133.XXX Purpose

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

133.XXX Definitions

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

(1) 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 1000 grams (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.

Etc....
§133.XXX 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 maternity facility at the level for each location of a facility, which the office deems appropriate.

(b) A healthcare facility is defined under these rules 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 Department of State Health Services (department) 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; compliance with Chapter 133 of this title, concerning Hospital Licensing. A stand-alone childrens’ facility that does not provide obstetrical services is exempt from obstetrical requirements. The final determination of the level of designation may not be the level requested by the facility.

(1) Level I (Basic Care Facility). The Level I maternity designated facility will:
   (A) provide care of pregnant and postpartum women who are relatively healthy, and do not have medical, surgical, or obstetrical conditions that pose a significant risk of maternal morbidity or mortality; and
   (B) have skilled personnel with documented training, competencies and continuing education specific for the population served.

(2) Level II (Specialty Care Facility). The Level II maternity designated facility will
   (A) provide care for pregnant and postpartum women who are uncomplicated or may have medical, surgical, or obstetrical conditions that may pose a mild to moderate risk of maternal morbidity or mortality. These patients may be directly admitted or transferred from another facility; and
   (B) have skilled personnel with documented training, competencies and continuing education specific for the population served.

Comment [ET1]: Level II not limited to only mild to mod risk.
Level III (Subspecialty Care Facility). The Level III maternity designated facility will:

(A) provide care for pregnant and postpartum women who have low risk conditions to those who have significant complex medical, surgical or obstetrical conditions that may pose high risk of maternal morbidity or mortality. These patients may be directly admitted or transferred from another facility;

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

(C) Facilitate transports; and

(D) provide outreach education to lower level designated facilities

Level IV (Comprehensive perinatal center). The Level IV maternity designated facility will:

(A) provide on-site medical and surgical care for the continuum of low risk up to the most complex maternal conditions and critically ill pregnant women and fetuses through the antepartum, intrapartum and postpartum care. These patients may be directly admitted or transferred from another facility;

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

(C) Facilitate transports; and

(D) provide outreach education to lower level designated facilities

Facilities seeking maternal facility designation levels II- IV 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.
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.XXX. Designation Process.

(a) Designation application submittal. The applicant shall submit the following documents to the Office of EMS/Trauma Systems Coordination (office):

(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 for Level I applicants, a designation survey report, including patient care reviews, if required by the office, completed not later than 120 days prior to the date of the application;

(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 $XXX.00; or
   (B) >100 licensed beds, the fee is $XXX.00.

(2) Level II maternal facility applicants, the fee is $XXXX.00.

(3) Level III maternal facility applicants, the fee is $XXXX.00.

(4) Level IV maternal facility applicants, the fee is $XXXX.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 as to why designation at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.

(1) The written appeal may include a signed letter(s) from the executive board of its PCR or individual healthcare facilities and/or EMS providers within the affected PCR with an explanation as to why designation at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.

(2) 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.

(3) 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 Assistant Commissioner of the Division for Regulatory Services (assistant commissioner).

(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 executive 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
(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.XXX Program Requirements

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

(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 and neonatal 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 and neonatal care, and ensures the health and safety of patients.

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

2. The 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 neonates and/or pregnant/postpartum women that include consultation and transport services;

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

   (E) 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 or other aspects of performance that the facility adopts or develops that reflect processes of care and is outcome based. Evidence shall support that aggregate patient data is continuously reviewed for trends and data is submitted to the department as requested;
(F) 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.

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

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

(K) the availability of personnel with knowledge and skills in breastfeeding.

(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, inclusive of the QAPI Program.

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

   (C) participating in ongoing staff education and training in the care of the maternal patient;
(D) oversight of the interfacility 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/infant 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) has at least 2 years clinical experience in maternity care:

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

(4) 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

(5) develop collaborative relationships with other MPM(s) of designated facilities within the applicable Perinatal Care Region.
Maternity Designation Level I.

(a) Level I (Basic Care).

(1) The level I facilities will be well suited for pregnant women who are relatively healthy, and do not have medical, surgical, or obstetrical conditions that pose a significant risk of maternal morbidity or mortality.

