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 and delivery 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;

(3) Is actively practicing and a member of the hospital's medical staff; and

(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.

Comment [ET1]: Sections prior to Levels of Care include Purpose; Definitions; Program Requirements. Quality Programs, Program Scope, Formal transport plans and requirements will be in the Program Requirements

Comment [ET2]: Several physicians are worried that this definition will mean they have to transfer a lot of patients out of their practice – in reality, likely not a lot of patients but high risk (ie, severe uncontrolled hypertension, renal insuff, etc

We will provide more in the Definition Section

Comment [ET3]: Suggested at Mar PAC meeting

Comment [ET4]: Actively practicing in the hospital where MMD

(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 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 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)

Comment [ET5]: Dr. Saade's concern

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

Comment [WU7]: Hospitals vs individual guidelines; GUIDELINES approved by MMD; according to Texas state code…

(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.

(D) During a delivery , there will be separate provider who is current with NRP immediately available to attend to the resuscitation of the newborn including intubation and administrative of medications if needed.

(6) 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.

(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) Ensure that a portable ultrasound unit will be available in the labor and delivery and/or antepartum area for urgent situations.

(C) 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 and interpretation of non stress testing and electronic fetal monitoring based on the clinical circumstance

(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

Comment [ET8]: Discussed at Mar PAC meeting

Comment [ET9]: Suggestion due to no other imaging requirements for level I; Is this reasonable for level 1?

Comment [ET10]: As discussed in Mar PAC meeting

(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 (in labor and del and/or postpartum), 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 by formal agreement or call schedule appropriate to the scope of patients cared for, and at a minimum should include an 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 with the blood bank, and including turn-around time for essential testing and providing of blood components, and emergency release policy for blood components in the 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

(13) 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) ensure that drills for high risk events such as shoulder dystocia, emergency cesarean delivery, eclampsia, and maternal hemorrhage

Comment [ET11]: Suggested by PAC Mar 29

Comment [ET12]: Rural hospitals state that requiring a "Board certified ob/gyn" may be restrictive; advise leave as is

Comment [ET13]: This Patient Safety Bundle would likely have a substantial impact on maternal mortality and morbidity…

Comment [ET14]: Recommended by a blood bank director as essential even for level I Emphasis: must be OB specific, collaborative between medical, nursing, hospital blood bank, lab, and local blood bank

Comment [ET15]: Shoulder dystocia **deleted** as discussed at Mar PAC meeting

Comment [ET16]: Drills have been shown to improve outcomes; placed in QUALITY area per Mar PAC meeting

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

Comment [WU17]: High risk and low frequency events = important

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

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

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

OUTCOMES: births, maternal deaths, maternal significant morbidity/near-misses; transfers, c-section rate and low risk primary cesarean rate; elective del less 39 weeks, antenatal corticosteroids, unattended deliveries; birth injuries; admission to ICU

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