



Ohio Administrative Code

Rule 3701-22-25 Freestanding children's hospitals with level III or level IV neonatal care services.

Effective: August 31, 2025

(A) A freestanding children's hospital with a level III neonatal care service will provide care 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 will provide care 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 will, 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 will 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 standards 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) Provision of a formal education program for staff that includes, at minimum:
 - (a) A nursing orientation that incorporates didactic education, simulation, skills verification, and competency and is tailored to the individual needs of each nurse based on clinical experience;
 - (b) The neonatal resuscitation program. The service will 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;
 - (c) A post resuscitation program. The service will 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
- (d) Ongoing continuing education that includes;
- (i) An annual educational needs assessment to determine the educational needs of the clinical nursing staff and ancillary team members;
 - (ii) Annual nursing education that addresses the annual needs assessment and incorporates simulation and skills verification of low-volume, high-risk procedures consistent with the types of care provided in the obstetric and neonatal care services and includes education related to serious safety events; and
 - (iii) Nursing staff participation in annual simulation and skills verification, including low-volume, high-risk procedures consistent with the types of care provided in the obstetric and neonatal care services.
- (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) A formal process for the on-site provision of services or the referral of patients to follow-up services, as appropriate, for the following:

(a) Developmental screening;

(b) Ophthalmology;

(c) Audiology;

(d) Child life specialist;

(e) Lactation clinical care, education, and support;

(f) Neonatal therapists to address the six core practice domains of environment, family or psychosocial health support, sensory system, neurobehavioral system, neuromotor and musculoskeletal systems, and oral feeding and swallowing by providers with neonatal experience, including:

(i) Physical therapy;

(ii) Occupational therapy; and

(iii) Speech therapy.

(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) Provision of ongoing education for referring hospitals;
- (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;
- (27) Provision of multidisciplinary planning related to management and therapy for newborn care; and
- (28) A process to appropriately identify infants at risk for retinopathy of prematurity to guarantee timely examination and treatment by having:
 - (a) Documented policies and procedures for the monitoring, treatment, and follow-up of retinopathy of prematurity; and
 - (b) The ability to perform on-site retinal examinations, or off-site interpretation of digital photographic retinal images, by a pediatric ophthalmologist or retinal specialist with expertise in retinopathy of prematurity.
- (D) Each provider will, in accordance with accepted standards of practice, develop and follow written policies and procedures to implement the written service plan set forth in paragraph (C) of this rule.



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

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

(a) Blood typing, crossmatch, and antibody testing;

(b) Neonatal blood gas monitoring;

(c) Analysis of small volume samples;

Low-volume specialty laboratory services may be provided by an outside laboratory, but the facility will have policies and procedures in place to verify timely and direct communication of all critical value results;

(d) The capability to process biopsies and perform autopsies; and

(e) Access to perinatal pathology services, if applicable.

(2) A blood bank capable of providing blood, blood products, substitutes, blood component therapy and irradiated, leukoreduced or cytomegalovirus (CMV)-negative blood with policies and procedures in place to facilitate emergent access to blood and blood component therapy so that the neonatal care service can provide a full range of hematologic interventions;

(3) Diagnostic imaging, including:

(a) X-ray; and

(b) Computed tomography;

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



(5) Each provider will have at least one registered pharmacist with experience in neonatal and/or pediatric pharmacology who will:

(a) Complete continuing education requirements specific to pediatric and neonatal pharmacology;

(b) Participate in multidisciplinary care, including participation in patient care rounds;

(c) Ensure that neonatal appropriate total parenteral nutrition (TPN) is available twenty-four hours a day and that written policies and procedures for the proper preparation and delivery of TPN are in place;

(d) Have policies and procedures in place to address drug shortages and to verify medications are appropriately allocated to the neonatal care service; and

(e) Have policies and procedures in place to verify neonatal competency for pharmacy staff supporting and preparing medications for neonatal patients.

(f) A pediatric/neonatal trained hospital pharmacist available by telephone or telehealth on a twenty-four-hour day basis. This requirement can be provided directly or by an agreement with a children's hospital.