(2) The Level I maternity designation facility will:

(A) Provide care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility at which a higher level of neonatal and/or maternity care is available

(B) Have skilled personnel with documented training, competencies and annual continuing education specific for the patient population served

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

(1) Is a currently practicing family medicine physician with experience in the care of pregnant women, or a physician specializing in obstetrics and gynecology;

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

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

(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 maternity care will be transferred to a higher level maternal designated facility unless the transfer will be unsafe.
(2) Supportive and emergency care delivered by appropriately trained personnel for unanticipated maternal-fetal problems that occur until the patient is stabilized or transferred.

(3) Ensure the ability to begin an emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

(4) Ensure adequate surgical assistance for cesarean deliveries commensurate to the complexity of the surgery.

(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.

(A) The primary provider caring for a pregnant or postpartum woman who is a family medicine physician or physician specializing in obstetrics and gynecology or a certified nurse midwife with appropriate physician back-up whose credentials have been reviewed by the MMD and:

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

(ii) Shall arrive at the patient’s bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for more critical circumstances

(iii) 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; and

(iv) If the physician is providing backup coverage shall arrive at the patient bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for some circumstances

(B) Certified nurse midwives who attend patients

i. Shall operate under guidelines reviewed and approved by the MMD

ii. Shall have through formal arrangement, a physician providing back-up and consultation, whose credentials reviewed by the MMD and shall be able to arrive at the patient’s bedside within a timeframe defined in (5) (a) (iii-iv)

(C) 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.

Comment [ET1]: From Perinatal Guidelines, 7ed, p24
(D) During a vaginal or cesarean delivery, there will be separate provider
who demonstrates a current status of successful completion of NRP
whose primary responsibility is the management of the neonate and
initiating resuscitation.

(E) At least one person must be immediately available on-site with the
skills to perform a complete neonatal resuscitation including
endotracheal intubation, establishment of vascular access and
administration of medications.

(6) Availability of appropriate anesthesia, laboratory, radiology, ultrasonography
and blood bank on a 24 hour basis as described in § 133.41(a), (h), and (s) of this
title respectively, including guidelines for massive transfusion, emergency
release of blood products, and management of multiple component therapy.

(A) Anesthesia with obstetrical experience or expertise shall be provided to
pregnant and postpartum women, and must be able to arrive to the patient’s
bedside commensurate to the patient’s condition, and no later than within
30 minutes of an urgent request, and may be shorter for some more critical
circumstances.

(B) If preliminary reading of imaging studies pending formal interpretation is
performed, then:
(i) the preliminary findings must be documented in the medical record,
and
(ii) there must be regular monitoring of the preliminary versus final
reading in the QAPI Program.

(7) A pharmacist shall be available for consultation on a 24 hour basis.

(A) If medication compounding is done by a pharmacy technician for
pregnant or postpartum women, a pharmacist will provide immediate
supervision of the compounding process.

(B) If medication compounding is done for pregnant or postpartum
women, the pharmacist will develop checks and balances to ensure the
accuracy of the final product.

(8) Ensure the availability of non stress testing and electronic fetal monitoring

(9) Hospitals offering a trial of labor for patients with prior cesarean delivery must
have the immediate availability of anesthesia, cesarean delivery, and neonatal
resuscitation capability during the trial of labor.

(10) Resuscitation – The facility shall have appropriately trained staff, policies
and procedures for the stabilization and resuscitation of pregnant or postpartum
women based on current standards of professional practice, including

(A) ensuring the availability of personnel who can stabilize pregnant or
postpartum women until transfer is possible
(B) having at least one person on site at all times who can be immediately available to provide ACLS including intubation, cardioversion or defibrillation, and direct the administration of medications for cardiopulmonary arrest.

(C) Having current guideline or protocols specifically addressing the resuscitation of the pregnant woman, and ensure that resuscitation equipment for pregnant and postpartum women is readily available at the labor and delivery area, including:

(i) Equipment for cardioversion and defibrillation
(ii) Resuscitation equipment and medications
(iii) Intubation equipment including fiber optic scopes for awake intubation

(11) Consultants available – shall have consultation available appropriate to the scope of patients cared for, and at a minimum should include a board certified obstetrician/gynecologist available by telephonic communication 24 hours a day.

