§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 facility’s Chief Executive Officer, verifying the results of a self-survey represent a complete and accurate assessment of the facility’s capabilities required in this subchapter.

(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 1000 grams (2 lbs., 3 oz.).

(3) CAP--Corrective Action Plan. A plan for the facility developed by the Office of EMS/Trauma Systems Section 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 level of 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 patient’s [woman’s] pregnancy.

(10) High-risk infant[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.]

(11)(12) Immediately--Without delay or within 15 minutes.

(12)(13) Infant--A child from birth to 1 year of age.

(13) Inter-facility transport--Movement of a patient from one hospital to another.

(14) Lactation consultant--A health care professional who specializes in the clinical management of breastfeeding.

(15) Focused Survey--A department-defined modified facility survey by a department-approved survey organization or the department. The specific goal of this survey is to review an identified non-compliant designation requirement to remove a contingency or requirement deficiencies.

(16)(15) Maternal--Pertaining to the pregnant and/or postpartum patient[mother].

(17)(16) NCPAP--Nasal continuous positive airway pressure.

(18)(17) Neonate--An infant from birth through 28 completed days after.

(19)(18) NMD--Neonatal Medical Director.

(20)(19) NPM--Neonatal Program Manager.

(21)(20) Neonatal Resuscitation Program (NRP)--A resuscitation course [that was] developed and [is] administered jointly by the American Heart Association/American Academy of Pediatrics.

(22)(21) On-site--Within the physical premises of the licensed facility[hospital] [Office of Emergency Medical Services (EMS)/Trauma Systems Coordination].
Operation Committee - This multidisciplinary committee is charged with the administrative oversight of the neonatal program and has the responsibility and oversight for approving defined neonatal policies, procedures, and guidelines all phases of neonatal care provided, defining the necessary staff competencies, monitoring compliance to designation requirements, and the aggregate overview of all QAPI activities, action plans, and outcomes.

Perinatal--Of, relating to, or being the period around childbirth, especially the five months before and one month after birth.

Perinatal Care Region (PCR)--The Perinatal Care Regions are established for descriptive and regional planning purposes. The PCRs are geographically divided by counties and are integrated into the existing 22 Trauma Service Areas (TSA) and the applicable Regional Advisory Council (RAC) of the TSA provided in §157.122 and §157.123 of this title.

POC--Plan of Correction. A report submitted to the department by the facility detailing how the facility will correct any deficiencies cited in the survey report or documented in the self-attestation.

Premature/prematurity--Birth at less than 37 weeks of gestation.

Postpartum--The six-week period following delivery.

QAPI Plan [Program]--Quality Assessment and Performance Improvement Plan[Program]. The facility’s continual assessment of compliance to the written standards of care or systems of care, and review of morbidity, and mortality to identify variances in care, the level of harm, level of review, opportunities for improvement with defined action plans that are monitored until the variance is corrected with the goal of improving patient and system outcomes.

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

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.

TSA--Trauma Service Area as described in §157.122 of this title relating to (Trauma Service Areas).

Urgent—Requiring immediate action or attention.

§133.183. General Requirements.

The Office of Emergency Medical Services (EMS)/Trauma Systems Section will recommend to the Executive Commissioner of the
Health and Human Services Commission (executive commissioner) the neonatal designation of an applicant/hospital at the appropriate level for each location, which the office deems appropriate.

(b) The department determines requirements for the levels of neonatal designation. Facilities seeking neonatal designation must demonstrate compliance to department-approved requirements and have the compliance validated by a department-approved survey organization. The facility must submit:

(1) a completed application for the neonatal designation;
(2) the designation site survey summary, including the medical record reviews;
(3) evidence of participation in the applicable PCR; and
(4) full payment of the non-refundable, non-transferrable designation fee as listed at dshs.texas.gov.

(c) Minimum requirements for neonatal designation.

(1) A 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.

(2) Each location will be considered separately for designation and the department will determine the designation level for each location, based on, but not limited to, the location's own resources and level of care capabilities; Perinatal Care Region (PCR) capabilities; and 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.

(3) The four levels of neonatal designation are:

(A) Level I (Well Care). The Level I neonatal designated facility will:

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

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

(iii) if an infant <35 weeks gestational age is retained, the facility
will[shall] provide the same level of care that the neonate would receive at a higher level designated neonatal facility and will[shall], through the QAPI Plan [program], complete an in-depth critical review and assessment of the care provided.

