

Legend: (Proposed New Rules)
Regular Print = Proposed new language

§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.

§133.182. Definitions.

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

(1) Attestation—a written statement, signed by the Chief Executive Officer of the facility, verifying the results of a self-survey represent a true and accurate assessment of the facility’s capabilities required in this subsection.

(2) Birth weight--The weight of the neonate recorded at time of birth.

(A) Low birth weight--Birth weight less than 2500 grams (5 lbs., 8 oz.);

(B) Very low birth weight (VLBW)--Birth weight less than 1500 grams (3 lbs., 5 oz.); and

(C) Extremely low birth weight (ELBW)--Birth weight less than 1000grams (2 lbs., 3 oz.).

(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.

(4) Commission--The Health and Human Services Commission.

(5) Department--The Department of State Health Services.

(6) Designation--A formal recognition by the executive commissioner of a facility's neonatal or maternal care capabilities and commitment, for a period of three years.

(7) EMS--Emergency medical services used to respond to an individual's perceived need for immediate medical care.

- (8) Executive commissioner--The executive commissioner of the Health and Human Services Commission.
- (9) Gestational age--The age of a fetus or embryo at a specific point during a woman's pregnancy.
- (10) High-risk Infant--A newborn that has a greater chance of complications because of conditions that occur during fetal development, pregnancy conditions of the mother, or problems that may occur during labor and/or birth.
- (11) Immediate supervision--The supervisor is actually observing the task or activity as it is performed.
- (12) Immediately--Without delay.
- (13) Infant--A child from birth to 1 year of age.
- (14) Lactation consultant--A health care professional who specializes in the clinical management of breastfeeding.
- (15) Maternal--Pertaining to the mother.
- (16) NCPAP--Nasal continuous positive airway pressure.
- (17) Neonate--An infant from birth through 28 completed days after.
- (18) NMD--Neonatal Medical Director.
- (19) NPM--Neonatal Program Manager.
- (20) Neonatal Resuscitation Program (NRP)--A resuscitation course that was developed and is administered jointly by the American Heart Association/American Academy of Pediatrics.
- (21) Office--Office of Emergency Medical Services (EMS)/Trauma Systems Coordination.
- (22) PCR--Perinatal Care Region.
- (23) Perinatal--Of, relating to, or being the period around childbirth, especially the five months before and one month after birth.
- (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.

- (25) Premature/prematurity--Birth at less than 37 weeks of gestation.
- (26) Postpartum--The six-week period following delivery.
- (27) QAPI--Quality Assessment and Performance Improvement Program.
- (28) RAC--Regional Advisory Council as described in §157.123 of this title (relating to Regional Emergency Medical Services/Trauma Systems).
- (29) Attestation--A written statement, signed by the Chief Executive Officer of the facility, verifying the results of a self-survey represent a true and accurate assessment of the facility's capabilities required in this subsection.
- (30) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.
- (31) TSA--Trauma Service Area as described in §157.122 of this title relating to (Trauma Service Areas).
- (32) Urgent--Requiring immediate action or attention.

§133.183. General Requirements.

(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 are exempt from obstetrical requirements. The final determination of the level of designation may not be the level requested by the facility.

(1) Level I (Well Nursery). The Level I neonatal designated facility will:

(A) provide care for mothers and their infants of ≥ 35 weeks gestational age who have routine, transient perinatal problems; and

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

(2) The Level II (Special Care Nursery). 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; and

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

(3) Level III (Neonatal Intensive Care Unit (ICU)). The Level III neonatal designated facility will:

(A) provide care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support;

(B) have access for consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or at another appropriate designated facility;

(C) have skilled medical staff and personnel with documented training, competencies and continuing education specific for the patient population served;

(D) facilitate transports; and

(E) provide outreach education to lower level designated facilities.

