Shoulder dystocia- assessment of risk factors, counseling of
573 patient, multi-disciplinary management
574

575 (15) Perinatal Education. A registered nurse with experience in
576 maternal care shall provide the supervision and coordination of staff
577 education. Perinatal education for high risk events will be provided at regular
578 intervals to prepare medical, nursing, and ancillary staff for these
579 emergencies.
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581 (16) Support personnel with knowledge and skills in breastfeeding
582 and lactation to meet the needs of mothers shall be available at all times.
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584 (17) Social services, pastoral care and bereavement services shall
585 be provided as appropriate to meet the needs of the patient population
586 served.
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588 (18) Nutritionist or dietician available and appropriate for population
589 served in compliance with the requirements in §133.41(d) of this title.
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591 **§133.187 Maternal Designation Level II**

592 (a) Level II (Specialty Care). The Level II maternal designated facility will:

593 (A) provide care for pregnant women and postpartum women
594 with medical, surgical, and/or obstetrical conditions that present a low
595 to moderate risk of maternal morbidity or mortality; and

596 (B) have skilled personnel with documented training,
597 competencies and continuing education annually specific for the
598 patient population served.

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600 (b) Maternal Medical Director (MMD). The MMD shall be a physician who:

601 (1) is a family medicine physician, obstetrician or maternal fetal
602 medicine physician with experience in the obstetrical care;

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604 (2) Demonstrates effective administrative skills and oversight of the
605 Quality Assessment and Performance Improvement (QAPI) Program;

606 (3) Has completed continuing medical education annually specific to
607 maternal care including complicated conditions.

608 (4) has regular and active participation in maternal care at the facility
609 where medical director services are provided; and

610

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

613

614 (c) Program Function and Services

615 (1) Triage and assessment of all patients admitted to the perinatal
616 service with:

617 (A) identification of pregnant women at high risk of delivering a
618 neonate that requires a higher level of neonatal care than the scope of
619 their neonatal facility shall be transferred to a higher level neonatal
620 designated facility prior to delivery unless the transfer is unsafe; and

621 (B) identification of pregnant or postpartum women with
622 conditions or complications that will require a higher level of maternal

623 care will be transferred to a higher level maternal designated facility
624 unless the transfer will be unsafe;

625 (C) provide care for pregnant women with the capability to
626 detect, stabilize, and initiate management of unanticipated maternal-
627 fetal or maternal problems that occur during the antepartum,
628 intrapartum, or postpartum period until the patient can be transferred
629 to a higher level of neonatal and/or maternal care; and

630 (2) a board certified maternal fetal medicine physician and medical
631 and surgical physicians available at all times and arrives at the patient
632 bedside within 30 minutes of an urgent request.

633 (3) Specialists will be available for consultation appropriate to the
634 patient population served.

635 (4) The ability to begin an emergency cesarean delivery and ensure
636 the availability of a physician with the training, skills, and privileges to
637 perform the surgery within a time period consistent with current
638 standards of professional practice and maternal care.

639 (6) Ensure that a qualified physician or certified nurse midwife with
640 appropriate physician back-up is available to attend all deliveries or
641 other obstetrical emergencies.

642 (7) The family medicine physician, obstetrician, maternal fetal
643 medicine physician, or a certified nurse midwife with appropriate
644 physician back-up, whose credentials have been reviewed by the MMD
645 and is on call:

646 (A) shall arrive at the patient's bedside within 30 minutes
647 of an urgent request;

648 (B) if not immediately available to respond or is covering
649 more than one facility, shall have appropriate backup coverage
650 available, documented in an on call schedule and readily
651 available to facility staff;

652 (C) the physician providing backup coverage shall arrive at
653 the patient's bedside within 30 minutes of an urgent request;
654 and

655 (D) has completed continuing education annually, specific
656 to the care of the pregnant and postpartum woman, including complicated
657 conditions.

658 (8) Certified nurse midwives who attend patients:

659 (A) Shall operate under guidelines reviewed and approved
660 by the MMD; and

661 (B) Shall have a formal arrangement with a physician is
662 responsible for:

663 1. providing back-up and consultation;

- 2. shall be able to arrive at the patient's bedside within 30 minutes of an urgent request; and
- 3. have credentials reviewed by the MMD.

