Legend: (Proposed New Rules)

Regular Print = Proposed new language

Subchapter J

§133.181 Purpose

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

§133.182 Definitions

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

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

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

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

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

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

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

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

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

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

(7) EMS--Emergency medical services used to respond to an individual's perceived need for immediate medical care.

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

(9) Gestational age--The age of a fetus or embryo at a specific point during a woman's pregnancy.

(10) High-risk Infant--A newborn that has a greater chance of complications because of conditions that occur during fetal development, pregnancy conditions of the mother, or problems that may occur during labor and/or birth.

(11) Immediate supervision--The supervisor is actually observing the task or activity as it is performed.

(12) Immediately--Without delay.

(13) Infant--A child from birth to 1 year of age.

(14) Intrapartum -

(14) Lactation consultant--A health care professional who specializes in the clinical management of breastfeeding.

(15) Maternal--Pertaining to the mother.

(16) NCPAP--Nasal continuous positive airway pressure.

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

(18) NMD--Neonatal Medical Director.

(19) NPM--Neonatal Program Manager.

(20) Neonatal Resuscitation Program (NRP)--A resuscitation course that was developed and is administered jointly by the American Heart Association/American Academy of Pediatrics.

(21) MFM – Maternal Fetal Medicine

(22) MMD – Maternal Medical Director

(23) MPM – Maternal Program Manager

(24) Obstetrical -

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

(22) PCR--Perinatal Care Region.

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

(24) POC--Plan of Correction. A report submitted to the office by the facility detailing how the facility will correct any deficiencies cited in the survey report or documented in the self-attestation.

(25) Premature/prematurity--Birth at less than 37 weeks of gestation.

(26) Postpartum--The six-week period following delivery.

(27) QAPI Program--Quality Assessment and Performance Improvement Program.

(28) RAC--Regional Advisory Council as described in §157.123 of this title (relating to Regional Emergency Medical Services/Trauma Systems).

(29) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(30) TSA--Trauma Service Area as described in §157.122 of this title relating to (Trauma Service Areas).

(31) Urgent--Requiring immediate action or attention.

§133.183 General Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(E) facilitate transports; and

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

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

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

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

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

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

(D) facilitate transports; and

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

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

(e) PCR's

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

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

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

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

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

§133.184 Designation Process.

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

(1) an accurate and complete designation application form for the appropriate level of designation, including full payment of the designation fee as listed in subsection (d) of this section;
(2) any subsequent documents submitted by the date requested by the office;
(3) a completed maternal attestation and self-survey report for Level I applicants or a designation survey report, including patient care reviews if required by the office, for Level II, III and IV applicants;
(4) a plan of correction (POC), detailing how the facility will correct any deficiencies cited in the survey report, to include: the corrective action; the title of the person responsible for ensuring the correction(s) is implemented; how the corrective action will be monitored; and the date by which the POC will be completed; and
(5) evidence of participation in the applicable Perinatal Care Region (PCR).
(b) Renewal of designation. The applicant shall submit the documents described in subsection (a)(1) - (5) of this section to the office not more than 180 days prior to the designation expiration date and at least 60 days prior to the designation expiration date.
(c) If a facility seeking designation fails to meet the requirements in subsection (a)(1) - (5) of this section, the application shall be denied.
(d) Non-refundable application fees for the three year designation period are as follows:
(1) Level I maternal facility applicants, the fees are as follows:
(A) <=100 licensed beds, the fee is $250.00; or
(B) >100 licensed beds, the fee is $750.00.
(2) Level II maternal facility applicants, the fee is $1,500.00.
(3) Level III maternal facility applicants, the fee is $2,000.00.
(4) Level IV maternal facility applicants, the fee is $2,500.00.
(A) All completed applications, received on or before July 1, 2020, including the application fee, evidence of participation in the PCR, an appropriate attestation if required, survey report, and that meet the requirements of the requested designation level, will be issued a designation for the full three-year term.
(B) Any facility that has not completed an on-site survey to verify compliance with the requirements for a Level II, III or IV designation at the time of application must provide a self-survey and attestation and will receive a Level I designation. The office, at its sole discretion may recommend a designation for less than the full three-year term. A designation for less than the full three-year term will have a pro-rated application fee consistent with the one, two or three-year term length.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) be voluntary;

(ii) be appointed by the office director;

(iii) be representative of maternal care providers and appropriate levels of designated maternal facilities; and

(iv) include representation from the office and the Perinatal Advisory Council.

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

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

§133.185 Program Requirements.

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

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

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

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

(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;

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

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

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

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

(1) The MMD and/or TMD shall have the authority and responsibility to monitor maternal patient care from admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Program.

