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

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| **§133.205 Program Requirements** | | | |
| (a) Maternal Program Philosophy. Designated facilities must have a family centered philosophy. The facility environment for perinatal care must meet the physiologic and psychosocial needs of the mothers, infants, and families. Parents must have reasonable access to their infants at all times and be encouraged to participate in the care of their infants. |  |  |  |
| (b) Maternal Program Plan.   * The facility must develop a written maternal operational plan for the maternal program that includes a detailed description of the scope of services and clinical resources available for all maternal patients and families. * The plan will define the maternal patient population evaluated, treated, transferred, or transported by the facility consistent with clinical guidelines based on current standards of maternal practice ensuring the health and safety of patients. |  |  |  |
| (1) The written Maternal Program Plan must be   * reviewed and approved by Maternal Program Oversight and * be submitted to the facility's governing body for review and approval. * The governing body must ensure that the requirements of this section are implemented and enforced. |  |  |  |
| (2) The written Maternal Program Plan must include, at a minimum: |  |  |  |
| (A) clinical guidelines based on current standards of maternal practice, and policies and procedures that are   * adopted, * implemented, and * enforced by the maternal program; |  |  |  |
| (B) a process to ensure and validate that these clinical guidelines based on current standards of maternal practice, policies, and procedures are reviewed and revised a minimum of every three years; |  |  |  |
| (C) written triage, stabilization, and transfer guidelines for pregnant and postpartum patients that include consultation and transport services; |  |  |  |
| (D) written guidelines or protocols for:   * prevention, * early identification, * early diagnosis, and * therapy   for conditions that place the pregnant or postpartum patient at risk for morbidity or mortality; |  |  |  |
| (E) 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 inpatient consultation, including:   * appropriate situations, * scope of care, and * documentation   that is monitored through the 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 compliance; |  |  |  |
| (F) written guidelines for discharge planning instructions and appropriate follow up appointments for all mothers and infants; |  |  |  |
| (G) written guidelines for the hospital disaster response, including:   * a defined mother and infant 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 maternal care can be sustained and adequate resources are available; |  |  |  |
| (H) requirements for minimal credentials for all staff participating in the care of maternal patients; |  |  |  |
| (I) provisions for providing continuing staff education, including annual competency and skills assessment that is appropriate for the patient population served; |  |  |  |
| (J) a perinatal staff registered nurse as a representative on the nurse staffing committee under §133.41 of this title (relating to Hospital Functions and Services); and |  |  |  |
| (K) the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served. |  |  |  |
| (3) The facility must have a documented QAPI Plan. The maternal program must measure, analyze, and track quality indicators and other aspects of performance that the facility adopts or develops that reflect processes of care and is outcome based. |  |  |  |
| (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 maternal QAPI Plan. |  |  |  |
| (B) The facility must demonstrate that the maternal QAPI Plan consistently assesses the provision of maternal care provided. The assessment will:   * identify variances in care, * the impact to the patient, and * the appropriate levels of review.   This process will:   * 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) Maternal facilities must review their incidence and management of placenta accreta spectrum disorder through the QAPI Plan and report the incidence and outcomes through the Maternal Program Oversight. |  |  |  |
| (D) The Maternal Medical Director (MMD) must:   * have the authority to make referrals for peer review, * receive feedback from the peer review process, and * ensure maternal physician representation in the peer review process for maternal cases. |  |  |  |
| (E) The MMD and the Maternal Program Manager (MPM) must participate in:   * the PCR meetings, * QAPI regional initiatives, and * regional collaboratives, and * submit requested data to assist with data analysis to evaluate regional outcomes as an element of their maternal QAPI Plan. |  |  |  |
