**Section 640.43 Level III** – **Standards for Perinatal Care**

To be designated as Level III, a hospital shall apply to the Department for designation; shall comply with all of the conditions prescribed in this Part for intensive (Level III) perinatal care; shall comply with all of the conditions prescribed in Subpart O of the Hospital Licensing Requirements applicable to the level of care necessary for the patients served; and shall comply with the following provisions (specifics regarding standards of care for both mothers and neonates as well as resource requirements to be provided shall be defined in the hospital's letter of agreement with its APC):

a) Level III − General Provisions

1) A Level III hospital shall provide all services outlined for Level I and II (Sections 640.41(a) and 640.42(a)), general, intermediate and special care, as well as diagnosis and treatment of high-risk pregnancy and neonatal problems. Both the obstetrical and neonatal services shall achieve Level III capability for Level III designation. The hospital shall provide for the education of allied health professionals and shall accept selected maternal and neonatal transports from Level I, Level II and Level II with Extended Neonatal Capabilities hospitals.

2) The Level III hospital shall make available a range of technical and subspecialty consultative support such as pediatric anesthesiology, ophthalmology, pediatric surgery, genetic services, intensive cardiac services and intensive neurosurgical services.

3) To qualify as a Level III hospital, these standards and resource requirements are necessary to ensure adequate competence in the management of certain high-risk patients. These criteria will be assessed by reviewing the resources and outcomes of each hospital's admissions, and which admissions include patients who are subsequently transferred, for the three most recent calendar years, combined, for which data are available.

4) A Level III hospital that elects not to provide all of the advanced level services shall have established policies and procedures for transfer of these mothers and infants to a hospital that can provide the service needed.

5) The Level III hospital shall maintain a system for recording patient admissions, discharges, birth weight, outcome, complications, and transports to meet requirements to support network CQI activities described in the hospital's letter of agreement with the APC. The hospital shall comply with the reporting requirements of the State Perinatal Reporting System.

b) Level III – Standards of Care

1) The Level III hospital shall have a policy requiring general obstetricians and newborn care physicians to obtain consultations from or transfer care to the appropriate subspecialists as outlined in the standards for Level II.

2) The Level III hospital shall accept all medically eligible Illinois residents. Medical eligibility is to be determined by the obstetric or neonatal director or his/her designee based on the Criteria for High-Risk Identification (Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists).

3) The Level III hospital shall provide or facilitate emergency transportation of patients referred to the hospital in accordance with guidelines for inter-hospital care of the perinatal patient (Guidelines for Perinatal Care)). If the Level III hospital is unable to accept the patient referred, the APC Level III hospital shall arrange for placement at another Level III hospital or appropriate Level II or Level II hospital with Extended Neonatal Capabilities.

4) The Level III hospital shall have a clearly identifiable telephone number, facsimile number or other electronic communication, either a special number or a specific extension answered by unit personnel, for receiving consultation requests and requests for admissions. This number shall be kept current with the Department and with the Regional Perinatal Network.

5) The Level III hospital shall provide and document continuing education for medical, nursing, respiratory therapy, and other staff providing general, intermediate and intensive care perinatal services.

6) The Level III hospital shall provide caesarean section decision-to-incision capabilities within 30 minutes.

7) The Level III hospital shall provide data relating to its activities and shall comply with the requirements of the State Perinatal Reporting System.

8) The medical co-directors of the Level III hospital shall be responsible for developing a system ensuring adequate physician-to-physician communication. Communication with referring physicians of patients admitted shall be sufficient to report patient progress before and at the time of discharge.

9) Hospitals shall have the capability for continuous electronic maternal-fetal monitoring for patients identified at risk, with staff available 24 hours a day, including physician and nursing, who are knowledgeable of electronic maternal-fetal monitoring use and interpretation. Physicians and nurses shall complete a competence assessment in electronic maternal-fetal monitoring every two years.

10) The Level III hospital, in collaboration with the APC, shall establish policies and procedures for the return transfer of high-risk mothers and infants to the referring hospital when they no longer require the specialized care and services of the Level III hospital.

11) The Level III hospital shall provide backup systems and plans shall be in place to prevent and respond to sudden power outage, oxygen system failure and interruption of medical grade compressed air delivery.

