

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:

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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

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

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

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

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

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25 (c) Program Function and Services

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

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

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

- 35 (2) Supportive and emergency care delivered by appropriately trained personnel for  
36 unanticipated maternal-fetal problems that occur until the patient is stabilized or  
37 transferred.
- 38 (3) Ensure the ability to begin an emergency cesarean delivery within a time interval  
39 that best incorporates maternal and fetal risks and benefits with the provision of  
40 emergency care.
- 41 (4) Ensure adequate surgical assistance for cesarean deliveries commensurate to  
42 the complexity of the surgery.
- 43 (5) Ensure that a qualified physician or certified nurse midwife with appropriate  
44 physician back-up is available to attend all deliveries or other obstetrical  
45 emergencies.
- 46 (A) The primary provider caring for a pregnant or postpartum woman  
47 who is a family medicine physician or physician specializing in  
48 obstetrics and gynecology or a certified nurse midwife with  
49 appropriate physician back-up whose credentials have been reviewed  
50 by the MMD and:
- 51 (i) Has completed continuing education annually, specific to the care  
52 of the pregnant and postpartum woman, including complicated  
53 conditions
- 54 (ii) Shall arrive at the patient's bedside within a timeframe  
55 commensurate to the patient's condition; for an urgent request,  
56 the timeframe may not be greater than 30 minutes and may be  
57 shorter for more critical circumstances
- 58 (iii) If not immediately available to respond or is covering more than  
59 one facility, be provided appropriate backup coverage who shall  
60 be available, documented in an on call schedule and readily  
61 available to facility staff; and
- 62 (iv) If the physician is providing backup coverage shall arrive at the  
63 patient bedside within a timeframe commensurate to the  
64 patient's condition; for an urgent request, the timeframe may not  
65 be greater than 30 minutes and may be shorter for some  
66 circumstances
- 67 (B) Certified nurse midwives who attend patients
- 68 i. Shall operate under guidelines reviewed and approved  
69 by the MMD
- 70 ii. Shall have through formal arrangement, a physician  
71 providing back-up and consultation, whose credentials  
72 reviewed by the MMD and shall be able to arrive at the  
73 patient's bedside within a timeframe defined in (5) (a)  
74 (iii-iv)
- 75 (C) An on-call schedule of providers, back-up providers, and provision for  
76 patients without a physician should be posted on the labor and  
77 delivery unit.

Comment [ET1]: From Perinatal Guidelines, 7ed, p24

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(D) 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.

Comment [ET2]: This can be the emergency room physician

- (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) 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

- 121 (i) Equipment for cardioversion and defibrillation  
122 (ii) Resuscitation equipment and medications  
123 (iii) Intubation equipment including fiber optic scopes for awake  
124 intubation  
125 (11) Consultants available – shall have consultation available appropriate to  
126 the scope of patients cared for, and at a minimum should include a board  
127 certified obstetrician/gynecologist available by telephonic communication 24  
128 hours a day.  
129 (12) The facility shall have written guidelines or protocols for various  
130 conditions that place the pregnant or postpartum woman at risk for morbidity  
131 and/or mortality, including promoting prevention, early identification, early  
132 diagnosis, therapy, stabilization, and transfer. The guidelines or protocols must  
133 address a minimum of:  
134 (A) Massive hemorrhage and transfusion of the pregnant or postpartum  
135 patient in coordination of the blood bank, and including management  
136 of unanticipated hemorrhage and/or coagulopathy  
137 (B) Obstetrical hemorrhage including promoting the identification of  
138 patients at risk, early diagnosis, and therapy including the immediate  
139 availability of medications and/or equipment to reduce morbidity and  
140 mortality.  
141 (C) Hypertensive disorders in pregnancy including eclampsia and the  
142 postpartum patient to promote early diagnosis and treatment to  
143 reduce morbidity and mortality  
144 (D) Sepsis and/or systemic infection in the pregnant or postpartum  
145 woman  
146 (E) Venous thromboembolism in pregnant and postpartum women, and  
147 to assessment of risk factors, prevention, early diagnosis and  
148 treatment  
149 (F) Shoulder dystocia- assessment of risk factors, counseling of patient,  
150 multi-disciplinary management  
151 (13) The facility will ensure that drills for high risk events such as shoulder  
152 dystocia, emergency cesarean delivery, eclampsia, and maternal hemorrhage  
153 will occur at regular intervals to help medical, nursing, and ancillary staff prepare  
154 for these emergencies.  
155 (14) The facility will ensure regular team training on an ongoing basis in the  
156 perinatal areas to promote staff communication and effectiveness in working  
157 together  
158 (15) Shall have a QAPI process and policies aimed to reduce maternal  
159 morbidity and mortality  
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161 (16) Perinatal Education. A registered nurse with experience in maternity  
162 care shall provide the supervision and coordination of staff education.  
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**Comment [ET3]:** This Patient Safety Bundle would likely have a substantial impact on maternal mortality and morbidity...