(9) An on-call schedule of providers, back-up providers, and provision for patients without a physician should be posted on the labor and delivery unit.

(10) Availability of appropriate anesthesia, laboratory, pharmacy, radiology, ultrasonography and blood bank services on a 24 hour basis as described in § 133.41(a), (h), and (s) of this title respectively.

(11) Anesthesia Services shall:

(A) arrive to the patient's bedside within 30 minutes of an urgent request.

(B) have anesthesia personnel with obstetrical experience or training available at all times for labor analgesia and surgical anesthesia.

(C) An anesthesiologist with training or experience in obstetric anesthesia available at all times for consultation.

(12) Laboratory Services shall:

(A) Ensure the availability of ABO-Rh specific or O-Rh negative blood, fresh frozen plasma and/or cryoprecipitate, and platelet products at all times; and

(B) Ensure guidelines or protocols for:

- 1. massive blood product transfusion,
- 2. emergency release of blood products, and
- 3. management of multiple component therapy.

(13) A pharmacist shall be available for consultation at all times.

(14) Medical Imaging.

(A) If preliminary reading of imaging studies pending formal interpretation is performed, the preliminary findings must be documented in the medical record.

(B) There must be regular monitoring of the preliminary versus final reading in the QAPI Program.

(C) Computed Tomography (CT) imaging and interpretation available at all times.

702 (D) Ultrasound availability.

703 1. Basic ultrasonographic imaging for maternal or fetal
704 assessment and interpretation available at all times; and

705 2. A portable ultrasound machine available in the labor and
706 delivery and antepartum unit for urgent bedside examination.
707

708 (15) Obstetrical Services.

709
710 (A) Ensure the availability and interpretation of non-stress
711 testing, and electronic fetal monitoring; and
712

713 (B) A trial of labor for patients with prior cesarean delivery must
714 have the immediate availability of anesthesia, cesarean delivery, and
715 maternal resuscitation capability during the trial of labor.
716

717 (16) Resuscitation. Written policies and procedures shall be specific to
718 the facility for the stabilization and resuscitation of pregnant or postpartum
719 women based on current standards of professional practice.
720

721 (17) At least one person must be immediately available on site at all
722 times who demonstrates current status of successful completion of ACLS and
723 the skills to perform a complete resuscitation.
724

725 (18) Ensure that resuscitation equipment for pregnant and postpartum
726 women is readily available in the labor and delivery, antepartum and
727 postpartum areas.
728

729 (19) The facility shall have written guidelines or protocols for various
730 conditions that place the pregnant or postpartum woman at risk for
731 morbidity and/or mortality, including promoting prevention, early
732 identification, early diagnosis, therapy, stabilization, and transfer. The
733 guidelines or protocols must address a minimum of:
734

735 (A) Massive hemorrhage and transfusion of the pregnant or
736 postpartum patient in coordination of the blood bank, including
737 management of unanticipated hemorrhage and/or coagulopathy;
738

739 (B) Obstetrical hemorrhage including promoting the identification
740 of patients at risk, early diagnosis, and therapy to reduce morbidity
741 and mortality;
742

743 (C) Hypertensive disorders in pregnancy including eclampsia and
744 the postpartum patient to promote early diagnosis and treatment to
745 reduce morbidity and mortality;

746
747 (C) Sepsis and/or systemic infection in the pregnant or
748 postpartum woman;

749
750 (E) Venous thromboembolism in pregnant and postpartum
751 women, and to assessment of risk factors, prevention, early diagnosis
752 and treatment;

753
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755
756 (20) The facility shall have nursing key leadership and staff with
757 formal training and experience in the provision of perinatal nursing
758 care and should coordinate with respective neonatal services.

759
760 (21) Perinatal Education. A registered nurse with experience in
761 maternal care including moderately complex and ill obstetric
762 patients shall provide the supervision and coordination of staff
763 education. Perinatal education for high risk events will be provided
764 at regular intervals to prepare medical, nursing, and ancillary staff
765 for these emergencies.

766
767 (22) Support personnel with knowledge and skills in lactation and
768 breastfeeding to meet the needs of mothers.

