

Neonatal Rules Webinar

- Today is the Level II – Special Care Nursery Neonatal Rules Webinar.
- Power Point Presentation – which will be mailed out to participants, RACs and other stakeholders.
- Questions – will be answered at the end of the presentation.

How do I send questions?

- 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:
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Hospital Level of Care Designations for Neonatal Care

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Objectives

- Review of Subchapter J Sections that pertain to Level II Neonatal Designation.
- Detailed review of Subchapter J Sections §133.185 and §133.187.
- Discuss deadlines for designation.
- Answer questions and next steps

Subchapter J



Texas Administrative Code

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 133	HOSPITAL LICENSING
SUBCHAPTER J	HOSPITAL LEVEL OF CARE DESIGNATIONS FOR NEONATAL AND MATERNAL CARE

Rules

§133.181	Purpose
§133.182	Definitions
§133.183	General Requirements
§133.184	Designation Process
§133.185	Program Requirements
§133.186	Neonatal Designation Level I
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§133.189	Neonatal Designation Level IV
§133.190	Survey Team

TAC § 133.181 Purpose

- The purpose of this section is to implement Health and Safety Code, Chapter 241, Subchapter H, Hospital Level of Care Designations for Neonatal and Maternal Care, which requires a level of care designation of neonatal services to be eligible to receive reimbursement through the Medicaid program for neonatal services.

TAC § 133.182 Definitions

- The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

TAC § 133.182 Definitions

- (3) CAP--Corrective Action(s) Plan. A plan for the facility developed by the Office of EMS/Trauma Systems Coordination that describes the actions required of the facility to correct identified deficiencies to ensure compliance with the applicable designation requirements.
- (11) Immediate supervision--The supervisor is actually observing the task or activity as it is performed.

TAC § 133.182 Definitions

- (12) Immediately--Without delay.
- (22) PCR--Perinatal Care Region.
- (24) POC--Plan of Correction. A report submitted to the office by the facility detailing how the facility will correct any deficiencies cited in the survey report or documented in the self-attestation.

TAC § 133.182 Definitions

- (28) RAC--Regional Advisory Council as described in §157.123 of this title (relating to Regional Emergency Medical Services/Trauma Systems).

- (a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Executive Commissioner of the Health and Human Services Commission (executive commissioner) the designation of an applicant/healthcare facility as a neonatal facility at the level for each location of a facility, which the office deems appropriate.

- (b) A healthcare facility is defined under this subchapter as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

- (c) Each location shall be considered separately for designation and the office will determine the designation level for that location, based on, but not limited to, the location's own resources and level of care capabilities; Perinatal Care Region (PCR) capabilities; compliance with Chapter 133 of this title, concerning Hospital Licensing. A stand-alone children's facility that does not provide obstetrical services is exempt from obstetrical requirements. The final determination of the level of designation may not be the level requested by the facility.

- (e) PCRs.
 - 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.

- **Level II Statistics required on application:**
 - Total Live Births Annually
 - Live Births <32 Weeks and <1500 grams, Not Transferred
 - Transfers Out
 - Total Multiple Births
 - Total newborns on assisted endotracheal ventilation for >24 hours or nasal continuous positive airway pressure (NCPAP) until condition improves.
 - Transfers In

- (d) Non-refundable application fees for the three year designation period are as follows:
 - (1) Level II neonatal facility applicants, the fees are as follows:
 - (2) Level II neonatal facility applicants, the fee is \$1,500.00.

- (A) All completed applications, received on or before July 1, 2018, including the application fee, evidence of participation in the PCR, an appropriate attestation if required, survey report, and that meet the requirements of the requested designation level, will be issued a designation for the full three-year term.

- (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. The office, at its sole discretion may recommend a designation for less than the full three-year term. A designation for less than the full three-year term will have a pro-rated application fee consistent with the one, two or three-year term length.

TAC § 133.184 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.

Guiding Principles

- If the rule does not specify the exact requirement (ex. Successful NRP 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.

- (a) Designated facilities shall have a family centered philosophy. Parents shall have reasonable access to their infants at all times and be encouraged to participate in the care of their infants. The facility environment for perinatal care shall meet the physiologic and psychosocial needs of the mothers, infants, and families.