- 164 (17) Ensures the availability and support personnel with knowledge and skills  
165 in breastfeeding to meet the needs of new mothers.  
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- 167 (18) Social services and pastoral care shall be provided as appropriate to meet  
168 the needs of the patient population served, including bereavement services.  
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DRAFT

1 Maternity Designation Level II (Specialty Care)

2 (a) Level II (Specialty Care)

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

7 (2) The Level II maternity designation facility will:

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- 9 (A) Provide care of pregnant women with the ability to detect, stabilize, and  
10 initiate management of unanticipated maternal–fetal or neonatal problems  
11 that occur during the antepartum, intrapartum, or postpartum period until  
12 patient can be transferred to a facility at which a higher level of neonatal  
13 and/or maternity care is available
- 14 (B) Provide skilled personnel with documented training, competencies and  
15 annual continuing education specific for the patient population served

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

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- 18 (1) Is a board eligible/ certified in obstetrics and gynecology or maternal fetal  
19 medicine with experience and special interest in the care and delivery of  
20 pregnant women;
- 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 medical staff
- 24 (4) Has completed continuing medical education annually specific to maternity care  
25 including complicated conditions.

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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.
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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 [WU2]: Will need define

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

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

Comment [ET3]: From Perinatal Guidelines, 7ed, p24

Comment [ET4]: This is in national guidelines but doesn't specify in-house vs consultation and to come in if requested, etc

- 79 (D) An on-call schedule of providers, back-up providers, and provision for  
80 patients without a physician should be posted on the labor and  
81 delivery unit.  
82 (E) During a delivery or cesarean, there will be separate provider  
83 immediately available to attend to the resuscitation of the newborn  
84 including intubation and administrative of medications if needed.  
85 (F) Availability of appropriate anesthesia, laboratory, radiology,  
86 ultrasonography and blood bank on a 24 hour basis as described in S  
87 133.41(a), (h), and (s) of this title respectively.  
88 (i) Ensure that the blood bank has the capability of to  
89 provide ABO-Rh specific or O-Rh negative blood, fresh  
90 frozen plasma and/or cryoprecipitate, and platelet  
91 products at the facility at all times  
92 (6) Anesthesia personnel  
93 (A) with obstetrical experience or expertise shall be provided to  
94 pregnant and postpartum women including labor analgesia and  
95 surgical anesthesia, and available at all times  
96 (B) A board certified anesthesiologist with special training or experience  
97 in obstetric anesthesia is available at all times for consultation  
98 (7) CT imaging available including interpretation on a 24 hour basis, and ideally MR  
99 imaging  
100 (8) Ultrasound availability. The facility will ensure:  
101 (A) Basic ultrasonographic imaging for maternal or fetal assessment including  
102 interpretation available on a 24 hour basis  
103 (B) A portable ultrasound machine will be available in the labor and delivery  
104 and antepartum unit for urgent bedside examination.  
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106 (9) Special equipment shall be available to accommodate the care and services for  
107 obese women  
108 (10) Ensure the availability and interpretation of non stress testing and  
109 electronic fetal monitoring  
110 (11) Hospitals offering a trial of labor for patients with prior cesarean delivery  
111 must have the immediate availability of anesthesia, cesarean delivery, and  
112 neonatal resuscitation capability during the trial of labor.  
113 (12) A registered pharmacist shall be available for consultation on a 24 hour  
114 basis.  
115 (A) If medication compounding is done by a pharmacy technician for  
116 neonates/infants, a pharmacist will provide immediate supervision of the  
117 compounding process.  
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119 (B) If medication compounding is done for neonates/infants, the  
120 pharmacist will develop checks and balances to ensure the accuracy of  
121 the final product.