769
770 (23) Social services, pastoral care and bereavement services shall
771 be provided as appropriate to meet the needs of the patient
772 population served.

773
774 (24) Nutritionist or dietician available and appropriate for the
775 patient population served in compliance with the requirements in
776 §133.41(d) of this title.

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778
779 **§133.188 Maternal Designation Level III**

780 (a) A Level III (Subspecialty Care). The Level III maternal designated
781 facility will:

- 782 (A) provide care for pregnant and postpartum women with low
783 risk conditions to significant complex medical, surgical and/or
784 obstetrical conditions that present a high risk of maternal
785 morbidity or mortality;
- 786 (B) Ensure access to consultation to a full range of medical
787 and maternal subspecialists and surgical specialists, and the capability
788 to perform major surgery on-site.
- 789 (G) have physicians with critical care training onsite to
790 actively collaborate with Maternal Fetal Medicine and
791 Obstetrical physicians at all times;
- 792
793 (H) have skilled personnel with documented training,
794 competencies and continuing education annually, specific
795 for the population served;
- 796
797 (I) facilitate transports; and
- 798
799 (J) provide outreach education to lower level designated
800 facilities including the Quality Assessment and
801 Performance Improvement (QAPI) process.
- 802
- 803 (b) Maternal Medical Director (MMD). The MMD shall be a physician who:
- 804 (1) is a board certified obstetrician or maternal fetal medicine
805 physician;
- 806
807 (2) demonstrates effective administrative skills and oversight of the
808 Quality Assessment and Performance Improvement (QAPI) Program;
- 809 (3) has completed continuing medical education annually specific to
810 maternal care including complicated conditions;
- 811 (4) has regular and active participation in maternal care at the facility
812 where medical director services are provided; and
- 813 (5) maintains active staff privileges as defined in the facility's medical
814 staff bylaws.
- 815
- 816 (c) If the facility has its own transport program, there shall be an identified
817 Transport Medical Director (TMD). The TMD shall be a physician who is a

818 board eligible/certified maternal fetal medicine specialist or board
819 eligible/board certified obstetrician with expertise and experience in
820 maternal transport.

821 (d) Program Function and Services.

822 (1) Triage and assessment of all patients admitted to the perinatal
823 service with:

824 (A) identification of pregnant women who are at high risk of
825 delivering a neonate that requires a higher level of maternal care shall
826 be transferred to a higher level maternal designated facility prior to
827 delivery unless the transfer is unsafe;

828 (B) identification of pregnant or postpartum women with
829 conditions and/or complications that will require a higher level of
830 maternal care will be transferred to a higher level maternal designated
831 facility unless the transfer will be unsafe;

832 (C) have the capability to detect, stabilize, and initiate
833 management of unanticipated maternal-fetal or maternal problems
834 that occur during the antepartum, intrapartum, or postpartum period
835 until the patient can be transferred to a higher level of maternal
836 and/or maternal care;

837 (D) Supportive and emergency care delivered by appropriately
838 trained personnel for unanticipated maternal-fetal problems that occur
839 until the patient is stabilized or transferred;

840 (E) The ability to begin an emergency cesarean delivery within
841 30 minutes.

842 (F) Ensure that a qualified physician, or a certified nurse midwife
843 with appropriate physician back-up, is available to attend all deliveries or
844 other obstetrical emergencies.

845
846 (2) The primary provider caring for a pregnant or postpartum woman
847 who is a family medicine physician, obstetrician, maternal fetal medicine
848 physician, or a certified nurse midwife with appropriate physician back-up,
849 whose credentials have been reviewed by the MMD and is on call:

850
851 (A) shall arrive at the patient's bedside within 30 minutes for an
852 urgent request;

853
854 (B) if the physician is not immediately available to respond or is
855 covering more than one facility, the facility must ensure that
856 appropriate backup coverage is available, documented in an on call
857 schedule and readily available to facility staff;

858

859 (C) ensure that the physician providing backup coverage shall
860 arrive at patient's bedside within 30 minutes for an urgent consult;

861
862 (A) has completed continuing education annually, specific to
863 the care of the pregnant and postpartum women.

