59C-1.042 Neonatal Intensive Care Services.

(1) It is the intent of the Agency to regulate the establishment of Level II and Level III Neonatal Intensive Care Services as defined in this rule. This rule defines the minimum requirements for personnel, equipment, and support services for the two levels of Neonatal Intensive Care Services as defined in this rule. In addition, this rule includes need methodologies for determining the need for additional neonatal intensive care unit beds for each level of care. A separate inventory for each level of neonatal intensive care unit beds shall be established by the Agency. It is the intent of the Agency to regulate the establishment of Neonatal Intensive Care Services which include ventilation to preterm and severely ill neonates.

(2) Definitions.

(a) "Agency." The Agency for Health Care Administration.

(b) "Approved Neonatal Intensive Care Bed." A proposed Level II bed or Level III bed for which a Certificate of Need, a letter of intent to grant a Certificate of Need, a signed stipulated agreement, or a final order granting a Certificate of Need was issued, consistent with the provisions of paragraph 59C-1.008(2)(b), F.A.C., as of the most recent published deadline for Agency initial decisions prior to publication of the Fixed Need Pool, as specified in paragraph 59C-1.008(1)(g), F.A.C.

(c) "Charity Care." As defined in Section 409.911(1), F.S.

(d) "Complex Neonatal Surgery." Any surgical procedure performed upon a neonate by a surgically-credentialed practitioner 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 be performed only in hospitals licensed under the provisions of Chapter 395, F.S., which are also authorized to provide Level III Neonatal Services.

(e) "District." A district of the Agency as defined in Section 408.032(5), F.S.

(f) "Fixed Bed Need Pool." The Fixed Bed Need Pool defined in subsection 59C-1.002(19), F.A.C.

(g) "Local Health Councils." The councils referenced in Section 408.033, F.S.

(h) "Neonatal Care Services." The aspect of perinatal medicine pertaining to the care of neonates. Hospital units providing neonatal care are classified according to the intensity and specialization of the care which can be provided. The Agency distinguishes three levels of neonatal care services:

1. "Level I Neonatal Services." Well-baby care services which include sub-ventilation care, intravenous feedings, and gavage to neonates are defined as Level I Neonatal Services. 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 facilities 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. Facilities with Level I neonatal services may only perform Level I neonatal services.

2. "Level II Neonatal Intensive Care Services." Services which include the provision of ventilator services, and at least 6 hours of nursing care per day, shall be defined as Level II Neonatal Intensive Care Services. 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 facility with Level II Neonatal Intensive Care Services for neonates of less than 1,000 grams birth weight only while waiting to transport the baby to a facility with Level III Neonatal Intensive Care Services. All neonates of 1,000 grams birth weight or less shall be transferred to a facility 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 also be transferred to a facility with Level III Neonatal Intensive Care Services. If a facility with a Level III Neonatal Intensive Care Service refuses to accept the transfer patient, the facility 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. Facilities with Level II Neonatal Intensive Care Services 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." Services which 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, shall be classified as Level III Neonatal Intensive Care Services. These services cannot be performed in a facility with Level II Neonatal Intensive Care Services only. Facilities with Level III Neonatal Intensive Care Services may perform all neonatal care services. A facility with a 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 facility 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 facility with Level III Neonatal Intensive Care Services. The provision of pediatric cardiac catheterization or pediatric open heart surgery each requires a separate Certificate of Need.

(i) "Neonatal Intensive Care Unit Bed." A patient care station within a Level II neonatal intensive care unit or Level III Neonatal Intensive Care Unit that includes, at a minimum, an incubator or other moveable or stationary devices which support the ill neonate. Beds in Level II or Level III Neonatal Intensive Care Units shall be separately listed in a hospital's licensed bed inventory.

1. "Level II Bed." 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 which is staffed to provide at least 6 hours of nursing care per neonate per day, and which has the capability of providing ventilator assistance, and the services as defined in subparagraph (2)(h)2., of this rule.

2. "Level III Bed." 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)(h)3., of this rule.