Comment [ET5]: This is in Perinatal Guidelines – should include?

Comment [ET6]: For urgent situations

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- (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

**Comment [ET7]:** By formal agreement or call schedule per MAR PAC meeting

**Comment [ET8]:** National Guidelines

- 166 (F) The management of the morbidly obese pregnant and post partum  
167 patient
- 168 (16) The facility shall have an adequate number of RN's with competence in  
169 level II maternity care criteria and ability to stabilize and transfer high-risk  
170 women and newborns who exceed their designation criteria
- 171 (17) The facility shall have nursing leadership and staff with formal training  
172 and experience in the provision of perinatal nursing care and should coordinate  
173 with respective neonatal services
- 174 (18) Shall have a QAPI process and policies aimed to reduce maternal  
175 morbidity and mortality including:
- 176 (A) Measuring key outcomes and making improvements on outcomes that  
177 are less than optimal;
- 178 (B) The facility will ensure that drills for high risk events such as shoulder  
179 dystocia, emergency cesarean delivery, eclampsia, clinical coagulopathy,  
180 respiratory failure, and maternal hemorrhage will occur at regular  
181 intervals to help medical, nursing, and ancillary staff prepare for these  
182 emergencies
- 183 (C) ensure regular team training on an ongoing basis in the perinatal areas to  
184 promote staff communication and effectiveness in working together
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- 186 (19) Perinatal Education. A registered nurse with experience in maternity  
187 care including moderately complex and ill obstetric patients shall provide the  
188 supervision and coordination of staff education.
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- 190 (20) Ensures the availability and support personnel with knowledge and skills  
191 in breastfeeding to meet the needs of mothers.
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- 193 (21) Social services and pastoral care shall be provided as appropriate to meet  
194 the needs of the patient population served, including bereavement services.

Comment [ET9]: This is in national guidelines

Comment [ET10]: Shoulder Dystocia deleted per Mar PAC meeting

Comment [WU11]: Should guidelines and OR table and bed for morbidly obese

Comment [WU12]: High risk and low frequency events, moved from separate categories

1 Maternity Designation Level III (Subspecialty Care)

2 (a) A Level III (Subspecialty Care)

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

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]: Will define

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8 (2) The Level III maternity designation facility will:

- 9  
10 (A) Provide care of pregnant women with the ability to detect, stabilize, and  
11 initiate management of unanticipated maternal–fetal or neonatal problems  
12 that occur during the antepartum, intrapartum, or postpartum period until  
13 patient can be transferred to a facility at which a higher level of neonatal  
14 and/or maternity care is available  
15 (B) Provide skilled personnel with documented training, competencies and  
16 annual continuing education specific for the patient population served  
17 (C) Facilitate transports; and  
18 (D) Provide outreach education to lower level designated facilities including  
19 assisting with quality and safety program.

Comment [ET3]: National Guidelines; education and outreach

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

- 22 (1) Is board certified in obstetrics and gynecology or maternal fetal medicine;  
23 (2) Demonstrates effective administrative skills and oversight of the Quality  
24 Assessment and Performance Improvement (QAPI) Program;  
25 (3) Has completed continuing medical education annually specific to maternity care  
26 including complicated conditions; and  
27 (4) Practicing actively and Is a member of the facility's medical staff

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

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

- 34 (1) Demonstrates effective administrative skills and oversight of the Quality  
35 Assessment and Performance Improvement (QAPI) Program;  
36 (2) Has completed continuing medical education annually specific to maternity care  
37 including complicated conditions; and  
38 (3) Is actively practicing and a member of the facility's medical staff

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(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