864
865 (3) Certified nurse midwives who attend patients:

866 (A) Shall operate under guidelines reviewed and approved by the
867 MMD; and

868
869 (B) Shall have a formal arrangement with a physician who will;

870
871 (i) provide back-up, consultation, and arrive at the patient's
872 bedside within 30 minutes of an urgent request; and

873
874 (ii) have credentials reviewed by the MMD.

875
876 (4) A board eligible/board certified obstetrician shall be on-site and
877 readily available at all times for urgent situations.

878
879 (5) An on-call schedule of providers, back-up providers, and provision
880 for patients without a physician should be posted on the labor and delivery
881 unit.

882
883 (6) Anesthesia Services shall be in compliance with the requirements
884 found at 133.41(a) of this title and shall have:

885
886 (A) Anesthesia personnel with obstetrical experience and
887 expertise shall be available onsite at all times;

888
889 (B) A board certified anesthesiologist with training or
890 experience in obstetric anesthesia is in charge of obstetric
891 anesthesia services;

892
893 (C) A board certified anesthesiologist with training or
894 experience in obstetric anesthesia including critically ill
895 obstetric patients will be available for consultation at all
896 times, and arrive onsite for urgent requests within 30
897 minutes; and

898
899 (D) Anesthesia personnel including back-up contact information
900 will be posted and readily available to the obstetrics staff including the
901 labor and delivery area.

902

903 (7) Laboratory Services shall be in compliance with the requirements
904 found at 133.41(h) of this title and shall have:

905 (A) Laboratory personnel onsite at all times; and

906 (B) A blood bank capable of:

907 (i) providing ABO-Rh specific or O-Rh negative blood, fresh
908 frozen plasma and cryoprecipitate, and platelet products
909 onsite at the facility at all times;

910 (ii) implementing a massive transfusion protocol;

911 (iii) ensuring guidelines for emergency release of blood
912 products, and the management of multiple component therapy;
913 and

914 (iv) perinatal pathology services are available.
915

916 (8) Medical Imaging Services shall be in compliance with the
917 requirements found at 133.41(h) of this title and shall have:

918 (D) personnel appropriately trained in the use of x-ray
919 equipment shall be available on-site at all times;

920 (E) advanced imaging including computed tomography,
921 magnetic resonance imaging, and echocardiography will be
922 available at all times including interpretation within 1 hour
923 on urgent requests;

924 (F) Basic ultrasonographic imaging for maternal or fetal
925 assessment including interpretation will be available at all
926 times; and

927 (D) A portable ultrasound machine will be available in the labor
928 and delivery and antepartum unit.
929

930 (9) Respiratory Therapy Services shall be in compliance with the
931 requirements found at 133.41(h) of this title and have a respiratory
932 therapist immediately available on-site at all times.
933

934 (10) Obstetrical Services.

935 (A) Ensure the availability and interpretation of non-stress
936 testing, and electronic fetal monitoring; and
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(B) A trial of labor for patients with prior cesarean delivery must have the immediate availability of anesthesia, cesarean delivery, and maternal resuscitation capability during the trial of labor.

(11) Pharmacy services shall be in compliance with the requirements found in 133.41 (q) of this title and will have a pharmacist with experience in perinatal pharmacology onsite and available at all times.

(12) Resuscitation. Written policies and procedures shall be specific to the facility for the stabilization and resuscitation of pregnant or postpartum women based on current standards of professional practice.

(13) At least one person must be immediately available on site at all times who demonstrates current status of successful completion of ACLS and the skills to perform a complete resuscitation.

(14) ensure that resuscitation equipment for pregnant and postpartum women is readily available in the labor and delivery, antepartum and postpartum areas.

