Use the following pages to review the elements within your program and evaluate for the evidence needed to demonstrate that each requirement is met.

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| **§133.185 Program Requirements** | | | |
| (a) Neonatal Program Philosophy. Designated facilities must have a family-centered philosophy. Parents must 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 must meet the physiologic and psychosocial needs of the mothers, infants, and families. |  |  |  |
| (b) Neonatal Program Plan.   * The facility must develop a written neonatal operational plan for the neonatal program that includes a detailed description of the scope of services and clinical resources available for all neonatal patients, mothers, and families. * The plan must define the neonatal patient population evaluated, treated, transferred, or transported by the facility consistent with clinical guidelines based on current standards of neonatal practice ensuring the health and safety of patients. |  |  |  |
| (1) The written Neonatal Program Plan must be   * reviewed and approved by Neonatal Program Oversight and * be submitted to the facility's governing body for review and approval. * The governing body must ensure the requirements of this section are implemented and enforced. |  |  |  |
| (2) The written Neonatal Program Plan must include, at a minimum: |  |  |  |
| (A) clinical guidelines based on current standards of neonatal practice, and policies and procedures that are   * adopted, * implemented, and * enforced by the neonatal program; |  |  |  |
| (B) a process to ensure and validate these clinical guidelines based on current standards of neonatal practice, policies, and procedures, are reviewed and revised a minimum of every three years; |  |  |  |
| (C) written triage, stabilization, and transfer guidelines for neonatal patients that include consultation and transport services; |  |  |  |
| (D) the role and scope of telehealth/telemedicine practices, if utilized, including: |  |  |  |
| (i) documented and approved written policies and procedures that outline the use of telehealth/telemedicine for inpatient hospital care or for consultation, including:   * appropriate situations, * scope of care, and * documentation   that is monitored through the neonatal QAPI Plan and process; and |  |  |  |
| (ii) written and approved procedures to gain informed consent from the patient or designee for the use of telehealth/telemedicine, if utilized, that are monitored for variances; |  |  |  |
| (E) written guidelines for discharge planning instructions and appropriate follow-up appointments for all neonates/infants; |  |  |  |
| (F) written guidelines for the hospital disaster response, including:   * a defined neonatal evacuation plan and process to relocate mothers and infants to appropriate levels of care with identified resources, and * this process must be evaluated annually to ensure neonatal care can be sustained and adequate resources are available; |  |  |  |
| (G) written minimal education and credentialing requirements for all staff participating in the care of neonatal patients, which are documented and monitored by the managers who have oversight of staff; |  |  |  |
| (H) written requirements for providing continuing staff education, including annual competencies and skills assessment that is appropriate for the patient population served, which are documented and monitored by the managers who have oversight of staff; |  |  |  |
| (I) documentation of meeting the requirement for a perinatal staff registered nurse to serve as a representative on the nurse staffing committee under §133.41 of this title (relating to Hospital Functions and Services); |  |  |  |
| (J) measures to monitor the availability of all necessary equipment and services required to provide the appropriate level of care and support for the patient population served; and |  |  |  |
| (K) documented guidelines for consulting support personnel with knowledge and skills in breastfeeding and lactation, which includes:   * expected response times, * defined roles, * responsibilities, and * expectations. |  |  |  |
| (3) The facility must have a documented and approved neonatal QAPI Plan. |  |  |  |
| (A) The Chief Executive Officer, Chief Medical Officer, and Chief Nursing Officer must implement a culture of safety for the facility and ensure adequate resources are allocated to support a concurrent, data-driven neonatal QAPI Plan. |  |  |  |
| (B) The facility must demonstrate that the neonatal QAPI Plan consistently assesses the provision of neonatal care provided. The assessment must:   * identify variances in care, * the impact to the patient, and * the appropriate levels of review.   This process must:   * identify opportunities for improvement and * develop a plan of correction to address the variances in care or the system response.   An action plan will track and analyze data through resolution or correction of the identified variance. |  |  |  |
| (C) The neonatal program must:   * measure, analyze, and track performance through defined quality indicators, core performance measures, and other aspects of performance that the facility adopts or develops to evaluate processes of care and patient outcomes.   Summary reports of these findings are reported through the Neonatal Program Oversight. |  |  |  |
| (D) All neonatal facilities must participate in a neonatal data initiative. Level III and IV neonatal facilities must participate in benchmarking programs to assess their outcomes as an element of the neonatal QAPI Plan. |  |  |  |