Comment [ET4]: Recommended by Dr. Saade

Comment [ET5]: From Perinatal Guidelines, 7ed, p24

80 patient's condition; for an urgent request, the timeframe may not  
81 be greater than 30 minutes and may be shorter for some  
82 circumstances

83 (B) Certified nurse midwives who attend patients

- 84 i. Shall operate under guidelines reviewed and approved  
85 by the MMD
- 86 ii. Shall have through formal arrangement, a physician  
87 providing back-up and consultation, whose credentials  
88 reviewed by the MMD and shall be able to arrive at the  
89 patient's bedside within a timeframe defined in (5) (A)  
90 (ii-iii)

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

Comment [ET6]: National guidelines

92 (D) An on-call schedule of providers, back-up providers, and provision for  
93 patients without a physician should be posted on the labor and  
94 delivery unit.

95 (E) During a vaginal or cesarean delivery, there will be separate provider  
96 who is current with NRP immediately available to attend to the  
97 resuscitation of the newborn including intubation and administrative  
98 of medications if needed.

99 (F) Availability of appropriate anesthesia, laboratory, radiology,  
100 ultrasonography and blood bank on a 24 hour basis as described in S  
101 133.41(a), (h), and (s) of this title respectively. The facility will ensure:

- 102 (i) that the blood bank has the capability to provide ABO-  
103 Rh specific or O-Rh negative blood, fresh frozen plasma  
104 and cryoprecipitate, and platelet products at the  
105 facility at all times;
- 106 (ii) Laboratory personnel are onsite at all times; and
- 107 (iii) Perinatal pathology services are available.

Comment [WU7]: Blood on site; massive transfusion

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109 (6) Anesthesia personnel

110 (A) Anesthesia personnel with obstetrical experience or expertise shall  
111 be provided to pregnant and postpartum women including labor  
112 analgesia and surgical anesthesia, and available onsite at all times

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

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

Comment [ET8]: For a level III, require to be onsite 24/7?

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

123 (8) Ultrasound Availability. The facility will ensure:

- 124 (A) Basic ultrasonographic imaging for maternal or fetal assessment including  
125 interpretation available on a 24 hour basis.
- 126 (B) A portable ultrasound machine will be available in the labor and delivery  
127 and antepartum unit for urgent bedside examination.
- 128 (9) A respiratory therapist with experience or expertise in pregnant or postpartum  
129 women will be immediately available on-site 24/7.
- 130 (10) Special equipment shall be available to accommodate the care and  
131 services for morbidly obese women
- 132 (11) Ensure the availability and interpretation of non stress testing and  
133 electronic fetal heart rate monitoring
- 134 (12) Hospitals offering a trial of labor for patients with prior cesarean delivery  
135 must have the immediate availability of anesthesia, cesarean delivery, and  
136 neonatal resuscitation capability during the trial of labor.
- 137 (13) Registered Pharmacist availability shall include:
- 138 (A) A registered pharmacist will be available onsite on 7 days a week, and on  
139 a 24 hour basis; and
- 140 (B) A **registered** pharmacist with experience and/or expertise in perinatal  
141 pharmacology shall be available for consultation on a 24 hour basis.
- 142 (C) If medication compounding is done by a pharmacy technician for  
143 obstetric patients, a pharmacist will provide immediate supervision of the  
144 compounding process.
- 145
- 146 (D) If medication compounding is done for obstetric patients, the  
147 pharmacist will develop checks and balances to ensure the accuracy of  
148 the final product.
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- 150 (14) Resuscitation – The facility shall have appropriately trained staff, policies  
151 and procedures for the stabilization and resuscitation of pregnant or postpartum  
152 women based on current standards of professional practice, including
- 153 (A) ensuring the availability of personnel who can stabilize pregnant or  
154 postpartum women until transfer is possible
- 155 (B) having at least one person on site at all times who can be immediately  
156 available to provide ACLS including intubation, cardioversion or defibrillation,  
157 and direct the administration of medications for cardiopulmonary arrest.
- 158 (C) Having current guideline or protocols specifically addressing the resuscitation  
159 of the pregnant woman, and ensure that resuscitation equipment for  
160 pregnant and postpartum women is readily available at the labor and  
161 delivery area, including
- 162 (i) Equipment for cardioversion and defibrillation
- 163 (ii) Resuscitation equipment and medications
- 164 (iii) Intubation equipment including fiber optic scopes for awake  
165 intubation

