Maternal Level III Rule Review

March 28, 2018
• Elizabeth Stevenson, RN
• Designation Program Manager
• Centers of Excellence for Fetal Diagnosis and Therapy, Maternal, Neonatal, Stroke and Trauma Designation
• Thank you to Kelli Kennedy with the DSHS Library for assisting today.
• Kelli will be fielding the questions during the webinar.
• You may ask questions at any time during the webinar.
• We will have a time after the webinar for answers to your questions.
Office of EMS/Trauma System

- You may type your questions in the chat box and hit “enter”;
- or
- You may email your questions to be answered at a later time to:
  Elizabeth.Stevenson@dshs.texas.gov
Objectives

Why Maternal Designation?
Overview of Rule Process
Perinatal Care Regions (PCR) participation by facility
Overview of the designation process
Level III Rule Review
Questions
Women’s Health in Texas

Population of Women of Childbearing Age (15-44) in Texas by Race/Ethnicity, 2014

- Anglo
- Black
- Hispanic
- Other
Women’s Health in Texas

Figure 1. Percentage of Texas maternal deaths and births in 2011-2012 by mother’s race/ethnicity.

Source: CHS Birth and Death Files, 2011-2012
Women’s Health in Texas

Figure 2. Top causes of maternal death in Texas in 2011-2012.

Source: CHS Death File, 2011-2012
Women’s Health in Texas

Figure 3. Survival plot of time elapsed between delivery and death, 2011-2012 maternal deaths

Source: CHS Birth, Fetal Death, and Death Files, 2011-2012
Legislative Overview

HB 15, 83rd R Legislative Session

Neonatal and Maternal Levels of Care
Establish perinatal care regions
Perinatal Advisory Council (PAC)
Neonatal and Maternal rules adopted by March 1, 2017
Neonatal designation by August 31, 2017
Maternal designation by August 31, 2018

HB 3433, 84th R
Neonatal and Maternal rules adopted by March 1, 2018
Neonatal designation by August 31, 2018
Maternal designation by August 31, 2020
Maternal Levels of Care

Rule Development Process

- Maternal Rules were developed over a 12 + month process
- Perinatal Advisory Council recommendations
- Stakeholder Meetings State-wide
- Published for public comment November 17, 2017 in the Texas Register
- Public Hearing December 20, 2017
- Published in the Texas Register, February 16, 2018
- Maternal Rules effective March 1, 2018
EMS-Trauma System Website

NEW!

Sign up to receive announcements by email regarding the EMS Trauma Systems program. This feature will serve as a tool to increase communication with stakeholders regarding new information added to the website.

Customer Service Survey

We value your feedback. Please take our online customer service survey at [https://www.surveymonkey.com/r/RLUsurvey](https://www.surveymonkey.com/r/RLUsurvey). Thank you.
Preferences for Notifications

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Maternal Designation Website

Maternal Levels of Care Designation

The purpose of the Maternal Levels of Care Designation is to implement House Bill 15, 83rd Legislature, Regular Session, 2013, which added Health and Safety Code, Subchapter H, Hospital Level of Care Designations for Neonatal and Maternal Care, Sections 241.181 - 241.187. House Bill 3433, 84th Legislature, Regular Session, 2015 amended Health and Safety Code, Chapter 241 and requires the development of initial rules to create the neonatal/maternal level of care designation by March 1, 2018. The maternal levels of care designation rule became effective on March 1, 2018 and the designation for maternal level of care is an eligibility requirement for Medicaid reimbursement beginning September 1, 2020.

Register for Hospital Level of Care Designations for Maternal Care Webinars

The rule for Hospital Level of Care Designations for Maternal Care became effective on March 1, 2018. The webinars will clarify questions about the rule content and provide examples of compliance with the different requirements for designation in the rule. The designation process will be described with specifics about survey organizations and designation timelines. Questions about the rule will be accepted at the end of the webinars.

Rules: Texas Administrative Code, Title 25, Chapter 133, Subchapter K.

