(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 reviewed 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) Pediatric anesthesiologists 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 shall be on-site and available at all times; personnel appropriately trained in ultrasound, computed tomography, magnetic resonance imaging, echocardiography and/or cranial ultrasound equipment shall be on-site
within one hour of an urgent request; and fluoroscopy shall be available 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, 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 ensure the timely evaluation and treatment of retinopathy of prematurity on-site by a pediatric ophthalmologist or retinal specialist with expertise in 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.

**Source Note:** The provisions of this §133.189 adopted to be effective June 9, 2016, 41 TexReg 4011