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

169 (15) Consultants available include:

170 (A) A physician specializing in maternal fetal medicine:

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

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

174 (B) A full complement of adult medical and surgical subspecialists readily  
175 available for inpatient face to face onsite consultation

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

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

Comment [ET9]: National guidelines

182 (18) The facility shall have written guidelines or protocols for various  
183 conditions that place the pregnant or postpartum woman at risk for morbidity  
184 and/or mortality, including promoting prevention, early identification, early  
185 diagnosis, therapy, stabilization, and transfer. The guidelines or protocols must  
186 address a minimum of:

187 (A) Massive hemorrhage and transfusion of the pregnant or postpartum  
188 patient in coordination of the blood bank, and including management  
189 of unanticipated hemorrhage and/or coagulopathy

190 (B) Obstetrical hemorrhage including promoting the identification of  
191 patients at risk, early diagnosis, and therapy to reduce morbidity and  
192 mortality.

193 (C) Hypertensive disorders in pregnancy including eclampsia and the  
194 postpartum patient to promote early diagnosis and treatment to  
195 reduce morbidity and mortality

196 (D) Sepsis and/or systemic infection in the pregnant or postpartum  
197 woman

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

201 (F) The management of the morbidly obese pregnant and post partum  
202 patient

Comment [ET10]: This is in national guidelines

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

Comment [ET11]: The principle of active  
collaboration is in the National Guidelines

208 (19) The facility shall have a continuous availability of adequate number of  
209 nursing leaders and RN's:

- 210 (A) with competence in level III maternity care criteria and ability to stabilize  
211 and transfer high-risk women and newborns who exceed their  
212 designation criteria; and  
213 (B) with special training and experience in the management of women with  
214 complex maternal illnesses and obstetric complications.  
215 (20) The facility shall have nursing leadership and staff with formal training  
216 and experience in the provision of perinatal nursing care and should coordinate  
217 with respective neonatal services  
218 (21) Shall have a QAPI process and policies aimed to reduce maternal  
219 morbidity and mortality including:  
220 (A) Measuring key outcomes and making improvements on outcomes that  
221 are less than optimal;  
222 (B) The facility will ensure that multidisciplinary drills for high risk events  
223 such as shoulder dystocia, emergency cesarean delivery, eclampsia,  
224 clinical coagulopathy, respiratory failure, and maternal hemorrhage will  
225 occur at regular intervals to help medical, nursing, and ancillary staff  
226 prepare for these emergencies  
227 (C) ensure regular team training on an ongoing basis in the perinatal areas to  
228 promote staff communication and effectiveness in working together  
229  
230 (22) Shall have a program for genetic diagnosis and counseling for genetic  
231 disorders, or have a policy and process for consultation referral to a closely  
232 related facility.  
233  
234 (23) Perinatal Education. A registered nurse with experience in maternity  
235 care including complex and critically ill patients shall provide the supervision and  
236 coordination of staff education.  
237  
238 (24) Ensures the availability and support personnel with knowledge and skills  
239 in breastfeeding to meet the needs of mothers.  
240  
241 (25) A certified lactation consultant shall be available at all times  
242  
243 (26) Social services and pastoral care shall be provided as appropriate to meet  
244 the needs of the patient population served, including bereavement services.  
245  
246 (27) Nutrition/Dietician- needed;  
247

Comment [WU12]: multistidilinary including doctors, etc

Comment [WU13]: High risk and low frequency events,

Comment [ET14]: Not in the guidelines, but this is an integral part of Maternity level III  
Next stime...

1 Maternity Designation Level IV (Regional Perinatal Healthcare Center – Comprehensive and  
2 Critical Care)

Comment [ET1]: Better name?

3 (a) A Level IV (Best name?)