(6) Respiratory therapy and pulmonary. The respiratory therapy service will:

(a) Have a full-time credentialed respiratory care practitioner, with education, training, or experience in neonatal respiratory care who:

(i) Has sufficient time allocated to provide direction and guidance as needed, of the respiratory therapists who provide care in the level III or level IV neonatal care service; and

(ii) Provide oversight of an annual simulation and skills verification of staff, including neonatal respiratory care modalities and low-volume, obstetric and high-risk neonatal respiratory procedures;

(b) Develop a written staffing plan for respiratory therapists that establishes flexibility for variable



census and acuity. This plan and actual staffing will be based on allocating the appropriate number of respiratory therapy staff to a care situation, attend to a safe and high-quality work environment, and be operationally reviewed annually for adherence and to verify respiratory therapy staffing is adequate for patient care need;

(c) Maintain appropriate staffing ratios for infants receiving supplemental oxygen and positive pressure ventilation; and

(d) Ensure that respiratory therapy practitioners:

(i) Have documented education, training, or experience in the respiratory support of newborns and infants;

(ii) Will be on-site twenty-four hours a day, seven days a week and immediately available to supervise assisted ventilation, assist in resuscitation, and attend deliveries;

(iii) Are current on neonatal resuscitation program training;

(iv) Have their credentials reviewed by the respiratory care leader annually; and

(v) Participate in annual simulation and respiratory skills verification, including low-volume, high-risk procedures consistent with the types of respiratory care provided in the obstetric and neonatal care services.

(7) Anesthesia, including an anesthesiologist with the ability to:

(a) Respond to the bedside within one hour of request or identified need;

(b) Act as the primary responsible anesthesia provider for all infants; and

(c) Be physically present for all neonatal surgical procedures for which they serve as the primary responsible anesthesia provider; and



(8) Neonatal nutrition:

- (a) Provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula for two or more additives to human milk;
 - (b) Develop standardized feeding protocols for the advancement of feedings based on the availability of, and family preference for human milk, donor human milk, fortification of human milk and formula; and
 - (c) Have policies and procedures in place for accurate verification and administration of human milk and formula, and to avoid misappropriation.
- (F) On a twenty four hour basis, each provider will 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;
 - (c) The ability to provide timely imaging interpretation by radiologists with pediatric expertise as requested;
 - (d) Personnel appropriately trained in ultrasonography, including cranial ultrasonography, to perform advanced imaging as requested; and
 - (e) Echocardiography, including the ability to consult with a pediatric cardiologist for timely echocardiography interpretation as requested; and
- (2) Biomedical engineering.

(G) Unit management: Each provider will 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 will 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) Neonatal nurse leader: A single, designated registered nurse with a bachelor's degree in nursing and a master's degree with experience and expertise in neonatal nursing and conditions, responsible for leading the organization and supervising the nursing services of a level III or level IV neonatal care service, who will:

(a) Be responsible for inpatient activities in the neonatal care service;

(b) Coordinate with respective neonatal and peditatric care services, as appropriate;

(c) Provide oversight of annual neonatal-specific education which includes low-volume, high-risk procedures consistent with the care provided in the level III or level IV neonatal care service;

(d) Foster collaborative relationships with multidisciplinary team members, facility leadership, and higher-level facilities to create a diverse, equitable, and inclusive environment to improve the quality of care and patient care outcomes; and



(e) If the neonatal nurse leader is involved with providing care to the neonatal patient, the neonatal nurse leader must be current on neonatal resuscitation.

(3) Neonatal nurse specialist: A registered nurse with master's degree in nursing, who has demonstrated expertise in neonatal health to provide clinical nursing expertise commensurate with the patient acuity and services provided, who will:

(a) Foster continuous quality improvement in nursing care;

(b) Develop and educate staff to provide evidence-based nursing care;

(c) Be responsible for mentoring new staff and developing team building skills;

(d) Provide leadership to multidisciplinary teams;

(e) Facilitate case management of high-risk neonatal patients;

(f) Cultivate collaborative relationships with multidisciplinary team members and facility leadership to improve the quality of care and patient care outcomes;

(g) If the neonatal nurse specialist is involved with providing care to the neonatal patient, the neonatal nurse specialist must be current on neonatal resuscitation; and

(h) The roles and responsibilities of the nurse specialist can be allocated to multiple individuals to perform this role.