(4) Level IV (Advanced Neonatal ICU). The Level IV neonatal designated facility will:

(A) provide care for mothers and comprehensive care of their infants of all gestational ages with the most complex and critically ill neonates/infants with any medical problems, and/or requiring sustained life support;

(B) have a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive on-site for face to face consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions;

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

(D) facilitate transports; and

(E) provide outreach education to lower level designated facilities.

(d) Facilities seeking neonatal facility designation shall be surveyed through an organization approved by the office to verify that the facility is meeting office-approved relevant neonatal facility requirements. The facility shall bear the cost of the survey.

(e) PCRs.

(1) The PCRs are established for descriptive and regional planning purposes and not for the purpose of restricting patient referral.

(2) The PCR will consider and facilitate transfer agreements through regional coordination.

(3) A written plan identifies all resources available in the PCRs for perinatal care including resources for emergency and disaster preparedness.

(4) The PCRs are geographically divided by counties and are integrated into the existing 22 TSAs and the applicable Regional Advisory Council (RAC) of the TSA provided in §157.122 and §157.123 of this title; will be administratively supported by the RAC; and will have fair and equitable representation on the board of the applicable RAC.

(5) Multiple PCRs can meet together for the purposes of mutual collaboration.

§133.184. Designation Process.

(a) Designation application submittal. The applicant shall submit the following documents to the Office of EMS/Trauma Systems Coordination (office):

(1) an accurate and complete designation application form for the appropriate level of designation, including full payment of the designation fee as listed in subsection (d) of this section;

(2) any subsequent documents submitted by the date requested by the office;

(3) a completed neonatal attestation for Level I applicants, a designation survey report, including patient care reviews, if required by the office, completed not later than 120 days prior to the date of the application;

(4) a plan of correction (POC), detailing how the facility will correct any deficiencies cited in the survey report, to include: the corrective action; the title of the person responsible for ensuring the correction(s) is implemented; how the corrective action will be monitored; and the date by which the POC will be completed; and

(5) evidence of participation in the applicable Perinatal Care Region (PCR).

(b) Renewal of designation. The applicant shall submit the documents described in subsection (a)(1) - (5) of this section to the office not more than 180 days prior to the designation expiration date and at least 60 days prior to the designation expiration date.

(c) If a facility seeking designation fails to meet the requirements in subsection (a)(1) - (5) of this section, the application shall be denied.

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

(1) Level I neonatal 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.

(2) Level II neonatal facility applicants, the fee is \$1,500.00.

(3) Level III neonatal facility applicants, the fee is \$2,000.00.

(4) Level IV neonatal facility applicants, the fee is \$2,500.00.

(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.

(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.

(e) If a facility disagrees with the level(s) determined by the office to be appropriate for initial designation or re-designation, it may make an appeal in writing not later than 60 days to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation as to why designation at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.

(1) The written appeal may include a signed letter(s) from the executive board of its PCR or individual healthcare facilities and/or EMS providers within the affected PCR with an explanation as to why designation at the level determined by the office would not be in the best interest of the citizens of the affected PCR or the citizens of the State of Texas.

(2) If the office upholds its original determination, the director of the office will give written notice of such to the facility not later than 30 days of its receipt of the applicant's complete written appeal.

(3) The facility may, not later than 30 days of the office's sending written notification of its denial, submit a written request for further review. Such written appeal shall then go to the Assistant Commissioner of the Division for Regulatory Services (assistant commissioner).

(f) The surveyor(s) shall provide the facility with a written, signed survey report regarding their evaluation of the facility's compliance with neonatal program requirements. This survey report shall be forwarded to the facility no later than 30 days of the completion date of the survey. The facility is responsible for forwarding a copy of this report to the office if it intends to continue the 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 neonatal program requirements.

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

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

(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).

(A) The facility shall submit to the office reports as required and outlined in the CAP. The office may require a second survey to ensure compliance with the requirements. The cost of the survey will be at the expense of the facility.

(B) If the office substantiates action that brings the facility into compliance with the requirements, the office shall recommend designation to the executive commissioner.