(j) "Neonatologist." A physician who is certified, or is eligible for certification, by an appropriate board in the area of neonatal-perinatal medicine.

(k) "Planning Horizon." The planning horizon for applications submitted between January 1 and June 30 of each year shall be July 2 years into the future subsequent to the application submission deadline; the planning horizon for applications submitted between July 1 and December 31 of each year shall be January 2 years into the future subsequent to the application deadline.

(l) "Specialty Beds." Specialty beds include comprehensive medical rehabilitation beds, psychiatric beds, substance abuse beds, as specified in subsection 59C-1.002(1), F.A.C., and Neonatal Intensive Care Services beds as specified by this rule.

(m) "Specialty Children's Hospitals." The hospitals referenced in subparagraph 59A-3.252(1)(b)1., F.A.C., without maternity units in the same facility.

(3) Need Determination.

(a) Applications for proposed Level II or Level III Neonatal Intensive Care Services shall be reviewed competitively within each District in accordance with the applicable review criteria in Section 408.035, F.S., and the standards and need determination criteria set forth in this rule. Hospitals proposing to provide both Level II and Level III Neonatal Intensive Care Services shall require separate Certificate of Need approval for each level of care. A favorable need determination for Level II or Level III beds will not normally be made unless a numeric bed need exists according to the need methodology specified in paragraphs (c) and (e), of this subsection.

(b) The future need for Level II and Level III Neonatal Intensive Care Services shall be determined twice a year and published as a Fixed Bed Need Pool by the Agency for the respective planning horizon.

(c) Level II Bed Need. The net bed need for Level II neonatal intensive care unit beds shall be calculated as follows:

$$NN2 = ((PD2 \times PB/AB)/(365 \times .80)) - LB2 - AB2$$

where:

1. NN2 equals the net need for Level II beds in a district.

2. PD2 equals the number of patient days in Level II beds in a district for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

3. AB is the total number of resident live births in a district for the most recent calendar year available from the Department of Health, Office of Vital Statistics at least 3 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

4. PB is the projected number of resident live births for the applicable planning horizon. To determine the number of births projected for each district, a 3-year average resident live-birth rate for each district shall be calculated using the sum of the resident live births for the 3 most recent calendar years available from the Department of Health, Office of Vital Statistics at least 3 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool. The projected number of resident live births in each district shall be determined by multiplying the 3-year average resident live birth rate by the district's estimated population of females aged 15 to 44 for the applicable planning horizon. The population estimate used to compute the 3-year average resident live birth rate shall be the sum of the July 1 estimates of the population of females aged 15 to 44 for the 3 years that are included in the 3-

year total of resident livebirths. Population estimates for each year shall be the most recent population estimates published by the Office of the Governor at least 3 months prior to publication of the Fixed Bed Need Pool.

5. (.80) equals the desired District average occupancy standard of 80% percent.

6. LB2 equals the number of licensed Level II beds as of the most recent published deadline for Agency initial decisions prior to the publication of the Fixed Bed Need Pool.

7. AB2 equals the number of approved Level II beds, as determined consistent with the provisions of paragraph (2)(a), of this rule.

(d) Regardless of whether bed need is shown under the need formula above, the establishment of new Level II Neonatal Intensive Care Unit beds within a district shall not normally be approved unless the average occupancy rate for Level II beds in the district equals or exceeds 80 percent for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

(e) Level III Bed Need. The net bed need for Level III neonatal intensive care unit beds shall be calculated as follows:

NN3 = ((PD3 × PB/AB) / (365 × .80)) – LB3 – AB3

where:

1. NN3 equals the net need for Level III beds in a district.

2. PD3 equals the number of patient days in Level III beds in a district for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

3. AB is the total number of resident live births in a district for the most recent calendar year available from the Department of Health, Office of Vital Statistics at least 3 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