| (F) The facility must have documented evidence of maternal QAPI summary reports reviewed and reported by Maternal Program Oversight that monitor and ensure the provision of services or procedures through the telehealth and telemedicine, if utilized, is in accordance with the standard of care applicable to the provision of the same service or procedure in an in-person setting. |  |  |  |
| (G) The facility must have documented evidence of maternal QAPI summary reports to support that aggregate maternal data are consistently reviewed to identify:   * developing trends, * opportunities for improvement, and * necessary corrective actions.   Summary reports must be provided through Maternal Program Oversight, available for site surveyors, and submitted to the department as requested. |  |  |  |
| (c) Medical Staff. The facility must have an organized maternal program that is recognized by the facility's medical staff and approved by the facility's governing body. |  |  |  |
| (1) The credentialing of the maternal medical staff must include a process for the delineation of privileges for maternal care. |  |  |  |
| (2) The maternal medical staff must participate in ongoing staff and team-based education and training in the care of the maternal patient. |  |  |  |
| (d) Medical Director. There must be an identified MMD and an identified Transport Medical Director (TMD) if the facility has its own transport program. The MMD and TMD must be credentialed by the facility for treatment of maternal patients and have their responsibilities and authority defined in a job description. The MMD is responsible for the provision of maternal care services and: |  |  |  |
| (1) examining qualifications of medical staff requesting maternal privileges and making recommendations to the appropriate committee for such privileges; |  |  |  |
| (2) assuring maternal medical staff competency in managing obstetrical emergencies, complications and resuscitation techniques; |  |  |  |
| (3) monitoring maternal patient care from transport if applicable, to admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Plan; |  |  |  |
| (4) participating in ongoing maternal staff and team-based education and training in the care of the maternal patient; |  |  |  |
| (5) overseeing the inter-facility maternal transport; |  |  |  |
| (6) collaborating with the MPM in areas to include:   * developing or revising policies, procedures and guidelines, * assuring medical staff and personnel competency, education and training; and * the QAPI Plan; |  |  |  |
| (7) frequently leading the maternal QAPI meetings with the MPM and participating in Maternal Program Oversight and other maternal meetings as appropriate; |  |  |  |
| (8) ensuring that the QAPI Plan is specific to maternal and fetal care, is ongoing, data-driven and outcome-based; |  |  |  |
| (9) participating as a clinically active and practicing physician in maternal care at the facility where medical director services are provided; |  |  |  |
| (10) maintaining active staff privileges as defined in the facility's medical staff bylaws; and |  |  |  |
| (11) developing collaborative relationships with other MMD(s) of designated facilities within the applicable Perinatal Care Region. |  |  |  |
| (e) MPM. The facility must identify a MPM who has the authority and oversight responsibilities written in his or her job description for the provision of maternal services through all phases of care, including discharge and identifying variances in care for inclusion in the QAPI Plan and: |  |  |  |
| (1) be a registered nurse with perinatal experience; |  |  |  |
| (2) be a clinically active and practicing registered nurse participating in maternal care at the facility where program manager services are provided; |  |  |  |
| (3) has the authority and responsibility to monitor the provision of maternal patient care services from admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Plan; |  |  |  |
| (4) collaborates with the MMD in areas to include:   * developing or revising policies, procedures and guidelines; * assuring staff competency, education, and training and * the QAPI Plan; |  |  |  |
| (5) frequently leads the maternal QAPI meetings and participates in Maternal Program Oversight and other maternal meetings as appropriate; |  |  |  |
| (6) ensures that the QAPI Plan is specific to maternal and fetal care, is ongoing, data-driven and outcome based, including telehealth/telemedicine utilization, when used; and |  |  |  |
| (7) develops collaborative relationships with other MPM(s) of designated facilities within the applicable Perinatal Care Region. |  |  |  |