(15) The facility shall have written guidelines or protocols for various conditions that place the pregnant or postpartum woman at risk for morbidity and/or mortality, including promoting prevention, early identification, early diagnosis, therapy, stabilization, and transfer. The guidelines or protocols must address a minimum of:

(A) Massive hemorrhage and transfusion of the pregnant or postpartum patient in coordination of the blood bank, including management of unanticipated hemorrhage and/or coagulopathy;

(B) Obstetrical hemorrhage including promoting the identification of patients at risk, early diagnosis, and therapy to reduce morbidity and mortality;

(C) Hypertensive disorders in pregnancy including eclampsia and the postpartum patient to promote early diagnosis and treatment to reduce morbidity and mortality;

(G) Sepsis and/or systemic infection in the pregnant or postpartum woman;

989 (E) Venous thromboembolism in pregnant and postpartum
990 women, and to assessment of risk factors, prevention, early diagnosis
991 and treatment;

992
993 (16) Management of critically ill pregnant or postpartum women,
994 including fetal monitoring in the ICU, respiratory failure and ventilator
995 support, procedure for emergency cesarean, coordination of nursing
996 care, and consultative or co-management roles to facilitate
997 collaboration; and

998
999 (17) The facility shall have key nursing leadership and staff with
1000 formal training and experience in the provision of perinatal nursing
1001 care and should coordinate with respective neonatal services.

1002
1003 (18) Shall have a program for genetic diagnosis and counseling for
1004 genetic disorders, or a policy and process for consultation referral to an
1005 appropriate facility.

1006
1007 (19) Perinatal Education. A registered nurse with experience in
1008 maternal care including moderately complex and ill obstetric patients shall
1009 provide the supervision and coordination of staff education. Perinatal
1010 education for high risk events will be provided at regular intervals to prepare
1011 medical, nursing, and ancillary staff for these emergencies.

1012
1013 (20) Support personnel with knowledge and skills in breastfeeding to
1014 meet the needs of mothers shall be available at all times.

1015
1016 (21) A certified lactation consultant shall be available at all times

1017
1018 (22) Social services, pastoral care and bereavement services shall be
1019 provided as appropriate to meet the needs of the patient population served.

1020
1021 (23) A dietician or nutritionist who has special training or experience in
1022 perinatal nutrition and can plan diets that meet the special needs of the
1023 pregnant woman in compliance with the requirements in 133.41(d) of this
1024 title.

1025
1026 **§133.189 Maternal Designation Level IV**

1027 (a) A Level IV (Comprehensive Care). The Level IV maternal designated
1028 facility will:

1029 (1) provide perinatal women with comprehensive care for low risk
1030 conditions to the most complex medical, surgical and/or obstetrical
1031 conditions and their fetuses, that present a high risk of maternal morbidity
1032 or mortality;

1033 (2) Ensure access to on site consultation to a full range of medical and
1034 maternal subspecialists and surgical specialists, and the capability to
1035 perform major surgery on-site.

1036 (3) have skilled personnel with documented training, competencies
1037 and continuing education annually, specific for the patient population
1038 served;

1039 (4) facilitate transports; and

1040 (5) provide outreach education to lower level designated facilities
1041 including the Quality Assessment and Performance Improvement (QAPI)
1042 process.

1043 (b) Maternal Medical Director (MMD). The MMD shall be a physician who:

1044 (1) is board certified in obstetrics and gynecology with expertise in the
1045 area of critical care obstetrics; or board certified in maternal fetal medicine;

1046 (2) demonstrates effective administrative skills and oversight of the
1047 Quality Assessment and Performance Improvement (QAPI) Program;

1048 (3) has completed continuing medical education annually specific to
1049 maternal care including complicated conditions;

1050 (4) has regular and active participation in maternal care at the facility
1051 where medical director services are provided; and

1052 (5) maintains active staff privileges as defined in the facility's medical
1053 staff bylaws.

1054 (c) If the facility has its own transport program, there shall be an
1055 identified Transport Medical Director (TMD). The TMD shall be a physician
1056 who is a board certified maternal fetal medicine physician or board certified
1057 obstetrician, with expertise and experience in critically ill maternal transport.

1058 (d) Program Function and Services.

1059 (1) Triage and assessment of all patients admitted to the perinatal
1060 service with:

1061 (A) identification of pregnant women who are at high risk of
1062 delivering a neonate that requires a higher level of maternal care shall
1063 be transferred to a higher level maternal designated facility prior to
1064 delivery unless the transfer is unsafe;

1065 (B) identification of pregnant or postpartum women with
1066 conditions and/or complications that will require a service not available
1067 at the facility, will be transferred to an appropriate maternal
1068 designated facility unless the transfer will be unsafe.