**(B)[(2)]** The Level II (Special Care[Nursery]). The Level II neonatal designated facility will:

- **(i)[(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

- **(ii)[(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

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

**(C)[(3)]** Level III (Neonatal Intensive Care[ICU]). The Level III neonatal designated facility will:

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

- **(ii)[(B)]** provide 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;

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

- **(iv)[(D)]** facilitate transports; and

- **(v)[(E)]** provide outreach education to lower-level designated facilities.

**(D)[(4)]** Level IV (Advanced Neonatal Intensive Care[ICU]). The Level IV neonatal designated facility will:

- **(i)[(A)]** provide [care for mothers and] comprehensive care for[of their] infants of all gestational ages with the most complex and critically ill neonates/infants and/or requiring sustained life support;
(ii)[(B)] have a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists available to arrive on-site in person for [face-to-face] consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions;

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

(iv)[(D)] facilitate transports; and

(v)[(E)] provide outreach education to lower-level designated facilities.

(4)[(d)] Facilities seeking neonatal facility designation must undergo an on-site or virtual survey as outlined in this section[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].

(A) The facility[hospital] is responsible for scheduling a neonatal designation survey through a department-approved survey organization.

(B) The facility[hospital] notifies the department of the neonatal designation survey date.

(C) The facility[hospital] is responsible for expenses associated with the neonatal designation survey.

(D) The facility[hospital] will not accept surveyors with any conflict of interest. If a conflict of interest is present, the facility[hospital] must decline the assigned surveyor through the surveying organization. A conflict of interest exists when the surveyor has a current or past relationship with the facility[hospital] or key facility[hospital] staff members. The conflict of interest includes a previous working relationship, residency training, or participation in a consultation program for the facility[hospital] within the past five years. Surveyors cannot be from the same TSA region or a contiguous region of the facility’s location. Level IV facilities should have surveyors located out-of-state. If the survey occurs with a surveyor who has a defined conflict of interest, the survey report will not be accepted by the department.

(E) The department, at its discretion, may appoint an observer to accompany the survey team, with the observer costs borne by the department.

(F) The survey team evaluates the facility’s[hospital’s] compliance with the department-approved requirements and documents all noncompliance issues identified in the survey summary and medical record reviews [patient care reviews].
(G) The facility[hospital] must provide the survey team access to records and
documentation regarding the QAPI Plan to include peer review activities and
minutes related to the neonatal patient. Failure to provide access to these records
will result in a determination by the department that the facility[hospital] seeking
neonatal[ ] designation is not in compliance with Texas Health and Safety Code,
Chapter 241, and the rules in this chapter.

[(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) A facility[hospital] seeking neonatal[ ] designation must submit a completed
[Designation] application packet. [The applicant shall submit the packet, inclusive-
of the following documents to the Office of EMS/Trauma Systems Coordination-
(office) within 120 days of the facility’s survey date:]

—(1) The completed application packet includes:

   — (A)[(1)] an accurate and complete neonatal designation application
   [form] for the requested [appropriate] level of designation; and

   — (B)[, including] full payment of the non-refundable, non-transferrable
designation fee as listed at dshs.texas.gov.[(d)] of this section];

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

   — (C)[(3)] a completed neonatal attestation and self-survey report for Level I
applicants or the documented neonatal designation site survey summary that
includes the requirement compliance findings and the medical record reviews for
Levels II, III and IV applicants, and the report is submitted to the department no
later than 60 days after the neonatal designation site survey date. A designation survey report, including patient care reviews if required by the office, for Level II, III, and IV applicants;

(D)[(4)] if required by the department, a plan of correction (POC) that addresses all requirements with identified noncompliance findings in the survey report and the POC must include: 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]

_____ (i) a statement of the cited noncompliant requirement;

_____ (ii) a statement describing the corrective action by the facility seeking neonatal[] designation to ensure compliance with the defined requirement;

_____ (iii) the title of the individuals responsible for ensuring the corrective actions are implemented;

_____ (iv) the date the corrective actions will be implemented;

_____ (v) how the corrective actions will be monitored;

_____ (vi) supporting documentation of the requirements reaching compliance; and

_____ (vii) corrective actions will be implemented within 60 days from the date the facility seeking neonatal[] designation received the official site survey summary;

(E)[(5)] written evidence of continual participation in the applicable PCR(s); and[Perinatal Care Region (PCR).]

(F) any subsequent documents submitted by the date requested by the department.

(b) If a facility[] seeking neonatal[] designation fails to submit the required application documents and full payment of the non-refundable, non-transferrable designation fee as listed in subsection (a)(1)(A) – (F) of this section, the application will not be processed. 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) The neonatal[] designation renewal process, a request to change the level of designation, or a change in ownership requiring re-designation follows the same
requirements outlined in subsection (a)(1)(A) – (F) of this section. If a facility-seeking designation fails to meet the requirements in subsection (a)(1) – (5) of this section, the application shall be denied.

