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. |  |  |  |
| **§133.187 Neonatal Designation Level II** | | | |
| (a) Level II (Special Care). The Level II neonatal designated facility must: |  |  |  |
| (1) provide care for mothers and their infants of generally more than or equal to 32 weeks gestational age and birth weight more than or equal to 1500 grams who have physiologic immaturity or problems that are expected to resolve rapidly and are not anticipated to require subspecialty services on an urgent basis; and |  |  |  |
| (A) if a facility is located more than 75 miles from the nearest Level III or IV designated neonatal facility and retains a neonate less than 32 weeks of gestation or having a birth weight of less than 1500 grams, the facility must provide the same level of care that the neonate would receive at a higher-level designated neonatal facility; and |  |  |  |
| (B) any facility that retains a neonate less than 32 weeks of gestation or a birth weight less than 1500 grams, must, through the neonatal QAPI Plan, complete an in-depth critical review and assessment of the care provided; |  |  |  |
| (2) provide care, either by 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 |  |  |  |
| (A) if the facility performs neonatal surgery, it must provide the same level of care that the neonate would receive at a higher-level designated facility; and |  |  |  |
| (B) the neonatal surgical procedure and follow-up must be reviewed through the neonatal QAPI Plan; and |  |  |  |
| (3) have skilled medical staff and personnel with documented training, competencies, and annual continuing education specific for the patient population served. |  |  |  |
| (b) Neonatal Medical Director (NMD). The NMD must be a physician who: |  |  |  |
| (1) is a board-eligible/certified neonatologist, with experience in the care of neonates/infants and maintains a current status of successful completion of the Neonatal Resuscitation Program (NRP) or a department-approved equivalent course; or |  |  |  |
| (2) is a pediatrician or neonatologist by the effective date of this section who: |  |  |  |
| (A) continuously provided neonatal care for the last consecutive two years and 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 neonatal QAPI Plan; |  |  |  |
| (D) maintains a current status of successful completion of the NRP or a department-approved equivalent course; and |  |  |  |
| (E) must complete annual continuing medical education specific to the care of neonates. |  |  |  |
| (c) **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 a higher-level of care are transferred to a higher-level facility 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) The on-call physician, advanced practice nurse, or physician assistant must have documented special competence in the care of neonates, privileges and credentials to participate in neonatal/infant care reviewed by the NMD, and: |  |  |  |
| (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; |  |  |  |
| (C) must 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, must ensure appropriate back-up coverage is available, back-up call providers are documented in the neonatal on-call schedule and must be readily available to respond to the facility staff; |  |  |  |
| (i) the back-up call physician, advanced practice nurse, or physician assistant must arrive at the patient bedside within 30 minutes of an urgent request; and |  |  |  |
| (ii) the on-call staff must be on-site to provide ongoing care and to respond to emergencies when a neonate/infant is maintained on endotracheal ventilation. |  |  |  |
| (4) The neonatal program ensures if surgeries are performed for neonates/infants,   * a surgeon privileged and credentialed to perform surgery on a neonate/infant is on-call and * must arrive at the patient bedside within a time period consistent with current standards of professional practice and neonatal care. * Surgeon response times must be reviewed and monitored through the neonatal QAPI Plan. |  |  |  |
| (5) Anesthesia providers with pediatric experience and competence must provide services in compliance with the requirements in §133.41 of this title (relating to Hospital Functions and Services). |  |  |  |
| (6) Dietitian or nutritionist with appropriate training and experience in neonatal nutrition 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) personnel on-site at all times as defined by written management guidelines, which may include when a neonate/infant is maintained on endotracheal ventilation; and |  |  |  |
| (B) 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 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 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, if requested. |  |  |  |
| (10) A speech, occupational, or physical therapist with sufficient neonatal expertise must provide therapy services to meet the needs of the population served. |  |  |  |
| (11) 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 and ultrasound equipment; |  |  |  |
| (B) personnel at the bedside within 30 minutes of an urgent request; |  |  |  |
| (C) personnel appropriately trained, available on-site to provide ongoing care and to respond to emergencies when an infant is maintained on endotracheal ventilation; |  |  |  |
| (D) interpretation capability of neonatal and perinatal x-rays and ultrasound studies are available at all times; |  |  |  |
| (E) if preliminary reading of imaging studies pending formal interpretation is performed, the preliminary findings must be documented in the medical record; and |  |  |  |
| (F) regular monitoring and comparison of preliminary and final readings through the radiology QAPI Plan and provide summary reports of activities at the Neonatal Program Oversight. |  |  |  |
| (12) A respiratory therapist, with experience and specialized training in the respiratory support of neonates/infants, whose credentials have been reviewed by the NMD, must 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. |  |  |  |
| (13) 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 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, 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 resuscitation and stabilization on any neonate/infant. |  |  |  |
| (14) A registered nurse with experience in neonatal care, including special care, or perinatal care must provide supervision and coordination of staff education. |  |  |  |
| (15) Social services,   * supportive spiritual care, and * counseling   must 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, * documented referral for treatment, and * follow-up of an at-risk infant,   which must be monitored through the neonatal QAPI Plan. |  |  |  |
| (17) The neonatal program ensures the availability of support personnel with knowledge and expertise in breastfeeding and lactation to assist and counsel mothers. |  |  |  |
| (18) The neonatal program ensures provisions for follow-through care at discharge for infants at high risk for neurodevelopmental, medical, or psychosocial complications. |  |  |  |