Comment [ET2]: 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

4 (1) The level IV facilities will be able to provide on-site medical and surgical care for  
5 the most complex maternal conditions and critically ill pregnant women and  
6 fetuses through the antepartum, intrapartum and postpartum care. These  
7 patients may be directly admitted or transferred from another facility.

8  
9 (2) The Level IV maternity designation facility will:

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

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

18 (C) Facilitate transports; and

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

Comment [ET3]: National Guidelines; education and outreach

21  
22 (b) Maternity Medical Director (MMD). The MMD shall be a physician who:

23 (1) Is board certified in maternal fetal medicine, or a board certified obstetrician  
24 gynecologist with special expertise in the area of critical care obstetrics;

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

27 (3) Has completed continuing medical education annually specific to maternity care  
28 including complicated conditions; and

29 (4) Is a member of the facility's medical staff

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

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

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

- 38 (2) Has completed continuing medical education annually specific to maternity care  
39 including complicated conditions; and  
40 (3) **Is actively practicing and a member of the facility's medical staff**

**Comment [ET4]:** Active practice & member of medical staff

41  
42 (e) Program Function and Services

- 43 (1) Triage and assessment of all patients admitted to the perinatal service with:  
44 (A) identification of pregnant women who are at high risk of delivering a neonate  
45 that requires a higher level of neonatal care than the scope of their neonatal  
46 facility shall be transferred to a higher level neonatal designated facility prior  
47 to delivery unless the transfer is unsafe  
48 (B) identification of pregnant or postpartum women with conditions or  
49 complications that will likely require a service at available at the facility, and  
50 will be transferred to a higher level maternal designated facility unless the  
51 transfer will be unsafe.

**Comment [ET5]:** Should be rare – but no hospital can do everything

- 52  
53 (2) Supportive and emergency care delivered by appropriately trained personnel for  
54 unanticipated maternal-fetal problems that occur until the patient is stabilized or  
55 transferred.

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

**Comment [ET6]:** Recommended by Dr. Saade

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

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

**Comment [ET7]:** From Perinatal Guidelines, 7ed, p24

- 65 (A) The primary provider caring for a pregnant or postpartum woman  
66 who is a family medicine physician or physician specializing in  
67 obstetrics and gynecology **or maternal fetal medicine**, or a certified  
68 nurse midwife with appropriate physician back-up whose credentials  
69 have been reviewed by the MMD and:  
70 (i) Has completed continuing education annually, specific to the care  
71 of the pregnant and postpartum woman, including complicated  
72 conditions  
73 (ii) Shall arrive at the patient's bedside within a timeframe  
74 commensurate to the patient's condition; for an urgent request,  
75 the timeframe may not be greater than 30 minutes and may be  
76 shorter for more critical circumstances  
77 (iii) If not immediately available to respond or is covering more than  
78 one facility, shall have appropriate backup coverage available,

79 documented in an on call schedule and readily available to facility  
80 staff; and the physician is providing backup coverage shall arrive  
81 at the patient bedside within a timeframe commensurate to the  
82 patient’s condition; for an urgent request, the timeframe may not  
83 be greater than 30 minutes and may be shorter for some  
84 circumstances

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

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

Comment [ET8]: National guidelines

94 (D) An on-call schedule of providers, back-up providers, and provision for  
95 patients without a physician should be posted on the labor and  
96 delivery unit.

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

101 (F) Availability of appropriate anesthesia, laboratory, radiology,  
102 ultrasonography and blood bank on a 24 hour basis as described in S  
103 133.41(a), (h), and (s) of this title respectively. The facility will ensure:

- 104 (i) that the blood bank has the capability to provide ABO-  
105 Rh specific or O-Rh negative blood, fresh frozen plasma  
106 and cryoprecipitate, and platelet products at the  
107 facility at all times;
- 108 (ii) Laboratory personnel are onsite at all times; and
- 109 (iii) Perinatal pathology services are available.