(12) 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, and including management of unanticipated hemorrhage and/or coagulopathy
(B) Obstetrical hemorrhage including promoting the identification of patients at risk, early diagnosis, and therapy including the immediate availability of medications and/or equipment 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
(D) 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

(13) The facility will ensure that drills for high risk events such as shoulder dystocia, emergency cesarean delivery, eclampsia, and maternal hemorrhage will occur at regular intervals to help medical, nursing, and ancillary staff prepare for these emergencies.

(14) The facility will ensure regular team training on an ongoing basis in the perinatal areas to promote staff communication and effectiveness in working together.
Shall have a QAPI process and policies aimed to reduce maternal morbidity and mortality.

Perinatal Education. A registered nurse with experience in maternity care shall provide the supervision and coordination of staff education.

Ensures the availability and support personnel with knowledge and skills in breastfeeding to meet the needs of new mothers.

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

Nutritionist or dietician appropriate for population served.
Maternity Designation Level II (Specialty Care)

(a) Level II (Specialty Care)

(1) The level II facilities will be well suited for pregnant women who may have medical, surgical, or obstetrical conditions that may pose a low to mild to moderate risk of maternal morbidity or mortality. These patients may be directly admitted or transferred from another facility.

(2) The Level II maternity designation facility will:

(A) Provide care of pregnant women with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility at which a higher level of neonatal and/or maternity care is available

(B) Provide skilled personnel with documented training, competencies and annual continuing education specific for the patient population served

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

(1) Is a board eligible/certified in obstetrics and gynecology or maternal fetal medicine with experience and special interest in the care and delivery of pregnant women;

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

(3) Is actively practicing and a member of the medical staff

(4) Has completed continuing medical education annually specific to maternity care including complicated conditions.

(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 maternity care will be transferred to a higher level maternal designated facility unless the transfer will be unsafe.
(2) Supportive and emergency care delivered by appropriately trained personnel for unanticipated maternal-fetal problems that occur until the patient is stabilized or transferred.

(3) Ensure the ability to begin emergency cesarean delivery including ensuring the availability of a physician with the training, skills, and privileges within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

(4) Ensure adequate surgical assistance for cesarean deliveries commensurate to the complexity of the surgery.

(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.

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

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

(ii) Shall arrive at the patient’s bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for more critical circumstances

(iii) 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; and the physician is providing backup coverage shall arrive at the patient bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for some circumstances

(B) Certified nurse midwives who attend patients

   i. Shall operate under guidelines reviewed and approved by the MMD

   ii. Shall have through formal arrangement, a physician providing back-up and consultation, whose credentials reviewed by the MMD and shall be able to arrive at the patient’s bedside within a timeframe defined in (5) (A) (ii-iii)

(C) An obstetrician/gynecologist shall be available at all times
(D) 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.

(E) During a vaginal or cesarean delivery, there will be separate provider who demonstrates a current status of successful completion of NRP whose primary responsibility is the management of the neonate and initiating resuscitation.

(F) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access and administration of medications.

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

(i) Ensure that the blood bank has the capability of to provide ABO-Rh specific or O-Rh negative blood, fresh frozen plasma and/or cryoprecipitate, and platelet products at the facility at all times.

(6) Anesthesia personnel

(A) with obstetrical experience or expertise shall be provided to pregnant and postpartum women including labor analgesia and surgical anesthesia, and available at all times.

(B) A board certified anesthesiologist with special training or experience in obstetric anesthesia is available at all times for consultation.

(7) CT imaging available including interpretation on a 24 hour basis, and ideally MR imaging.

(8) Ultrasound availability. The facility will ensure:

(A) Basic ultrasonographic imaging for maternal or fetal assessment including interpretation available on a 24 hour basis

(B) A portable ultrasound machine will be available in the labor and delivery and antepartum unit for urgent bedside examination.

(9) Special equipment shall be available to accommodate the care and services for obese women

(10) Ensure the availability and interpretation of non stress testing and electronic fetal monitoring.

(11) Hospitals offering a trial of labor for patients with prior cesarean delivery must have the immediate availability of anesthesia, cesarean delivery, and neonatal resuscitation capability during the trial of labor.

(12) A registered pharmacist shall be available for consultation on a 24 hour basis.
(A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist will provide immediate supervision of the compounding process.

(B) If medication compounding is done for neonates/infants, the pharmacist will develop checks and balances to ensure the accuracy of the final product.