4. PB is the projected number of resident live births for the applicable planning horizon. To determine the number of births projected for each district, a 3-year average resident live-birth rate for each district shall be calculated using the sum of the resident live births for the 3 most recent calendar years available from the Department of Health, Office of Vital Statistics at least 3 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool. The projected number of resident live births in each district shall be determined by multiplying the 3-year average resident live birth rate by the district's estimated population of females aged 15 to 44 for the applicable planning horizon. The population estimate used to compute the 3 year average resident live birth rate shall be the sum of the July 1 estimates of the population of females aged 15 to 44 for the 3 years that are included in the 3-year total of resident live births. Population estimates for each year shall be the most recent population estimates published by the Office of the Governor at least 3 months prior to publication of the Fixed Bed Need Pool.

5. (.80) equals the desired District average occupancy standard of 80% percent.

6. LB3 equals the number of licensed Level III beds as of the most recent published deadline for Agency initial decisions prior to the publication of the Fixed Bed Need Pool.

7. AB3 equals the number of approved Level III beds, as determined consistent with the provisions of paragraph (2)(a), of this rule.

(f) Regardless of whether bed need is shown under the need formula above, the establishment of new Level III Neonatal Intensive Care Unit beds within a District shall not normally be approved unless the average occupancy rate for Level III beds in the district equals or exceeds 80% percent for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

(g) Services to Medically Indigent and Medicaid Patients. In a comparative review, preference shall be given to hospitals which propose to provide Neonatal Intensive Care Services to Children's Medical Services patients, Medicaid patients, and non-children's medical services patients who are defined as charity care patients. The applicant shall estimate, based on its historical patient data by type of payer, the percentage of Neonatal Intensive Care Services patient days that will be allocated to:

1. Charity Care Patients;

2. Medicaid patients; and,

3. Private pay patients, including self pay.

(4) Level II and Level III Service Continuity. To help assure the continuity of services provided to Neonatal Intensive Care Services patients:

(a) The establishment of Level III Neonatal Intensive Care Services shall not normally be approved unless the hospital also provides Level II Neonatal Intensive Care Services. Hospitals may be approved for Level II Neonatal Intensive Care Services

without providing Level III services.

(b) Applicants proposing to provide Level II or Level III Neonatal Intensive Care Services shall ensure developmental follow-up on patients after discharge to monitor the outcome of care and assure necessary referrals to community resources.

(5) Minimum Unit Size. Hospitals proposing the establishment of new Level III Neonatal Intensive Care Services shall propose a Level III Neonatal Intensive Care Unit of at least 15 beds, and should have 10 or more Level II neonatal intensive care unit beds. A provider shall not normally be approved for Level III Neonatal Intensive Care Services only. Hospitals proposing the establishment of new Level II Neonatal Intensive Care Services only shall propose a Level II Neonatal Intensive Care Unit with a minimum of 10 beds.

(6) Minimum Birth Volume Requirement. A hospital shall not normally be approved for Level III Neonatal Intensive Care Services unless the hospital had a minimum service volume of 1,500 live births for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool. Hospitals applying for Level II Neonatal Intensive Care Services shall not normally be approved unless the hospital had a minimum service volume of 1,000 live births for the most recent 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool. Specialty children's hospitals are exempt from these requirements.

(7) Geographic Access. Level II and Level III Neonatal Intensive Care Services shall be available within 2 hours ground travel time under normal traffic conditions for 90% percent of the population in a service District.

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

(a) Physician Staffing.

1. Level II Neonatal Intensive Care Services shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24-hour coverage, and who are either board certified or board eligible in neonatal-perinatal medicine.

2. Level III Neonatal Intensive Care Services shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24 hours coverage, and who are either board certified or board eligible in neonatal-perinatal medicine. In addition, facilities with Level III Neonatal Intensive Care Services shall be required to maintain a maternal fetal medical specialist on active staff of the hospital with unlimited staff privileges. A maternal fetal specialist is defined as a board-certified obstetrician who is qualified by training, experience, or special competence certification in maternal-fetal medicine. Specialty children's hospitals are exempt from this provision.