(d) The facility[] will submit the required documents described in subsection (a)(1)(A) – (F) of this section, to the department no later than 90 days before the facility’s current neonatal designation expiration date. 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) The facility[] will submit the neonatal designation fee in full payment with the required application documents. 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 of how the facility meets the requirements for the designation level.

(1) 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.

(2) 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 facility has the right to withdraw its application for neonatal designation
any time before being recommended for designation by the department.

(g) The facility must seek renewal of its neonatal designation 90 days before the
expiration date of its facility's neonatal designation.

(h) The facility's neonatal designation will expire if the facility fails to provide a
complete neonatal designation application packet to the department by its current
designation expiration date.

(i) The neonatal designation application packet, in its entirety including any
recommendations or follow-up from the department, must be written as an element
of the facility's neonatal quality assessment performance improvement plan (QAPI
Plan) and subject to confidentiality as described in Texas Health and Safety Code,
§241.184, Confidentially; Privilege.

(j) The department reviews the application packet to determine the neonatal designation recommendation.

(k) The department defines the final neonatal designation level awarded to the
facility and this designation level may be different than the level requested based
on the neonatal survey designation summary report.

(l) If the department determines the facility meets the requirements for
neonatal designation, the department provides the facility with a designation
award letter and a designation certificate.

(1) The facility shall display its neonatal designation certificate in a public
area of the licensed premises that is readily visible to patients, employees, and
visitors.

(2) The facility shall not alter the neonatal designation certificate. Any
alteration voids neonatal designation for the remainder of that designation period.

(m) The survey organization shall provide the facility with a
written, signed survey summary including medical record reviews regarding their evaluation of the facility’s compliance with neonatal program requirements. This survey summary 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 the survey summary and medical record reviews to the department with the required documents to continue the designation process within 60 days of completion of the site survey (virtual or in-person survey).

[(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.]

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

(o)(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.

(p)(3) If a facility does not meet the requirements for the level of designation requested, the department 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.

(q)(4) If a facility is designated with noncompliance to requirements, the department shall notify the facility of the identified deficiencies. The department shall prepare a corrective action plan (CAP) to guide the facility in correcting deficiencies. The CAP may include requiring the facility to have a focused survey.

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

(B) If the department substantiates action that brings the facility into compliance with the requirements, the department will remove the contingencies.

(r) If a facility disagrees with the level determined by the department, it may make an appeal in writing to the EMS/Trauma Systems Section Director not later than 30 days of the designation award. The written appeal must be from the facility’s Chief Executive Officer or Chief Nursing Officer with documented evidence of compliance of how the facility meets the requirements for the designation level.

(1) The EMS/Trauma Systems Section shall establish a three-person appeal panel to assess the facility’s designation appeal. The appeal panel includes a representative of the department, a representative of the commission, and an
independent person who has expertise in the specialty area for which the facility is seeking a level of care designation, is not an employee of or affiliated with either the department or the commission and does not have a conflict of interest with the facility, department, or commission. The department will establish a panel of seven independent individuals to assist with designation appeals. These individuals must rotate after each appeal.

(A) The independent individual must apply for an appeal panel position on a form prescribed by the department.

(B) Individuals applying for this role will be approved by the commissioner.

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

[(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.]

(3) If the designation appeal panel disagrees with the department's original designation recommendation for corrective action, the records shall be referred to the assistant commissioner for recommendation to the executive commissioner. Appropriate level of neonatal designation shall be awarded.

(s) If a facility disagrees with the designation appeal panel's decision regarding its designation status, 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 Texas Government Code, Chapter 2001.

(t) Exceptions and Notifications

(1) A designated neonatal facility must provide written notification of any temporary event or decision preventing the facility from complying with requirements of its current neonatal designation level. This notification shall outline...
the neonatal facility requirements that the facility cannot comply with. The notification shall be provided to the following:

(A) all emergency medical services (EMS) providers that transfer neonatal patients to or from the designated neonatal facility;

(B) the health care facilities to which it customarily transfers-out or transfers-in neonatal patients;

(C) applicable PCRs and RACs; and

(D) the department.