(13) Resuscitation – The facility shall have appropriately trained staff, policies and procedures for the stabilization and resuscitation of pregnant or postpartum women based on current standards of professional practice, including:

(A) ensuring the availability of personnel who can stabilize pregnant or postpartum women until transfer is possible

(B) having at least one person on site at all times who can be immediately available to provide ACLS including intubation, cardioversion or defibrillation, and direct the administration of medications for cardiopulmonary arrest.

(C) Having current guideline or protocols specifically addressing the resuscitation of the pregnant woman, and ensure that resuscitation equipment for pregnant and postpartum women is readily available at the labor and delivery area, including:

(i) Equipment for cardioversion and defibrillation

(ii) Resuscitation equipment and medications

(iii) Intubation equipment including fiber optic scopes for awake intubation

(14) Consultants available including:

(A) a physician specializing in maternal fetal medicine shall be available by formal agreement or call schedule on site, by phone, or by telemedicine as needed.

(B) Medical and surgical consultants available onsite to stabilize obstetrical patients who have been admitted to the facility or transferred from other facilities

(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, and 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

(D) 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) The management of the morbidly obese pregnant and post partum patient, including special equipment.

(16) The facility shall have an adequate number of RN’s with competence in level II maternity care criteria and ability to stabilize and transfer high-risk women and newborns who exceed their designation criteria

(17) The facility shall have 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 QAPI process and policies aimed to reduce maternal morbidity and mortality including:
   (A) Measuring key outcomes and making improvements on outcomes that are less than optimal;
   (B) The facility will ensure that drills for high risk events such as shoulder dystocia, emergency cesarean delivery, eclampsia, clinical coagulopathy, respiratory failure, and maternal hemorrhage will occur at regular intervals to help medical, nursing, and ancillary staff prepare for these emergencies
   (C) ensure regular team training on an ongoing basis in the perinatal areas to promote staff communication and effectiveness in working together

(19) Perinatal Education. A registered nurse with experience in maternity care including moderately complex and ill obstetric patients shall provide the supervision and coordination of staff education.

(20) Ensures the availability and support personnel with knowledge and skills in breastfeeding to meet the needs of mothers.

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

(22) Nutritionist or dietician to offer consultation for the population served.
Maternity Designation Level III (Subspecialty Care)

(a) A Level III (Subspecialty Care)

(1) The level III facilities will be well suited for caring for the continuum of pregnant women who have low risk conditions to significantly complex medical, surgical, or obstetrical conditions that may pose high risk of maternal morbidity or mortality. These patients may be directly admitted or transferred from another facility.

(2) The Level III maternity designation facility will:

(A) Provide care of pregnant women with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility at which a higher level of neonatal and/or maternity care is available

(B) Provide skilled personnel with documented training, competencies and annual continuing education specific for the patient population served

(C) Facilitate transports; and

(D) Provide outreach education to lower level designated facilities including assisting with quality and safety program.

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

(1) Is board certified in obstetrics and gynecology with experience and training in obstetrics, or 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 maternity care including complicated conditions; and

(4) Practicing actively and is a member of the facility’s medical staff

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

(d) Director of Maternal Fetal Medicine Service is a board-certified maternal fetal medicine specialist who:

(1) Demonstrates effective administrative skills and oversight of the Quality Assessment and Performance Improvement (QAPI) Program;
(2) Has completed continuing medical education annually specific to maternity care including complicated conditions; and

(3) is actively practicing in the facility’s in-patient services and a member of the facility’s medical staff.

(e) 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 maternity care will be transferred to a higher level maternal designated facility unless the transfer will be unsafe.

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

(3) Ensure the ability to begin emergency cesarean delivery including ensuring the availability of a physician with the training, skills, and privileges within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

(4) Ensure adequate surgical assistance for cesarean deliveries commensurate to the complexity of the surgery.

(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.

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

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

(ii) Shall arrive at the patient’s bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for more critical circumstances.
(iii) 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; and the physician is providing backup coverage shall arrive at the patient bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for some circumstances.

(B) Certified nurse midwives who attend patients

i. Shall operate under guidelines reviewed and approved by the MMD

ii. Shall have through formal arrangement, a physician providing back-up and consultation, whose credentials reviewed by the MMD and shall be able to arrive at the patient’s bedside within a timeframe defined in (5) (A) (ii-iii)

(C) An obstetrician/gynecologist shall be available on site at all times

(D) 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.