(C) If a facility disagrees with the office's decision regarding its designation application or status, it may request a secondary review by a designation review committee. Membership on a designation review committee will:

- (i) be voluntary;
- (ii) be appointed by the office director;
- (iii) be representative of neonatal care providers and appropriate levels of designated neonatal facilities; and

(iv) include representation from the office and the Perinatal Advisory Council.

(D) If a designation review committee disagrees with the office's recommendation for corrective action, the records shall be referred to the assistant commissioner for recommendation to the executive commissioner.

(E) If a facility disagrees with the office's recommendation at the end of the secondary review, the facility has a right to a hearing, in accordance with a hearing request referenced in §133.121(9) of this title (relating to Enforcement Action), and Government Code, Chapter 2001.

§133.185. Program Requirements.

(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) provisions for disaster response to include evacuation of mothers and infants to appropriate levels of care;

(E) a Quality Assessment and Performance Improvement (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;

(F) requirements for minimal credentials for all staff participating in the care of neonatal patients;

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

(H) a perinatal staff registered nurse as a representative on the nurse staffing committee under §133.41(o)(2)(F) of this title;

(I) the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served; and

(J) 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.

§133.186. Neonatal Designation Level I.

- (a) Level I (Well Nursery). The Level I neonatal designated facility will:
 - (1) provide care for mothers and their infants of ≥ 35 weeks gestational age who have routine, transient perinatal problems; and
 - (2) have skilled personnel with documented training, competencies and continuing education specific for the patient population served.
- (b) Neonatal Medical Director (NMD). The NMD shall be a physician who:
 - (1) is a currently practicing pediatrician, family medicine physician, or physician specializing in obstetrics and gynecology with experience in the care of neonates/infants;
 - (2) demonstrates a current status on successful completion of the Neonatal Resuscitation Program (NRP);
 - (3) demonstrates effective administrative skills and oversight of the Quality Assessment and Performance Improvement (QAPI) Program; and
 - (4) 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 patients who are at high risk of delivering a neonate that requires a higher level of care who will be transferred to a higher level facility prior to delivery unless the transfer would be 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 primary physician, advanced practice nurse and/or physician assistant with special competence in the care of neonates, who has been approved by the NMD and is on call, and:

(A) shall demonstrate a current status on successful completion of the American Heart Association/American Academy of Pediatrics for the resuscitation of all infants NRP;

(B) has 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, be provided appropriate backup coverage who shall be available, documented in an on call schedule and readily available to facility staff; and

(E) if the physician, advanced practice nurse and/or physician assistant is providing backup coverage, shall arrive at the patient bedside within 30 minutes of an urgent request.

(5) Availability of appropriate anesthesia, laboratory, radiology, ultrasonography and blood bank services on a 24 hour basis as described in §133.41(a), (h), and (s) of this title, respectively.

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

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

(6) A pharmacist shall be available for consultation on a 24 hour basis.

(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.

(7) Resuscitation. The facility shall have appropriately trained staff, policies and procedures for the stabilization and resuscitation of neonates based on current standards of professional practice; shall ensure the availability of personnel who can stabilize distressed neonates including those ≤ 35 weeks gestation until they can be transferred to a higher level facility.

(A) Each birth shall be attended by at least one person who demonstrates a current status of successful completion of the NRP whose primary responsibility is for 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) Basic NRP equipment and supplies shall be immediately available for trained staff to perform resuscitation and stabilization on any neonate/infant.

(8) Perinatal Education. A registered nurse with experience in neonatal and/or perinatal care shall provide supervision and coordination of staff education.

(9) Ensures the availability of support personnel with knowledge and skills in breastfeeding to meet the needs of new mothers.

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

§133.187. Neonatal Designation Level II.

(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) will 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; 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 is:

(1) a board eligible/certified neonatologist, or board eligible/certified pediatrician 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 Quality Assessment and Performance Improvement 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 the 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, who has been approved 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 back-up 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 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).

(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 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” 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.

(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, 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.

§133.188. Neonatal Designation Level III.

