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Maternal Level I Rule Review

March 22, 2018

Office of EMS/Trauma System

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- Designation Program Manager
- Trauma, Stroke, Neonatal, Maternal and Centers of Excellence for Fetal Diagnosis and Therapy

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- 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 questions.

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- 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 I Rule Review
- Questions

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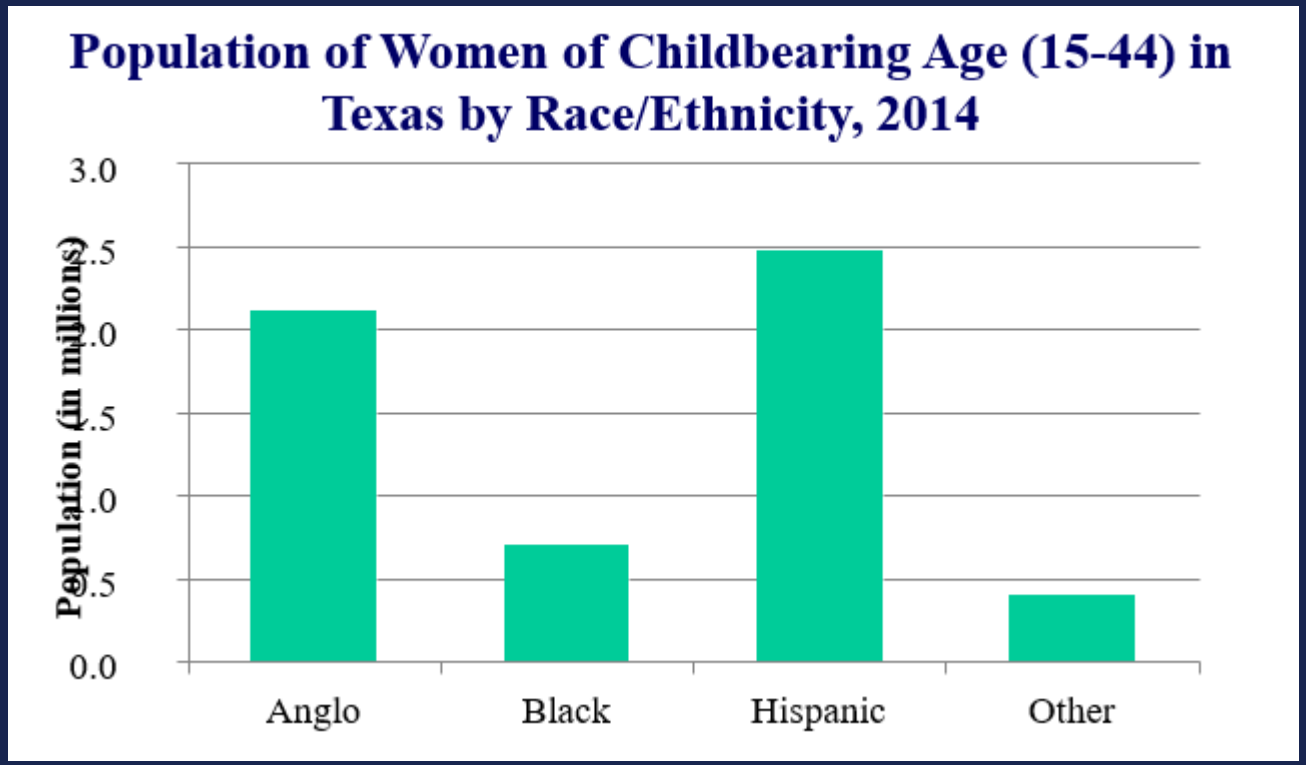
Women's Health in Texas