(2) If the designated neonatal facility is unable to comply with requirements to maintain its current designation status, it shall submit to the department a POC as described in subsection (a)(1)(D)(i)-(vii) of this section, and a request for a temporary exception to the requirements. Any request for an exception shall be submitted in writing from the chief executive officer of the facility and define the facility’s plan of correction with a timeline to become compliant with the neonatal facility requirements. The department shall review the request and the POC, and either grant the exception, with a specific timeline based on the public interest, or deny the exception. If the facility is not granted an exception, or it is not compliant to the requirements at the end of the exception period, the department shall elect one of the following:

(A) re-designate the facility at the level appropriate to its revised capabilities; or

(B) the department may outline an agreement with the facility to satisfy all requirements for the level of care designation within a time specified under the agreement, which may not exceed the first anniversary of the effective date of the agreement; or

(C) the department may waive one specific requirement for a level of care designation if the department determines the waiver is justified considering:

(i) the expected impact on accessibility of care in the geographic area served by the facility[] if the waiver is not granted;

(ii) the expected impact on the quality of care and patient safety;

(iii) whether these services can be met with telemedicine services; and

(iv) a facility[] that enters a waiver agreement is required to satisfy all other requirements for the level of designation that are not waived in the agreement.
(D) Waivers expire with the expiration of the current designation status but may be renewed. The department may specify any conditions for ongoing reporting during this time.

(E) The department shall maintain a current list on their website of facilities that have contingency agreements or an approved waiver with the department and an aggregated list of the requirements conditionally met or waived.

(F) Facilities that have contingency agreements or an approved waiver with the department shall post on the facility’s website the nature and general terms of the agreement.

(u) An application for a higher or lower level of neonatal designation may be submitted to the department at any time.

(1) A designated neonatal facility that is increasing its neonatal capabilities may choose to apply for a higher level of designation at any time. The facility must follow the designation process as described in subsection (a)(1)(A) – (F) of this section to apply for the higher level.

(2) A designated neonatal facility that is unable to maintain compliance with the facility’s current level of neonatal designation may choose to apply for a lower level of designation at any time.

(v) Before relinquishing its neonatal facility designation, the facility shall provide 30 days written, advance notice of the relinquishment to the department, the applicable RACs, EMS providers, and health care facilities in which customarily transfer-out or transfer-in neonatal patients. If the facility is relinquishing its neonatal facility designation, the facility shall provide 30 days written, advance notice of the relinquishment to the department, the applicable RACs, EMS providers, and health care facilities in which customarily transfer-out or transfer-in neonatal patients. The facility is responsible to continue to provide neonatal care services and ensure neonatal care continuity for the region remains in place for the thirty days following the notice of relinquishing its neonatal designation.

(w) A facility shall not use the terms "neonatal facility," "neonatal hospital," "neonatal center," "advanced neonatal intensive care unit or hospital," “neonatal intensive care unit or hospital,” "neonatal special care hospital," “neonatal well care hospital,” or similar terminology in its signs or advertisements or in the printed materials and information it provides to the public, unless the facility is currently designated at that level of neonatal facility.

(x) At any time, the department has the right to review, inspect, evaluate, and audit all neonatal patient records, neonatal multidisciplinary QAPI Plan documents, peer review activities, as well as any other documents relevant to neonatal care in a designated neonatal facility or facility seeking neonatal facility designation to verify compliance with the Texas Health and Safety Code, Chapter 241 and this section.
(y) The department maintains confidentiality of such records to the extent authorized by Texas Government Code, Chapter 552.

(z) The neonatal designation site review of the facility applying for neonatal designation will be scheduled in-person or virtually as requested by the facility, by the survey organization or by the department when deemed appropriate.

(aa) The department may deny, suspend, or revoke the designation if a designated neonatal facility ceases to provide services to meet or maintain compliance with the requirements of this section or if it violates Chapter 133 of this title, concerning requirements resulting in enforcement action or an agreed order.

§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 Operational Plan. The facility shall develop a written operational plan for the neonatal program that includes a detailed description of the scope of services and the clinical resources available to all neonatal patients, mothers, and families, and defines the neonatal patient population evaluated and/or treated, transferred, or transported by the facility.

(1) The written operational plan to include the program standards of care, policies and procedures shall be reviewed and approved by the Neonatal Operations Committee, chaired by the neonatal medical director and then forwarded to the facility's governing body for review. The governing body shall ensure that the requirements of this section are implemented and enforced.

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

(A) standards of neonatal care practices that the program policies and procedures are based upon that are adopted, implemented and enforced for the neonatal services it provides;

(B) a scheduled three-year review and revision schedule for all neonatal care policies and procedures;

(C) written triage, stabilization and transfer guidelines for neonates that include consultation and transport services;

(D) the role and scope of telemedicine practices including:

(i) defined standards of care and guidelines specific to the use of telemedicine resources where applicable;
(ii) a written plan for the appropriate use of telemedicine in the facility that is compliant with the Occupations Code, §111.001; and

(iii) a process that monitors the agreement compliance, protocol compliance, and outcomes of the neonatal telemedicine encounters through the QAPI Plan.