(a) Level III (Neonatal Intensive Care Unit (ICU)). The Level III neonatal designated facility will:

(1) provide care for mothers and comprehensive care of their infants of all gestational ages with mild to critical illnesses or requiring sustained life support;

(2) have access for consultation to a full range of pediatric medical subspecialists and pediatric surgical specialists, and the capability to perform major pediatric surgery on-site or through arrangement for appropriate transfer to a higher level designated facility;

(3) have skilled medical staff and personnel with documented training, competencies and continuing education specific for the patient population served;

(4) facilitate transports; and

(5) provide outreach education to lower level designated facilities.

(b) Neonatal Medical Director (NMD). The NMD shall be a physician who is a board eligible/certified neonatologist and demonstrates a current status on successful completion of the Neonatal Resuscitation Program (NRP).

(c) If the facility has its own transport program, there shall be an identified Transport Medical Director (TMD). The TMD or Co-Director shall be a physician who is a board eligible/certified neonatologist or pediatrician with expertise and experience in neonatal/infant transport.

(d) Program Functions and Services.

(1) Triage and assessment of all patients admitted to the perinatal service with identification of pregnant patients who are at high risk of delivering a neonate that requires a higher level of care who will be transferred to a higher level facility prior to delivery unless the transfer is unsafe.

(2) Supportive and emergency care shall be 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 within 30 minutes.

(4) At least one of the following neonatal providers shall be on-site at all times and includes pediatric hospitalists, neonatologists, and/or neonatal nurse practitioners, as appropriate, who have demonstrated competence in management of severely ill neonates/infants, who has been approved by the NMD and is on call, and:

(A) has a current status of successful completion of the NRP;

(B) has completed continuing education annually, specific to the care of neonates;

(C) if the on-site provider is not a neonatologist, a neonatologist shall be available for consultation at all times and shall arrive on-site within 30 minutes of an urgent request;

(D) if the neonatologist is covering more than one facility, the facility must ensure that a back-up neonatologist be available, documented in an on call schedule and readily available to facility staff; and

(E) ensure that the neonatologist providing back-up coverage shall arrive on-site within 30 minutes.

(5) When neonatal surgery or invasive procedures are required, anesthesiologists with pediatric expertise, shall directly provide the anesthesia care to the neonate, in compliance with the requirements found in §133.41(a) of this title (relating to Hospital Functions and Services).

(6) A dietitian or nutritionist who has special training in perinatal and neonatal nutrition and can plan diets that meet the special needs of neonates/infants is available at all times, in compliance with the requirements found in §133.41(d) of this title.

(7) Laboratory services shall be in compliance with the requirements found at §133.41(h) of this title and shall have:

- (A) laboratory personnel on-site at all times;
- (B) perinatal pathology services available;
- (C) a blood bank capable of providing blood and blood component therapy; and
- (D) neonatal blood gas monitoring capabilities.

(8) Pharmacy services shall be in compliance with the requirements found in §133.41(q) of this title and will have a pharmacist, with experience in neonatal/pediatric and 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 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; will incorporate the “As Low as Reasonably Achievable” principle when obtaining imaging in neonatal and maternal patients; and shall have:

(A) personnel appropriately trained in the use of x-ray equipment, ultrasound, computed tomography, magnetic resonance imaging, and/or cranial ultrasound, echocardiography equipment on-site and available at all times; fluoroscopy shall be available;

(B) interpretation of neonatal and perinatal diagnostic imaging studies by radiologists with pediatric expertise at all times; and

(C) pediatric echocardiography with pediatric cardiology interpretation and consultation within one hour of an urgent request.

(11) Speech language pathologist with neonatal/infant experience shall be available to evaluate and manage feeding and/or swallowing disorders.

(12) 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.

(13) Resuscitation. Written policies and procedures shall be 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 who demonstrate current status of successful completion of the NRP shall attend each neonate in the event of multiple births.