(E) During a vaginal or cesarean delivery, there will be separate provider who demonstrates a current status of successful completion of NRP whose primary responsibility is the management of the neonate and initiating resuscitation.

(F) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access and administration of medications.

(G) Availability of appropriate anesthesia, laboratory, radiology, ultrasonography and blood bank on a 24 hour basis as described in S 133.41(a), (h), and (s) of this title respectively. The facility will ensure:

(i) that the blood bank has the capability to provide ABO-Rh specific or O-Rh negative blood, fresh frozen plasma and cryoprecipitate, and platelet products onsite at the facility at all times, and capability to implement a massive transfusion protocol, emergency release of blood products, and the management of multiple component therapy

(ii) Laboratory personnel are onsite at all times; and

(iii) Perinatal pathology services are available.

(6) Anesthesia personnel
Anesthesia personnel with obstetrical experience shall be provided to pregnant and postpartum women including labor analgesia and surgical anesthesia, and available onsite at all times

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

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

a. If a facility is 100 miles or more from the nearest level III or IV maternity designated facility, then the facility may utilize telemedicine for consultation, provided that the facility:
   i. Shall ensure that its anesthesia personnel are prepared to evaluate and manage complex and critically ill obstetric patients.
   ii. Shall describe in its program plan the appropriate patients commensurate with its anesthesia personnel
   iii. Quality Assurance in collaboration with a board certified anesthesiologist as in 6(C)

(D) Anesthesia personnel including back-up contact information will be posted and easily accessible in the obstetric care including the labor and delivery area

(7) Personnel appropriately trained in the use of x-ray equipment shall be available on-site at all times. Advanced imaging including CT imaging available and MR imaging, and echocardiography will be available 24/7 including interpretation, which will be available within 1 hour on urgent requests on a 24 hours basis

(8) Ultrasound Availability. The facility will ensure:
   (A) Basic ultrasonographic imaging for maternal or fetal assessment including interpretation available on a 24 hour basis.
   (B) A portable ultrasound machine will be available in the labor and delivery and antepartum unit for urgent bedside examination.

(9) A respiratory therapist with experience in pregnant or postpartum women will be immediately available on-site 24/7.

(10) Special equipment shall be available to accommodate the care and services for morbidly obese and super-obese women.

(11) Ensure the availability and interpretation of non stress testing and electronic fetal heart rate monitoring

(12) Hospitals offering a trial of labor for patients with prior cesarean delivery must have the immediate availability of anesthesia, personnel to initiate cesarean delivery, and neonatal resuscitation capability during the trial of labor.

(13) Registered Pharmacist availability shall include:
   (A) A registered pharmacist will be available onsite on 7 days a week, and on a 24 hour basis; and
(B) A registered pharmacist with experience in perinatal pharmacology shall be available for consultation on a 24 hour basis.

(C) If medication compounding is done by a pharmacy technician for obstetric patients, a pharmacist will provide immediate supervision of the compounding process.

(D) If medication compounding is done for obstetric patients, the pharmacist will develop checks and balances to ensure the accuracy of the final product.

(14) Resuscitation – The facility shall have appropriately trained staff, policies and procedures for the stabilization and resuscitation of pregnant or postpartum women based on current standards of professional practice, including

(A) ensuring the availability of personnel who can stabilize pregnant or postpartum women until transfer is possible

(B) having at least one person on site at all times who can be immediately available to provide ACLS including intubation, cardioversion or defibrillation, and direct the administration of medications for cardiopulmonary arrest.

(C) Having current guideline or protocols specifically addressing the resuscitation of the pregnant woman, and ensure that resuscitation equipment for pregnant and postpartum women is readily available at the labor and delivery, antepartum and postpartum areas, including

(i) Equipment for cardioversion and defibrillation

(ii) Resuscitation equipment and medications

(iii) Intubation equipment including fiber optic scopes for awake intubation

(D) Appropriate equipment and personnel available onsite to ventilate and monitor women in labor and delivery until they can be safely transported to the ICU

(15) Consultants available include:

(A) A physician specializing in maternal fetal medicine:

(i) Shall have in-patient privileges at the facility and shall be available on site, by phone, or by telemedicine as needed.