(E) ensure appropriate follow up for all neonates/infants;

(F) provisions for disaster response to include an all hazards response, business continuity plan, that is tested annually, to ensure needed resources can be sustained, and a focused evacuation plan and process to relocate mothers and infants to appropriate levels of care with identified resources;

(G) a Quality Assessment Performance Improvement (QAPI) Plan as described in §133.41(r) of this title (relating to Hospital Functions and Services).

(i) The Chief Executive Officer and Chief Nursing Officer shall implement a culture of safety for the facility and provide the resources to support a concurrent, data-driven QAPI Plan.

(ii) The facility shall demonstrate that the neonatal program’s QAPI plan continually assesses the provision of neonatal care provided. This assessment shall on an ongoing basis, identify variances in care, and define the level of harm. The facility will define the appropriate levels of review and define the opportunities for improvement, and develop a corrective action plan. The action plan is tracked and analyzed using data through to resolution or correction of the identified variance, until compliance is achieved and maintained.

(iii) The neonatal program’s QAPI plan identifies core performance measures that are monitored and tracked for compliance to evaluate processes of care and outcomes and report these findings through the Neonatal Operations Committee.

(v) Level III and IV Neonatal facilities must have a defined neonatal peer review committee with a defined structure and attendance as an element of their QAPI plan. The neonatal medical director shall identify cases for discussion at this committee. [the infrastructure and resources for an effective neonatal peer review committee.]

(vi) The neonatal medical director and program manager shall participate in the perinatal regional collaboratives and submit requested data to assist with data analysis to evaluate regional outcomes as an element of their neonatal QAPI
(vii) Evidence shall support that aggregate patient data is continuously reviewed for trends and data is submitted to the department as requested; and[]

(viii) Level III and IV facilities shall participate in a neonatal benchmarking program annually and share their outcomes at the Neonatal Operations Committee to identify opportunities for improvement.

[(H)][(G)] requirements for minimal credentials for all staff participating in the care of neonatal patients;

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

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

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

[(L)][(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 bylaws [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,] who is responsible for the oversight of 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, oversight, and responsibility to monitor neonatal patient care through all phases of care, from admission, stabilization, operative intervention(s) if applicable, through discharge, and has the authority to identify variances in care for inclusion in the quality assessment performance improvement plan.[].

(2) The responsibilities and authority of the NMD shall include [but are not limited to]:

(A) examining qualifications of medical staff and advanced practice providers requesting neonatal privileges and making[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) collaborating with the NPM, maternal teams, consulting physicians and nursing to include[, but not limited to['] developing, implementing or [and/or] revising:[participating in the development, review and assurance of the implementation of the]

   (i) written policies, procedures and guidelines for neonatal care in the facility;[

   (ii) a QAPI [written] Plan;

   (iii) criteria for transfer, consultation or higher level of care;[

   (iv) assuring staff competency, education, and training;[ and

   (v) assuring staff participation in perinatal regional collaboratives.[]

(F) regular and active participation in neonatal care at the facility where medical director services are provided;

(G) ensuring that the QAPI Plan [Program] is specific to neonatal/infant care, is continuous['], data driven and outcome-based; co-chairing the Neonatal Operations Committee with the NPM and chairing [and regularly participates in] the neonatal QAPI meetings[meeting]; and

(H) maintaining active staff privileges as defined in the facility's medical staff bylaws.

(e) Neonatal Program Manager (NPM). A [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 a department-approved[an office-approved] equivalent:

(3) have the authority, oversight, and responsibility to monitor the provision of neonatal patient care services through all phases of care, from admission, stabilization, operative intervention(s) if applicable, through discharge, inclusive of the QAPI Plan [Program] as defined in subsection (b)(2)(F)[(E)] of this section.
(4) collaborate with the NMD, maternal program, consulting physicians, and nursing to include, but not limited to: developing and revising policies, procedures and guidelines; assuring staff competency, education, and training; [the QAPI Program; and regularly participates in the neonatal QAPI meeting; and]

(5) ensure the QAPI Plan is specific to neonatal/infant care, is continuous, data driven, and outcome-based; facilitate the neonatal QAPI meetings; and co-chair the Neonatal Operations Committee with the NMD; and

(6) develop collaborative relationships with other NPM(s) of designated facilities within the applicable Perinatal Care Region and the defined regional perinatal collaboratives.