(D) Each high-risk delivery shall have in attendance at least two providers who demonstrate current status of successful completion of the NRP whose only responsibility is the management of the neonate.

(E) A full range of resuscitative equipment, supplies, and medications shall be immediately available for trained staff to perform complete resuscitation and stabilization on each neonate/infant.

(14) Perinatal education. A registered nurse with experience in neonatal care, including neonatal intensive care, and/or perinatal care shall provide supervision and coordination of staff education.

(15) Pastoral care and/or counseling shall be provided as appropriate to the patient population served.

(16) Social services shall be provided as appropriate to the patient population served.

(17) Ensure the timely evaluation of retinopathy of prematurity, monitoring, referral for treatment and follow-up, in the case of an at-risk infant.

(18) A certified lactation consultant shall be available at all times.

(19) Ensure provisions for follow up care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications.

§133.189. Neonatal Designation Level IV.

(a) Level IV (Advanced Neonatal Intensive Care Unit). The Level IV neonatal designated facility will:

(1) provide care for the mothers and comprehensive care of their infants of all gestational ages with the most complex and critically ill neonates/infants with any medical problems, and/or requiring sustained life support;

(2) ensure that a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists are available to arrive on-site for face to face consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions;

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

(4) facilitate transports; and

(5) provide outreach education to lower level designated facilities.

(b) Neonatal Medical Director (NMD). The NMD shall be a physician who is a board eligible/certified neonatologist and demonstrates a current status on successful completion of the Neonatal Resuscitation Program (NRP).

(c) If the facility has its own transport program, there shall be an identified Transport Medical Director (TMD). The TMD and/or Co-Director shall be a physician who is a board eligible/certified neonatologist.

(d) Program Functions and Services.

(1) Triage and assessment of all patients admitted to the perinatal service with identification of pregnant patients who are at high risk of delivering a neonate that requires a

higher level of care who will be transferred to another facility prior to delivery unless the transfer is unsafe.

(2) Supportive and emergency care shall be 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 within 30 minutes.

(4) Board certified/board eligible neonatologists whose credentials have been approved by the NMD and is on call, and who:

(A) shall demonstrate a current status on successful completion of the NRP;

(B) have completed continuing education annually, specific to the care of neonates; and

(C) shall be on-site and immediately available at the neonate/infant bedside as requested.

(5) Anesthesiologists with pediatric expertise shall directly provide anesthesia care to the neonate, in compliance with the requirements in §133.41(a) of this title.

(6) A dietitian or nutritionist who has special training in perinatal and neonatal nutrition and can plan diets that meet the special needs of neonates in compliance with the requirements in §133.41(d) of this title.

(7) A comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists will be immediately available to arrive on-site for face to face consultation and care for an urgent request.

(8) Laboratory services shall be in compliance with the requirements in §133.41(h) of this title and shall have:

(A) appropriately trained and qualified laboratory personnel on-site at all times;

(B) perinatal pathology services;

(C) a blood bank capable of providing blood and blood component therapy; and

(D) neonatal/infant blood gas monitoring capabilities.

(9) Pharmacy services shall be in compliance with the requirements in §133.41(q) of this title and shall have a pharmacist, with experience in neonatal/pediatric and perinatal pharmacology available on-site 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 shall develop and implement checks and balances to ensure the accuracy of the final product.

(C) Total parenteral nutrition appropriate for neonates/infants shall be available.

(10) An occupational or physical therapist with neonatal expertise shall be available to meet the needs of the population served.

(11) Medical Imaging. Radiology services shall be in compliance with the requirements in §133.41(s) of this title will incorporate the “As Low as Reasonably Achievable” principle when obtaining imaging in neonatal and maternal patients; and shall have:

(A) personnel appropriately trained in the use of x-ray equipment, ultrasound, computed tomography, magnetic resonance imaging, echocardiography and/or cranial ultrasound equipment and fluoroscopy on-site at all times;

(B) neonatal and perinatal diagnostic imaging studies available at all times with interpretation by radiologists with pediatric expertise, available within one hour of an urgent request; and

(C) pediatric echocardiography with pediatric cardiology interpretation and consultation within one hour of an urgent request.