(ii) Shall be able to arrive onsite for an urgent request within 30 minutes

(B) A full complement of adult medical and surgical subspecialists as well as behavioral health consultants readily available for inpatient face to face onsite consultation

(16) Stabilize obstetrical patients who have been admitted to the facility or transferred from other facilities

(17) Shall have the availability of Medical and Surgical Intensive Care Units that are able to accept pregnant and postpartum women and have critical care providers onsite to actively collaborate with Maternal Fetal Medicine and Obstetrician specialists at all times

Comment [ETS]: National guidelines
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, and 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.

(D) 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) 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.

The facility shall have a continuous availability of adequate number of nursing leaders and RN's:

(A) with competence in level III maternity care criteria and ability to stabilize and transfer high-risk women and newborns who exceed their designation criteria; and

(B) with special training and experience in the management of women with complex maternal illnesses and obstetric complications.

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

Shall have a QAPI process and policies aimed to reduce maternal morbidity and mortality including:

(A) Measuring key outcomes and making improvements on outcomes that are less than optimal;

(B) The facility will ensure that multidisciplinary drills for high risk events such as shoulder dystocia, emergency cesarean delivery, eclampsia, clinical coagulopathy, respiratory failure, and maternal hemorrhage will occur at regular intervals to help medical, nursing, and ancillary staff prepare for these emergencies.

Comment [ET6]: The principle of active collaboration is in the National Guidelines.
(C) ensure regular team training on an ongoing basis in the perinatal areas to promote staff communication and effectiveness in working together.

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

(23) Perinatal Education. A registered nurse with experience in maternity care including complex and critically ill patients shall provide the supervision and coordination of staff education.

(24) Ensures the availability and support personnel with knowledge and skills in breastfeeding to meet the needs of mothers.

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

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

(27) A dietician or nutritionist who has special training or experience in perinatal and maternal 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.

Comment [ET7]: Same language as neo language.
Maternity Designation Level IV (Comprehensive Perinatal Center) –

(a) A Level IV (Comprehensive Perinatal Center)
   (1) The level IV facilities will be able to provide on-site medical and surgical care for the continuum of low risk to the most complex maternal conditions and critically ill pregnant women and fetuses through the antepartum, intrapartum and postpartum care. These patients may be directly admitted or transferred from another facility.

   (2) The Level IV maternity designation facility will:

   (A) Provide care of pregnant women with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period, and in the case of conditions that be cannot be handled in the facility, stabilize until patient can be transferred to a facility
   (B) Provide skilled personnel with documented training, competencies and annual continuing education specific for the patient population served
   (C) Facilitate transports; and
   (D) Provide outreach education to lower level designated facilities including assisting with quality and safety programs.

(b) Maternity Medical Director (MMD). The MMD shall be a physician who:
   (1) Is board certified in maternal fetal medicine, or a board certified obstetrician gynecologist with special expertise in the area of critical care obstetrics;
   (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 maternity care including complicated conditions; and
   (4) Is in active practice and a member of the facility’s medical staff

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

(d) Director of Maternal Fetal Medical Service is a board-certified maternal fetal medicine specialist who:
   (1) Demonstrates effective administrative skills and oversight of the Quality Assessment and Performance Improvement (QAPI) Program;
(2) Has completed continuing medical education annually specific to maternity care including complicated conditions; and
(3) Is actively practicing and a member of the facility’s medical staff

(e) 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 and/or complications that will likely require a service not available at the facility, and transfer to an appropriate maternal designated facility unless the transfer will be unsafe.

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

(3) Ensure the ability to begin emergency cesarean delivery including ensuring the availability of a physician with the training, skills, and privileges within a timeframe which best incorporates maternal and fetal risks and benefits with the provision of emergency care.

(4) Ensure adequate surgical assistance for cesarean deliveries commensurate to the complexity of the surgery.