12) The Level III hospital shall provide or develop a referral agreement with a developmental follow-up clinic to provide neuro-developmental services for the neonatal population. Hospital policies and procedures shall describe the at-risk population and the referral procedure to be followed for enrolling the infant in developmental follow-up. Infants shall be scheduled for assessments at regular intervals. Neuro-developmental assessments shall be communicated to the primary care physicians. Referrals shall be made for interventional care in order to minimize neurologic sequelae. A system shall be established to track, record and report neuro-developmental outcome data for the population, as required to support network CQI activities.

13) Neonatal surgical services shall be available 24 hours a day.

c) Level III – Resource Requirements

1) Obstetric activities shall be directed and supervised by a full-time subspecialty obstetrician certified by the American Board of Obstetrics and Gynecology in the subspecialty of Maternal and Fetal Medicine, or an osteopathic physician with equivalent training and experience and certification by the American Osteopathic Board of Obstetricians and Gynecologists. The director of the obstetric services shall ensure the backup supervision of his or her services by a physician with equivalent credentials.

2) Neonatal activities shall be directed and supervised by a full-time pediatrician certified by the American Board of Pediatrics sub-board of neonatal/perinatal medicine, or a licensed osteopathic physician with equivalent training and experience and certification by the American Osteopathic Board of Pediatricians/Neonatal-Perinatal Medicine. The director of the neonatal services shall ensure the backup supervision of his or her services by a physician with equivalent credentials.

3) An administrator/manager with a master's degree shall direct, in collaboration with the medical directors, the planning, development and operation of the non-medical aspects of the Level III hospital and its programs and services.

A) The obstetric and newborn nursing services shall be directed by a full-time nurse experienced in perinatal nursing, with a master's degree.

B) Half of all neonatal intensive care direct nursing care hours shall be provided by registered nurses who have two years or more of nursing experience in a Level III NICU. All NICU direct nursing care hours shall be provided or supervised by registered nurses who have advanced neonatal intensive care training and documented competence in neonatal pathophysiology and care technologies used in the NICU. All nursing staff working in the NICU shall have yearly competence assessment in neonatal intensive care nursing.

4) Obstetric anesthesia services under the direct supervision of a board- certified anesthesiologist with training in maternal, fetal and neonatal anesthesia shall be available 24 hours a day. The directors of obstetric anesthesia services shall ensure the backup supervision of their services when they are unavailable.

5) Pediatric-neonatal respiratory care services shall be directed by a full-time respiratory care practitioner with a bachelor's degree.

A) The respiratory care practitioner responsible for the NICU shall have at least three years of experience in all aspects of pediatric and neonatal respiratory care at a Level III NICU and completion of the neonatal/pediatrics specialty examination of the National Board for Respiratory Care.

B) Respiratory care practitioners with experience in neonatal ventilatory care shall staff the NICU according to the respiratory care requirements of the patient population, with a minimum of one dedicated neonatal respiratory care practitioner for newborns on assisted ventilation, and with additional staff provided as necessary to perform other neonatal respiratory care procedures.

6) A physician for the program shall assume primary responsibility for initiating, supervising and reviewing the plan for management of distressed infants in the delivery room. Hospital policies and procedures shall assign responsibility for identification and resuscitation of distressed neonates to individuals who are both specifically trained and immediately available in the hospital at all times. Capability to provide neonatal resuscitation in the delivery room may be satisfied by current completion of a neonatal resuscitation program by medical, nursing and respiratory care staff or a rapid response team.

7) A board-certified or active candidate obstetrician shall be present and available in the hospital 24 hours a day. Maternal-fetal medicine consultation shall be available 24 hours a day.

8) Medical director-neonatal: to direct the neonatal portion of the program. Neonatal activities shall be directed and supervised by a full-time pediatrician certified by the American Board of Pediatrics Sub-Board of Neonatal/Perinatal Medicine or a licensed osteopathic physician with equivalent training and experience and certified by the American Osteopathic Board of Pediatricians/Neonatal-Perinatal Medicine. The directors of the neonatal services shall ensure the back-up supervision of their services when they are unavailable.

9) Neonatal surgical services shall be supervised by a board-certified surgeon or active candidate in pediatric surgery appropriate for the procedures performed at the Level III hospital.