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

114 (A) This includes comanagement of ICU-admitted obstetric patients

115 (B) An MFM team member with full privileges is available at all times for on-  
116 site consultation and management

117 (C) The team must be led by a board-certified MFM with expertise in critical  
118 care obstetrics

119 (7) Anesthesia personnel  
120

- 121 (A) Anesthesia personnel with obstetrical experience or expertise shall  
122 be provided to pregnant and postpartum women including labor  
123 analgesia and surgical anesthesia, and available onsite at all times  
124 (B) A board certified anesthesiologist with special training or experience  
125 in critical care obstetric anesthesia is in charge of obstetric anesthesia  
126 services  
127 (C) A board certified anesthesiologist with special training or experience  
128 in obstetric anesthesia including critically ill obstetric patients will be  
129 available for consultation at all times, and be able to arrive onsite for  
130 urgent situations within 30 minutes  
131 (8) Personnel appropriately trained in the use of x-ray equipment shall be available  
132 on-site at all times. Advanced imaging including CT imaging available and MR  
133 imaging, and echocardiography will be available 24/7 including interpretation,  
134 which will be available within 1 hour on urgent requests on a 24 hours basis  
135 (9) A radiologist with critical interventional radiology skills relevant to pregnant or  
136 postpartum women must be readily available at all times  
137 (10) Ultrasound Availability. The facility will ensure:  
138 (A) Basic ultrasonographic imaging for maternal or fetal assessment including  
139 interpretation available on a 24 hour basis.  
140 (B) A portable ultrasound machine will be available in the labor and delivery  
141 and antepartum unit for urgent bedside examination.  
142 (11) A respiratory therapist with experience or expertise in pregnant or  
143 postpartum women will be immediately available on-site 24/7.  
144 (12) Special equipment shall be available to accommodate the care and  
145 services for morbidly obese women  
146 (13) Ensure the availability and interpretation of non stress testing and  
147 electronic fetal monitoring  
148 (14) Hospitals offering a trial of labor for patients with prior cesarean delivery  
149 must have the immediate availability of anesthesia, cesarean delivery, and  
150 neonatal resuscitation capability during the trial of labor.  
151 (15) Registered Pharmacist availability shall include:  
152 (A) A registered pharmacist will be available onsite on 7 days a week, and on  
153 a 24 hour basis; and  
154 (B) A registered pharmacist with experience and/or expertise in perinatal  
155 pharmacology shall be available for consultation on a 24 hour basis.  
156 (C) If medication compounding is done by a pharmacy technician for  
157 obstetric patients, a pharmacist will provide immediate supervision of the  
158 compounding process.  
159  
160 (C) If medication compounding is done for obstetric patients, the  
161 pharmacist will develop checks and balances to ensure the  
162 accuracy of the final product.

Comment [ET9]: Is this enough? Actively practicing? Member of medical staff?

- 163 (16) Intensive Care Services- The facility shall have on-site ICU care for  
164 obstetric patients with the onsite medical and surgical care, and  
165 collaborative care with the maternal fetal medicine care team
- 166 (17) Resuscitation – The facility shall have appropriately trained staff, policies  
167 and procedures for the stabilization and resuscitation of pregnant or postpartum  
168 women based on current standards of professional practice, including  
169 (A) ensuring the availability of personnel who can stabilize pregnant or  
170 postpartum women until transfer is possible  
171 (B) having at least one person on site at all times who can be immediately  
172 available to provide ACLS including intubation, cardioversion or defibrillation,  
173 and direct the administration of medications for cardiopulmonary arrest.  
174 (C) Having current guideline or protocols specifically addressing the resuscitation  
175 of the pregnant woman, and ensure that resuscitation equipment for  
176 pregnant and postpartum women is readily available at the labor and  
177 delivery area, including  
178 (i) Equipment for cardioversion and defibrillation  
179 (ii) Resuscitation equipment and medications  
180 (iii) Intubation equipment including fiber optic scopes for awake  
181 intubation  
182 (D) Appropriate equipment and personnel available onsite to ventilate and  
183 monitor women in labor and delivery until they can be safely transported to  
184 the ICU
- 185 (18) Consultants available include:  
186 (A) A full complement of adult medical and surgical subspecialists readily  
187 available for inpatient face to face onsite consultation , who shall  
188 collaborate with the MFM care team
- 189 (19) Stabilize obstetrical patients who have been admitted to the facility or  
190 transferred from other facilities
- 191 (20) Shall have the availability of Medical and Surgical Intensive Care Units  
192 that are able to accept pregnant and postpartum women and have critical care  
193 providers onsite to actively collaborate with Maternal Fetal Medicine and  
194 Obstetrician specialists at all times
- 195 (21) The facility shall have written guidelines or protocols for various  
196 conditions that place the pregnant or postpartum woman at risk for morbidity  
197 and/or mortality, including promoting prevention, early identification, early  
198 diagnosis, therapy, stabilization, and transfer. The guidelines or protocols must  
199 address a minimum of:  
200 (A) Massive hemorrhage and transfusion of the pregnant or postpartum  
201 patient in coordination of the blood bank, and including management  
202 of unanticipated hemorrhage and/or coagulopathy  
203 (B) Obstetrical hemorrhage including promoting the identification of  
204 patients at risk, early diagnosis, and therapy to reduce morbidity and  
205 mortality.