1069 (2) Supportive and emergency care shall be delivered by appropriately
1070 trained personnel, for unanticipated maternal-fetal problems that occur
1071 during labor and delivery, through the disposition of the patient.

1072 (3) Ensure that a qualified physician, or a certified nurse midwife with
1073 appropriate physician back-up, is available to attend all deliveries or other
1074 obstetrical emergencies.

1075 (4) The ability to perform an emergency cesarean within 30 minutes.

1076 (5) The primary provider caring for a pregnant or postpartum woman
1077 who is a family medicine physician, obstetrician, or maternal fetal medicine
1078 physician, or a certified nurse midwife with appropriate physician back-up,
1079 whose credentials have been reviewed by the MMD and:

1080 (A) shall arrive at the patient's bedside within 30 minutes for
1081 an urgent request;

1082 (B) if the physician is not immediately available to respond or
1083 is covering more than one facility, the facility must ensure
1084 that appropriate backup coverage is available, documented
1085 in an on call schedule and readily available to facility staff;

1086 (C) ensure that the physician providing backup coverage shall
1087 arrive at the patient bedside within 30 minutes for an
1088 urgent request; and

1089 (D) has completed continuing education annually, specific to the
1090 care of the pregnant and postpartum woman, including complicated
1091 and critical conditions.

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- 1097 (6) Certified nurse midwives who provide care for patients:
1098
1099 (A) Shall operate under guidelines reviewed and approved by the
1100 MMD;
1101 (B) Shall have a formal arrangement with a physician who will;
1102 (i) provide back-up, consultation and arrive at the patient's
1103 bedside within 30 minutes of an urgent request.
1104 (iii) have credentials reviewed and approved by the MMD;
1105
1106 (7) A board certified/board eligible obstetrician shall be on-site at all
1107 times.
1108
1109 (8) An on-call schedule of providers, back-up providers, and provision
1110 for patients without a physician should be posted on the labor and delivery
1111 unit.
1112
1113 (9) Anesthesia Services shall be in compliance with the requirements
1114 found at 133.41(h) of this title and shall have:
1115
1116 (A) Anesthesia personnel with obstetrical experience and
1117 expertise shall be available onsite at all times;
1118
1119 (B) A board certified anesthesiologist with training or experience
1120 in obstetric anesthesia is in charge of obstetric anesthesia services;
1121
1122 (C) A board certified anesthesiologist with training or experience
1123 in obstetric anesthesia including critically ill obstetric patients will be
1124 available for consultation at all times, and arrive onsite for urgent
1125 requests within 30 minutes; and
1126
1127 (D) Anesthesia personnel including back-up contact information
1128 will be posted and readily available to the obstetrics staff including the
1129 labor and delivery area.
1130
1131
1132
1133 (10) Laboratory Services shall be in compliance with the requirements
1134 found at 133.41(h) of this title and shall have:
1135 (i) Laboratory personnel are onsite at all
1136 times;
1137 (ii) A blood bank capable of:
1138 a. providing ABO-Rh specific or O-Rh
1139 negative blood, fresh frozen plasma and

- 1140 cryoprecipitate, and platelet products
- 1141 onsite at the facility at all times,
- 1142 b. implementing a massive transfusion
- 1143 protocol;
- 1144 (iii) ensuring guidelines for emergency release
- 1145 of blood products, and the management of
- 1146 multiple component therapy; and
- 1147 (iv) Perinatal pathology services are available.
- 1148

1149 (11) Medical Imaging Services shall be in compliance with the
1150 requirements found at 133.41(h) of this title and shall have:

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- 1152
- 1153 a. personnel appropriately trained in the use of x-ray
- 1154 equipment shall be available on-site at all times.
- 1155 b. Advanced imaging including computed
- 1156 tomography (CT), magnetic resonance
- 1157 imaging(MRI), and echocardiography will be
- 1158 available at all times including interpretation
- 1159 within 1 hour on urgent requests.
- 1160 (B) A radiologist with critical interventional radiology
- 1161 skills must be available at all times
- 1162
- 1163
- 1164 a. Basic ultrasonographic imaging for maternal or
- 1165 fetal assessment including interpretation will be
- 1166 available at all times.
- 1167 b. A portable ultrasound machine will be available in
- 1168 the labor and delivery and antepartum unit.
- 1169

1170 (12) Respiratory Therapy Services shall be in compliance with the
1171 requirements found at 133.41(h) of this title and shall have a respiratory
1172 therapist immediately available on-site at all times.

