

10A NCAC 13B .3102 PLAN APPROVAL

(a) The facility design and construction shall be in accordance with the construction standards of the Division, the North Carolina Building Code, and local municipal codes.

(b) Submission of Plans:

- (1) Before construction is begun, color marked plans and specifications covering construction of the new buildings, alterations or additions to existing buildings, or any change in facilities shall be submitted to the Division for approval.
- (2) The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.
- (3) In order to avoid unnecessary expense in changing final plans, as a preliminary step, proposed plans in schematic form shall be submitted by the applicant to the Division for review.
- (4) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.
- (5) Plans shall be submitted in triplicate in order that the Division may distribute a copy to the Department of Insurance for review of North Carolina State Building Code requirements and to the Department of Environment and Natural Resources for review under state sanitation requirements.

(c) Location:

- (1) The site for new construction or expansion shall be approved by the Division.
- (2) Hospitals shall be so located that they are free from noise from railroads, freight yards, main traffic arteries, schools and children's playgrounds.
- (3) The site shall not be exposed to smoke, foul odors, or dust from industrial plants.
- (4) The area of the site shall be sufficient to permit future expansion and to provide parking facilities.
- (5) Available paved roads, water, sewage and power lines shall be taken into consideration in selecting the site.

(d) The bed capacity and services provided in a facility shall be in compliance with G.S. 131E, Article 9 regarding Certificate of Need. A facility shall be licensed for no more beds than the number for which required physical space and other required facilities are available. Neonatal Level II, III and IV beds are considered part of the licensed bed capacity. Level I bassinets are not considered part of the licensed bed capacity however, no more bassinets shall be placed in service than the number for which required physical space and other required facilities are available.

*History Note: Authority G.S. 131E-79;
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.*

FROM HOSPITAL LICENSURE RULES

10A NCAC 13B .4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

- (1) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may include, small for gestational age or large for gestational age neonates.
- (2) LEVEL II: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or LEVEL IV neonatal services, but who still require more nursing hours than normal infant. This may include infants who require close observation in a licensed acute care bed
- (3) LEVEL III: Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care. The beds in this level may serve as a "step-down" unit from Level IV. Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.
- (4) LEVEL IV (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing

care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

- (b) The facility shall provide for the availability of equipment, supplies, and clinical support services.
- (c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

10A NCAC 13B .6203 NEONATAL LEVEL I AND LEVEL II NURSERY UNIT

- (a) Neonatal infant units shall be on the same floor as post-partum nursing units. No nursery shall open directly into another nursery. Each nursery shall contain the following:
 - (1) Lavatory located within 20 feet travel distance of each bassinet;
 - (2) Emergency calling system;
 - (3) Glazed observation windows for viewing infants from public areas; and
 - (4) Charting facilities.
- (b) A full term nursery shall contain not more than 24 bassinets. The minimum floor area per bassinet shall be 30 square feet exclusive of fixed work or storage counters, toilet rooms, or vestibules less than six feet wide. There shall be available three feet clear in all directions for each bassinet.
- (c) Each nursery shall be served by a connecting workroom. It shall contain gowning facilities at the entrance for staff and housekeeping personnel, lavatory, and storage area. One workroom may serve more than one nursery.
- (d) Space for examination and treatment shall contain a counter, storage, and a lavatory. It may serve more than one nursery room and may be located in a workroom.
- (e) If commercially-prepared formula is not used, space and equipment to accommodate the handling, storage, and preparation of formula shall be provided.
- (f) A janitor's closet for the exclusive use of the housekeeping staff in maintaining the nursery suite shall be provided. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.
- (g) Doors to nurseries shall be no less than three feet wide. If doors are provided directly from nurseries to public corridors or public spaces, they shall be equipped with "one-way" hardware for exit only to prevent unauthorized entry.
- (h) Smoke detection shall be provided in each nursery bed space.

*History Note: Authority G.S. 131E-79;
Eff. January 1, 1996.*

10A NCAC 13B .6204 NEONATAL LEVEL III AND LEVEL IV NURSERY

- (a) Units shall be accessible to post-partum nursing and delivery units.
- (b) The nursery shall be located and arranged to preclude unrelated traffic through the nursery.
- (c) Each nursery shall contain the following:
 - (1) Lavatory located within 20 feet travel distance of each bassinet;
 - (2) Emergency calling system; and
 - (3) Charting facilities.
- (d) There shall be six feet between bassinets for Neonatal Level IV units and five feet between bassinets for Neonatal Level III units. Neonatal Level IV nurseries shall have 80 square feet per bassinet not including corridors and cabinets. Neonatal Level III nurseries shall have 50 square feet per bassinet not including cabinets and corridors. Corridors or aisles shall have at least eight feet of clear width for access to bassinets.
- (e) Each nursery shall be served by a connecting workroom. It shall contain gowning facilities at the entrance for staff and housekeeping personnel, lavatory, and storage. One workroom may serve more than one nursery. The workroom may be omitted if equivalent work area and facilities are provided within the nursery. Gowning and hand washing facilities shall be provided at the entrance to each nursery.
- (f) Space for examination and treatment shall be provided and shall contain a counter, storage, and lavatory. It may serve more than one nursery room and may be located in a workroom.
- (g) If commercially prepared formula is not used, space and equipment to accommodate the handling, storage, and preparation of formula shall be provided.
- (h) A janitor's closet for the exclusive use of the housekeeping staff in maintaining the nursery suite shall be provided. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(i) Doors to nurseries shall be no less than three feet wide. If doors are provided directly from nurseries to public corridors or public spaces, they shall be equipped with "one-way" hardware for exit only to prevent unauthorized entry.