10) Neonatal surgical anesthesia services under the direct supervision of a board-certified anesthesiologist with extensive training or experience in pediatric anesthesiology shall be available 24 hours a day.

11) Neonatal neurology services under the direct supervision of a board-certified or active candidate pediatric neurologist shall be available for consultation in the NICU 24 hours a day.

12) Neonatal radiology services under the direct supervision of a radiologist with extensive training or experience in neonatal radiographic and ultrasound interpretation shall be available 24 hours a day.

13) Neonatal cardiology services under the direct supervision of a pediatric board-certified or active candidate by the American Board of Pediatrics sub-board of pediatric cardiology shall be available for consultation 24 hours a day. In addition, cardiac ultrasound services and pediatric cardiac catheterization services by staff with specific training and experience shall be available 24 hours a day.

14) A board-certified or active candidate ophthalmologist with experience in the diagnosis and treatment of the visual problems of high-risk newborns (e.g., retinopathy of prematurity) shall be available for appropriate examinations, treatment and follow-up care of high-risk newborns.

15) Pediatric sub-specialists with specific training and extensive experience or subspecialty board certification or active candidacy (where applicable) shall be available 24 hours a day, including, but not limited to, pediatric urology, pediatric otolaryngology, neurosurgery, pediatric cardiothoracic surgery and pediatric orthopedics appropriate for the procedures performed at the Level III hospital.

16) Genetic counseling services shall be available for inpatients and outpatients, and the hospital shall provide for genetic laboratory testing, including, but not limited to, chromosomal analysis and banding, fluorescence in situ hybridization (FISH), and selected allele detection.

17) The Level III hospital shall designate at least one person to coordinate the community nursing follow-up referral process, to direct discharge planning, to make home care arrangements, to track discharged patients, and to ensure appropriate enrollment in a developmental follow-up program. The community nursing referral process shall consist of notifying the follow-up nurse in whose jurisdiction the patient resides of discharge information on all patients. The Illinois Department of Human Services will identify and update referral resources for the area served by the unit. The hospital shall establish a protocol that defines the educational criteria necessary for commonly required home care modalities, including, but not limited to, continuous oxygen therapy, electronic cardio-respiratory monitoring, technologically assisted feeding and intravenous therapy.

18) One or more full-time social workers with perinatal/neonatal experience shall be available to the Level III hospital.

19) One registered pharmacist with experience in perinatal pharmacology shall be available for consultation on therapeutic pharmacology issues 24 hours a day.

20) One dietitian with experience in perinatal nutrition shall be available to plan diets and education to meet the special needs of high-risk mothers and neonates in both inpatient and outpatient settings.

d) Application for Hospital Designation, Redesignation or Change in Network

1) To be designated or to retain designation, a hospital shall submit the required application documents to the Department. For information needed to complete any of the processes, see Section 640.50 and Section 640.60.

2) The following information shall be submitted to the Department to facilitate the review of the hospital's application for designation or redesignation:

A) Appendix A (fully completed);

B) Resource Checklist (fully completed) (Appendices L, M, N and O);

C) A proposed letter of agreement between the hospital and the APC (unsigned); and

D) The curriculum vitae for all directors of patient care, i.e., obstetrics, neonatal, ancillary medical, and nursing (both obstetrics and neonatal).

3) When the information described in subsection (d)(2) is submitted, the Department will review the material for compliance with this Part. This documentation will be the basis for a recommendation for approval or disapproval of the applicant hospital's application for designation.

4) The medical co-directors of the APC (or their designees), the medical directors of obstetrics and maternal and newborn care, and a representative of hospital administration from the applicant hospital shall be present during the PAC's review of the application for designation.

5) The Department will make the final decision and inform the hospital of the official determination regarding designation. The Department's decision will be based upon the recommendation of the PAC and the hospital's compliance with this Part, and may be appealed in accordance with Section 640.45. The Department will consider the following criteria to determine if a hospital is in compliance with this Part:

A) Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);

B) Proposed letter of agreement between the applicant hospital and its APC in accordance with Section 640.70;

C) Appropriate outcome information contained in Appendix A and the Resource Checklist;

D) Other documentation that substantiates a hospital's compliance with particular provisions or standards of perinatal care set forth in this Part; and

E) Recommendation of Department program staff.

(Source: Amended at 35 Ill. Reg. 2583, effective January 31, 2011)