| **§133.209 Level IV** | | | |
| (a) A Level IV (Comprehensive Care). The Level IV maternal designated facility must: |  |  |  |
| (1) provide comprehensive care for pregnant and postpartum patients with low risk conditions to the most complex medical, surgical or obstetrical conditions and their fetuses, that present a high risk of maternal morbidity or mortality; |  |  |  |
| (2) ensure access to on-site consultation to a comprehensive range of:   * medical and maternal subspecialists, * surgical specialists and * behavioral health specialists; |  |  |  |
| (3) ensure capability to perform major surgery on-site; |  |  |  |
| (4) have physicians with critical care training available at all times to actively collaborate with Maternal Fetal Medicine physicians or Obstetrics and Gynecology physicians with obstetrics training, experience and privileges in maternal care; |  |  |  |
| (5) have a maternal fetal medicine critical care team with expertise and privileges to manage or co-manage highly complex, critically ill or unstable maternal patients; |  |  |  |
| (6) have a placenta accreta spectrum disorder multidisciplinary care team with expertise to complete:   * risk factor screening, * evaluation, * diagnosis, * consultation, and * management of patients with anticipated or unanticipated placenta accreta spectrum disorder, including postpartum care; |  |  |  |
| (7) have skilled personnel with documented training, competencies, and annual continuing education, specific for the patient population served; |  |  |  |
| (8) facilitate transports; and |  |  |  |
| (9) provide outreach education related to:   * trends identified through the QAPI Plan, * specific requests, and * system needs,   to lower level designated facilities, and as appropriate and applicable, to:   * non-designated facilities, * birthing centers, * independent midwife practices, and * prehospital providers. |  |  |  |
| (b) Maternal Medical Director (MMD). The MMD must be a physician who: |  |  |  |
| (1) is a board-certified obstetrics and gynecology physician with expertise in the area of critical care obstetrics; or a board-certified maternal fetal medicine physician, both with privileges in maternal care; |  |  |  |
| (2) demonstrates administrative skills and oversight of the QAPI Plan; and |  |  |  |
| (3) has completed annual continuing education specific to maternal care, including complicated conditions. |  |  |  |
| (c) If the facility has its own transport program, there must be an identified Transport Medical Director (TMD). The TMD must be a physician who is a board-certified maternal fetal medicine physician or board-certified obstetrics and gynecology physician with obstetrics privileges, with expertise and experience in critically ill maternal transport. |  |  |  |
| **(d) Program Functions and Services** |  |  |  |
| (1) Triage and assessment of all patients admitted to the perinatal service. |  |  |  |
| (A) Pregnant patients who are identified at high risk of delivering a neonate that requires a higher level of neonatal care must be transferred to a higher level neonatal designated facility prior to delivery unless the transfer is unsafe. |  |  |  |
| (B) Pregnant or postpartum patients identified with conditions or complications that require a service not available at the facility, must be transferred to an appropriate maternal designated facility unless the transfer is unsafe. |  |  |  |
| (2) Supportive and emergency care must be delivered by appropriately trained personnel, for unanticipated maternal-fetal problems that occur during labor and delivery, through the disposition of the patient. |  |  |  |
| (3) A board-certified or board-eligible obstetrics and gynecology physician with maternal privileges must be on-site at all times and available for urgent situations. |  |  |  |
| (4) Ensure that a qualified physician, or a certified nurse midwife with appropriate physician back-up, is available to attend all deliveries or other obstetrical emergencies. |  |  |  |
| (5) Intensive Care Services. The facility must have an adult Intensive Care Unit (ICU) and critical care capabilities for maternal patients, including: |  |  |  |
| (A) a comprehensive range of medical and surgical critical care specialists and advanced subspecialists on the medical staff; |  |  |  |
| (B) a maternal fetal medicine critical care team with experience and expertise in the care of complex or critically ill maternal patients available to co-manage maternal patients; and |  |  |  |
| (C) availability of obstetric nursing and support personnel with experience in care for critically ill maternal patients. |  |  |  |
