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 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

Comment [ET6]: From Perinatal Guidelines, 7ed, p24

Comment [ET7]: This is in national guidelines but doesn’t specify in-house vs consultation and to come in if requested, etc. Some community level II’s recommend keep as is (not board certified)
(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 delivery or cesarean, there will be separate provider immediately available to attend to the resuscitation of the newborn including intubation and administrative of medications if needed.

(F) 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 of 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

(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.