(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.
   (A) The primary provider caring for a pregnant or postpartum woman who is a family medicine physician or physician specializing in obstetrics and gynecology or maternal fetal medicine, or a certified nurse midwife with appropriate physician back-up whose credentials have been reviewed by the MMD and:
      (i) Has completed continuing education annually, specific to the care of the pregnant and postpartum woman, including complicated conditions
      (ii) Shall arrive at the patient’s bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for more critical circumstances
      (iii) 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; and the physician is providing backup coverage shall arrive at the patient bedside within a timeframe commensurate to the patient’s condition; for an urgent request, the timeframe may not be greater than 30 minutes and may be shorter for some circumstances.

(B) Certified nurse midwives who attend patients
   i. Shall operate under guidelines reviewed and approved by the MMD
   ii. Shall have through formal arrangement, a physician providing back-up and consultation, whose credentials reviewed by the MMD and shall be able to arrive at the patient’s bedside within a timeframe defined in (5) (A) (ii-iii)

(C) An obstetrician/gynecologist shall be available on site at all times

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

(E) During each delivery, there will be separate provider who demonstrates current status of successful completion of the NRP whose primary responsibility is for the management of the neonate and initiating resuscitation.

(F) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access and administration of medications.

(G) Availability of appropriate anesthesia, laboratory, radiology, ultrasonography and blood bank on a 24 hour basis as described in §133.41(a), (h), and (s) of this title respectively. The facility will ensure:
   (i) that the blood bank has the capability to provide ABO-Rh specific or O-Rh negative blood, fresh frozen plasma and cryoprecipitate, and platelet products at the facility at all times;
   (ii) Laboratory personnel are onsite at all times; and
   (iii) Perinatal pathology services are available.

(6) Maternal Fetal Medicine Critical Care Team- The facility shall have a MFM critical care team with expertise to assume responsibility for pregnant women and women in the postpartum period who are critical condition or have complex medical conditions.
   (A) This includes co-management of ICU-admitted obstetric patients
   (B) An MFM team member with full privileges is available at all times for on-site consultation and management
   (C) The team must be led by a board-certified MFM with expertise in critical care obstetrics

Comment [ET1]: National guidelines
Comment [ET2]: Same terminology as neonatal rules
(7) Anesthesia personnel
(A) Anesthesia personnel with obstetrical experience shall be provided to pregnant and postpartum women including labor analgesia and surgical anesthesia, and available onsite at all times
(B) A board certified anesthesiologist with special training or experience in critical care obstetric anesthesia, who is actively practicing and a member of the medical staff, is in charge of obstetric anesthesia services
(C) A board certified anesthesiologist with experience in obstetric anesthesia including familiarity of managing critically ill obstetric patients will be available on-site at all times

(8) Personnel appropriately trained in the use of x-ray equipment shall be available on-site at all times. Advanced imaging including CT imaging available and MR imaging, and echocardiography will be available 24/7 including interpretation, which will be available within 1 hour on urgent requests on a 24 hours basis

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

(10) Ultrasound Availability. The facility will ensure:
(A) Basic ultrasonographic imaging for maternal or fetal assessment including interpretation available on a 24 hour basis.
(B) A portable ultrasound machine will be available in the labor and delivery and antepartum unit for urgent bedside examination.

(11) A respiratory therapist with experience or familiarity with the management of pregnant or postpartum women will be immediately available on-site 24/7.

(12) Special equipment shall be available to accommodate the care and services for morbidly obese and super-obese women

(13) Ensure the availability and interpretation of non stress testing and electronic fetal monitoring

(14) Hospitals offering a trial of labor for patients with prior cesarean delivery must have the immediate availability of anesthesia, cesarean delivery, and neonatal resuscitation capability during the trial of labor.

(15) Registered Pharmacist availability shall include:
(A) A registered pharmacist will be available onsite on 7 days a week, and on a 24 hour basis; and
(B) A registered pharmacist with experience in perinatal pharmacology shall be available for consultation on a 24 hour basis.
(C) If medication compounding is done by a pharmacy technician for obstetric patients, a pharmacist will provide immediate supervision of the compounding process.
(C) If medication compounding is done for obstetric patients, the pharmacist will develop checks and balances to ensure the accuracy of the final product.