| (6) Maternal Fetal Medicine Critical Care Team. The facility must have a Maternal Fetal Medicine (MFM) critical care team whose members have expertise to assume responsibility for pregnant or postpartum patients who are in critical condition or have complex medical conditions, including; |  |  |  |
| (A) co-management of ICU-admitted obstetric patients; |  |  |  |
| (B) a MFM team member with full obstetrical privileges available at all times for:   * on-site consultation and management, and * to arrive at the patient bedside within 30 minutes of an urgent request; and |  |  |  |
| (C) a board-certified MFM physician with expertise in critical care obstetrics to lead the team. |  |  |  |
| (7) Management of critically ill pregnant or postpartum patients, including   * fetal monitoring in the ICU, * respiratory failure and ventilator support, * procedure for emergency cesarean, * coordination of nursing care, and * consultative or co-management roles to facilitate collaboration. |  |  |  |
| (8) The facility must have a Placenta Accreta Spectrum Disorder Team whose members have expertise in the diagnosis and management of pregnant or postpartum patients with anticipated and unanticipated placenta accreta spectrum disorder, including: |  |  |  |
| (A) a multidisciplinary primary response team must be comprised of a minimum of the following: |  |  |  |
| (i) an anesthesiologist with training and expertise in obstetrical anesthesiology; |  |  |  |
| (ii) obstetrics and gynecology physician or maternal fetal medicine physician; |  |  |  |
| (iii) surgeon or surgeons with expertise in pelvic, urologic, or gastroenterological surgery; |  |  |  |
| (iv) neonatologist; |  |  |  |
| (v) experienced nursing staff; and |  |  |  |
| (vi) experienced operating room personnel; |  |  |  |
| (B) a secondary response team must be comprised of a minimum of the following: |  |  |  |
| (i) a radiologist with interventional radiology skills; and |  |  |  |
| (ii) a blood bank or transfusion medicine specialist; |  |  |  |
| (C) all primary and secondary response team members must have full hospital privileges; and |  |  |  |
| (i) a representative of each component of the primary response team must be:   * available at all times for inpatient consultation and management, and * arrive at the bedside within 30 minutes of an urgent request   to attend to a patient with placenta accreta spectrum disorder; |  |  |  |
| (ii) a representative of each component of the secondary response team must be:   * available at all times for consultation and management, and * be available to arrive at the patient bedside within a time frame commensurate with the clinical situation and consistent with current standards; |  |  |  |
| (D) representatives of each component of the primary and secondary response teams must participate in regular, ongoing staff and team-based education and training to care for patients with placenta accreta spectrum disorder; |  |  |  |
| (E) a board-certified maternal fetal medicine physician or a board-certified obstetrics and gynecology physician, who has expertise in the diagnosis and management of placenta accreta spectrum disorder, must lead the team; |  |  |  |
| (F) evidence that the facility participates in regular, ongoing outreach and education specific to placenta accreta spectrum disorder to other maternal facilities not specializing in placenta accreta spectrum disorder, inclusive of QAPI Plan; |  |  |  |
| (G) a documented on-call schedule of primary and secondary response team members is readily available to the facility and maternal staff on the labor and delivery unit and operating suite; and |  |  |  |
| (H) evidence that representatives of the primary and secondary response teams participate in the maternal program's QAPI process for the review of all placenta accreta spectrum disorder cases and assist the PCR with the review of placenta accreta spectrum disorder cases, as requested. |  |  |  |
| (9) Behavioral Health Services. |  |  |  |
| (A) Consultation by a behavioral health professional, with experience in maternal or neonatal counseling must be available on-site at all times for in-person visits when requested for prenatal, peri-operative, and postnatal needs of the patient within a time period consistent with current standards of professional practice and maternal care. |  |  |  |
| (B) Consultation by a psychiatrist, with experience in maternal or neonatal counseling must be available for in-person visits when requested within a time period consistent with current standards of professional practice and maternal care. |  |  |  |