Scheduled Maternal Levels of Care Webinars*:

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Texas Administrative Code

Subchapters

SUBCHAPTER A GENERAL PROVISIONS
SUBCHAPTER B HOSPITAL LICENSE
SUBCHAPTER C OPERATIONAL REQUIREMENTS
SUBCHAPTER D VOLUNTARY AGREEMENTS
SUBCHAPTER E WAIVER PROVISIONS
SUBCHAPTER F INSPECTION AND INVESTIGATION PROCEDURES
SUBCHAPTER G ENFORCEMENT
SUBCHAPTER H FIRE PREVENTION AND SAFETY REQUIREMENTS
SUBCHAPTER I PHYSICAL PLANT AND CONSTRUCTION REQUIREMENTS
SUBCHAPTER J HOSPITAL LEVEL OF CARE DESIGNATIONS FOR NEONATAL AND MATERNAL CARE
SUBCHAPTER K HOSPITAL LEVEL OF CARE DESIGNATIONS FOR MATERNAL CARE
SUBCHAPTER L CENTERS OF EXCELLENCE FOR FETAL DIAGNOSIS AND THERAPY
Texas Administrative Code

TITLE 25
PART 1
CHAPTER 133
SUBCHAPTER K

HEALTH SERVICES
DEPARTMENT OF STATE HEALTH SERVICES
HOSPITAL LICENSING
HOSPITAL LEVEL OF CARE DESIGNATIONS FOR MATERNAL CARE

Rules

§133.201 Purpose
§133.202 Definitions
§133.203 General Requirements
§133.204 Designation Process
§133.205 Program Requirements
§133.206 Maternal Designation Level I
§133.207 Maternal Designation Level II
§133.208 Maternal Designation Level III
§133.209 Maternal Designation Level IV
§133.210 Survey Team
Maternal Rule Definitions

Available – Relating to staff who can be contacted for consultation at all time without delay.

Designation – A formal recognition by the Executive Commissioner of the facility's maternal care capabilities and commitment for a period of three years.

Immediately – without delay
Maternal Rule Definitions

Lactation Consultant – A health care professional who specializes in the clinical management of breastfeeding.

On-site – at the facility and able to rapidly arrive at the patient bedside for urgent requests.

Urgent – requiring immediate action or attention

At all times – 24/7/365
General Requirements

- Our office recommends the appropriate designation for a facility to the Executive Commissioner of HHSC.

- Multiple locations under a single license requires that each location is separately designated.

- Final designation may not be the level requested by the facility.
PCR - Perinatal Care Regions

• Aligned with the Trauma Service Areas (TSAs) due to established infrastructure to support the functions of the PCRs.
• Established for regional planning purposes, including emergency and disaster preparedness.
• Not established for the purpose of restricting patient referral.
• Designated facilities must participate in the PCR.
Designation Process

Level III facilities will be surveyed by an approved organization and evaluated for compliance and non-compliance with the rule.

The application packet submittal will be discussed in a webinar at a later date.
Designation Process

Organizations Performing Surveys

- TETAF – Texas EMS, Trauma and Acute Care Foundation
- [http://texasperinatalservices.org](http://texasperinatalservices.org)
- ACOG – American College of Obstetricians and Gynecologists
- [http://acog.org/LOMCTexas](http://acog.org/LOMCTexas)
The application for designation will be released June 1, 2018.

All facilities applying for Level III designation will submit the following.

- Completed application
- Application Fee
- A survey report of compliance or non-compliance with the rules.
- Letter of participation from the Perinatal Care Region.
- Plan of Correction if the facility has potential deficiencies.
d) Non-refundable application fees for the three-year designation period are as follows:

(3) Level III maternal facility applicants, the fee is $2,000.00.
Plan of Correction

Plan of Correction if the facility has potential deficiencies to include:

- The deficiency;
- The corrective action;
- Title of responsible person for implementation of action;
- How the action will be monitored; and
- The date by which the POC will be complete.
Designation Process

- Every Texas licensed hospital that provides maternal care must be designated to receive Medicaid reimbursement.
- Designation for maternal care is required by August 31, 2020.
- Applications for designation must be submitted to our office before July 1, 2020.
- Surveys must be completed before May 1, 2020.
Designation Process

(B) Any facility that has not completed an on-site survey to verify compliance with the requirements for a Level II, III or IV designation at the time of application must provide a self-survey and attestation and will receive a Level I designation.
Designation Process

(D) The office, at its discretion, may designate a facility for a shorter term designation for any application received prior to September 1, 2018.