1173
1174 (13) Obstetrical Services.

1175
1176 (A) Ensure the availability and interpretation of non-stress
1177 testing, and electronic fetal monitoring; and

1178
1179 (B) A trial of labor for patients with prior cesarean delivery must
1180 have the immediate availability of anesthesia, cesarean delivery, and
1181 maternal resuscitation capability during the trial of labor.

1182

1183 (13) Pharmacy services shall be in compliance with the requirements
1184 found in 133.41 (q) of this title and will have a pharmacist with experience
1185 in perinatal pharmacology onsite and available at all times.

1186
1187 (14) Intensive Care Services. The facility shall have on-site ICU
1188 care for obstetric patients with onsite medical and surgical care, in
1189 collaboration with the maternal fetal medicine care team.

1190 (15) Maternal Fetal Medicine Critical Care Team- The facility shall have
1191 a Maternal Fetal Medicine (MFM) critical care team with expertise to assume
1192 responsibility for pregnant women and women in the postpartum period who
1193 are in critical condition or have complex medical conditions.

1194 c. This includes co-management of ICU-admitted
1195 obstetric patients

1196 d. An MFM team member with full privileges is
1197 available at all times for on-site consultation and
1198 management

1199 e. The team must be led by a board-certified MFM
1200 with expertise in critical care obstetrics.

1201

1202 (16) Resuscitation. Written policies and procedures shall be specific to
1203 the facility for the stabilization and resuscitation of pregnant or postpartum
1204 women based on current standards of professional practice.

1205

1206 (17) At least one person must be immediately available on site at all
1207 times who demonstrates current status of successful completion of ACLS and
1208 the skills to perform a complete resuscitation.

1209

1210 (18) ensure that resuscitation equipment for pregnant or postpartum
1211 women is readily available in the labor and delivery, antepartum and
1212 postpartum areas.

1213

1214 (19) The facility shall have written guidelines or protocols for various
1215 conditions that place the pregnant or postpartum woman at risk for
1216 morbidity and/or mortality, including promoting prevention, early
1217 identification, early diagnosis, therapy, stabilization, and transfer. The
1218 guidelines or protocols must address a minimum of:

1219

1220 (A) Massive hemorrhage and transfusion of the pregnant or
1221 postpartum patient in coordination of the blood bank, including
1222 management of unanticipated hemorrhage and/or coagulopathy;

1223

1224 (B) Obstetrical hemorrhage including promoting the identification
1225 of patients at risk, early diagnosis, and therapy to reduce morbidity
1226 and mortality;

1227
1228 (C) Hypertensive disorders in pregnancy including eclampsia and
1229 the postpartum patient to promote early diagnosis and treatment to
1230 reduce morbidity and mortality;

1231
1232 (H) Sepsis and/or systemic infection in the pregnant or
1233 postpartum woman;

1234
1235 (E) Venous thromboembolism in pregnant and postpartum
1236 women, and to assessment of risk factors, prevention, early diagnosis
1237 and treatment;

1238
1239 (G) Management of critically ill pregnant or postpartum women,
1240 including fetal monitoring in the ICU, respiratory failure and ventilator
1241 support, procedure for emergency cesarean, coordination of nursing
1242 care, and consultative or co-management roles to facilitate
1243 collaboration.

1244
1245 (20) The facility shall have nursing leadership and staff with formal
1246 training and experience in the maternal critical care and will coordinate with
1247 respective neonatal services.

1248
1249 (21) Measures key outcomes and makes improvements on outcomes
1250 that are less than optimal.

1251
1252 (22) Shall have a program for genetic diagnosis and counseling for
1253 genetic disorders, or a policy and process for consultation referral to an
1254 appropriate facility.