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

(c) Special Skills of Nursing Staff. Nurses in Level II and Level III Neonatal Intensive Care Units shall be trained to administer cardio-respiratory monitoring, assist in ventilation, administer I.V. fluids, provide pre-operative and post-operative care of newborns requiring surgery, manage neonates being transported, and provide emergency treatment of conditions such as apnea, seizures, and respiratory distress.

(d) Respiratory Therapy Technician Staffing. At least one certified respiratory care practitioner therapist with expertise in the care of neonates shall be available in hospitals with Level II or Level III Neonatal Intensive Care Services at all times. There shall be at least one respiratory therapist technician for every four infants receiving assisted ventilation.

(e) Blood Gas Determination. Blood gas determination shall be available and accessible on a 24-hour basis in all hospitals with Level II or Level III Neonatal Intensive Care Services.

(f) Ancillary Service Requirements. Hospitals providing Level II or Level III Neonatal Intensive Care Services shall provide on-site, on a 24-hour basis, x-ray, obstetric ultrasound, and clinical laboratory services. Anesthesia shall be available on an on-call basis within 30 minutes. Clinical laboratory services shall have the capability to perform microstudies.

(g) Nutrition Services. Each hospital with Level II or Level III Neonatal Intensive Care Services shall have a dietician or nutritionist to provide information on patient dietary needs while in the hospital and to provide the patient's family instruction or counseling regarding the appropriate nutritional and dietary needs of the patient after discharge.

(h) Social Services. Each hospital with Level II or Level III Neonatal Intensive Care Services shall make available the services of the hospital's social services department to patients' families which shall include, but not be limited to, 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.

(i) Developmental Disabilities Intervention Services. Each hospital that provides Level II or III Neonatal Intensive Care Services shall provide in-hospital intervention services for infants identified as being at high risk for developmental disabilities to include developmental assessment, intervention, and parental support and education.

(j) Discharge Planning. Each hospital that provides Level II or Level III Neonatal Intensive Care Services shall have an interdisciplinary staff responsible for discharge planning. Each hospital shall designate a person responsible for discharge planning.

(9) Level II Neonatal Intensive Care Unit Standards. The following standards shall apply to Level II Neonatal Intensive Care Services:

(a) Nurse to Neonate Staffing Ratio. Hospitals shall have a nurse to neonate ratio of at least 1:4 in Level II Neonatal Intensive Care Units at all times. At least 50% percent of the nurses shall be registered nurses.

(b) Requirements for Level II Neonatal Intensive Care Unit Patient Stations. Each patient station in a Level II Neonatal Intensive Care Unit shall have, at a minimum:

1. Fifty square feet per infant;
2. Two wall mounted suction outlets preferably equipped with a unit alarm to signal loss of vacuum;
3. Eight electrical outlets;
4. Two oxygen outlets and an equal number of compressed air outlets and adequate provisions for mixing these gases;
5. An incubator or radiant warmer;
6. One heated humidifier and oxyhood;
7. One respiration or heart rate monitor;
8. One resuscitation bag and mask;
9. One infusion pump;
10. At least one oxygen analyzer for every three beds;
11. At least one non-invasive blood pressure monitoring device for every three beds;
12. At least one portable suction device; and,
13. Not less than one ventilator for every three beds.

(c) Equipment Required to be Available to Each Level II Neonatal Intensive Care Unit. Each Level II Neonatal Intensive Care Unit shall have available to the unit on demand:

1. An EKG machine with print-out capability;
2. Transcutaneous oxygen monitoring equipment; and,
3. Availability of continuous blood pressure measurement.

(10) Level III Neonatal Intensive Care Unit Standards. The following standards shall apply to Level III Neonatal Intensive Care Services:

(a) Pediatric Cardiologist. A facility providing Level III Neonatal Intensive Care Services shall have a pediatric cardiologist, who is either board certified or board eligible in pediatric cardiology, available for consultation at all times.

(b) Nurse to Neonate Staffing Ratio. Hospitals shall have a nurse to neonate ratio of at least 1:2 in Level III Neonatal Intensive Care Units at all times. At least 50% percent of the nurses shall be registered nurses.