| (10) The primary provider caring for a pregnant or postpartum patient who is a:   * family medicine physician with obstetrics training and experience, * obstetrics and gynecology physician, * maternal fetal medicine physician, or * a certified nurse midwife, physician assistant or nurse practitioner with appropriate physician back-up,   whose credentials have been reviewed by the MMD and is on call: |  |  |  |
| (A) must arrive at the patient bedside within 30 minutes for an urgent request; and |  |  |  |
| (B) must complete annual continuing education, specific to the care of pregnant and postpartum patients, including complicated and critical conditions. |  |  |  |
| (11) Certified nurse midwives, physician assistants and nurse practitioners who provide care for maternal patients: |  |  |  |
| (A) must operate under guidelines reviewed and approved by the MMD; and |  |  |  |
| (B) must have a formal arrangement with a physician with obstetrics training or experience, and with maternal privileges who must: |  |  |  |
| (i) provide back-up and consultation; |  |  |  |
| (ii) arrive at the patient bedside within 30 minutes of an urgent request; and |  |  |  |
| (iii) meet requirements for medical staff as described in §133.205 of this title (relating to Program Requirements) respectively. |  |  |  |
| (12) An on-call schedule of providers, back-up providers, and provision for patients without a physician must be readily available to facility and maternal staff and posted on the labor and delivery unit. |  |  |  |
| (13) Ensure that the physician providing back-up coverage must arrive at the patient bedside within 30 minutes for an urgent request. |  |  |  |
| (14) Anesthesia Services must comply with the requirements found at §133.41 of this title (relating to Hospital Functions and Services) and must have: |  |  |  |
| (A) anesthesia personnel with experience and expertise in obstetric anesthesia must be available on-site at all times; |  |  |  |
| (B) a board-certified anesthesiologist with training or experience in obstetric anesthesia in charge of obstetric anesthesia services; |  |  |  |
| (C) a board-certified or board-eligible anesthesiologist with training or experience in obstetric anesthesia, including critically ill obstetric patients available for consultation at all times, and arrive at the patient bedside within 30 minutes for urgent requests; and |  |  |  |
| (D) anesthesia personnel on call, including back-up contact information, posted and readily available to the facility and maternal staff and posted in the labor and delivery area. |  |  |  |
| (15) Laboratory Services must comply with the requirements found at §133.41 of this title and must have: |  |  |  |
| (A) laboratory personnel on-site at all times; |  |  |  |
| (B) a blood bank capable of: |  |  |  |
| (i) providing ABO-Rh specific or O-Rh negative blood, fresh frozen plasma, cryoprecipitate, and platelet components on-site at all times; |  |  |  |
| (ii) implementing a massive transfusion protocol; |  |  |  |
| (iii) ensuring guidelines for emergency release of blood components; and |  |  |  |
| (iv) managing multiple blood component therapy; and |  |  |  |
| (C) perinatal pathology services available. |  |  |  |
| (16) Medical Imaging Services must comply with the requirements found at §133.41 of this title and must have: |  |  |  |
| (A) personnel appropriately trained in the use of x-ray equipment available on-site at all times; |  |  |  |
| (B) advanced imaging, including computed tomography (CT), magnetic resonance imaging (MRI), and echocardiography available at all times; |  |  |  |
| (C) interpretation of CT, MRI and echocardiography within a time period consistent with current standards of professional practice and maternal care; |  |  |  |
| (D) a radiologist with critical interventional radiology skills available at all times; |  |  |  |
| (E) advanced ultrasonographic imaging for maternal or fetal assessment, including interpretation available at all times; and |  |  |  |
| (F) a portable ultrasound machine available in the labor and delivery and antepartum unit. |  |  |  |
| (17) Pharmacy services must comply with the requirements found in §133.41 of this title and must have a pharmacist with experience in perinatal pharmacology available at all times. |  |  |  |
| (18) Respiratory Therapy Services must comply with the requirements found at §133.41 of this title and must have a respiratory therapist immediately available on-site at all times. |  |  |  |
| (19) Obstetrical Services. |  |  |  |
| (A) The ability to begin an emergency cesarean delivery within a time period consistent with current standards of professional practice and maternal care. |  |  |  |
| (B) Ensure the availability and interpretation of non-stress testing, and electronic fetal monitoring. |  |  |  |