(E) An application for a higher or lower level designation may be submitted at any time.
Designation Process

g) The office shall review the findings of the survey report and any POC submitted by the facility, to determine compliance with the maternal designation program requirements.

(1) A recommendation for designation shall be made to the executive commissioner based on compliance with the requirements.

(2) A maternal level of care designation shall not be denied to a facility that meets the minimum requirements for that level of care designation.
Designation Process

(3) If a facility does not meet the requirements for the level of designation requested, the office shall recommend designation for the facility at the highest level for which it qualifies and notify the facility of the requirements it must meet to achieve the requested level of designation.

(4) If a facility does not comply with requirements, the office shall notify the facility of deficiencies and required corrective action(s) plan (CAP).
If the rule does not specify the exact requirement (ex. Successful ACLS completion), it is up to the facility to define the expectation appropriate for the population served.

Medical Practice decisions are not regulated by the Department of State Health Services.
(b) Program Plan. The facility shall develop a written plan of the maternal program that includes a detailed description of the scope of services available to all maternal patients, defines the maternal patient population evaluated and/or treated, transferred, or transported by the facility, that is consistent with accepted professional standards of practice for maternal care, and ensures the health and safety of patients.
Program Requirements

(2) The written maternal program plan shall include, at a minimum:

(C) written triage, stabilization, and transfer guidelines for pregnant and postpartum patients that include consultation and transport services;
Program Requirements

(D) written guidelines or protocols for prevention, early identification, early diagnosis, and therapy for conditions that place the pregnant or postpartum patient at risk for morbidity and/or mortality;

(E) provisions for unit specific disaster response to include evacuation of maternal patients and infants to appropriate levels of care;
Program Requirements

(F) a Quality Assessment and Performance Improvement (QAPI) Program as described in §133.41 of this title (relating to Hospital Functions and Services). The facility shall demonstrate that the maternal program evaluates the provision of maternal care on an ongoing basis, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until a resolution is achieved. The maternal program shall measure, analyze, and track quality indicators and other aspects of performance that the facility adopts or develops that reflect processes of care and is outcome based. Evidence shall support that aggregate patient data is continuously reviewed for trends and data is submitted to the department as requested;
Program Requirements

(G) requirements for minimal credentials for all staff participating in the care of maternal patients;

(H) provisions for providing continuing staff education, including annual competency and skills assessment that is appropriate for the patient population served;

(I) a perinatal staff registered nurse as a representative on the nurse staffing committee under §133.41 of this title; and

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

(c) Medical Staff. The facility shall have an organized maternal program that is recognized by the medical staff and approved by the facility's governing body.

(1) The credentialing of the maternal medical staff shall include a process for the delineation of privileges for maternal care.

(2) The maternal medical staff will participate in ongoing staff and team based education and training in the care of the maternal patient.
Program Requirements

d) Medical Director. There shall be an identified Maternal Medical Director (MMD) and/or Transport Medical Director (TMD) as appropriate, responsible for the provision of maternal care services and credentialed by the facility for the treatment of maternal patients. The responsibilities and authority of the MMD and/or TMD shall include:

(1) examining qualifications of medical staff requesting maternal privileges and making recommendations to the appropriate committee for such privileges;
Program Requirements

(2) assuring maternal medical staff competency in managing obstetrical emergencies, complications and resuscitation techniques;

(3) monitoring maternal patient care from transport if applicable, to admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Program;

