Ohio Administrative Code

Rule 3701-7-09 Level III service standards.

Effective: October 1, 2019

(A) Obstetric license. A level III obstetrical service shall provide antepartum, intrapartum and postpartum care for obstetrical patients, including:

(1) All low-risk patients;

(2) All uncomplicated patients with higher-risk conditions;

(3) All high-risk patients;

(4) Patients with more complex maternal or fetal conditions as identified by the service, such as patients;

(a) With suspected placenta accreta or placenta previa with prior uterine surgery;

(b) With suspected placenta percreta;

(c) With adult respiratory syndrome; or

(d) Requiring expectant management of early severe preeclampsia at less than thirty-four weeks of gestation;

(5) Intensive care through an on-site intensive care unit that is equipped to:

(a) Provide labor and delivery in the intensive care unit;

(b) Provide medical and surgical care of complex obstetrical conditions; and

(c) Bring intensive care unit services to the obstetrical unit;

(6) The management of unanticipated complications of labor and delivery; and

(7) The management of emergencies.

(B) Obstetric transfer. A level III obstetrical service shall transfer to a level IV obstetric service care any pregnant woman for intrapartum care:

(1) With a complex medical condition that requires critical care or intensive care beyond that which the facility can provide; or

(2) If the newborn is anticipated to need advanced medical and surgical care beyond that which the transferring service is licensed to provide.

Exception: A level III obstetrical service may provide care where an emergency medical condition exists as defined by the Emergency Medical Treatment and Labor Act, 42 U.S.C. 1395dd (2012), and is evidenced by the following:

(a) The mother is having contractions; and

(b) When, in the clinical judgment of a qualified obstetrical practitioner working under that practitioners scope of practice:

(i) There is inadequate time to effect a safe transfer of the mother to an appropriate higher level hospital before delivery; or

(ii) The transfer will pose a threat to the health or safety of either the mother or the fetus.

(C) When considering a woman's condition and the likelihood of pregnancy-related complications, paragraphs (A) and (B) of this rule do not preclude the admission of:

(1) A pregnant woman to the maternity unit for care or services for a non-obstetrical issue, but that may require monitoring of the health of the mother, the fetus, or both;

(2) Women for antepartum care at any stage of the maternity cycle where labor is not imminent;

(3) Non-infectious gynecologic patients; or

(4) Non-infectious female surgical patients in accordance with policies and procedures approved by the service's director.

(D) Neonatal license. A level III neonatal care service shall provide intensive, intermediate and routine care to newborns, including to:

(1) All low risk newborns;

(2) All complicated newborns;

(3) Extremely low birth weight infants;

(4) Newborns requiring advanced respiratory care, other than extracorporeal membrane oxygenation, including high-frequency ventilation and inhaled nitric oxide. This paragraph notwithstanding, a level III neonatal care service that was providing pulmonary extracorporeal membrane oxygenation that did not require cardiac intervention under rule 3701-7-11 of the Administrative Code as it existed prior to the effective date of this rule may continue to provide extracorporeal membrane oxygenation that does not require cardiac intervention;

(5) Newborns requiring major surgery as identified by the service, other than newborns requiring immediate surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass, as designated by the service, either on-site or at a nearby, closely-related institution; and

(6) Newborns that require emergency resuscitation or stabilization for transport.

(E) Newborn transfers. When a level III obstetrical service cannot timely transfer a pregnant woman pursuant to paragraph (B)(2) of this rule, the level III neonatal care service shall transfer a newborn to a level IV neonatal care service if the newborn is anticipated to need advanced medical or

surgical care beyond that which the transferring service is licensed to provide, unless all of the following are met:

(1) The level III neonatal care service has in place a valid memorandum of agreement with one or more level IV neonatal care services, providing for consultation on the retention of the infant between the level III neonatal care service attending physician and the neonatologist on the staff of the level IV neonatal care service;

(2) The consultation with, and the concurrence of, the neonatologist on the staff of the level IV neonatal care service is documented by the level III neonatal care service in the patient medical record and as otherwise may be determined by the service; and

(3) The risks and benefits to the newborn for both retention at the level III neonatal care service and transfer of the newborn to a level IV neonatal care service are discussed with the parent, parents, or legal guardian of the newborn and appropriately documented.

(F) Informed consent. When discussing transfer of a pregnant woman or a newborn to another facility in accordance with this rule, the transferring service shall document and provide the patient or patient's legal guardian with:

(1) The recommendations from any consultations with a level IV service;

(2) The risks and benefits associated with the patient's transfer or retention; and

(3) Any other information required by the hospital's policies and procedures.

(G) In the event the patient or patient's legal guardian refuses transfer to a recommended hospital, the service shall document the refusal of transfer and provide treatment to the patient or patients in accordance with hospital policies and procedures. The service shall update the patient or patient's legal guardian as the patient's condition warrants.