- (b) Program Plan. The facility shall develop a written plan of the neonatal program that includes a detailed description of the scope of services available to all maternal and neonatal patients, defines the neonatal patient population evaluated and/or treated, transferred, or transported by the facility, that is consistent with accepted professional standards of practice for neonatal and maternal care, and ensures the health and safety of patients.

- (1) The written plan and the program policies and procedures shall be reviewed and approved by the facility's governing body. The governing body shall ensure that the requirements of this section are implemented and enforced.
- (2) The written neonatal program plan shall include, at a minimum:
 - (A) standards of neonatal practice that the program policies and procedures are based upon that are adopted, implemented and enforced for the neonatal services it provides;
 - (B) a periodic review and revision schedule for all neonatal care policies and procedures;

- (C) written triage, stabilization and transfer guidelines for neonates and/or pregnant/postpartum women that include consultation and transport services;
- (D) ensure appropriate follow up for all neonates/infants;
- (E) provisions for disaster response to include evacuation of mothers and infants to appropriate levels of care;

- (F) a QAPI Program as described in §133.41(r) of this title (relating to Hospital Functions and Services). The facility shall demonstrate that the neonatal program evaluates the provision of neonatal care on an ongoing basis, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until a resolution is achieved. The neonatal program shall measure, analyze, and track quality indicators or 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;

- (G) requirements for minimal credentials for all staff participating in the care of neonatal 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(o)(2)(F) of this title;

- (J) the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served; and
- (K) the availability of personnel with knowledge and skills in breastfeeding.

- (c) Medical Staff. The facility shall have an organized, effective neonatal program that is recognized by the medical staff and approved by the facility's governing body. The credentialing of the medical staff shall include a process for the delineation of privileges for neonatal care.

- (d) Medical Director. There shall be an identified Neonatal Medical Director (NMD) and/or Transport Medical Director (TMD) as appropriate, responsible for the provision of neonatal care services and credentialed by the facility for the treatment of neonatal patients.

- (1) The NMD and/or TMD shall have the authority and responsibility to monitor neonatal patient care from admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program.
- (2) The responsibilities and authority of the NMD and/or TMD shall include but are not limited to:

- (A) examining qualifications of medical staff requesting neonatal privileges and makes recommendations to the appropriate committee for such privileges;
- (B) assuring staff competency in resuscitation techniques;
- (C) participating in ongoing staff education and training in the care of the neonatal patient;

- (D) oversight of the inter-facility neonatal transport;
- (E) participating in the development, review and assurance of the implementation of the policies, procedures and guidelines of neonatal care in the facility including written criteria for transfer, consultation or higher level of care;
- (F) regular and active participation in neonatal care at the facility where medical director services are provided;

- (G) ensuring that the QAPI Program is specific to neonatal/infant care, is ongoing, data driven and outcome based; and regularly participates in the neonatal QAPI meeting; and
- (H) maintaining active staff privileges as defined in the facility's medical staff bylaws.

- (e) Neonatal Program Manager (NPM). The NPM responsible for the provision of neonatal care services shall be identified by the facility and:
 - (1) be a registered nurse:
 - (2) have successfully completed and is current in the Neonatal Resuscitation Program (NRP) or an office-approved equivalent:

- (3) have the authority and responsibility to monitor the provision of neonatal patient care services from admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Program as defined in subsection (b)(2)(E) of this section.
- (4) collaborate with the NMD in areas to include, but not limited to: developing and/or revising policies, procedures and guidelines; assuring staff competency, education, and training; the QAPI Program; and regularly participates in the neonatal QAPI meeting; and
- (5) develop collaborative relationships with other NPM(s) of designated facilities within the applicable Perinatal Care Region.

(a) Level II (Special Care Nursery).

- (1) The Level II neonatal designated facility will:
 - (A) provide care for mothers and their infants of generally ≥ 32 weeks gestational age and birth weight ≥ 1500 grams who have physiologic immaturity or who have problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis; and
 - (B) either provide care, including assisted endotracheal ventilation for less than 24 hours or nasal continuous positive airway pressure (NCPAP) until the infant's condition improves, or arrange for appropriate transfer to a higher level designated facility. If the facility performs neonatal surgery, the facility shall provide the same level of care that the neonate would receive at a higher level designated facility and shall, through the QAPI Program, complete an in depth critical review of the care provided; and
 - (C) provide skilled personnel that have documented training, competencies and annual continuing education specific for the patient population served.