(4) participating in ongoing maternal staff and team based education and training in the care of the maternal patient;
Program Requirements

(5) overseeing the inter-facility maternal transport;

(6) collaborating with the MPM in areas to include: developing and/or revising policies, procedures and guidelines, assuring medical staff and personnel competency, education and training; and the QAPI Program;

(7) frequently leading and participating in the maternal QAPI meetings;
Program Requirements

(8) ensuring that the QAPI Program is specific to maternal and fetal care, is ongoing, data driven and outcome based;

(9) participating as a clinically active and practicing physician in maternal care at the facility where medical director services are provided;

(10) maintaining active staff privileges as defined in the facility's medical staff bylaws; and

(11) developing collaborative relationships with other MMD(s) of designated facilities within the applicable Perinatal Care Region.
**Program Requirements**

e) Maternal Program Manager (MPM). The MPM responsible for the provision of maternal care services shall be identified by the facility and:

(1) be a registered nurse with perinatal experience;

(2) be a clinically active and practicing registered nurse participating in maternal care at the facility where program manager services are provided;

(3) has the authority and responsibility to monitor the provision of maternal patient care services from admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Program;
Program Requirements

(4) collaborates with the MMD in areas to include: developing and/or revising policies, procedures and guidelines; assuring staff competency, education, and training and the QAPI Program;

(5) frequently leads and participates in the maternal QAPI meetings;

(6) ensures that the QAPI Program is specific to maternal and fetal care, is ongoing, data driven and outcome based; and

(7) develops collaborative relationships with other MPM(s) of designated facilities within the applicable Perinatal Care Region.
Level III (SubSpecialty Care)

(a) A Level III (Subspecialty Care). The Level III maternal designated facility will:

(1) provide care for pregnant and postpartum patients with low risk conditions to significant complex medical, surgical and/or obstetrical conditions that present a high risk of maternal morbidity or mortality;

(2) ensure access to consultation to a full range of medical and maternal subspecialists, surgical specialists, and behavioral health specialists;
Level III (SubSpecialty Care)

OBSTETRIC CARE
CONSENSUS

Levels of Maternal Care

Number 2 • February 2015
Level III (SubSpecialty Care)

(3) ensure capability to perform major surgery on-site;

(4) have physicians with critical care training available at all times to actively collaborate with Maternal Fetal Medicine physicians and/or Obstetrics and Gynecology Physicians with obstetrics training and privileges in maternal care;
Level III (SubSpecialty Care)

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

(6) facilitate transports; and

(7) provide outreach education to lower level designated facilities, including the Quality Assessment and Performance Improvement (QAPI) process.
Level III (SubSpecialty Care)

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

(1) is a board certified obstetrics and gynecology physician with obstetrics training and experience, or a board certified maternal fetal medicine physician, both with privileges in maternal care;

(2) demonstrates administrative skills and oversight of the QAPI Program; and

(3) has completed annual continuing education specific to maternal care, including complicated conditions.
(c) If the facility has its own transport program, there shall be an identified Transport Medical Director (TMD). The TMD shall be a physician who is a board certified maternal fetal medicine specialist or board certified obstetrics and gynecology physician with privileges and experience in obstetrical care and maternal transport.
d) Program Functions and Services.

(1) Triage and assessment of all patients admitted to the perinatal service.

(A) Pregnant patients who are identified 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) Pregnant or postpartum patients identified with conditions and/or complications that require a higher level of maternal care shall be transferred to a higher level maternal designated facility unless the transfer is unsafe.
(2) Provide care for pregnant patients with the capability to detect, stabilize, and initiate management of unanticipated maternal-fetal or maternal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a higher level of neonatal and/or maternal care.

(3) Supportive and emergency care shall be delivered by appropriately trained personnel for unanticipated maternal-fetal problems that occur requiring a higher level of maternal care, until the patient is stabilized or transferred;
(4) An obstetrics and gynecology physician with maternal privileges shall be on-site at all times and available for urgent situations.

