59A-3.249 Neonatal Intensive Care Units.

(1) A hospital may not provide neonatal intensive care services prior to licensure of NICU beds as evidenced by the bed type appearing on the face of the hospital license.

(a) A hospital establishing neonatal intensive care services must apply for licensure of Level II, III, or IV NICU beds by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C.

(b) A hospital with a Level II, Level III, or Level IV NICU must have, directly or by contract, an emergency 24-hour neonatal transportation system in accordance with Rule 64J-1.006, F.A.C. administered by the Department of Health. Hospitals providing Level II neonatal intensive care services must have a written transfer agreement with a hospital providing Level III or Level IV neonatal intensive care services and hospitals providing Level III neonatal intensive care services must have a written transfer agreement with a hospital providing Level IV neonatal intensive care services.

(c) A hospital providing Level III or Level IV neonatal intensive care services may utilize any licensed NICU bed at the level of neonatal intensive care services required to meet the patient’s needs if the staffing, equipment, and supplies required by this rule for the level of service is met. Hospitals must convert all existing NICU beds to the highest level of NICU beds on the license within one year from the effective date of this rule.

(2) Level II Neonatal Intensive Care Services. Hospitals that are licensed for Level II NICU beds, but not Level III or Level IV NICU beds may perform only Level II Neonatal Intensive Care Services.

(a) Each Level II NICU must be directed by a board certified pediatrician or neonatologist.

(b) The following staff, either directly or by contract, must be readily available to provide emergency care as needed:

1. Physicians with expertise in the treatment of neonates;

2. Neonatal nurses. The nursing staff must be under the supervision of a head nurse with experience and training in neonatal intensive care nursing. The head nurse must be a registered professional nurse. Nurses must be trained to administer cardio-respiratory monitoring, assist in ventilation, administer intravenous fluids, provide pre-operative and post-operative care of patients requiring surgery, manage patients being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress;

I. At least one-half of the nursing personnel assigned to each work shift in Level II NICUs must be registered professional nurses.
II. The nurse to neonate ratio must be at least 1:4 for neonates receiving Level II neonatal intensive care services;

3. Respiratory Therapist. Each hospital with a Level II NICU must have at least one certified respiratory care therapist with expertise in the care of neonates continuously available in the hospital at all times. There must be at least one respiratory therapy technician for every four patients receiving assisted ventilation;

4. Pediatric hospitalists;

5. Neonatologists;

6. Radiology technicians; and

7. Clinical laboratory technicians.

(c) Each unit must provide:

1. On-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Clinical laboratory services must include blood gas analysis, and have the capability to perform microstudies;

2. Anesthesia services available on an on-call basis within 30 minutes;

3. A dietician or nutritionist to provide information on patient dietary needs and to provide the patient’s family instructions or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge;

4. Social services to patients’ families, including family counseling and referral to appropriate agencies for services. Children potentially eligible for the Medicaid, Children’s Medical Services, or Developmental Services Programs shall be referred to the appropriate eligibility worker for eligibility determination;

5. Intervention services for patients identified as being at high risk for developmental disabilities to include developmental assessment, intervention, and parental support and education; and

6. Interdisciplinary staff responsible for discharge planning in accordance with hospital policies and procedures as specified in Rule 59A-3.254(2), F.A.C.

(d) Each bed shall have:

1. An incubator and radiant warmer;

2. One heated humidifier and oxyhood;

3. One respiration or heart rate monitor;

4. One resuscitation bag and mask;

5. One infusion pump; and
6. At least one portable suction device.

(e) Each unit must have available on demand:

1. At least one oxygen analyzer for every three beds;
2. At least one non-invasive blood pressure monitoring device for every three beds;
3. At least one ventilator for every three beds;
4. An EKG machine with printout capability;
5. Transcutaneous oxygen monitoring equipment;
6. Continuous blood pressure measurement;
7. A portable x-ray; and

(3) Level III Neonatal Intensive Care Services. Hospitals providing Level III NICU services must meet the staffing, equipment, and service standards required of Level II NICUs in addition to the standards noted within this subsection. Hospitals providing Level III NICU services may perform Level II and Level III Neonatal Intensive Care Services.

(a) Each Level III NICU must be directed by a full-time, board certified neonatologist. Hospitals with Level III NICUs must maintain the organized medical staff required of Level II NICUs readily available in addition to the following specialists:

1. Pediatric medical subspecialists;
2. Pediatric anesthesiologists;
3. Pediatric surgeons;
4. Pediatric ophthalmologists; and
5. Maternal-fetal medicine specialists.

(b) Neonatal nurses. The nurse to neonate ratio must be at least 1:2 for neonates receiving Level III neonatal intensive care services.

(c) A Level III NICU must be capable of life support as needed. Level III NICUs must have the equipment and services required of a Level II NICU and the following equipment and services must be continuously available:

1. Devices capable of measuring continuous arterial oxygenation in the patient;
2. Advanced respiratory support & physiologic monitoring equipment;
3. Laboratory & imaging facilities;

4. Nutrition & pharmacy support (pediatric expertise);

5. Social services;

6. Pastoral care; and

7. Advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging; and echocardiography.

(4) Level IV Neonatal Intensive Care Services. Hospitals providing Level IV NICU services must meet the staffing, equipment, and service standards required of Level III NICUs in addition to the standards noted within this subsection. Hospitals providing Level IV NICU services may perform Level II and Level III Neonatal Intensive Care Services.