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

(3)

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

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

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

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

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

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

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

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

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

(1) be a registered nurse;

(2) have the authority and responsibility to monitor the provision of maternal patient care services from admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Program as defined in subsection (b)(2)(E) of this section;

(3) collaborate with the MMD in areas to include, but not limited to: developing and/or revising policies, procedures and guidelines; assuring staff competency, education, and training; the QAPI Program; and regularly participates in the maternal QAPI meeting; and

(4) develops collaborative relationships with other MPM(s) of designated facilities within the applicable Perinatal Care Region.

§133.186 Maternal Designation Level I.

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

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

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

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

(1) a family medicine physician or an obstetrician;

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

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

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

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

(c) Program Function and Services

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

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

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

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

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

(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.

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

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

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

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

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

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

(10) Obstetrical Services.

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

(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) 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.

(12) 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.

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

(14) 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;

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

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

(F) Shoulder dystocia- assessment of risk factors, counseling of patient, multi-disciplinary management

(15) Perinatal Education. A registered nurse with experience in maternal care shall provide the supervision and coordination of staff education. Perinatal education for high risk events will be provided at regular intervals to prepare medical, nursing, and ancillary staff for these emergencies.

(16) Support personnel with knowledge and skills in breastfeeding and lactation to meet the needs of mothers shall be available at all times.

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

(18) Nutritionist or dietician available and appropriate for population served in compliance with the requirements in §133.41(d) of this title.

§133.187 Maternal Designation Level II

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

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

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

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

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

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

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

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

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

(c) Program Function and Services

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

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

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

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

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

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

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

(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.

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

(7) The family medicine physician, obstetrician, maternal fetal medicine physician, or a certified nurse midwife with appropriate physician back-up, 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, shall have appropriate backup coverage 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.

(8) 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 is responsible for:

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.

(D) Ultrasound availability.

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

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

(15) Obstetrical Services.

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

(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.

(16) 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.

(17) 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.

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

(19) 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;

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

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

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

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

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

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

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

§133.188 Maternal Designation Level III

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

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

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

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

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

(I) facilitate transports; and

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

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

(1) is a board certified obstetrician or maternal fetal medicine physician;

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

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

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

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

(c) If the facility has its own transport program, there shall be an identified Transport Medical Director (TMD). The TMD shall be a physician who is a

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

(d)Program Function and Services.

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

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

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

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

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

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

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

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

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

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

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

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

(3)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;

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

(ii) have credentials reviewed by the MMD.

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

(5) 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.

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

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

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

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

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

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

(A)Laboratory personnel onsite at all times; and

(B) A blood bank capable of:

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

(ii) implementing a massive transfusion protocol;

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

(iv) perinatal pathology services are available.

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

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

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

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

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

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

(10) Obstetrical Services.

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

(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;

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

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

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

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

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

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

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

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

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

§133.189 Maternal Designation Level IV

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

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

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

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

(4) facilitate transports; and

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

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

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

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

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

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

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

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

(d)Program Function and Services.

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

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

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

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

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

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

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

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

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

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

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

(6) Certified nurse midwives who provide care for patients:

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

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

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

(iii) have credentials reviewed and approved by the MMD;

(7) A board certified/board eligible obstetrician shall be on-site at all times.

(8) 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.

(9) Anesthesia Services shall be in compliance with the requirements found at 133.41(h) of this title and shall have:

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

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

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

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

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

(i) Laboratory personnel are onsite at all times;

(ii) A blood bank capable of:

a. providing ABO-Rh specific or O-Rh negative blood, fresh frozen plasma and

cryoprecipitate, and platelet products onsite at the facility at all times,

b. implementing a massive transfusion protocol;

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

(iv) Perinatal pathology services are available.

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

a. personnel appropriately trained in the use of x-ray equipment shall be available on-site at all times.

b. Advanced imaging including computed tomography (CT), magnetic resonance imaging(MRI), and echocardiography will be available at all times including interpretation within 1 hour on urgent requests.

(B) A radiologist with critical interventional radiology skills must be available at all times

a. Basic ultrasonographic imaging for maternal or fetal assessment including interpretation will be available at all times.

b. A portable ultrasound machine will be available in the labor and delivery and antepartum unit.

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

(13) Obstetrical Services.

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

(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.

(13) 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.

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

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

c. This includes co-management of ICU-admitted obstetric patients
d. An MFM team member with full privileges is available at all times for on-site consultation and management
e. The team must be led by a board-certified MFM with expertise in critical care obstetrics.

(16) 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.

(17) 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.

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

(19) 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;

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

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

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

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

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

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

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

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

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

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

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

§133.190 Survey Team

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

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

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

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

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

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

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

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

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

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

(5) have current credentials as follows:

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

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

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

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

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

(2) reviewing equipment and the physical plant;

(3) conducting interviews with facility personnel; and

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

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