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Women's Health in Texas

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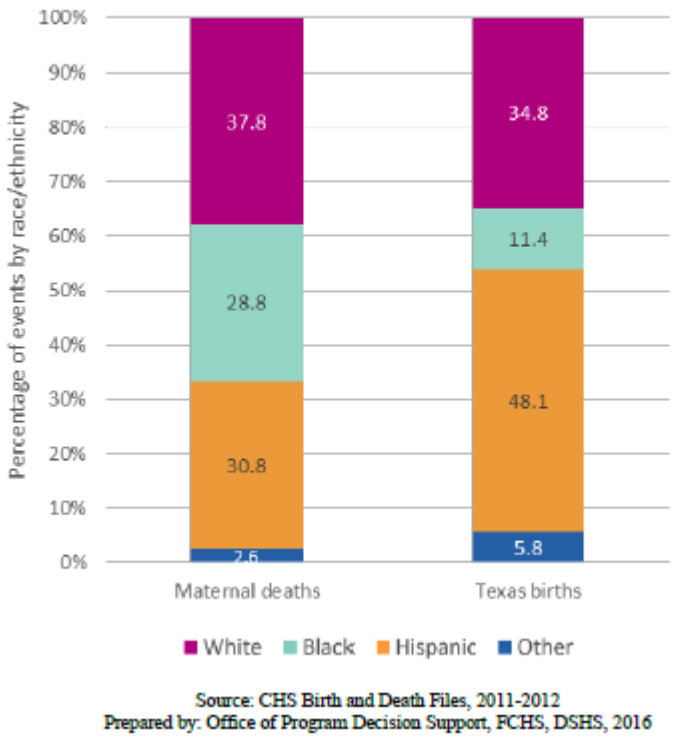
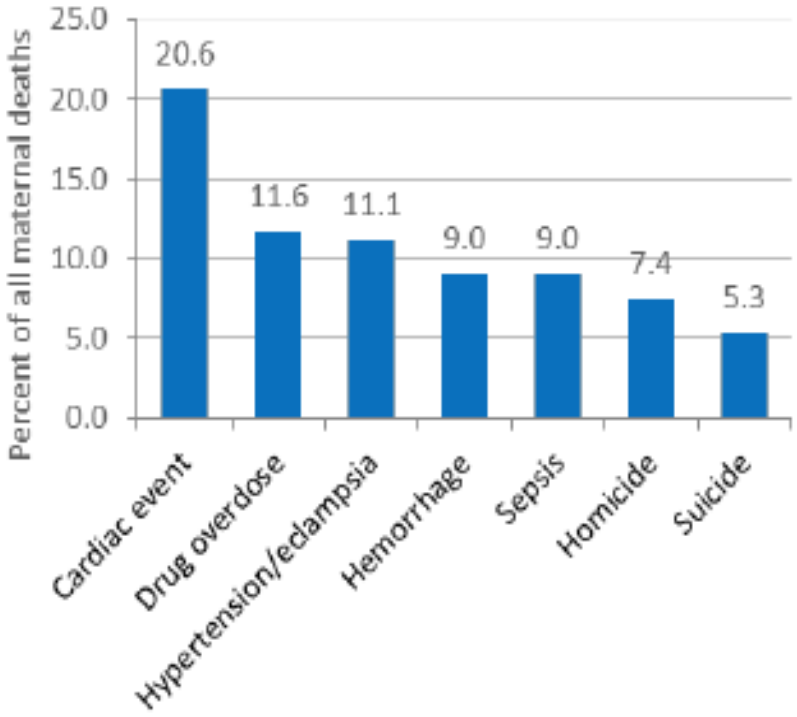
Figure 1. Percentage of Texas maternal deaths and births in 2011-2012 by mother's race/ethnicity.



Source: CHS Birth and Death Files, 2011-2012
Prepared by: Office of Program Decision Support, FCHS, DSHS, 2016

Women's Health in Texas

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



Source: CHS Death File, 2011-2012
Prepared by: Office of Program Decision Support, FCHS, DSHS, 2016

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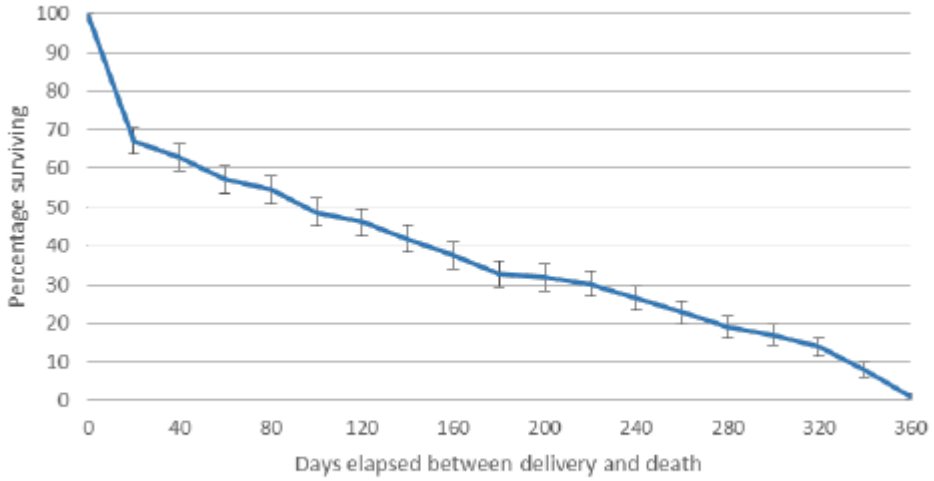
Women's Health in Texas