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

Resuscitation – The facility shall have appropriately trained staff, policies and procedures for the stabilization and resuscitation of pregnant or postpartum women based on current standards of professional practice, including:

(A) ensuring the availability of personnel who can stabilize pregnant or postpartum women until transfer is possible;

(B) having at least one person on site at all times who can be immediately available to provide ACLS including intubation, cardioversion or defibrillation, and direct the administration of medications for cardiopulmonary arrest;

(C) Having current guidelines or protocols specifically addressing the resuscitation of pregnant women, and ensure that resuscitation equipment for pregnant and postpartum women is readily available at the labor and delivery, antepartum and postpartum areas, including:

(i) Equipment for cardioversion and defibrillation
(ii) Resuscitation equipment and medications
(iii) Intubation equipment including fiber optic scopes for awake intubation

(D) Appropriate equipment and personnel available onsite to ventilate and monitor women in labor and delivery until they can be safely transported to the ICU.

Consultants available include:

(A) A full complement of adult medical and surgical subspecialists readily available for inpatient face to face onsite consultation including behavioral health, who shall collaborate with the MFM critical care team

(19) Stabilize obstetrical patients who have been admitted to the facility or transferred from other facilities

(20) Shall have the availability of Medical and Surgical Intensive Care Units that are able to accept pregnant and postpartum women and have critical care providers onsite to actively collaborate with Maternal Fetal Medicine and Obstetrician specialists at all times

(21) 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, and 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.

(D) 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) The management of the morbidly and super-obese pregnant and postpartum patient.

(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.

(22) The facility shall have a continuous availability of adequate number of nursing leaders and RN’s:

(A) with competence in level IV maternity care criteria and ability to stabilize and transfer high-risk women and newborns; and

(B) with special training and experience in the management of women with critically ill and complex maternal illnesses and obstetric complications.

(23) The facility shall have nursing leadership and staff with formal training and experience in maternal critical care and should coordinate with respective neonatal services, including the continuous availability of an adequate number of RN’s who have experience in the care of women with highly complex medical illnesses and obstetric conditions.

(24) Shall have a QAPI process and policies aimed to reduce maternal morbidity and mortality including:

(A) Measuring key outcomes and making improvements on outcomes that are less than optimal;

(B) The facility will ensure that drills for high risk events such as shoulder dystocia, emergency cesarean delivery, eclampsia, clinical coagulopathy, respiratory failure, and maternal hemorrhage will occur at regular intervals to help medical, nursing, and ancillary staff prepare for these emergencies.

(C) Ensure regular team training on an ongoing basis in the perinatal areas to promote staff communication and effectiveness in working together.

(25) Shall have a program for genetic diagnosis and counseling for these disorders, or have a policy and process for consultation referral to a closely related facility.
(26) Perinatal Education. A registered nurse with experience in maternity care including complex and critically ill patients shall provide the supervision and coordination of staff education.

(27) Ensures the availability and support personnel with knowledge and skills in breastfeeding to meet the needs of mothers.

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

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

(30) A Nutrition/Dietician with special training or experience in maternal or postpartum nutrition and can plan diets that meet the special needs of critically ill patients.
§133.XXX. Survey Team.

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

(1) Level I facilities maternity 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 (i) one obstetrician or maternal fetal medicine specialist; and (ii) one obstetrical nurse, all active in the management of pregnant/postpartum patients at a facility providing the same or a higher level of maternity care.

(3) Level III facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum of (i) one maternal fetal medicine specialist or an obstetrician/gynecologist with special experience and/or expertise in complicated maternity patients; and (ii) one obstetrical nurse, all approved in advance by the office and currently active in the management of maternity patients at a facility providing the same or a higher level of maternity 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

(i) one maternal fetal medicine specialist,

(ii) one obstetrical nurse, and

(iii) one additional clinical personnel who may be an obstetrician special experience and/or expertise in complicated maternity patients, or an anesthesiologist with special experience and/or expertise in complicated obstetrical patients, or a critical care physician or critical care nurse,

all approved in advance by the office and currently active in the management of obstetrical patients at a facility providing the same level of maternity care.

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

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

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

(3) have direct experience in the preparation for and successful completion of maternity facility verification/designation;
(4) have successfully completed an office-approved maternity facility site surveyor course and be successfully re-credentialed every four years; and

(5) have current credentials as follows:
(A) a registered nurse who is currently actively caring for obstetrical patients;
(B) a physician who is board certified in the respective specialty; and
(C) have 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 Quality Assessment and Performance Improvement Program activities including peer review; the program plan; policies and procedures; and other documents relevant to maternity 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.