(j) Smoke detection shall be provided in each nursery bed space.

*History Note: Authority G.S. 131E-79;
Eff. January 1, 1996*

FROM CERTIFICATE OF NEED RULES

SECTION .1400 – CRITERIA AND STANDARDS FOR NEONATAL SERVICES

10A NCAC 14C .1401 DEFINITIONS

The definitions in this Rule shall apply to all rules in this Section:

- (1) "Approved neonatal service" means a neonatal service that was not operational prior to the beginning of the review period.
- (2) "Existing neonatal service" means a neonatal service in operation prior to the beginning of the review period.
- (3) "High-risk obstetric patients" means those patients requiring specialized services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery. The services are characterized by specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before, during, and after delivery.
- (4) "Level I neonatal services" means services provided by an acute care hospital to full term and pre-term neonates that are stable, without complications, and may include neonates that are small for gestational age or large for gestational age.
- (5) "Level II neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates and infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or Level IV neonatal services, but still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.
- (6) "Level III neonatal service" means services provided by an acute care hospital in a licensed acute care bed to neonates or infants that are high-risk, small (approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not intensive care. Level III neonates or infants require less constant nursing care than Level IV services, but care does not exclude respiratory support.
- (7) "Level IV neonatal service" means neonatal intensive care services provided by an acute care hospital in a licensed acute care bed to high-risk medically unstable or critically ill neonates (approximately under 32 weeks of gestational age) or infants requiring constant nursing care or supervision not limited to continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.
- (8) "Neonatal bed" means a licensed acute care bed used to provide Level II, III or IV neonatal services.
- (9) "Neonatal intensive care services" shall have the same meaning as defined in G.S. 131E-176(15b).
- (10) "Neonatal service area" means a geographic area defined by the applicant from which the patients to be admitted to the service will originate.
- (11) "Neonatal services" means any of the Level I, Level II, Level III or Level IV services defined in this Rule.
- (12) "Obstetric services" means any normal or high-risk services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery.
- (13) "Perinatal services" means services provided during the period shortly before and after birth.

History Note: Authority G.S. 131E-177(1); 131E-183;

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Amended Eff. November 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003.

10A NCAC 14C .1402 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant proposing to develop a Level I nursery in the facility for the first time or new or additional Level II, III or IV neonatal beds shall use the Acute Care Facility/Medical Equipment application form.
- (b) An applicant proposing to develop a Level I nursery in the facility for the first time or new or additional Level II, III or IV neonatal beds shall provide the following information:
- (1) the current number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds operated by the applicant;
 - (2) the proposed number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds to be operated following completion of the proposed project;
 - (3) evidence of the applicant's experience in treating the following patients at the facility during the past twelve months, including:
 - (A) the number of obstetrical patients treated at the acute care facility;
 - (B) the number of neonatal patients treated in Level I nursery bassinets, Level II beds, Level III beds and Level IV beds, respectively;
 - (C) the number of inpatient days at the facility provided to obstetrical patients;
 - (D) the number of inpatient days provided in Level II beds, Level III beds and Level IV beds, respectively;
 - (E) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs; and
 - (F) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level II, Level III or Level IV);
 - (4) the projected number of neonatal patients to be served identified by Level I, Level II, Level III and Level IV neonatal services for each of the first three years of operation following the completion of the project, including the methodology and assumptions used for the projections;
 - (5) the projected number of patient days of care to be provided in Level I bassinets, Level II beds, Level III beds, and Level IV beds, respectively, for each of the first three years of operation following completion of the project, including the methodology and assumptions used for the projections;
 - (6) if proposing to provide Level I or Level II neonatal services in the facility for the first time, documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility;
 - (7) if proposing to provide Level I or Level II neonatal services in the facility for the first time, documentation of a written plan to transport infants to Level III or Level IV neonatal services as the infant's care requires;
 - (8) evidence that the applicant shall have access to a transport service with at least the following components:
 - (A) trained personnel;
 - (B) transport incubator;
 - (C) emergency resuscitation equipment;
 - (D) oxygen supply, monitoring equipment and the means of administration;
 - (E) portable cardiac and temperature monitors; and
 - (F) a mechanical ventilator;
 - (9) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;