§133.186. Neonatal Designation Level I.

(a) Level I (Well Care). The Level I neonatal designated facility will:

(1) provide care for infants generally of ≥35 weeks gestational age who have routine, transient perinatal problems;

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

(3) if an infant <35 weeks gestational age is retained, the facility shall provide the same level of care that the neonate would receive at a higher-level designated neonatal facility; the facility must, through the QAPI Plan complete an in-depth critical review and assessment of the care provided to the infant.

(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) or a department-approved equivalent;

(3) demonstrates effective administrative skills and oversight of the QAPI Plan; and

(4) has completed continuing medical education annually specific to the care of neonates.

(c) Program Functions and Services.

(1) The NMD collaborates with the NPM, maternal program,
consulting physicians, and nursing to ensure 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.]

(2)[(4)] The primary physician, advanced practice nurse 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 maintain a current status on successful completion of the American Heart Association/American Academy of Pediatrics for the resuscitation of all infants NRP or a department-approved equivalent;

(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, appropriate backup coverage shall be available, documented in an on-call schedule readily available to facility staff; and

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

(3) establish and maintain documented prearranged consultative agreements with written standards of care and protocols for additional medical, surgical and support services, which can include telemedicine capabilities. Evaluate agreement compliance, services and neonatal outcomes through the QAPI Plan to ensure quality care is provided through these consultative services.

(4)[(5)] Availability of appropriate anesthesia, laboratory, radiology, respiratory, ultrasonography and blood bank services on a 24-hour basis as described in §133.41(a), (h), and (s) of this title, respectively. If services are called-back during off hours, the response times are monitored through the QAPI process.

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

(B) The facility must ensure regular monitoring and comparison of the preliminary and final readings in the QAPI Plan [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.

(7) If medication compounding is done for neonates/infants, the pharmacist will implement, maintain and evaluate [develop] checks and balances to ensure the accuracy of the final product through their QAPI process.

(6) Resuscitation. The facility shall have appropriately trained staff, written guidelines specific to the facility for the stabilization and resuscitation of neonates based on current standards 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 or a department equivalent 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 or a department equivalent shall be on-site and immediately available upon request;

(D) Additional providers who demonstrate current status of successful completion of the NRP or department-approved equivalent present at:

(i) multiple birth deliveries to care for each neonate;

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery; and

(iii) deliveries determined high-risk for the pregnant patient or neonate.

(E) Neonatal resuscitative[Basic NRP] equipment, [and] supplies, and medications shall be immediately available for trained staff to perform resuscitation and stabilization on any neonate/infant.
Perinatal Education. A registered nurse with experience in neonatal or perinatal care shall provide supervision and coordination of staff education.

Ensures the availability of support personnel with knowledge and skills in breastfeeding to assist and counsel mothers.

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 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. The facility must, through the QAPI Plan, complete an in-depth critical review and assessment of the care provided; and

(C) have 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 ≤ 1500 grams, the facility shall provide the same level of care that the neonate would receive at a higher-level designated neonatal facility. The facility must through the QAPI Plan, complete an in-depth critical review and assessment of the care provided.

(b) Neonatal Medical Director (NMD). The NMD shall be a physician who is:

(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 a department-approved equivalent; 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 Plan [Program];

(D) demonstrates a current status on successful completion of the NRP or a department-approved equivalent; and

(E) has completed continuing medical education annually specific to the care of neonates.

(c) Program Functions and Services.

(1) The Neonatal Program collaborates [Collaborates-]with the maternal program, consulting physicians, and nursing to ensure pregnant patients who are at high risk of delivering a neonate that requires a higher level of care will be transferred to a higher-level facility prior to delivery unless the transfer would be unsafe. [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.

(2)(4) The physician, advanced practice nurse, or [and/or] physician assistant with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on-call[on call, and]:

(A) shall maintain[demonstrate] a current status on successful completion of the NRP or a department-approved equivalent;

(B) has[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 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.

(3) Establish and maintain documented prearranged consultative agreements with written standards of care and protocols for additional medical, surgical and support services, which can include telemedicine capabilities. Evaluate agreement compliance, services and neonatal outcomes through the QAPI Plan to ensure standard of care is provided.

(4) If surgeries are performed, the surgeon with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on-call shall arrive at the patient bedside within 30 minutes of an urgent request.

(5) Anesthesia providers with pediatric experience and competence will provide services in compliance with the requirements 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 in §133.41(d) of this title.