- (2) If a facility is located more than 75 miles from the nearest Level III or IV designated neonatal facility, and retains a neonate between 30 and 32 weeks of gestation having a birth weight of between 1250 - 1500 grams, the facility shall provide the same level of care that the neonate would receive at a higher level designated neonatal facility and shall, through the QAPI Program, complete an in depth critical review of the care provided.

- (b) Neonatal Medical Director (NMD). The NMD shall be a physician who:
 - (1) a board eligible/certified neonatologist, with experience in the care of neonates/infants and demonstrates a current status on successful completion of the Neonatal Resuscitation Program (NRP); or
 - (2) by the effective date of this rule, a pediatrician or neonatologist who:

- (A) has continuously provided neonatal care for the last consecutive two years; has experience and training in the care of neonates/infants including assisted endotracheal ventilation and NCPAP management;
- (B) maintains a consultative relationship with a board eligible/certified neonatologist;
- (C) demonstrates effective administrative skills and oversight of the QAPI Program;
- (D) demonstrates a current status on successful completion of the NRP; and
- (E) has completed continuing medical education annually specific to the care of neonates.

- (c) Program Functions and Services.
 - (1) Triage and assessment of all patients admitted to the perinatal service with identification of pregnant women with a high likelihood of delivering a neonate requiring a higher level of care be transferred prior to delivery unless the transfer is unsafe.
 - (2) Supportive and emergency care delivered by appropriately trained personnel for unanticipated maternal-fetal problems that occur during labor and delivery through the disposition of the patient.
 - (3) The ability to perform an emergency cesarean delivery.

- (4) The physician, advanced practice nurse and/or physician assistant with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on call, and:
 - (A) shall demonstrate a current status on successful completion of the NRP;
 - (B) shall have completed continuing education annually, specific to the care of neonates;

- (C) shall arrive at the patient bedside within 30 minutes of an urgent request;
- (D) if not immediately available to respond or is covering more than one facility, appropriate backup coverage shall be available, documented in an on call schedule and readily available to facility staff;
- (E) the physician, advanced practice nurse and/or physician assistant providing backup coverage, shall arrive at the patient bedside within 30 minutes of an urgent request; and

- (F) shall be on-site to provide ongoing care and to respond to emergencies when a neonate/infant is maintained on endotracheal ventilation.
- (5) Anesthesia services with pediatric experience will be provided in compliance with the requirements found in §133.41(a) of this title (relating to Hospital Functions and Services).

TAC § 133.187 Level II Designation

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TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 133	HOSPITAL LICENSING
SUBCHAPTER C	OPERATIONAL REQUIREMENTS
RULE §133.41	Hospital Functions and Services

(a) Anesthesia services. If the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified physician in accordance with the Medical Practice Act and the Nursing Practice Act. The hospital is responsible for and shall document all anesthesia services administered in the hospital.

(1) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service.

(2) Delivery of services. Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedure shall include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(A) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (1) of this subsection shall be performed within 48 hours prior to surgery.

(B) An intraoperative anesthesia record shall be provided. The record shall include any complications or problems occurring during the anesthesia including time, description of symptoms, review of affected systems, and treatments rendered. The record shall correlate with the controlled substance administration record.

(C) A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the post-anesthesia care unit and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient's oxygen saturation level.

(i) With respect to inpatients, a post-anesthesia evaluation for proper anesthesia recovery shall be performed after transfer from the post-anesthesia care unit and within 48 hours after surgery by the person administering the anesthesia, registered nurse (RN), or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(ii) With respect to outpatients, immediately prior to discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

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- (6) Dietitian or nutritionist with sufficient training and experience in neonatal and maternal nutrition, appropriate to meet the needs of the population served, shall be available and in compliance with the requirements found in §133.41(d) of this title.
- (7) Laboratory services shall be in compliance with the requirements found in §133.41(h) of this title and shall have:
 - (A) personnel on-site at all times when a neonate/infant is maintained on endotracheal ventilation;
 - (B) a blood bank capable of providing blood and blood component therapy; and
 - (C) neonatal/infant blood gas monitoring capabilities.