(4) Nurse educator: A registered nurse with a bachelor's degree in nursing and a master's degree, who has sufficient time allocated to perform the roles and responsibilities of the role who is responsible for:

(a) Cultivating collaborative relationships with the neonatal nurse leader and facility leadership to improve the quality of care and patient care outcomes;



(b) Evaluating the educational needs of the clinical staff, developing didactic and skill-based educational tools, overseeing education and skills verification, and evaluating retention of content, critical thinking skills, and competency relevant to neonatal care services; and

(c) A registered nurse employed as a nurse educator as of October 1, 2024, who has not obtained a master's degree will have five years from that date to complete a master's degree program.

(5) A geneticist or genetics counselor 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.

(H) Specialists. Medical, surgical, radiological and pathology specialists will 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 will 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;

(e) Gastroenterologists;

(f) Nutritionists;

(g) Infectious disease;

(h) Pulmonologists;

(i) Ophthalmologists;

(j) Immunologists;

(k) Pharmacologists; and

(l) General surgery;

(2) Pediatric surgical:

(a) Orthopedic surgeons;

(b) Urologic surgeons; and

(c) Otolaryngologic surgeons; and

(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 will 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 will have:

(1) A master's prepared social worker. Individuals employed in this position on the effective date of these rules who do not meet the qualifications of this rule shall have five years from the effective date of this rule to come into compliance with the certification requirement. Additional social workers will be provided based upon the size and needs of the patient population. Social workers will:

(a) Provide assessments, family support services, and medical social work;

(b) Have a written description that clearly identifies the responsibilities and functions of the obstetric and neonatal care service social worker;

(c) Have social services available for each family with an infant in the neonatal care service as needed;

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

(a) Collaborate with the medical team to establish feeding protocols, develop patient-specific feeding plans, and help determine nutritional needs at discharge;

(b) Establish policies and procedures to verify proper preparation and storage of human milk and formula;

(c) Participate in multidisciplinary care, including participation in patient care rounds;

(d) Ensure that policies and procedures are in place for dietary consultation for infants in the neonatal care service;



(3) Personnel with the knowledge and skills to support lactation including:

(a) A certified lactation consultant, as defined in rule 3701-22-01 of the Administrative Code, available for on-site consultation on weekdays and certified lactation consultant services will be accessible by telehealth or telephone twenty-four hours a day, seven days a week. This can be provided by free services available to healthcare providers and their patients through other avenues such as a hotline. Individuals employed in this position on the effective date of these rules who do not meet the qualifications of this rule shall have five years from the effective date of this rule to come into compliance with the certification requirement;

(b) Lactation support may be provided under the direction of the certified lactation consultant by lactation counselor/educator staff or registered nurse staff educated and trained on how to provide lactation support to the mother and neonate.

(c) The provider will ensure that certified lactation consultant staff maintain continuing education and certification requirements, as applicable, and ensure adequately trained lactation coverage is available based on the specific need and volume of the neonatal population served.

(4) Child life services or the equivalent, will be available for on-site consultation to support patient- and family-centered care by establishing and maintaining therapeutic relationships between patients, family members, multidisciplinary team members, and community resources.

(L) If the provider utilizes licensed practical nurses (LPNs) or nonlicensed direct care providers to support the clinical nursing staff, the facility will:

(1) Have written criteria that define the LPN's or nonlicensed direct care provider's scope of obstetric or neonatal care;

(2) Provide annual education specific to the care of the obstetric and neonatal population served; and

(3) Have a written staffing plan that establishes collaborative work assignments in accordance with the facility's policies and procedures.



(M) If the provider utilizes physician assistants (PA):

(1) Physician supervision for the PA will be provided by:

(a) A neonatologist or a board certified pediatrician when the PA is providing care to a neonate; or

(b) An obstetrician or maternal-fetal medicine physician when the PA is providing care to the obstetric patient.

(2) The PA will have appropriate education and demonstrated competence, commensurate with the acuity and volume of patients served, to provide direct supervision of newborns;

(3) The PA is responsible for maintaining clinical expertise and knowledge of current therapy by participating in continuing medical education and scholarly activities;

(4) The PA will maintain national certification, including one hundred hours of continuing medical education every two years and a recertification exam given by the "National Commission on Certification of Physician Assistants" every ten years;

(5) The level III or Level IV service will maintain written criteria that define the PA's scope of obstetric or neonatal care; and

(6) If the PA is involved with providing care to the neonatal patient, the PA must be current on neonatal resuscitation.