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
Prepared by: Office of Program Decision Support, FCHS, DSHS, 2016

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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

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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**

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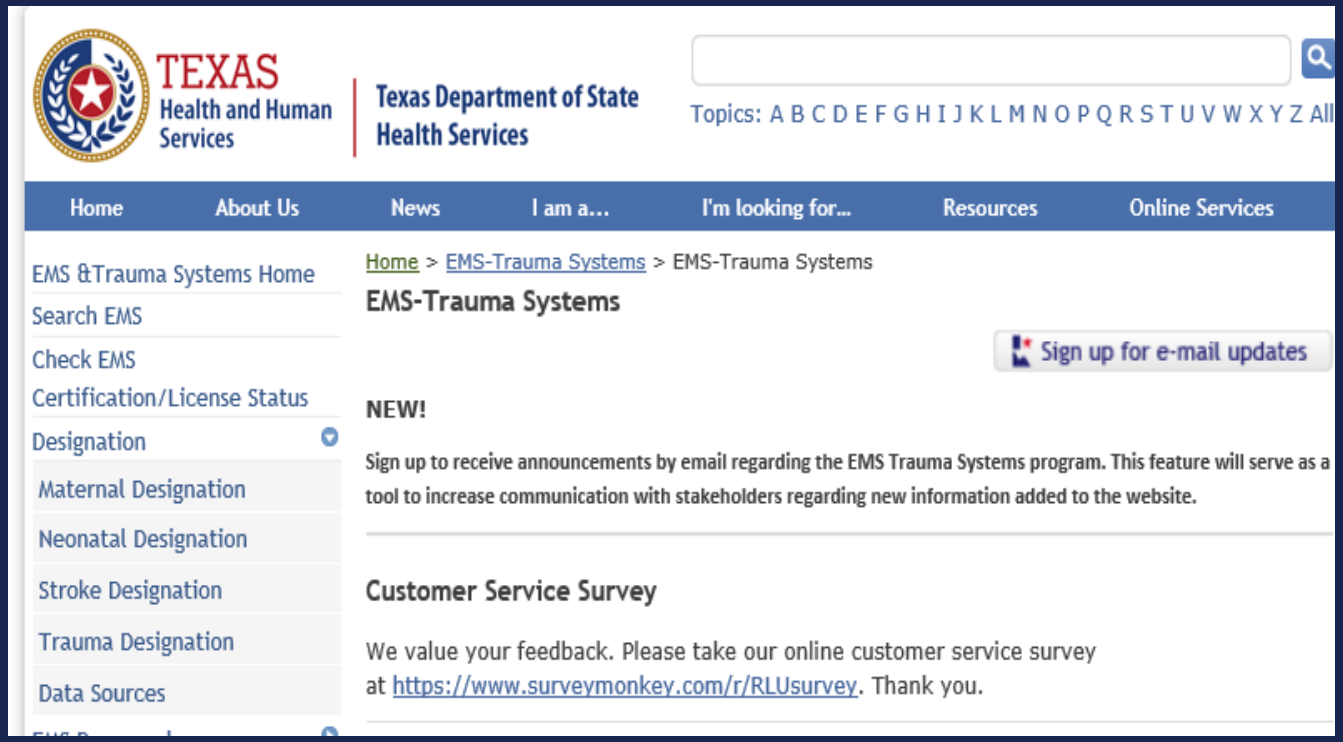
EMS-Trauma System Website



