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Level II service standards.

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

(1) All uncomplicated patients

(2) Selected complicated patients as identified by the service, such as patients with:

(a) Trial of labor after cesarean delivery;

(b) Uncomplicated cesarean delivery; or

(c) Preeclampsia without severe features;

(3) Selected high-risk patients as identified by the service, such as patients with:

(a) Severe preeclampsia; or

(b) placenta previa in which a placenta accreta has been ruled out by ultrasound or magnetic resonance imaging;

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

(5) The management of emergencies.

(B) Obstetric transfer. A level II obstetrical service shall transfer to a level III or level IV obstetric service, as appropriate, of any pregnant woman for intrapartum care:

(1) With a high-risk condition beyond those designated by the service; or

(2) At less than thirty-two weeks gestation or with a fetus expected to weigh less than one thousand five hundred grams.

Exception: A level II 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 practitioner's 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 less than thirty two weeks gestation 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 with uncomplicated, complicated, and high-risk conditions for antepartum care 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 II neonatal care service shall provide intermediate and routine care to newborns, including to:

(1) All low-risk newborns;

(2) All uncomplicated newborns;

(3) Newborns with selected complicated conditions as identified by the service, such as newborns:

(a) With physiologic immaturity such as apnea of prematurity;

(b) With an inability to maintain body temperature;

(c) With an inability to take oral feedings;

(d) Who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need sub-specialty services on an urgent basis; and

(e) Who are convalescing from intensive care;

(4) Newborns requiring mechanical ventilation for brief durations of less than twenty-four hours or continuous positive airway pressure; and

(5) Newborns requiring emergency resuscitation or stabilization for transport.

(E) Newborn transfer. When a level II obstetrical service cannot effect a timely transfer of a pregnant woman pursuant to paragraph (B)(2) of this rule, the level II neonatal care service shall transfer a newborn that is less than thirty-two weeks gestation or

weighs less than one thousand five hundred grams to a neonatal care service licensed to provide the needed care unless all of the following conditions are met:

- (1) The level II neonatal care service has in place a valid memorandum of agreement with one or more neonatal care service licensed to provide the needed care providing for consultation on the retention of the infant between the level II neonatal care service attending physician and a neonatologist on the staff of that neonatal care service licensed to provide the needed care;
- (2) The consultation with, and the concurrence of, the neonatologist on the staff of the neonatal care service licensed to provide the needed care is documented by the level II neonatal care service in the patient medical record and as otherwise may be determined by the service. Such documentation shall be made available to the director upon request; and
- (3) The risks and benefits to the newborn for both retention at the level II neonatal care service and transfer of the newborn to a neonatal care service licensed to provide the needed care are discussed with the parent, parents, or legal guardian of the newborn and appropriately documented. Such documentation shall be made available to the director upon request.

(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 higher-level 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 based on the "Guidelines for perinatal care" and address, at minimum:

- (1) The selected complicated and high-risk conditions for which care will be provided based on the:
  - (a) Patient population;

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- (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; 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 referral of 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 or referral of both obstetric and neonatal transports;

(20) Criteria for the acceptance of both obstetric and neonatal transports from other services, which may include the reverse transport of newborns who otherwise do not meet the level II gestational age and weight restrictions, based on demonstrated capability to provide the appropriate services;

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

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

(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 staff and support services to meet the needs of patients and 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 limited to x-ray;
- (4) Portable ultrasound visualization equipment for diagnosis and evaluation; and
- (5) Respiratory therapy and pulmonary.

(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) Computed tomography;
  - (b) Magnetic resonance imaging; and
  - (c) Fluoroscopy;
- (2) Pharmacy;
- (3) Anesthesia, except that when a patient or patients are receiving anesthesia to include labor epidural, an anesthesiologist or certified registered nurse anesthetist shall be on-site; and
- (4) Biomedical engineering.

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

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- (1) A board-certified obstetrician and a board-certified pediatrician as co-directors of the obstetric and neonatal care service. The co-directors shall establish procedures for patients and shall integrate and coordinate a system for consultation, in-service education and communication with referring obstetric and neonatal care services;
- (2) A neonatologist or a pediatrician in consultation with an on-staff neonatologist, to manage the care of newborns and to provide for:
  - (a) A system for consultation and referral;
  - (b) Continuing education programs;
  - (c) Communication and coordination with the obstetrical service; and
  - (d) Defining and establishing appropriate policies, protocols, and procedures for the unit nursery or nurseries and neonatal follow-up as may be indicated;
- (3) A director of anesthesia services who is a board eligible or board certified anesthesiologist;
- (4) A single, designated, full-time registered nurse with a bachelor's degree in nursing with demonstrated expertise in obstetric care, or neonatal care, or both responsible for leading the organization and supervising of nursing services in the neonatal care service and the obstetrical service.
- (5) A registered nurse to provide clinical perinatal nursing expertise commensurate with the patient acuity and services provided. Expertise may be demonstrated through education, certification or a minimum of five years perinatal experience;
- (N) Specialists. Each provider shall have medical, surgical, radiological and pathology specialists on-call based upon the medical needs of the patients.
- (O) Sub-specialists. Each provider shall have a maternal-fetal medicine sub-specialist available for consultation.
- (P) 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.
- (Q) In addition to the requirements of paragraph (P) of this rule, each provider shall have a physician or certified registered nurse practitioner (neonatal) to attend to

newborns at each high-risk delivery.

(R) 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.

(S) Each provider shall have qualified staff on-duty 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;

(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, of which two members shall have successfully completed the neonatal resuscitation program and be capable of complete neonatal resuscitation; and

(T) 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.