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Freestanding children's hospitals with level III or level IV neonatal care services; special delivery services.

(A) A freestanding children's hospital with a level III neonatal care service shall provide care for for newborns, including:

(1) Low-risk newborns;

(2) Convalescing and moderately ill newborns;

(3) Extremely low birth weight infants;

(4) Newborns who require advanced respiratory care, other than extracorporeal membrane oxygenation, such as high-frequency ventilation and inhaled nitric oxide; and

(5) Newborns who require major surgery other than surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass.

(B) A freestanding children's hospital with a level IV neonatal care service shall provide care for for newborns and fetuses, including:

(1) Low-risk newborns;

(2) Convalescing and moderately ill newborns;

(3) Extremely low birth weight infants;

(4) Newborns who require advanced respiratory care, including extracorporeal membrane oxygenation;

(5) Newborns who require major surgery, such as surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass;

(6) Newborns at extreme high-risk;

(7) Newborns receiving specialized services such as:

(a) Cardiac surgery;

(b) Organ transplants; or

(c) Treatments of rare inborn metabolic errors.

(C) Written service plan. Each freestanding children's hospital with a level III or level IV neonatal care service shall, using licensed health care professionals acting within the scopes of their practice, develop a written service plan for the care and services to be provided. The written service plan shall be based on the "Guidelines for

perinatal care" and address, at minimum:

(1) The specialized services provided by the service 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 unit;

(4) Discharge from the unit;

(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) Provision of a formal education program for staff that includes, 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 direct care staff to provide care 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 neonatal patients to ensure identification of appropriate consultation requirements or referral of high-risk patients;
  - (16) Follow-up services to patients or refer patients for appropriate follow-up;
  - (17) Infection control, consistent with current infection control guidelines issued by the United States centers for disease control and prevention;
  - (18) Consultation or referral of neonatal transport;
  - (19) Coordination and facilitation of neonatal transports from referring hospitals on a twenty four hour basis;
  - (20) Consultation for neonatal care services on a twenty-four hour basis;
  - (21) Developmental follow-up of at-risk newborns in the service or refer such newborns to appropriate programs;
  - (22) Provision of developmental follow-up of at-risk newborns in the service or refer such newborns to appropriate programs;
  - (23) Continuing education for referring hospital;

(24) Provision of opportunities for graduate medical education such as pediatric residencies or neonatal medicine fellowships;

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

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

(27) Provision of multidisciplinary planning related to management and therapy for newborn care.

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

(E) Support services. 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.

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

(1) Diagnostic imaging, including:

(a) Magnetic resonance imaging;

(b) Fluoroscopy; and

(c) Echocardiography; and

(2) Biomedical engineering.

(G) Each provider shall have qualified individuals on-staff appropriate for the services provided including:

(1) A board certified neonatologist as director of the neonatal care service. The director shall coordinate and integrate the following, including:

(a) A system for consultation;

(b) In-service education programs;

(c) Coordination and communication with support services;

(d) In collaboration with other members of the neonatal team, define and establish appropriate protocols and procedures for newborn patients;  
and

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

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

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

(H) Specialists. Medical, surgical, radiological and pathology specialists shall be on-call based on the medical needs of the patients.

(I) Sub-Specialists. Each freestanding children's hospital with a level III or level IV neonatal care service shall have, either on-site or at a nearby closely related hospital or institution, qualified sub-specialists that may include:

(1) Pediatric:

(a) Nephrologists;

(b) Hematologists;

(c) Metabologists;

(d) Endocrinologists;

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(e) Gastroenterologists;

(f) Nutritionists;

(g) Infectious disease;

(h) Pulmonologists;

(i) Immunologists; and

(j) Pharmacologists;

(2) Pediatric surgical:

(a) Orthopedic surgeons;

(b) Urologic surgeons; and

(c) Otolaryngologic surgeons;

(3) For a freestanding children's hospital with a level IV neonatal care service, additional pediatric surgical:

(a) Cardiovascular surgeons; and

(b) Neurosurgeons.

(J) Each provider shall have sufficient registered nurses with the appropriate education and demonstrated competence, commensurate with the acuity and volume of patients served, on-duty at all times to provide direct supervision of newborns.

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

(1) At least one 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; and

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

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

(L) Special delivery services. A freestanding children's hospital may provide special delivery services to low-risk pregnant women as part of a comprehensive multidisciplinary program of fetal and neonatal care when it is determined that the fetus, once delivered, will require immediate highly subspecialty neonatal intensive

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care or neonatal surgery typically provided by a level III or level IV neonatal care service.

(M) Each freestanding children's hospital that provides special delivery services shall, in conjunction with contracted obstetric staff or a licensed obstetrical service, develop and follow a patient care plan for both the pregnant woman and the newborn for each delivery. The comprehensive care plan shall, include, at minimum:

(1) A delineation of responsibilities for the provision of obstetrical care and neonatal care, including support personnel and services at all stages of labor;

(2) Provision of antepartum and postpartum care of the pregnant woman, to include supervision by an obstetrician or maternal-fetal medicine specialist, and on-site nursing services provided by a least one registered nurse competent in obstetric care with additional registered nurses based on the acuity of the patient.

(3) Parameters for transfer of the pregnant woman should risks present themselves before, during, or after pregnancy;

(4) A staffing plan for when actively providing special delivery services, in addition to the requirements of paragraphs (F) to (K) of this rule, that includes, at minimum, the following qualified staff on-site to attend each delivery:

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

(b) A neonatologist to attend to the newborn;

(c) Maternal-fetal medicine or fetal surgeon during operative procedures;

(d) A neonatal multidisciplinary team of staff for deliveries, headed by a neonatologist with additional registered nurse staff competent in neonatal care based on acuity of newborn; and

(e) At least one registered nurse competent in obstetric care with additional registered nurses based on the acuity of the patient.

(N) Each freestanding children's hospital that provides special delivery services shall meet the following:

(1) Rooms in which special delivery services are provided shall meet all requirements for labor, delivery, and recovery rooms as set forth in rule 3701-7-06 of the Administrative Code; and

(2) Perform cesarean deliveries in an operating room that is or in close proximity to the area in which special delivery services are provided.

(O) When being used for delivery, each freestanding children's hospital that provides special delivery services shall have the ability to perform all 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.