

3701-7-10

Level IV service standards.

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

(1) All uncomplicated patients;

(2) All complicated patients;

(3) All high-risk patients, including patients with:

(a) Severe maternal cardiac conditions;

(b) Severe pulmonary hypertension or liver failure;

(c) Pregnant women requiring neurosurgery or cardiac surgery; and

(d) Pregnant women in unstable condition and in need of an organ transplant;

(4) 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;

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

(6) The management of emergencies.

(B) A level IV neonatal care service must be located in a hospital or other institution and 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 newborns;

(4) Newborns requiring advanced respiratory care, including extracorporeal membrane oxygenation; and

(5) Newborns requiring major newborn surgery, including surgical repair of serious congenital malformations that require cardiac bypass.

(C) A level IV obstetrical service may admit:

(1) A pregnant woman to the maternity unit for care or services for a

3701-7-10

2

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;

(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) 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 based on the "Guidelines for perinatal care" and address, at minimum:

(1) The high-risk 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) Final disposition of a deceased patient, stillbirth, or fetal death;

(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 a high risk delivery receive training in the neonatal resuscitation program;

(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 or referral for 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 or 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 refer 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.
- (E) 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 (D) of this rule.
- (F) 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.
- (G) 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;

3701-7-10

5

(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.

(H) 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.

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

(1) A board-certified maternal-fetal medicine subspecialist or 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 obstetric care 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 care 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 certified by the American college of medical 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.
- (J) 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.
- (K) Sub-specialists. Each provider shall have, either on-site or at a nearby closely related hospital or institution qualified subspecialists that may include:

 - (1) Medical/surgical:

 - (a) Maternal-fetal medicine;
 - (b) Critical care;
 - (c) General surgery;

3701-7-10

7

(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;

(c) Otolaryngologic surgeons;

(d) Cardiovascular surgeons;

(e) Neurosurgeons; and

(f) Anesthesiologists.

(L) Each provider shall have physician or a certified registered nurse midwife to attend each delivery, with an individual who has successfully completed the neonatal resuscitation program and who is capable of initiating and completing full resuscitation on-site, except that at high-risk deliveries, the individual must attend the delivery.

3701-7-10

8

(M) In addition to the requirements of paragraph (L) of this rule, each provider shall have a physician or certified registered nurse practitioner (neonatal) to attend to newborns at each high-risk delivery.

(N) Each provider shall ensure every newborn requiring mechanical ventilation or continuous positive airway pressure has an initial evaluation by a physician or certified registered 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.

(O) Each provider shall have qualified staff on-duty for direct care of patients, 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 cesarean 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;

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

(3) A multi-disciplinary team, of which two members shall have successfully completed the neonatal resuscitation program and be capable of complete neonatal resuscitation.

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

(1) A licensed social worker to provide psychosocial assessments, family support services, and medical social work. 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 needs of the patient population; and.