(7) Laboratory services shall be in compliance with the requirements 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 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.
If medication compounding is done for neonates/infants, the pharmacist will implement, maintain and evaluate checks and balances to ensure the accuracy of the final product.

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

A speech, occupational, or physical therapist with sufficient neonatal expertise shall be available to meet the needs of the population served.

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 and ultrasound equipment;

(B) personnel at the bedside within 30 minutes of an urgent request;

(C) if services are called-back during off hours, the response times are monitored through the QAPI process;

(D) 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

(E) interpretation capability of neonatal and perinatal x-rays and ultrasound studies available at all times.

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

The facility must ensure regular monitoring and comparison of the preliminary and final readings through the QAPI Plan.

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.

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 or a department-approved
equivalent 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 or a department-approved equivalent shall be on-site and immediately
available upon request.

(D) Additional providers who demonstrate current status of successful
completion of the NRP or a department-approved equivalent present at: [shall-
attend each neonate in the event of multiple births.]

(i) multiple birth deliveries to care for each neonate;
(ii) deliveries with unanticipated maternal-fetal problems that occur
during labor and delivery; and
(iii) deliveries determined high-risk for the pregnant patient or neonate.

(E) Neonatal resuscitative[A full range of NRP] equipment, [and] supplies,
and medications 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], or [and/or] perinatal care shall provide supervision
and coordination of staff education.

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

(15) Written and implemented policies and procedures to ensure [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 comprehensive care for infants of all gestational ages with mild to critical illnesses or requiring sustained life support;
2. provide 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;
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) or a department-approved equivalent.

(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. The Neonatal Program collaborates with maternal services, consulting physicians, and nursing to ensure 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 and available at all times: pediatric hospitalists, neonatologists, neonatal nurse practitioners or neonatal physician assistants, as appropriate, who have demonstrated competence in management of severely ill neonates/infants,
whose credentials have been reviewed by the NMD and is on-call:

(A) shall maintain current status of successful completion of the NRP or a department-approved equivalent;

(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 readily available to facility staff; and

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

(3) Establish and maintain documented prearranged consultative agreements with written standards of care and protocols for additional medical, surgical and support services, which can include telemedicine capabilities. Evaluate these agreements, services and neonatal outcomes through the QAPI Plan to ensure standard of care is provided.

(4) If surgeries are performed, the surgeon with special competence in the care of neonates, whose credentials have been reviewed by the NMD and is on-call shall arrive at the patient bedside within 30 minutes of an urgent request.

(5) Anesthesiologists with pediatric expertise and competence, shall direct and evaluate the anesthesia care provided to neonates, in compliance with the requirements in §133.41(a) of this title (relating to Hospital Functions and Services).

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

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

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

(B) perinatal pathology services available for the population served;

(C) pathology resources available in the operative suite at the request of the
operating surgeon;

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

(E)(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;]

(A)(B) If medication compounding is done for neonates/infants, the pharmacist will implement, maintain and evaluate [develop] checks and balances to ensure the accuracy of the final product.

(B)(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.]

(9)(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 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; fluoroscopy shall be available;]

(B) 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; fluoroscopy shall be available,[7] and the response times are monitored through the QAPI process;

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

(D)(C) The facility must ensure regular monitoring and comparison of the
preliminary and final readings in the QAPI Plan; and

(E[D])(C) pediatric echocardiography with pediatric cardiology interpretation and consultation completed within a time period consistent with current standards of professional practice [within one hour of an urgent request] and the response times are monitored through the QAPI process.

Speech language pathologist, an occupational therapist, or a physical therapist with neonatal/infant expertise and experience shall be available to:

(A) evaluate and manage feeding and/or swallowing disorders; and

(B) provide therapy services to meet the needs of the population served.

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 on-site and immediately available.

Resuscitation. Written policies and procedures shall be 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 or a department-approved equivalent 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 or a department-approved equivalent present at:

(i) multiple birth deliveries to care for each neonate; and

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery.

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

(E) Neonatal [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.

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

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

(15) Social services shall be provided as appropriate to meet the needs of the patient population served.

(16) Written and implemented policies and procedures to ensure the timely evaluation of retinopathy of prematurity, monitoring, referral for treatment and follow-up, in the case of an at-risk infant.

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

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

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

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

(d) Program Functions and Services.

(1) The Neonatal Program collaborates [Collaborates] with maternal services, consulting physicians, and nursing to ensure [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 an appropriate [another 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.]

(2) [(4)] Board certified/board eligible neonatologists whose credentials have been reviewed by the NMD and is on-call, and who:

(A) shall maintain [demonstrate] a current status on successful completion of the NRP or a department-approved equivalent;

(B) has[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.