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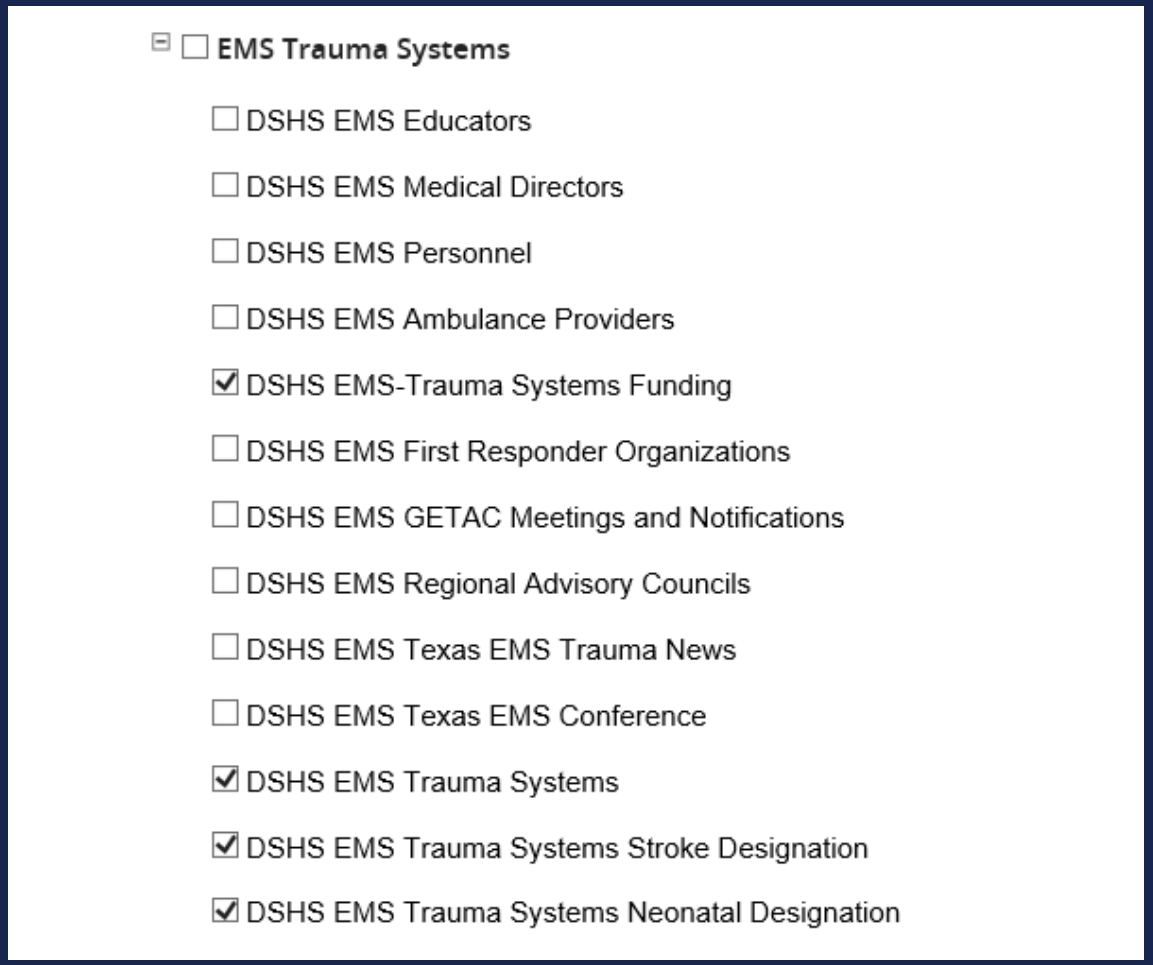
Preferences for Notifications