| (E) The Neonatal Medical Director (NMD) must:   * have the authority to make referrals for peer review, * receive feedback from the peer review process, and * ensure neonatal physician representation in the peer review process for neonatal cases. |  |  |  |
| (F) The NMD and Neonatal Program Manager (NPM) must participate in:   * PCR meetings, * regional QAPI initiatives, and * regional collaboratives, and * submit requested data to assist with data analysis to evaluate regional outcomes as an element of the facility's neonatal QAPI Plan. |  |  |  |
| (G) The facility must have documented evidence of neonatal QAPI summary reports reviewed and reported by Neonatal Program Oversight that monitor and ensure the provision of services or procedures through telehealth and telemedicine, if utilized, is in accordance with the standards of care applicable to the provision of the same service or procedure in an in-person setting. |  |  |  |
| (H) The facility must have documented evidence of neonatal QAPI summary reports to support that aggregate neonatal data are consistently reviewed to identify:   * developing trends, * opportunities for improvement, and * necessary corrective actions.   Summary reports must be provided through the Neonatal Program Oversight, available for site surveyors, and submitted to the department as requested. |  |  |  |
| (c) Medical Staff. The facility must have an organized, effective neonatal program that is recognized by the facility's medical staff and approved by the facility's governing body. |  |  |  |
| (1) The credentialing of the neonatal medical staff must include a process for the delineation of privileges for neonatal care. |  |  |  |
| (2) The neonatal medical staff must participate in ongoing staff and team-based education and training in the care of the neonatal patient. |  |  |  |
| (d) Medical Director. There must be an identified NMD and an identified Transport Medical Director (TMD) if the facility has its own transport program. The NMD and TMD must be credentialed by the facility for treatment of neonatal patients and have their responsibilities and authority defined in a job description. The NMD and TMD must maintain a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course. |  |  |  |
| (1) The NMD is responsible for the provision of neonatal care services and must: |  |  |  |
| (A) examine qualifications of medical staff and advanced practice providers requesting privileges to participate in neonatal/infant care, and make recommendations to the appropriate committee for such privileges; |  |  |  |
| (B) ensure neonatal medical staff and advanced practice provider competencies in managing neonatal emergencies, complications, and resuscitation techniques; |  |  |  |
| (C) monitor neonatal patient care from transport, to admission, stabilization, and operative intervention(s), as applicable, through discharge, and review variances in care through the neonatal QAPI Plan; |  |  |  |
| (D) participate in ongoing neonatal staff and team-based education and training in the care of the neonatal patient; |  |  |  |
| (E) oversee the inter-facility neonatal transport as appropriate; |  |  |  |
| (F) collaborate with the NPM, maternal teams, consulting physicians, and nursing leaders and units providing neonatal care to include developing, implementing, or revising: |  |  |  |
| (i) written policies, procedures, and guidelines for neonatal care that are implemented and monitored for variances; |  |  |  |
| (ii) the neonatal QAPI Plan, specific reviews, and data initiatives; |  |  |  |
| (iii) criteria for transfer, consultation, or higher-level of care; and |  |  |  |
| (iv) medical staff, advanced practice providers, and personnel competencies, education, and training; |  |  |  |
| (G) participate as a clinically active and practicing physician in neonatal care at the facility where medical director services are provided; |  |  |  |
| (H) ensure that the neonatal QAPI Plan is specific to neonatal/infant care, is ongoing, data driven, and outcome based; |  |  |  |
| (I) frequently lead the neonatal QAPI meetings with the NPM and participate in the Neonatal Program Oversight and other neonatal meetings, as appropriate; |  |  |  |
| (J) maintain active staff privileges as defined in the facility's medical staff bylaws; and |  |  |  |
| (K) develop and maintain collaborative relationships with other NMDs of designated neonatal facilities within the applicable PCR. |  |  |  |
| (2) The TMD is responsible for the facility neonatal transport program and must: |  |  |  |
| (A) collaborate with the transport team to:   * develop, * revise, and * implement written policies, procedures, and guidelines,   for neonatal care that are implemented and monitored for variances; |  |  |  |
| (B) participate in ongoing transport staff competencies, education, and training; |  |  |  |
| (C) review and evaluate transports from initial activation of the transport team through delivery of patient, resources, quality of patient care provided, and patient outcomes; and |  |  |  |
| (D) integrate review findings into the overall neonatal QAPI Plan and process. |  |  |  |
| (3) The NMD may also serve as the TMD. |  |  |  |
| (e) NPM. The facility must identify an NPM who has the authority and oversight responsibilities written in his or her job description, for the provision of neonatal services through all phases of care, including discharge, and identifying variances in care for inclusion in the neonatal QAPI Plan. |  |  |  |
| (1) The NPM must be a registered nurse with defined education, credentials, and experience for neonatal care applicable to the level of care being provided. |  |  |  |
| (2) The NPM must maintain a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course. |  |  |  |