(5) Maternal Fetal Medicine physician with inpatient privileges shall be available at all times for consultation and arrive at the patient bedside within 30 minutes of an urgent request to co-manage patients.
Level III (SubSpecialty Care)

(6) Intensive Care Services. The facility shall provide critical care services for critically ill pregnant or postpartum patients, including fetal monitoring in the Intensive Care Unit (ICU), respiratory failure and ventilator support, procedure for emergency cesarean, coordination of nursing care, and consultative or co-management roles to facilitate collaboration.
Level III  (SubSpecialty Care)

(7) Medical and surgical physicians, including critical care specialists, shall be available at all times and arrive at the patient bedside within 30 minutes of an urgent request.
Level III (SubSpecialty Care)

(8) Consultation by a behavioral health professional, with training and/or experience in maternal counseling shall be available at all times and arrive for in-person visits when requested within a time period consistent with current standards of professional practice and maternal care.

(9) Ensure that a qualified physician, or a certified nurse midwife with appropriate physician back-up, is available to attend all deliveries or other obstetrical emergencies.
(10) The primary provider caring for a pregnant or postpartum patient who is a family medicine physician with obstetrics training and experience, obstetrics and gynecology physician, maternal fetal medicine physician, or a certified nurse midwife, physician assistant or nurse practitioner with appropriate physician back-up, whose credentials have been reviewed by the MMD and is on call:
Level III  (SubSpecialty Care)

(A) shall arrive at the patient bedside within 30 minutes for an urgent request; and

(B) shall complete annual continuing education, specific to the care of pregnant and postpartum patients, including complicated and critical conditions.
Level III  (SubSpecialty Care)

(11) Certified nurse midwives, physician assistants and nurse practitioners who provide care for maternal patients:

(A) shall operate under guidelines reviewed and approved by the MMD; and
Level III (SubSpecialty Care)

(B) shall have a formal arrangement with a physician with obstetrics training and/or experience, and with maternal privileges who will:

(i) provide back-up and consultation;

(ii) arrive at the patient bedside within 30 minutes of an urgent request; and

(iii) meet requirements for medical staff as described in §133.205 of this title (relating to Program Requirements) respectively.
(12) An on-call schedule of providers, back-up providers, and provision for patients without a physician will be readily available to facility and maternal staff and posted on the labor and delivery unit.

(13) Ensure that the physician providing back-up coverage shall arrive at the patient bedside within 30 minutes for an urgent request.
Anesthesia Services shall comply with the requirements found at §133.41 of this title (relating to Hospital Functions and Services) and shall have:

(A) anesthesia personnel with experience and expertise in obstetric anesthesia shall be available on-site at all times;
Level III  (SubSpecialty Care)

(B) a board certified anesthesiologist with training or experience in obstetric anesthesia in charge of obstetric anesthesia services;

(C) an anesthesiologist with training and/or experience in obstetric anesthesia, including critically ill obstetric patients available for consultation at all times, and arrive at the patient bedside within 30 minutes for urgent requests; and

(D) anesthesia personnel on call, including back-up contact information, posted and readily available to the facility and maternal staff and posted in the labor and delivery area.
Level III (SubSpecialty Care)

(15) Laboratory Services shall comply with the requirements found at §133.41 of this title and shall have:

(A) laboratory personnel on-site at all times;

(B) a blood bank capable of:
Level III (SubSpecialty Care)

(i) providing ABO-Rh specific or O-Rh negative blood, fresh frozen plasma, cryoprecipitate, and platelet components on-site at the facility at all times;

(ii) implementing a massive transfusion protocol;

(iii) ensuring guidelines for emergency release of blood components; and

(iv) managing multiple blood component therapy; and

(C) perinatal pathology services available.
Level III  (SubSpecialty Care)

(16) Medical Imaging Services shall comply with the requirements found at §133.41 of this title and shall have:

(A) personnel appropriately trained in the use of x-ray equipment available on-site at all times;

(B) advanced imaging, including computed tomography (CT), magnetic resonance imaging (MRI), and echocardiography available at all times;
Level III (SubSpecialty Care)

(C) interpretation of CT, MRI and echocardiography within a time period consistent with current standards of professional practice and maternal care;

(D) basic ultrasonographic imaging for maternal or fetal assessment, including interpretation available at all times; and

(E) a portable ultrasound machine available in the labor and delivery and antepartum unit.
(17) Pharmacy services shall comply with the requirements found in §133.41 of this title and shall have a pharmacist with experience in perinatal pharmacology available at all times.