(H) Written service plan. Each provider shall, using licensed health care professionals acting within their scopes of practice, develop a written service plan for the care and services to be provided by

the service. The written service plan shall be in accordance with the "Guidelines for perinatal care" or other applicable professional standard and address, at minimum:

(1) The more complex maternal or fetal conditions for which the care will be provided based on the:

(a) Patient population;

(b) Acuity of patients;

(c) Volume of patients; and

(d) Competency of staff;

(2) Criteria for determining those conditions that can be routinely managed by the service;

(3) Admission to the service;

(4) Discharge from the service;

(5) Patient care in accordance with accepted professional standards;

(6) Referrals for obtaining public health, dietetic, genetic, and toxicology services not available in-house;

(7) Minimum competency requirements for staff in accordance with recognized national standards and ensure that all staff are competent to perform services based on education, experience and demonstrated ability;

(8) Administration of blood and blood products;

(9) Provision of phototherapy;

(10) Provision of respiratory therapy;

(11) Unit-based surgeries and surgical suite-based surgeries;

(12) Post-mortem care;

(13) A formal education program for staff including, at minimum:

(a) The neonatal resuscitation program. The service shall ensure all labor and delivery registered nurses and any other practitioner likely to attend to a neonate at a high risk or more complicated delivery receive training in the neonatal resuscitation program; and

(b) A post- resuscitation program. The service shall ensure individuals caring for newborns receive training in a post resuscitation program to include, at minimum:

(i) The identification and treatment of signs and symptoms related to hypoglycemia, hypothermia, and pneumothorax;

(ii) Blood pressure (normal ranges, factors that can impair cardiac output);

(iii) Lab work, including perinatal and postnatal risks factors and clinical signs of sepsis;

(iv) Principles of assisted ventilation, continuous positive airway pressure, positive pressure ventilation, assisting and securing endo-tracheal tube insertion, and chest x-rays;

(v) Emotional support to parents with sick infants; and

(vi) Quality improvement to identify problems and the importance of debriefing to evaluate care in the post-resuscitation period; and

(c) Ongoing continuing education;

(14) Provision of care by direct care staff to individuals in other areas of the hospital, including, but not limited to the emergency department and the intensive care unit;

(15) Risk assessment of obstetric and neonatal patients to ensure identification of appropriate consultation requirements for or referral of high-risk patients;

(16) Follow-up services to patients or refer patients for appropriate follow-up;

(17) Education for mothers regarding personal care and nutrition, newborn care and nutrition, and newborn feeding;

(18) Infection control, consistent with current infection control guidelines issued by the United States centers for disease control and prevention;

(19) Consultation for and referral of both obstetric and neonatal transports;

(20) The coordination and facilitation, on a twenty-four hour basis, of both obstetric and neonatal transports, which may include the reverse transport of newborns;

(21) Consultation for maternal-fetal medicine on a twenty-four hour basis;

(22) Developmental follow-up of at-risk newborns in the service or referral of such newborns to appropriate programs;

(23) Continuing education for referring hospitals;

(24) Provision of opportunities for graduate medical education such as pediatric or obstetrics-gynecology residencies and neonatal or maternal-fetal medicine fellowships;

(25) Provision of opportunities for clinical experience for purposes of graduate nursing education, or continuing education, or both;

(26) Participation, on an ongoing basis, in basic or clinical obstetrics or neonatology research; and

(27) Provision of multi-disciplinary planning relating to management and therapy through the

postpartum period.

(I) Each provider shall, in accordance with accepted professional standards, develop and follow written policies and procedures to implement the written service plan required by paragraph (H) of this rule.

(J) Each provider shall have the ability to perform all of the following:

(1) An emergency cesarean delivery in accordance with facility policy, but no later than thirty minutes from the time that the decision is made to perform the procedure;

(2) Fetal monitoring; and

(3) Resuscitation and stabilization of newborns and emergency care for the mother and newborn in each delivery room.

(K) Support services (on-site). Each provider shall have the following staff and services on-site on a twenty-four hour basis:

(1) Clinical laboratory, capable of providing any necessary testing;

(2) Blood, blood products, and substitutes;

(3) Diagnostic imaging, including:

(a) X-ray; and

(b) Computed tomography;

(4) Portable ultrasound visualization equipment for diagnosis and evaluation;

(5) Pharmacy;

(6) Respiratory therapy and pulmonary; and

(7) Anesthesia.

(L) Support services (on-call). On a twenty four hour basis, each provider shall have the following services on-site, with staff necessary to provide the services on-call:

(1) Diagnostic imaging, including:

(a) Magnetic resonance imaging;

(b) Fluoroscopy; and

(c) Echocardiography; and

(2) Biomedical engineering.