- (8) Pharmacy services shall be in compliance with the requirements found in §133.41(q) of this title and shall have a pharmacist with experience in neonatal/perinatal pharmacology available at all times.
 - (A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist will provide immediate supervision of the compounding process.
 - (B) If medication compounding is done for neonates/infants, the pharmacist will develop checks and balances to ensure the accuracy of the final product.
 - (C) Total parenteral nutrition (TPN) appropriate for neonates/infants shall be available.
- (9) An occupational or physical therapist with sufficient neonatal expertise shall be available to meet the needs of the population served.

- (10) Medical Imaging. Radiology services shall be in compliance with the requirements found in §133.41(s) of this title and will incorporate the "As Low as Reasonably Achievable" (ALARA) principle when obtaining imaging in neonatal and maternal patients; and shall have:
 - (A) personnel appropriately trained, in the use of x-ray and ultrasound equipment;
 - (B) personnel at the bedside within 30 minutes of an urgent request;
 - (C) appropriately trained personnel shall be available on-site to provide ongoing care and to respond to emergencies when an infant is maintained on endotracheal ventilation; and
 - (D) interpretation capability of neonatal and perinatal x-rays and ultrasound studies available at all times.

- (11) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the NMD, shall be immediately available on-site when:
 - (A) a neonate/infant is on a respiratory ventilator to provide ongoing care and to respond to emergencies; or
 - (B) a neonate/infant is on a Continuous Positive Airway Pressure (CPAP) apparatus.

- (12) Resuscitation. The facility shall have written policies and procedures specific to the facility for the stabilization and resuscitation of neonates based on current standards of professional practice.
 - (A) Each birth shall be attended by at least one provider who demonstrates current status of successful completion of the NRP whose primary responsibility is the management of the neonate and initiating resuscitation.
 - (B) At least one person must be immediately available on-site with the skills to perform a complete neonatal resuscitation including endotracheal intubation, establishment of vascular access and administration of medications.

- (C) Additional providers with current status of successful completion of the NRP shall be on-site and immediately available upon request.
- (D) Additional providers who demonstrate current status of successful completion of the NRP shall attend each neonate in the event of multiple births.
- (E) A full range of NRP equipment and supplies shall be immediately available for trained staff to perform resuscitation and stabilization on any neonate/infant.

TAC § 133.187 Level II Designation

- (13) Perinatal Education. A registered nurse with experience in neonatal care, including special care nursery, and/or perinatal care shall provide supervision and coordination of staff education.
- (14) Social services and pastoral care shall be provided as appropriate to the patient population served.
- (15) Ensure the timely evaluation of retinopathy of prematurity (ROP), monitoring, referral for treatment and follow-up, in the case of an at-risk infant.
- (16) Ensure the availability of support personnel with knowledge and expertise in lactation to meet the needs of new mothers while breastfeeding.
- (17) Ensure provisions for follow up care at discharge for infants at high risk for neurodevelopmental, medical or psychosocial complications.



Designation Deadline Dates

- Each hospital that provides neonatal care will need to be designated by September 1, 2018 to receive Medicaid funds.
- Applications must be received in our office before July 1, 2018 to be approved for designation by the Executive Commissioner before September 1, 2018.

DSHS Website

- The DSHS website is now available. Yay!
- The website will be updated with this webinar, the rule, educational opportunity dates and a Frequently Asked Questions (FAQ) section.


  Advanced

Inicio en español | Text Size:  

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Reference Center

[EMS-Trauma Systems](#) > Neonatal System Development

Neonatal System Development

 Sign up for e-mail updates

The purpose of the Neonatal Levels of Care Designation is to comply with 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 requires the development of initial rules to create the neonatal / maternal level of care designation by March 1, 2018. Currently only the neonatal level of care designation rule has been developed and is in the rule adoption process, expected to become effective on or about May 20, 2016. The designation for neonatal level of care is an eligibility requirement for Medicaid reimbursement beginning September 1, 2018.

Proposed Neonatal Designation Rule

The official publication was posted on the Texas Register November 20, 2015.
[Hospital Level of Care Designations for Neonatal and Maternal Care](#) (HTML)

Last updated March 21, 2016

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Neonatal Designation Coordinator

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Contact Information

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Questions?