| (3) The NPM must: |  |  |  |
| (A) ensure staff competency in resuscitation techniques; |  |  |  |
| (B) participate in ongoing staff and team-based education and training in the care of the neonatal patient; |  |  |  |
| (C) monitor utilization of telehealth/telemedicine, if used; |  |  |  |
| (D) collaborate with the NMD, maternal program, consulting physicians, and nursing leaders and units providing neonatal care to include developing, implementing, or revising: |  |  |  |
| (i) written policies, procedures, and guidelines for neonatal care that are implemented and monitored for variances; |  |  |  |
| (ii) the neonatal QAPI Plan, specific reviews, and data initiatives; |  |  |  |
| (iii) criteria for transfer, consultation, or higher-level of care; and |  |  |  |
| (iv) staff competencies, education, and training; |  |  |  |
| (E) regularly and actively participate in neonatal care at the facility where program manager services are provided; |  |  |  |
| (F) consistently review the neonatal care provided and ensure the neonatal QAPI Plan is specific to neonatal/infant care, data driven, and outcome-based; |  |  |  |
| (G) frequently lead the meetings and participate in Neonatal Program Oversight and other neonatal meetings as appropriate; and |  |  |  |
| (H) develop and maintain collaborative relationships with other NPMs of designated neonatal facilities within the applicable PCR. |  |  |  |
| **§133.189 Neonatal Designation Level IV** | | | |
| (a) Level IV (Advanced Neonatal Intensive Care). The Level IV neonatal designated facility must: |  |  |  |
| (1) provide care for the mothers and comprehensive care for their infants of all gestational ages with the most complex and critical medical and surgical conditions or requiring sustained life support; |  |  |  |
| (2) ensure access to a comprehensive range of:   * pediatric medical subspecialists and * pediatric surgical subspecialists   are available to arrive on-site in person for consultation and care, and the capability to perform major pediatric surgery including the surgical repair of complex conditions on-site; |  |  |  |
| (3) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served; |  |  |  |
| (4) facilitate neonatal transports; and |  |  |  |
| (5) provide outreach education related to:   * trends identified through the neonatal QAPI Plan, * specific requests, and * system needs to lower-level neonatal designated facilities, and   as appropriate and applicable, to:   * non-designated facilities, * birthing centers, * independent midwife practices, and * prehospital providers. |  |  |  |
| (b) Neonatal Medical Director (NMD). The NMD must be a physician who is a board-eligible/certified neonatologist and maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course. |  |  |  |
| (c) If the facility has its own transport program, there must be an identified Transport Medical Director (TMD). The TMD or Transport Medical Co-Director must be a physician who is a board-eligible/certified neonatologist with expertise and experience in neonatal/infant transport. |  |  |  |
| **(d)** **Program Functions and Services.** |  |  |  |
| (1) The neonatal program must collaborate with:   * the maternal program, * consulting physicians, and * nursing leadership   to ensure pregnant patients who are at high risk of delivering a neonate that requires specialized care are transferred to a facility with specialized care capabilities before delivery unless the transfer would be unsafe. |  |  |  |
| (2) The facility provides appropriate, supportive, and emergency care delivered by trained personnel for unanticipated maternal-fetal or neonatal problems that occur during labor and delivery, through the disposition of the patient. |  |  |  |
| (3) A board-eligible/certified neonatologist, with documented competence in the management of the most complex and critically ill neonates/infants, with neonatal privileges and credentials reviewed by the NMD, must be on-site and immediately available at the neonate/infant bedside as requested. The neonatologist: |  |  |  |
| (A) must maintain a current status of successful completion of the NRP or a department-approved equivalent course; |  |  |  |
| (B) must complete annual continuing education specific to the care of neonates; and |  |  |  |
| (C) must ensure the facility has a back-up neonatal provider if the neonatologist is not immediately available. |  |  |  |
| (4) Pediatric anesthesiologists must direct and evaluate anesthesia care provided to neonates in compliance with the requirements in §133.41 of this title (relating to Hospital Functions and Services). |  |  |  |
| (5) A comprehensive range of:   * pediatric medical subspecialists and * pediatric surgical subspecialists   privileged and credentialed to participate in neonatal/infant care must be available to arrive on-site for in-person consultation and care within a time period consistent with current standards of professional practice and neonatal care.  The pediatric medical and pediatric surgical subspecialists' response times must be reviewed and monitored through the neonatal QAPI Plan. |  |  |  |
| (6) Dietitian or nutritionist with appropriate training and experience in neonatal nutrition, plans diets that meet the needs of the neonate/infant and critically ill neonatal patient and provides services for the population served, in compliance with the requirements in §133.41 of this title. |  |  |  |
| (7) Laboratory services must be in compliance with the requirements in §133.41 of this title and must have: |  |  |  |
| (A) appropriately trained and qualified laboratory personnel on-site at all times; |  |  |  |