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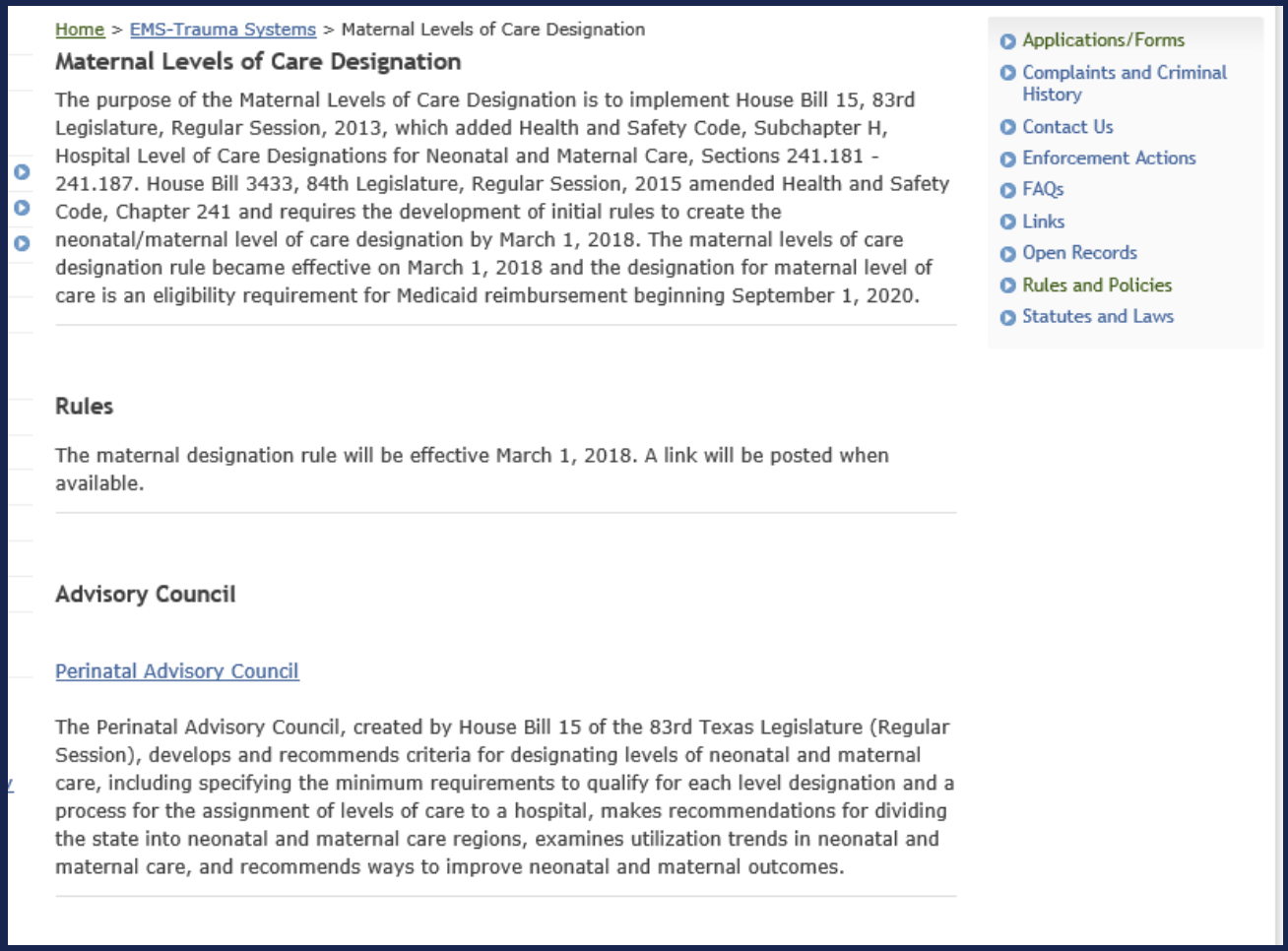
Maternal Designation Website



Home > EMS-Trauma Systems > Maternal Levels of Care Designation

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.

Rules

The maternal designation rule will be effective March 1, 2018. A link will be posted when available.

Advisory Council

Perinatal Advisory Council

The Perinatal Advisory Council, created by House Bill 15 of the 83rd Texas Legislature (Regular Session), develops and recommends criteria for designating levels of neonatal and maternal care, including specifying the minimum requirements to qualify for each level designation and a process for the assignment of levels of care to a hospital, makes recommendations for dividing the state into neonatal and maternal care regions, examines utilization trends in neonatal and maternal care, and recommends ways to improve neonatal and maternal outcomes.

- Applications/Forms
- Complaints and Criminal History
- Contact Us
- Enforcement Actions
- FAQs
- Links
- Open Records
- Rules and Policies
- Statutes and Laws

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Texas Administrative Code

Texas Administrative Code

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 133	HOSPITAL LICENSING

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

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Maternal Rule

Texas Administrative Code

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 133	HOSPITAL LICENSING
SUBCHAPTER K	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

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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

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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

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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.

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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.

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Designation Process

Level I facilities will conduct a self-survey for compliance and non-compliance with the rule.

The application packet submittal and the self-audit will be discussed in a webinar at a later date.

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Designation Process

Organizations Performing Surveys

- TETAF – Texas EMS, Trauma and Acute Care Foundation
  - Website – tetaf.org
- ACOG – American Congress of Obstetricians and Gynecologists

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Designation Process

The application for designation will be released June 1, 2018.

All facilities applying for Level I designation will complete a self-survey.

- Completed application
- Application Fee
- A self-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.

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Designation Process

d) Non-refundable application fees for the three-year designation period are as follows:

(1) Level I maternal facility applicants, the fees are as follows:

(A) <=100 licensed beds, the fee is $250.00; or

(B) >100 licensed beds, the fee is $750.00.

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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.