1255
1256 (23) Perinatal Education. A registered nurse with experience in
1257 maternal care including moderately complex and ill obstetric patients shall
1258 provide the supervision and coordination of staff education. Perinatal
1259 education for high risk events will be provided at regular intervals to prepare
1260 medical, nursing, and ancillary staff for these emergencies.

1261
1262 (24) Support personnel with knowledge and skills in breastfeeding to
1263 meet the needs of mothers shall be available at all times.

1264
1265 (25) A certified lactation consultant shall be available at all times
1266

1267 (26) Social services, pastoral care and bereavement services shall be
1268 provided as appropriate to meet the needs of the patient population served.
1269

1270 (27) A dietician or nutritionist who has special training or experience in
1271 maternal nutrition and can plan diets that meet the special needs of the
1272 pregnant woman and critically ill patients in compliance with the
1273 requirements in 133.41(d) of this title.
1274

1275 **§133.190 Survey Team**

1276 (a)The survey team composition shall be as follows:

1277 (1) Level I facilities maternal program staff shall conduct a self-survey,
1278 documenting the findings on the approved office survey form. The office may
1279 periodically require validation of the survey findings, by an on-site review
1280 conducted by department staff.
1281

1282 (2) Level II facilities shall be surveyed by a team that is multi-
1283 disciplinary and includes at a minimum of one obstetrician and one maternal
1284 nurse, all approved in advance by the office and currently active in the
1285 management of maternal patients at a facility providing the same or a
1286 higher level of maternal care
1287

1288 (3) Level III facilities shall be surveyed by a team that is multi-
1289 disciplinary and includes at a minimum of one obstetrician or maternal fetal
1290 medicine physician and one maternal nurse, all approved in advance by the
1291 office and currently active in the management of maternal patients at a
1292 facility providing the same or a higher level of maternal care. An additional
1293 surveyor may be requested by the facility or at the discretion of the office.

1294 (4) Level IV facilities shall be surveyed by a team that is multi-
1295 disciplinary and includes at a minimum of one obstetrician, a maternal fetal
1296 medicine physician and one maternal nurse, all approved in advance by the
1297 office and currently active in the management of maternal patients at a
1298 facility providing the same level of maternal care.
1299

1300 (b) Office-credentialed surveyors must meet the following criteria:

1301
1302 (1) have at least three years of experience in the care of maternal
1303 patients;
1304

1305 (2) be currently employed/practicing in the coordination of care for
1306 maternal patients;
1307

1308 (3) have direct experience in the preparation for and successful completion
1309 of maternal facility verification/designation;

1310
1311 (4) have successfully completed an office-approved maternal facility site
1312 surveyor course and be successfully re-credentialed every four years; and

1313
1314 (5) have current credentials as follows:

1315
1316 (A) a registered nurse who has successfully completed an office approved
1317 site survey internship; or

1318
1319 (B) a physician who is board certified in the respective specialty, and has
1320 successfully completed an office approved site survey internship.

1321
1322 (c) All members of the survey team, except department staff, shall come
1323 from a Perinatal Care Region outside the facility's location and at least 100
1324 miles from the facility. There shall be no business or patient care relationship
1325 or any potential conflict of interest between the surveyor or the surveyor's
1326 place of employment and the facility being surveyed.

1327
1328 (d) The survey team shall evaluate the facility's compliance with the
1329 designation criteria by:

1330
1331 (1) reviewing medical records; staff rosters and schedules; documentation
1332 of QAPI Program activities including peer review; the program plan; policies
1333 and procedures; and other documents relevant to maternal care;

1334
1335 (2) reviewing equipment and the physical plant;

1336
1337 (3) conducting interviews with facility personnel; and

1338
1339 (4) evaluating appropriate use of telemedicine capabilities where
1340 applicable.

1341
1342 (e) All information and materials submitted by a facility to the office under
1343 Health and Safety Code, §241.183(d), are subject to confidentiality as
1344 articulated in Health and Safety Code, §241.184, Confidentiality; Privilege,
1345 and are not subject to disclosure under Government Code, Chapter 552, or
1346 discovery, subpoena, or other means of legal compulsion for release to any
1347 person.

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