(18) Respiratory Therapy Services shall comply with the requirements found at §133.41 of this title and have a respiratory therapist immediately available on-site at all times.
Level III (SubSpecialty Care)

(19) Obstetrical Services.
(A) The ability to begin an emergency cesarean delivery within a time period consistent with current standards of professional practice and maternal care.
(B) Ensure the availability and interpretation of non-stress testing, and electronic fetal monitoring.
(C) A trial of labor for patients with prior cesarean delivery shall have the capability of anesthesia, cesarean delivery, and maternal resuscitation on-site during the trial of labor.
(20) Resuscitation. The facility shall have written policies and procedures specific to the facility for the stabilization and resuscitation of the pregnant or postpartum patient based on current standards of professional practice. The facility:

(A) ensures staff members, not responsible for the neonatal resuscitation, are immediately available on-site at all times who demonstrate current status of successful completion of ACLS and the skills to perform a complete resuscitation; and

(B) ensures that resuscitation equipment, including difficult airway management equipment for pregnant and postpartum patients, is readily available in the labor and delivery, antepartum and postpartum areas.
Level III (SubSpecialty Care)

(21) The facility shall have written guidelines or protocols for various conditions that place the pregnant or postpartum patient 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:
Level III (SubSpecialty Care)

(A) massive hemorrhage and transfusion of the pregnant or postpartum patient in coordination of the blood bank, 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;
Level III  (SubSpecialty Care)

(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 patient;

(E) venous thromboembolism in the pregnant and postpartum patient, including assessment of risk factors, prevention, early diagnosis and treatment;
Level III (SubSpecialty Care)

(F) shoulder dystocia, including assessment of risk factors, counseling of patient, and multi-disciplinary management; and

(G) behavioral health disorders, including depression, substance abuse and addiction that includes screening, education, consultation with appropriate personnel and referral.
(22) The facility shall have nursing leadership and staff with training and experience in the provision of maternal nursing care who will coordinate with respective neonatal services.

(23) The facility shall have a program for genetic diagnosis and counseling for genetic disorders, or a policy and process for consultation referral to an appropriate facility.
(24) Perinatal Education. A registered nurse with experience in maternal care, including moderately complex and ill obstetric patients, shall provide the supervision and coordination of staff education. Perinatal education for high risk events will be provided at frequent intervals to prepare medical, nursing, and ancillary staff for these emergencies.

(25) Support personnel with knowledge and skills in breastfeeding to meet the needs of maternal patients shall be available at all times.
(26) A certified lactation consultant shall be available at all times.

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

(28) Dietician or nutritionist available with training and experience in maternal nutrition and can plan diets that meet the needs of the pregnant and postpartum patient shall comply with the requirements in §133.41 of this title.
Resources

Resource documents available on the maternal designation website to perform a self-assessment of the maternal program at your facility to identify compliance with the requirements in the rule.
Deadlines

Each hospital that provides maternal care must be designated by August 31, 2020 to receive Medicaid reimbursement.

Applications must be received in our office before July 1, 2020 to be approved for designation by the Executive Commissioner before September 1, 2020.

Surveys must occur before May 1, 2020 to ensure designation by the deadline.
Contact Information

• Please send your name, title, facility name, email address and phone number to:

• Jewell.Potter@dshs.texas.gov
Maternal Rule Review

- A webinar is scheduled tomorrow for Level IV.

- Meetings around the state to review the maternal rule TBA.

- Add information to the maternal designation website as it becomes available.
Questions?
Thank you

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