

1 Maternity Designation Level I.

2 (a) Level I (Basic Care).

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

6 (2) The Level I maternity designation facility will:

7
8 (A) Provide care of uncomplicated pregnancies with the ability to detect, stabilize,
9 and initiate management of unanticipated maternal–fetal or neonatal problems
10 that occur during the antepartum, intrapartum, or postpartum period until
11 patient can be transferred to a facility at which a higher level of neonatal and/or
12 maternity care is available

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

15
16 (b) Maternity Medical Director (MMD). The MMD shall be a physician who:

17
18 (1) Is a currently practicing family medicine physician with experience in the care of
19 and delivery of pregnant women, or a physician specializing in obstetrics and
20 gynecology;

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

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

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

26
27 (c) Program Function and Services

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

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

33 (B) identification of pregnant or postpartum women with conditions or
34 complications that will likely require a higher level of maternity care will be
35 transferred to a higher level maternal designated facility unless the transfer
36 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

- 37 (2) Supportive and emergency care delivered by appropriately trained personnel for
38 unanticipated maternal-fetal problems that occur until the patient is stabilized or
39 transferred.
- 40 (3) Ensure the ability to begin an emergency cesarean delivery including ensuring
41 the availability of a physician with the training, skills and privileges within a time
42 interval that best incorporates maternal and fetal risks and benefits with the
43 provision of emergency care.
- 44 (4) Ensure adequate surgical assistance for cesarean deliveries commensurate to
45 the complexity of the surgery.
- 46 (5) Ensure that a qualified physician or certified nurse midwife with appropriate
47 physician back-up is available to attend all deliveries or other obstetrical
48 emergencies.
 - 49 (A) The primary provider caring for a pregnant or postpartum woman
50 who is a family medicine physician or physician specializing in
51 obstetrics and gynecology or a certified nurse midwife with
52 appropriate physician back-up whose credentials have been reviewed
53 by the MMD and:
 - 54 (i) Has completed continuing education annually, specific to the care
55 of the pregnant and postpartum woman, including complicated
56 conditions
 - 57 (ii) Shall arrive at the patient’s bedside within a timeframe
58 commensurate to the patient’s condition; for an urgent request,
59 the timeframe may not be greater than 30 minutes and may be
60 shorter for more critical circumstances
 - 61 (iii) If not immediately available to respond or is covering more than
62 one facility, be provided appropriate backup coverage who shall
63 be available, documented in an on call schedule and readily
64 available to facility staff; and
 - 65 (iv) If the physician is providing backup coverage shall arrive at the
66 patient bedside within a timeframe commensurate to the
67 patient’s condition; for an urgent request, the timeframe may not
68 be greater than 30 minutes and may be shorter for some
69 circumstances
 - 70 (B) Certified nurse midwives who attend patients
 - 71 i. Shall operate under guidelines reviewed and approved
72 by the MMD
 - 73 ii. Shall have through formal arrangement, a physician
74 providing back-up and consultation, whose credentials
75 reviewed by the MMD and shall be able to arrive at the
76 patient’s bedside within a timeframe defined in (5) (a)
77 (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...

- 78 (C) An on-call schedule of providers, back-up providers, and provision for
79 patients without a physician should be posted on the labor and
80 delivery unit.
81 (D) During a delivery , there will be separate provider who is current with
82 NRP immediately available to attend to the resuscitation of the
83 newborn including intubation and administrative of medications if
84 needed.
85

Comment [ET8]: Discussed at Mar PAC meeting

- 86 (6) Availability of appropriate anesthesia, laboratory, radiology, ultrasonography
87 and blood bank on a 24 hour basis as described in S 133.41(a), (h), and (s) of this
88 title respectively.

89 (A) Anesthesia with obstetrical experience or expertise shall be provided to
90 pregnant and postpartum women, and must be able to arrive to the patient's
91 bedside commensurate to the patient's condition, and no later than within
92 30 minutes of an urgent request, and may be shorter for some more critical
93 circumstances.

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

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

96 (C) If preliminary reading of imaging studies pending formal interpretation is
97 performed, then:

- 98 (i) the preliminary findings must be documented in the medical record,
99 and
100 (ii) there must be regular monitoring of the preliminary versus final
101 reading in the QAPI Program.

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

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

106 (B) If medication compounding is done for pregnant or postpartum
107 women, the pharmacist will develop checks and balances to ensure the
108 accuracy of the final product.
109

- 110 (8) Ensure the availability and interpretation of non stress testing and electronic
111 fetal monitoring based on the clinical circumstance

Comment [ET10]: As discussed in Mar PAC meeting

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

- 115 (10) Resuscitation – The facility shall have appropriately trained staff, policies
116 and procedures for the stabilization and resuscitation of pregnant or postpartum
117 women based on current standards of professional practice, including
118 (A) ensuring the availability of personnel who can stabilize pregnant or
119 postpartum women until transfer is possible
120

- 121 (B) having at least one person on site at all times who can be immediately
122 available to provide ACLS including intubation, cardioversion or defibrillation,
123 and direct the administration of medications for cardiopulmonary arrest.
124 (C) Having current guideline or protocols specifically addressing the resuscitation
125 of the pregnant woman, and ensure that resuscitation equipment for
126 pregnant and postpartum women is readily available (in labor and del and/or
127 postpartum), including
128 (i) Equipment for cardioversion and defibrillation
129 (ii) Resuscitation equipment and medications
130 (iii) Intubation equipment including fiber optic scopes for awake
131 intubation

132 (11) Consultants available – shall have consultation available by formal
133 agreement or call schedule appropriate to the scope of patients cared for, and at
134 a minimum should include an obstetrician/gynecologist available by telephonic
135 communication 24 hours a day.

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

- 141 (A) Massive hemorrhage and transfusion of the pregnant or postpartum
142 patient in coordination with the blood bank, and including turn-
143 around time for essential testing and providing of blood components,
144 and emergency release policy for blood components in the
145 management of unanticipated hemorrhage and/or coagulopathy
146 (B) Obstetrical hemorrhage including promoting the identification of
147 patients at risk, early diagnosis, and therapy including the immediate
148 availability of medications and/or equipment to reduce morbidity and
149 mortality.
150 (C) Hypertensive disorders in pregnancy including eclampsia and the
151 postpartum patient to promote early diagnosis and treatment to
152 reduce morbidity and mortality
153 (D) Sepsis and/or systemic infection in the pregnant or postpartum
154 woman
155 (E) Venous thromboembolism in pregnant and postpartum women, and
156 to assessment of risk factors, prevention, early diagnosis and
157 treatment

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

- 160 (A) Measuring key outcomes and making improvements on outcomes
161 that are less than optimal;
162 (B) ensure that drills for high risk events such as shoulder dystocia,
163 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

164 will occur at regular intervals to help medical, nursing, and ancillary
165 staff prepare for these emergencies.
166 (C) ensure regular team training on an ongoing basis in the perinatal
167 areas to promote staff communication and effectiveness in working
168 together

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

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

173
174 (15) Ensures the availability and support personnel with knowledge and skills
175 in breastfeeding to meet the needs of mothers.

176
177 (16) Social services and pastoral care shall be provided as appropriate to meet
178 the needs of the patient population served, including bereavement services.
179

180
181
182
183 OUTCOMES: births, maternal deaths, maternal significant morbidity/near-misses;
184 transfers, c-section rate and low risk primary cesarean rate; elective del less 39 weeks,
185 antenatal corticosteroids, unattended deliveries; birth injuries; admission to ICU

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