(M) Unit management: Each provider shall have qualified individuals on-staff appropriate for the services provided, including:

(1) A board-certified obstetrician and a board-certified neonatologist as co-directors for the obstetric and neonatal care service. The co-directors shall coordinate and integrate the following:

(a) A system for consultation;

(b) In-service education programs;

(c) Coordination and communication with support services and other obstetrical services;

(d) Defining and establishing, in collaboration with other members of the obstetric team, appropriate protocols and procedures for obstetric patients; and

(e) Treatment of patients in the neonatal intensive care unit who are not under the care of other

physicians;

(2) A board-certified maternal-fetal medicine subspecialist to serve as director of the maternal-fetal medicine service;

(3) A single, designated registered nurse with a bachelor's degree in nursing and a master's degree responsible for leading the organization and supervising the nursing services in the obstetrical service;

(4) A single, designated registered nurse with a bachelor's degree in nursing and a master's degree responsible for leading the organization and supervising the nursing services in the neonatal care service;

(5) A registered nurse with a master's degree in nursing and an area of specialization in perinatal care to provide clinical nursing expertise commensurate with the patient acuity and services provided;

(6) A director of obstetric anesthesia services who is a board-eligible or board-certified anesthesiologist;

(7) A geneticist or genetics counselor who is certified by the American college of medical genetics or eligible for such certification to:

(a) Identify families at risk for genetic abnormalities;

(b) Obtain family genetic history;

(c) Provide genetic counseling in complicated cases; and

(d) If necessary, refer complicated cases to an on-staff medical geneticist.

(N) Specialists. Each provider shall have medical, surgical, radiological and pathology specialists either on-site or on-call based on the medical needs of the patients.

(O) Sub-specialists. Each provider shall have qualified sub-specialists available for consultation, and, if necessary, patient care either on-site or at a nearby closely related hospital or institution, appropriate for the services provided and based upon the medical needs of the patient, that may include:

(1) Medical-surgical:

(a) Maternal-fetal medicine;

(b) Critical care;

(c) General surgery;

(d) Infectious disease;

(e) Hematology;

(f) Cardiology;

(g) Nephrology; and

(h) Neurology;

(2) Pediatric:

(a) Hematology;

(b) Nephrology

(c) Metabolic;

(d) Endocrinology;

(e) Gastroenterology;

(f) Nutrition;

(g) Immunology; and

(h) Pharmacology; and

(3) Pediatric surgical:

(a) Orthopedic surgeons;

(b) Urologic surgeons; and

(c) Otolaryngologic surgeons.

(P) For every anticipated low-risk delivery or uncomplicated delivery with higher-risk conditions, each provider shall have an obstetrician, physician, or certified nurse midwife acting within their scope of practice and under a standard care arrangement with a collaborating physician, in attendance.

For an unanticipated high-risk delivery, every attempt shall be made to secure a second physician or certified nurse practitioner to care for the neonate.

(Q) For every anticipated high-risk delivery, each provider shall have in attendance:

(1) An obstetrician or physician;

(2)) A second physician or certified nurse practitioner acting within their scope of practice and under a standard care arrangement with a collaborating physician to care for the neonate; and

(3) Members of the multi-disciplinary team required by paragraph (T) of this rule, one of whom can initiate resuscitation, and one of whom can complete full resuscitation. This can be the same

individual.

(R) For every delivery with more complex maternal or fetal conditions, each provider shall have in attendance:

(1) An obstetrician or maternal fetal medicine specialist capable of performing a cesarean section;

(2) A neonatologist or physician to attend to the neonate;

(3) Maternal-fetal medicine or fetal surgeon, as appropriate, during operative procedures; and

(4) Members of the multi-disciplinary team required by paragraph (T) of this rule, one of whom can initiate resuscitation, and one of whom can complete full resuscitation. This can be the same individual.

(S) Each provider shall ensure every newborn requiring mechanical ventilation or continuous positive airway pressure has an initial evaluation by a physician or certified nurse practitioner (neonatal). If stable, qualified staff with experience in newborn airway management and diagnosis and management of air leaks must be on-site to care for such newborns.

(T) Each provider shall have on-duty, qualified staff appropriate for the services provided including at minimum:

(1) Registered nurse staffing, including:

(a) At least two registered nurses competent in obstetric and neonatal care for labor and delivery;

(b) A registered nurse with obstetric and neonatal experience for each patient in the second stage of labor;

(c) A registered nurse to circulate for the cesarean section deliveries;

(d) Additional registered nurses with the appropriate education and demonstrated competence,

commensurate with the acuity and volume of patients served, to provide direct supervision of newborns; and

(e) Additional registered nurses with the appropriate education and demonstrated competence, commensurate with the acuity and volume of patients served, to provide direct supervision of obstetric patients; and

(2) At least one member of the nursing staff to attend to newborns when they are not with the mother or her designee; and

(3) A multi-disciplinary team, each of whom have successfully completed the neonatal resuscitation can initiate resuscitation. One member of the multi-disciplinary team shall be capable of completing full resuscitation.

(U) Other disciplines. Each provider shall have the following practitioners on-staff:

(1) A licensed social worker to provide psychosocial assessments and family support services. Additional social workers shall be provided based upon the size and needs of the patient population;

(2) A licensed dietitian with knowledge of maternal and newborn nutrition and knowledge of parenteral/enteral nutrition management of at-risk newborns; and

(3) A certified lactation consultant. Additional certified lactation consultants shall be provided based upon the size and needs of the patient population.