- (10) documentation to show that the new or additional Level I, Level II, Level III or Level IV neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;
 - (11) a floor plan of the proposed area drawn to scale;
 - (12) documentation of visual observation by unit staff of all patients from one or more vantage points; and
 - (13) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.
- (c) If proposing to provide Level III or Level IV neonatal services in the facility for the first time, the applicant shall also provide the following information:
- (1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide specialized levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;
 - (2) evidence that existing and approved neonatal services in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level III and Level IV services;
 - (3) an analysis of the proposal's impact on existing Level III and Level IV neonatal services which currently serve patients from the applicant's primary service area;
 - (4) the availability of high risk OB services at the site of the applicant's planned neonatal service;
 - (5) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and
 - (6) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including the following:
 - (A) the admission and discharge of patients;
 - (B) infection control;
 - (C) safety practices;
 - (D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and
 - (E) the protocols for obtaining emergency physician care for a sick infant.

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010.

10A NCAC 14C .1403 PERFORMANCE STANDARDS

- (a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards:
- (1) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the overall average annual occupancy of the combined number of existing Level II, Level III and Level IV beds in the facility is at least 75 percent, over the 12 months immediately preceding the submittal of the proposal;
 - (2) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the projected overall average annual occupancy of the combined

number of Level II, Level III and Level IV beds proposed to be operated during the third year of operation of the proposed project shall be at least 75 percent; and

- (3) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this rule.

(b) If an applicant proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet need exists in the applicant's defined neonatal service area, unless the State Medical Facilities Plan includes a need determination for neonatal beds in the service area. The need for Level III and Level IV beds shall be computed for the applicant's neonatal service area by:

- (1) identifying the annual number of live births occurring at all hospitals within the proposed neonatal service area, using the latest available data compiled by the State Center for Health Statistics;
- (2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the State Center for Health Statistics;
- (3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and
- (4) determining the need for Level III and Level IV beds in the proposed neonatal service area as the product of:
 - (A) the product derived in (3) of this Paragraph, and
 - (B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);
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Eff. January 4, 1994;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. February 1, 2009;
Amended Eff. November 1, 2009;
Temporary Amendment Eff. February 1, 2010;
Amended Eff. November 1, 2010.*

10A NCAC 14C .1404 SUPPORT SERVICES

(a) An applicant proposing to provide new Level I, Level II, Level III or Level IV services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) competence to manage uncomplicated labor and delivery of normal term newborn;
- (2) capability for continuous fetal monitoring;
- (3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;
- (4) obstetric services;
- (5) anesthesia services;
- (6) capability of cesarean section within 30 minutes at any hour of the day; and
- (7) twenty-four hour on-call blood bank, radiology, and clinical laboratory services.

(b) An applicant proposing to provide new Level III Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) competence to manage labor and delivery of premature newborns and newborns with complications;
- (2) twenty-four hour availability of microchemistry hematology and blood gases;
- (3) twenty-four hour coverage by respiratory therapy;
- (4) twenty-four hour radiology coverage with portable radiographic capability;

- (5) oxygen and air and suction capability;
- (6) electronic cardiovascular and respiration monitoring capability;
- (7) vital sign monitoring equipment which has an alarm system that is operative at all times;
- (8) capabilities for endotracheal intubation and mechanical ventilatory assistance;
- (9) cardio-respiratory arrest management plan;
- (10) isolation capabilities;
- (11) social services staff;
- (12) occupational or physical therapies with neonatal expertise; and
- (13) a registered dietician or nutritionist with training to meet the special needs of neonates.

(c) An applicant proposing to provide new Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) pediatric surgery services;
- (2) ophthalmology services;
- (3) pediatric neurology services;
- (4) pediatric cardiology services;
- (5) on-site laboratory facilities;
- (6) computed tomography and pediatric cardiac catheterization services;
- (7) emergency diagnostic studies available 24 hours per day;
- (8) designated social services staff; and
- (9) serve as a resource center for the statewide perinatal network.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
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Temporary Amendment Eff. March 15, 2002:
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10A NCAC 14C .1405 STAFFING AND STAFF TRAINING

An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:

- (1) If proposing to provide new Level I or II services the applicant shall provide documentation to demonstrate that:
 - (a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;
 - (b) a physician is designated to be responsible for neonatal care; and
 - (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (2) If proposing to provide new Level III services the applicant shall provide documentation to demonstrate that:
 - (a) the nursing care shall be supervised by a registered nurse;
 - (b) the service shall be staffed by a pediatrician certified by the American Board of Pediatrics; and
 - (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (3) If proposing to provide new Level IV services the applicant shall provide documentation to demonstrate that:
 - (a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;
 - (b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and

- (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (4) All applicants shall submit documentation which demonstrates the availability of appropriate inservice training or continuing education programs for neonatal staff.
- (5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.
- (6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);
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