(12) Speech language pathologist with neonatal expertise shall be available to evaluate and manage feeding and/or swallowing disorders.

(13) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the Neonatal Medical Director, shall be on-site and immediately available.

(14) Resuscitation. The facility shall have written policies and procedures specific to the facility for the stabilization and resuscitation of neonates/infants 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 who demonstrate current status of successful completion of the NRP shall attend each neonate in the event of multiple births.

(D) Each high-risk delivery shall have in attendance at least two providers who demonstrate current status of successful completion of the NRP whose only responsibility is the management of the neonate.

(E) A full range of resuscitative equipment, supplies and medications shall be immediately available for trained staff to perform resuscitation and stabilization on each neonate/infant.

(15) Perinatal Education. A registered nurse with experience in neonatal care, including neonatal intensive care, and/or perinatal care shall provide supervision and coordination of staff education.

(16) Pastoral care and/or counseling shall be provided as appropriate to the patient population served.

(17) Social services shall be provided as appropriate to the patient population served.

(18) The facility must have a documented policy regarding the timely evaluation of retinopathy of prematurity in the event that an infant at risk is present, and a documented policy for the monitoring, treatment and follow-up of retinopathy of prematurity.

(19) A certified lactation consultant shall be available at all times.

(20) Ensure provisions for follow up care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications.

§133.190. Survey Team.

(a) The survey team composition shall be as follows:

(1) Level I facilities neonatal program staff shall conduct a self-survey, documenting the findings on the approved office survey form. The office may periodically require validation of the survey findings, by an on-site review conducted by department staff.

(2) Level II facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum of one neonatologist and one neonatal nurse, all active in the management of neonatal patients at a facility providing a higher level of neonatal care.

(3) Level III facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum of one neonatologist and one neonatal nurse, all approved in advance by the office and currently active in the management of neonatal patients. An additional surveyor may be requested by the facility or at the discretion of the office.

(4) Level IV facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum of one neonatologist, a pediatric surgeon and one neonatal nurse, all approved in advance by the office and currently active in the management of neonatal patients. If the facility holds a current pediatric surgery verification by the American College of Surgeons, the facility may be exempted from having a pediatric surgeon as a member of the survey team.

(b) Office-credentialed surveyors must meet the following criteria:

(1) have at least three years of experience in the care of neonatal patients;

(2) be currently employed/practicing in the coordination of care for neonatal patients;

(3) have direct experience in the preparation for and successful completion of neonatal facility verification/designation;

(4) have successfully completed an office-approved neonatal facility site surveyor course and be successfully re-credentialed every four years; and

(5) have current credentials as follows:

(A) a registered nurse who is current in the NRP;

(B) a physician who is board certified in the respective specialty, and current in the NRP; and

(C) have successfully completed an office approved site survey internship.

(c) All members of the survey team, except department staff, shall come from a Perinatal Care Region outside the facility's location and at least 100 miles from the facility. There shall be no business or patient care relationship or any potential conflict of interest between the surveyor or the surveyor's place of employment and the facility being surveyed.

(d) The survey team shall evaluate the facility's compliance with the designation criteria by:

(1) reviewing medical records; staff rosters and schedules; documentation of Quality Assessment and Performance Improvement Program activities including peer review; the program plan; policies and procedures; and other documents relevant to neonatal care;

- (2) reviewing equipment and the physical plant;
- (3) conducting interviews with facility personnel; and
- (4) evaluating appropriate use of telemedicine capabilities where applicable.

(e) All information and materials submitted by a facility to the office under Health and Safety Code, §241.183(d), are subject to confidentiality as articulated in Health and Safety Code, §241.184, Confidentiality; Privilege, and are not subject to disclosure under Government Code, Chapter 552, or discovery, subpoena, or other means of legal compulsion for release to any person.