| (B) pediatric pathology services available for the population served; |  |  |  |
| (C) pediatric surgical or intra-operative frozen section pathology services available in the operative suite at the request of the operating surgeon; and |  |  |  |
| (D) a blood bank capable of providing blood and blood component therapy within the timelines defined in approved blood transfusion guidelines. |  |  |  |
| (8) The facility must provide neonatal/infant blood gas monitoring capabilities. |  |  |  |
| (9) Pharmacy services must be in compliance with the requirements in §133.41 of this title and must have a pharmacist with experience in neonatal/pediatric pharmacology available on-site at all times. |  |  |  |
| (A) If medication compounding is done by a pharmacy technician for neonates/infants, a pharmacist must provide immediate supervision of the compounding process. |  |  |  |
| (B) When medication compounding is done for neonates/infants, the pharmacist must implement guidelines to ensure the accuracy of the compounded final product and must ensure: |  |  |  |
| (i) the process is monitored through the pharmacy QAPI plan; and |  |  |  |
| (ii) summary reports of activities are presented at the Neonatal Program Oversight. |  |  |  |
| (C) Total parenteral nutrition appropriate for neonates/infants must be available. |  |  |  |
| (10) Radiology services must be in compliance with the requirements in §133.41 of this title, incorporate the "As Low as Reasonably Achievable" principle when obtaining imaging in neonatal patients, and must have: |  |  |  |
| (A) personnel appropriately trained in the use of x-ray equipment on-site and available at all times; |  |  |  |
| (B) personnel appropriately trained in ultrasound, computed tomography, and cranial ultrasound equipment be on-site within a time period consistent with current standards of professional practice; |  |  |  |
| (C) fluoroscopy be available at all times; |  |  |  |
| (D) neonatal diagnostic imaging studies and radiologists with pediatric expertise to interpret neonatal diagnostic imaging studies, available at all times; |  |  |  |
| (E) a radiologist with pediatric expertise to interpret images consistent with the patient condition and within a time period consistent with current standards of professional practice with monitoring of variances through the neonatal QAPI Plan and process; |  |  |  |
| (F) preliminary findings documented in the medical record, if preliminary reading of imaging studies pending formal interpretation is performed; and |  |  |  |
| (G) regular monitoring and comparison of the preliminary and final readings through the radiology QAPI Plan and provide a summary report of activities at the Neonatal Program Oversight. |  |  |  |
| (11) Pediatric echocardiography with pediatric cardiology interpretation and consultation completed within a time period consistent with current standards of professional practice. |  |  |  |
| (12) Speech, occupational, or physical therapists with neonatal/infant expertise and experience must: |  |  |  |
| (A) evaluate and recommend management of feeding and swallowing disorders as appropriate for the patient's condition; and |  |  |  |
| (B) provide therapy services to meet the needs of the population served. |  |  |  |
| (13) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed and approved by the Neonatal Medical Director, must be on-site and immediately available. |  |  |  |
| (14) The facility must have:   * staff with appropriate training for managing neonates/infants, * written policies, procedures, and guidelines specific to the facility for the stabilization and resuscitation of neonates/infants based on current standards of professional practice.   Variances from these standards are monitored through the neonatal QAPI Plan. |  |  |  |
| (A) Each birth must be attended by at least one person who maintains a current status of successful completion of the NRP or a department-approved equivalent course and whose primary focus is 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 personnel who maintain a current status of successful completion of the NRP or a department-approved equivalent course must be on-site and immediately available upon request for the following: |  |  |  |
| (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 or suspected to be high-risk for the pregnant patient or neonate. |  |  |  |
| (D) Variances from these standards are monitored through the neonatal QAPI Plan and process and reported at the Neonatal Program Oversight. |  |  |  |
| (E) Neonatal resuscitative equipment, supplies, and medications must be immediately available for trained staff to perform complete resuscitation and stabilization for each neonate/infant. |  |  |  |
| (15) A registered nurse with experience in neonatal care, including advanced neonatal intensive care, must provide supervision and coordination of staff education. |  |  |  |
| (16) Social services,   * supportive spiritual care, and * counseling   must be provided as appropriate to meet the needs of the patient population served. |  |  |  |
| (17) Written and implemented policies and procedures to ensure:   * timely evaluation and * treatment of retinopathy of prematurity on-site   by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity of an at-risk infant.  Patient follow-up of retinopathy of prematurity must be documented and monitored through the neonatal QAPI Plan. |  |  |  |
| (18) The neonatal program ensures a certified lactation consultant must be available at all times to assist and counsel mothers. |  |  |  |
| (19) The neonatal program ensures provisions for follow-through care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications. |  |  |  |