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Designation Process

- Every Texas licensed hospital that provides maternal care needs to be designated by August 31, 2020 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.

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Designation Process

(C) A facility applying for Level I designation requiring an attestation may receive a shorter term designation at the discretion of the office. A designation for less than the full three-year term will have a pro-rated application fee.

(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.

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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.

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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).

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Guiding Principles

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.

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Program Requirements

(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.

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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;

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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;

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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;

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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.

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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.

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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;

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

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Program Requirements

(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;

(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;

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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.

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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;

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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.

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Level I (Basic Care)

a) Level I (Basic Care). The Level I maternal designated facility will:

(1) provide care for pregnant and postpartum patients who are generally healthy, and do not have medical, surgical, or obstetrical conditions that present a significant risk of maternal morbidity or mortality; and

(2) have skilled personnel with documented training, competencies and annual continuing education specific for the patient population served.

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Level I (Basic Care)

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

(1) is a family medicine physician or an obstetrics and gynecology physician, with obstetrics training and experience, and with privileges in maternal care;

(2) demonstrates administrative skills and oversight of the Quality Assessment and Performance Improvement (QAPI) program; and

(3) has completed annual continuing education specific to maternal care.

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Level I (Basic Care)

c) 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.

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Level I (Basic Care)

(2) Provide care for patients with uncomplicated pregnancies 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) An obstetrics and gynecology physician with obstetrics training and experience shall be available at all times.

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Level I (Basic Care)

(4) Medical, surgical and behavioral health specialists shall be available at all times for consultation appropriate to the patient population served.

(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.

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Level I (Basic Care)

(6) The primary physician or certified nurse midwife with competence in the care of pregnant patients, whose credentials have been reviewed by the MMD and is on call:

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

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

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Level I (Basic Care)

(7) 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

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

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Level I (Basic 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.

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Level I (Basic Care)

(8) 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.

(9) Ensure that physicians providing back-up coverage shall arrive at the patient bedside within 30 minutes of an urgent request.

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Level I (Basic Care)

(10) Appropriate anesthesia, laboratory, pharmacy, radiology, respiratory therapy, ultrasonography and blood bank services shall be available on a 24-hour basis as described in §133.41 of this title (relating to Hospital Functions and Services) respectively.

(A) Anesthesia personnel with training and experience in obstetric anesthesia shall be available at all times and arrive to the patient bedside within 30 minutes of an urgent request.

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Level I (Basic Care)

(B) Laboratory and blood bank services shall have guidelines or protocols for:

(i) massive blood component transfusion;

(ii) emergency release of blood components; and

(iii) management of multiple blood component therapy.

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Level I (Basic Care)

(C) Medical Imaging Services.

(i) If preliminary reading of imaging studies pending formal interpretation is performed, the preliminary findings must be documented in the medical record.

(ii) There shall be regular monitoring of the preliminary versus final reading in the QAPI Program.

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Level I (Basic Care)

(iii) Basic ultrasonographic imaging for maternal or fetal assessment, including interpretation available at all times.

(iv) A portable ultrasound machine immediately available at all times to the labor and delivery and antepartum unit.

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Level I (Basic Care)

(D) A pharmacist shall be available for consultation at all times.

(11) Obstetrical Services.

(A) The ability to begin an emergency cesarean delivery and ensure the availability of a physician with the training, skills, and privileges to perform the surgery within a time period consistent with current standards of professional practice and maternal care.

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Level I (Basic 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.

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Level I (Basic Care)

(12) 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 immediately available at all times to the labor and delivery, antepartum and postpartum areas.

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Level I (Basic Care)

(13) 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:

(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;

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Level I (Basic 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;

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Level I (Basic 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.

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Level I (Basic Care)

(14) Perinatal Education. A registered nurse with experience in maternal care 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.

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

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Level I (Basic Care)

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

(17) Dietician or nutritionist available with appropriate training and experience for population served in compliance with the requirements in §133.41 of this title.

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Resources

Resource documents 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.

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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 occur before May 1, 2020 to ensure designation by the deadline.

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Contact Information

- Please send your name, title, facility name, email address and phone number to:
- Jewell.Potter@dshs.texas.gov

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Maternal Rule Review

- Webinars are scheduled next week for the higher level facilities.
- Plan to Schedule meetings around the state to review the maternal rule.
- Add information to the maternal designation website as it becomes available.

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Questions?

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Thank you

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512-834-6794 Office

Webinar Questions

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Maternal Rules Webinar

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