| (C) A trial of labor for patients with prior cesarean delivery must have the capability of anesthesia, cesarean delivery, and maternal resuscitation on-site during the trial of labor. |  |  |  |
| (20) Resuscitation. The facility must have written policies and procedures specific to the facility for the stabilization and resuscitation of the pregnant or postpartum patient based on current standards of professional practice. The facility: |  |  |  |
| (A) ensures staff members, not responsible for the neonatal resuscitation, are immediately available on-site at all times who:   * demonstrate current status of successful completion of ACLS, or a department-approved equivalent course, and * the skills to perform a complete resuscitation; and |  |  |  |
| (B) ensures that resuscitation equipment, including difficult airway management equipment for pregnant and postpartum patients, is readily available in the labor and delivery, antepartum and postpartum areas. |  |  |  |
| (21) The facility must have a written hospital preparedness and management plan for patients with placenta accreta spectrum disorder who are undiagnosed until delivery, including:   * educating and training hospital and medical staff   who may be involved in the treatment and management of placenta accreta spectrum disorder about:   * risk factors, * diagnosis, and * management. |  |  |  |
| (22) The facility must have written guidelines or protocols for various conditions that place the pregnant or postpartum patient at risk for morbidity or mortality, including:   * promoting prevention, * early identification, * early diagnosis, * therapy, * stabilization, and * transfer.   The guidelines or protocols must address a minimum of: |  |  |  |
| (A) massive hemorrhage and transfusion of the pregnant or postpartum patient in coordination of the blood bank, including management of unanticipated hemorrhage or coagulopathy; |  |  |  |
| (B) obstetrical hemorrhage, including:   * promoting the identification of patients at risk, * early diagnosis, and * therapy to reduce morbidity and mortality; |  |  |  |
| (C) placenta accreta spectrum disorder, including:   * team education, * risk factor screening, * evaluation, * diagnosis, * fostering telemedicine medical services and referral as appropriate, * treatment, and * multidisciplinary management of both anticipated and unanticipated placenta accreta spectrum disorder cases, including postpartum care; |  |  |  |
| (D) hypertensive disorders in pregnancy, including eclampsia and the postpartum patient to promote early diagnosis and treatment to reduce morbidity and mortality; |  |  |  |
| (E) sepsis or systemic infection in the pregnant or postpartum patient; |  |  |  |
| (F) venous thromboembolism in the pregnant and postpartum patient, including:   * assessment of risk factors, * prevention, * early diagnosis and * treatment; |  |  |  |
| (G) shoulder dystocia, including:   * assessment of risk factors, * counseling of patient, and * multidisciplinary management; and |  |  |  |
| (H) behavioral health disorders, including:   * depression, * substance abuse and addiction   that includes:   * screening, * education, * consultation with appropriate personnel and * referral. |  |  |  |
| (23) The facility must have nursing leadership and staff with training and experience in the provision of maternal critical care who must coordinate with respective neonatal services. |  |  |  |
| (24) The facility must have a program for genetic diagnosis and counseling for genetic disorders, or a policy and process for consultation referral to an appropriate facility. |  |  |  |
| (25) Perinatal Education.   * A registered nurse with experience in maternal care, including moderately complex and ill obstetric patients, * must provide the supervision and coordination of staff education. * Perinatal education for high-risk events must be provided at frequent intervals to prepare medical, nursing, and ancillary staff for these emergencies. |  |  |  |
| (26) Support personnel with knowledge and skills in breastfeeding to meet the needs of maternal patients must be available at all times. |  |  |  |
| (27) A certified lactation consultant must be available at all times. |  |  |  |
| (28) Social services,   * pastoral care and * bereavement services   must be provided as appropriate to meet the needs of the patient population served. |  |  |  |
| (29) Dietician or nutritionist available with training and experience in maternal nutrition and can plan diets that meet the needs of the pregnant and postpartum patient and critically ill maternal patient must comply with the requirements in §133.41 of this title. |  |  |  |