(c) Requirements for Level III Neonatal Intensive Care Unit Patient Stations. Each patient station in a Level III Neonatal Intensive Care Unit shall have, at a minimum:

1. Eighty square feet per infant;
2. Two wall mounted suction outlets preferably equipped with an alarm to signal loss of vacuum;
3. Twelve electrical outlets;
4. Two oxygen outlets and an equal number of compressed air outlets with adequate provision for mixing these gases;
5. An incubator and radiant warmer;
6. One heated humidifier and oxyhood;
7. One respiration or heart rate monitor;
8. One resuscitation bag and mask;
9. One infusion pump;
10. At least one non-invasive blood pressure monitoring device for every three beds;
11. At least one portable suction device; and,

12. Availability of devices capable of measuring continuous arterial oxygenation in the patient.

(d) Equipment Required in Each Level III Neonatal Intensive Care Unit. Each Level III Neonatal Intensive Care Unit shall be equipped with:

1. An EKG machine with print-out capability;

2. Portable suction equipment; and,

3. Not less than one ventilator for every three beds.

(11) Emergency Transportation Services. Each hospital providing Level II Neonatal Intensive Care Services or Level III Neonatal Intensive Care Services shall have or participate in an emergency 24-hour patient transportation system.

(a) Provision of Emergency Transportation. Hospitals providing Level II or Level III Neonatal Intensive Care Services must operate a 24-hour emergency transportation system directly, or contract for this service, or participate through a written financial or non-financial agreement with a provider of emergency transportation services.

(b) Requirements for Emergency Transportation System. Emergency transportation systems, as defined in paragraph (11)(a), shall conform to Rule 64J-1.006, F.A.C.

(12) Transfer Agreements. A hospital providing only Level II Neonatal Intensive Care Services shall provide documentation of a transfer agreement with a facility providing Level III Neonatal Intensive Care Services in the same or nearest service District for patients in need of Level III services. Facilities providing Level III Neonatal Intensive Care Services shall not unreasonably withhold consent to transfer agreements which provide for transfers based upon availability of service in the Level III facility, and which will be applied uniformly to all patients requiring transfer to Level III, as defined in subparagraph 2(e)2. An applicant for Level II or Level III Neonatal Intensive Care Services shall include, as part of the application, a written protocol governing the transfer of Neonatal Intensive Care Services patients to other inpatient facilities.

(13) Data Reporting Requirements. All hospitals with Level II or Level III Neonatal Intensive Care Services shall provide the Agency or its designee with patient utilization and data relating to patient utilization of Level II and Level III Neonatal Intensive Care Services. The following data shall be provided to the Agency or its designee.

Utilization Data. Level II or Level III Neonatal Intensive Care Services providers shall report the number of admissions and patient days for Level II and Level III Neonatal Intensive Care Services. Data shall be reported to the Agency or its designee within 45 days after the end of each calendar quarter.

Rulemaking Authority 408.034(3), (8), 408.15(8) FS. Law Implemented 408.032(17), 408.034(3), 408.035, 408.036(1)(f), 408.039(4)(a) FS. History–New 1-1-77, Amended 11-1-77, 6-5-79, 4-24-80, 2-1-81, 4-1-82, 11-9-82, 2-14-83, 4-7-83, 6-9-83, 6-10-83, 12-12-83, 3-5-84, 5-14-84, 7-16-84, 8-30-84, 10-15-84, 12-25-84, 4-9-85, Formerly 10-5.11, Amended 6-19-86, 11-24-86, 1-25-87, 3-2-87, 3-12-87, 8-11-87, 8-7-88, 8-28-88, 9-12-88, 4-19-89, 10-19-89, 5-30-90, 7-11-90, 8-6-90, 10-10-90, 12-23-90, Formerly 10-5.011(1)(v), 10-5.042, Amended 1-4-93, 8-24-93, 2-22-95, 4-10-96, 3-15-17.