(a) General hospitals providing Level IV NICU services must provide obstetric services for women with high risk pregnancies.

(b) Hospitals providing Level IV services must:

1. Maintain continuous availability of complex neonatal surgery;

2. Assure age and size appropriate transport to and from other facilities;

3. Coordinate continuing education programs for staff;

4. Provide outreach education for other hospitals in their service area;

5. Meet the equipment and service standards required of Level III NICUs;

6. Maintain the organized medical staff required of Level III NICUs; and

7. Maintain continuous availability of pediatric surgical subspecialists to provide emergency care as needed.
(1) The licensee of a hospital issued a certificate of need to establish Level II or Level III Neonatal Intensive Care services must apply for licensure of the Neonatal Intensive Care Unit (NICU) beds by submitting a hospital licensure application as specified in subsection 59A-3.066(2), F.A.C. A Level II NICU must have and maintain at least 10 beds and a Level III NICU must have and maintain at least 15 beds, except hospitals verified as a trauma center pursuant to s. 395.4001(15), F.S. may have and maintain a Level III NICU of at least 5 beds.

(a) A hospital must have a minimum of 1,000 births per year averaged over 2 years to have and maintain a Level II NICU.

(b) Hospitals currently licensed as a Level II NICU and having a minimum of 1,500 births during the previous 12 months may apply for licensure as a Level III NICU. Hospitals must maintain a minimum of 1,500 births per year averaged over the previous 2 years to maintain licensure as a Level III NICU.

(2) In addition to the definitions contained in Rule 59A-3.065, F.A.C., the following definitions shall apply to this section:

(a) “Complex Neonatal Surgery” means any surgical procedure performed upon a neonate by a practitioner credentialed to perform surgical procedures licensed under the provisions of Chapters 458 or 459, F.S., which is associated with entry into or traversing a body cavity, such as the abdomen, thorax, or cranium, with a requirement for either general anesthesia or conscious sedation. Such procedures shall only be performed in hospitals licensed under the provisions of Chapter 395, F.S., providing licensed Level III Neonatal Intensive Care Services.

(b) “Neonatal Care Services” means the aspect of perinatal medicine pertaining to the care of neonates. Hospitals providing neonatal care are classified according to the intensity and specialization of the care that can be provided.

1. “Level I Neonatal Services” means well-baby care services, which include sub-ventilation care, intravenous feedings, and gavage to neonates. Level I Neonatal Services do not include ventilator assistance except for resuscitation and stabilization. Upon beginning ventilation, the hospital shall implement a patient treatment plan which shall include the transfer of the neonate to a Level II or Level III Neonatal Intensive Care Service at such time that it becomes apparent that ventilation assistance will be required beyond the neonate’s resuscitation and stabilization. The hospital shall establish a triage procedure to assess the need for transfer of obstetrical patients to hospitals with Level II or Level III Neonatal Intensive Care Services prior to their delivery where there is an
obstetrical indication that resuscitation will be required for their neonates. Hospitals that do not have licensed Level II or Level III NICU beds may only perform Level I neonatal services.

2. “Level II Neonatal Intensive Care Services” means services that include the provision of ventilator services, and at least 6 hours of nursing care per day. Level II services shall be restricted to neonates of 1,000 grams birth weight and over with the following exception. Ventilation may be provided in a hospital with Level II Neonatal Intensive Care Services for neonates of less than 1,000 grams birth weight only while waiting to transport the neonate to a hospital with Level III Neonatal Intensive Care Services. All neonates of 1,000 grams birth weight or less shall be transferred to a hospital with Level III Neonatal Intensive Care Services. Neonates weighing more than 1,000 grams requiring one or more of the Level III services, as defined by this rule, shall be transferred to a hospital with Level III Neonatal Intensive Care Services. If a hospital with a Level III Neonatal Intensive Care Service refuses to accept the transfer of the patient, the hospital with the Level II Neonatal Intensive Care Service will be found in compliance with this subparagraph upon a showing of continuous good faith effort to transfer the patient as documented in the patient’s medical record. Hospitals that are licensed for Level II NICU beds, but not Level III NICU beds may perform only Level I Neonatal Services and Level II Neonatal Intensive Care Services as defined by this rule.

3. “Level III Neonatal Intensive Care Services” means services that include the provision of continuous cardiopulmonary support services, 12 or more hours of nursing care per day, complex neonatal surgery, neonatal cardiovascular surgery, pediatric neurology and neurosurgery, and pediatric cardiac catheterization. Hospitals with Level III Neonatal Intensive Care Services may perform all neonatal care services. A hospital providing Level III Neonatal Intensive Care Service that does not provide treatment of complex major congenital anomalies that require the services of a pediatric surgeon, or pediatric cardiac catheterization and cardiovascular surgery shall enter into a written agreement with a hospital providing Level III Neonatal Intensive Care Services in the same or nearest service area for the provision of these services. All other services shall be provided at each hospital with Level III Neonatal Intensive Care Services.