Comment [ET10]: National guidelines

- 206 (C) Hypertensive disorders in pregnancy including eclampsia and the  
207 postpartum patient to promote early diagnosis and treatment to  
208 reduce morbidity and mortality  
209 (D) Sepsis and/or systemic infection in the pregnant or postpartum  
210 woman  
211 (E) Venous thromboembolism in pregnant and postpartum women, and  
212 to assessment of risk factors, prevention, early diagnosis and  
213 treatment  
214 (F) The management of the morbidly obese pregnant and post partum  
215 patient  
216 (G) Management of critically ill pregnant or postpartum women,  
217 including fetal monitoring in the ICU, respiratory failure and ventilator  
218 support, procedure for emergency cesarean, coordination of nursing  
219 care, and consultative or co-management roles to facilitate  
220 collaboration.  
221 (22) The facility shall have a continuous availability of adequate number of  
222 nursing leaders and RN's:  
223 (A) with competence in level IV maternity care criteria and ability to stabilize  
224 and transfer high-risk women and newborns; and  
225 (B) with special training and experience in the management of women with  
226 critically ill and complex maternal illnesses and obstetric complications.  
227 (23) The facility shall have nursing leadership and staff with formal training  
228 and experience in maternal critical care and should coordinate with respective  
229 neonatal services, including the continuous availability of an adequate number  
230 of RN's who have experience in the care of women with highly complex medical  
231 illnesses and obstetric conditions  
232 (24) Shall have a QAPI process and policies aimed to reduce maternal  
233 morbidity and mortality including:  
234 (A) Measuring key outcomes and making improvements on outcomes that  
235 are less than optimal;  
236 (B) The facility will ensure that drills for high risk events such as shoulder  
237 dystocia, emergency cesarean delivery, eclampsia, clinical coagulopathy,  
238 respiratory failure, and maternal hemorrhage will occur at regular  
239 intervals to help medical, nursing, and ancillary staff prepare for these  
240 emergencies  
241 (C) ensure regular team training on an ongoing basis in the perinatal areas to  
242 promote staff communication and effectiveness in working together  
243  
244 (25) Shall have a program for genetic diagnosis and counseling for these  
245 disorders, or have a policy and process for consultation referral to a closely  
246 related facility.  
247

Comment [ET11]: This is in national guidelines

Comment [ET12]: The principle of active collaboration is in the National Guidelines

Comment [WU13]: High risk and low frequency events,

Comment [ET14]: Not in the guidelines, but this is an integral part of Maternity level IV

- 248 (26) Perinatal Education. A registered nurse with experience in maternity  
249 care including complex and critically ill patients shall provide the supervision and  
250 coordination of staff education.  
251
- 252 (27) Ensures the availability and support personnel with knowledge and skills  
253 in breastfeeding to meet the needs of mothers.  
254
- 255 (28) A certified lactation consultant shall be available at all times  
256
- 257 (29) Social services and pastoral care shall be provided as appropriate to meet  
258 the needs of the patient population served, including bereavement services.  
259
- 260 (30) Nutrition/Dietician?

DRAFT