(3) A comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists will be immediately available to arrive on-site in person within 30 minutes of an urgent request for consultation and care.

(4) [(5)] Pediatric anesthesiologists shall direct and evaluate [directly provide] anesthesia care provided to the neonate, in compliance with the requirements in §133.41(a) of this title.

(5) [(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.]
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 for the population served;

(C) pathology resources available in the operative suite at the request of the operating surgeon;

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

(E) neonatal blood gas monitoring capabilities.

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, maintain, and evaluate 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.

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

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

(C) pediatric echocardiography with pediatric cardiology interpretation and consultation complete within a time period consistent with current standards of professional practice[within one hour of an urgent request].

(9)[(12)] Speech language pathologist, an occupational therapist, or a physical therapist with neonatal/infant expertise and experience shall be available to:

(A) evaluate and manage feeding and/or swallowing disorders; and

(B) provide therapy services to meet the needs of the population served.

(10)[(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.

(11)[(14)] Resuscitation. Written [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 or a department-approved equivalent 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 or a department-approved equivalent present at:

(i) multiple birth deliveries to care for each neonate; and

(ii) deliveries with unanticipated maternal-fetal problems that occur during labor and delivery.

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

(E) Neonatal[A full range of] resuscitative equipment, supplies and medications shall be immediately available for trained staff to perform resuscitation and stabilization on any[each] neonate/infant.
Perinatal Education. A registered nurse with experience in neonatal care, including advanced neonatal intensive care, shall provide supervision and coordination of staff education.

Pastoral care or [and/or] counseling shall be provided as appropriate to the patient population served.

Social services shall be provided as appropriate to meet the needs of the patient population served.

Written and implemented policies, procedures, and guidelines to ensure the timely evaluation [and treatment] of retinopathy of prematurity on-site, monitoring, referral for treatment and follow-up 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].

A certified lactation consultant shall be available at all times.

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 department [office] survey form. The department [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 approved in advance by the department [office] and currently active in the management of neonatal patients at a facility providing the same or 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 department [office] and currently active in the management of neonatal patients at a facility providing the same or a higher level of neonatal care. A pediatric surgeon is required to survey all facilities that perform surgical procedures. An additional surveyor may be requested by the facility or at the discretion of the department [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 [with pediatric expertise] and one neonatal nurse, all approved in advance by the
department[office-] and currently active in the management of neonatal patients at a facility providing the same level of neonatal care. [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) Department-credentialed[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 in a designated neonatal facility;

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

(4) have successfully completed a department-approved [an office-approved] neonatal facility site surveyor course;

(5)[and] be successfully re-credentialed every three[four] years; and

(6)[(5)] have current credentials as follows:

(A) a registered nurse who is current in the NRP or a department-approved equivalent, and has successfully completed a department-approved [an office-approved] site survey internship; or

(B) a [physician who is] board-certified neonatologist [in the respective specialty,] current in the NRP or a department-approved equivalent, and has successfully completed a department-[an office-]approved site survey internship; or

(C) a board-certified pediatric surgeon who [is board certified, has demonstrated expertise in pediatric surgery, and ]has successfully completed a department-[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 and have no[. 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]. A conflict of interest exists when the surveyor has a current or past relationship with the facility[ ] or key facility[ ] staff members. This includes a previous working relationship, residency, training, or participation in a consultation program for the facility[ ] within the past five years.

(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 QAPI Plan [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 the defined standards of care and policies specific to the appropriate use of telemedicine resources [capabilities] where applicable, including:

(A) a written plan for the appropriate use of telemedicine in the facility[ ] that is compliant with Health and Safety Code, §111.001; and

(B) a process that monitors the documented agreement compliance, protocol compliance and outcomes of the neonatal telemedicine encounters.

(e) All information and materials submitted by a facility to the department[office] under Health and Safety Code, §241.183(d), are subject to confidentiality as articulated in Health and Safety Code, §241.184, Confidentially; 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.

§133.191. PCRs.

(a) The PCR will consider and facilitate transfer agreements through regional coordination and coordinate regional perinatal system QAPI reviews.

(b) The PCRs will not restrict patient referrals.

(c) A written plan identifies all resources available in the PCRs for perinatal care including resources for emergency and disaster preparedness to include assistance with facility evacuations and placement of neonatal patients.

(d) The PCRs will be administratively supported by the RAC; and will have fair and equitable representation on the board of the applicable RAC.

(e) Each PCR may define data needs for regional collaboratives.

(f) Multiple PCRs may meet for the purposes of mutual collaboration.