(c) “Neonatal Intensive Care Unit Bed” or “NICU bed” means a patient care station within a Level II or Level III NICU that includes an incubator or other moveable or stationary devices supporting the ill neonate. Level II and Level III NICU beds shall be listed separately on a hospital’s license.
1. “Level II NICU Bed” means a patient care station within a neonatal intensive care unit with the capability of providing Neonatal Intensive Care Services to ill neonates of 1,000 grams birth weight or over, and that is staffed to provide at least 6 hours of nursing care per neonate per day, and that has the capability of providing ventilator assistance, and the services as defined in subparagraph (2)(b)2., of this rule.

2. “Level III NICU Bed” means a patient care station within a neonatal intensive care unit with the capability of providing Neonatal Intensive Care Services to severely ill neonates regardless of birth weight, and which is staffed to provide 12 or more hours of nursing care per neonate per day, and the services as defined in subparagraph (2)(b)3., of this rule.

(d) “Service area” means a district as defined in Section 408.032(5), F.S.

(3) Quality of Care Standards for Level II and Level III Neonatal Intensive Care Services.

(a) Each Level II and Level III NICU must be directed by a neonatologist or a group of neonatologists who are members of the organized medical staff of the hospital without limited privileges and provide 24-hour coverage, and who are either board certified or board eligible in neonatal-perinatal medicine.

1. Each hospital with a Level III NICU must have a pediatric cardiologist, who is either board certified or board eligible in pediatric cardiology, available for consultation at all times.

2. Each Class I hospital with a Level III NICU must have a board-certified obstetrician who is qualified by training, experience, or special competence certification in maternal-fetal medicine as a member of the organized medical staff without limited staff privileges.

(b) The nursing staff in Level II and Level III NICUs must be under the supervision of a head nurse with experience and training in neonatal intensive care nursing. The head nurse must be a registered professional nurse. At least one-half of the nursing personnel assigned to each work shift in Level II and Level III NICUs must be registered professional nurses.

1. The nurse to neonate ratio must be at least 1:4 in a Level II NICU at all times. At least one-half of the nurses must be registered professional nurses.

2. The nurse to neonate ratio must be at least 1:2 in a Level III NICU at all times. At least one-half of the nurses must be registered professional nurses.

3. Nurses in a Level II or Level III NICU must be trained to administer cardio-respiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of patients requiring surgery.
manage patients being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress.

(c) Each hospital with a Level II or Level III NICU must have at least one certified respiratory care therapist with expertise in the care of neonates available at all times. There must be at least one respiratory therapy technician for every four patients receiving assisted ventilation.

(d) Each hospital with a Level II or Level III NICU must provide:

1. On-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Clinical laboratory services must include blood-gas analysis, and have the capability to perform microstudies;
2. Anesthesia services available on an on-call basis within 30 minutes;
3. A dietician or nutritionist to provide information on patient dietary needs and to provide the patient’s family instructions or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge;
4. Social services to patients’ families, including family counseling and referral to appropriate agencies for services. Children potentially eligible for the Medicaid, Children’s Medical Services, or Developmental Services Programs shall be referred to the appropriate eligibility worker for eligibility determination;
5. Intervention services for patients identified as being at high risk for developmental disabilities to include developmental assessment, intervention, and parental support and education; and
6. Interdisciplinary staff responsible for discharge planning in accordance with hospital policies and procedures as specified in Rule 59A-3.254(2), F.A.C.

(e) Each Level II and Level III NICU bed shall have:

1. An incubator and radiant warmer;
2. One heated humidifier and oxyhood;
3. One respiration or heart-rate monitor;
4. One resuscitation bag and mask;
5. One infusion pump; and
6. At least one portable suction device.

(f) Each Level II and Level III NICU must have available on demand:

1. At least one oxygen analyzer for every three beds;
2. At least one non-invasive blood-pressure monitoring device for every three beds;
3. At least one ventilator for every three beds;
4. An EKG machine with printout capability;
5. Transcutaneous oxygen monitoring equipment; and
6. Continuous blood pressure measurement.

(g) In addition to the above, each Level III NICU must have on demand availability of devices capable of measuring continuous arterial oxygenation in the patient.

(h) Hospitals with a Level II NICU only must have a transfer agreement with a hospital with a Level III NICU located in the same or nearest service area.

(i) Hospitals with a Level II or Level III NICU must have, directly or by contract, an emergency 24-hour neonatal transportation system as defined by the Department of Health in Rule 64J-1.006, F.A.C.

(j) Hospitals with a Level II or Level III NICU must comply with the Agency requirements for data submission as authorized under section 395.1055 and Chapter 408, Part I, F.S.

(k) Nothing in this section shall be construed to prevent a hospital from providing neonatal care services to its patients. However, no hospital shall have neonatal intensive care unit beds unless it has obtained a valid certificate of need as required by section 408.031 through 408.045, F.S.; and meets the requirements of Rule 59A-3.080, F.A.C. as evidenced by approval issued by the Agency's Office of Plans and Construction.