**Section 640.41 Level I – Standards for Perinatal Care**

To be designated as Level I, a hospital shall apply to the Department as described in Section 640.60; shall comply with all the conditions described in Subpart O of the Hospital Licensing Requirements that are applicable to the level of care necessary for the patients served; and shall comply with the following provisions:

a) Level I − General Provisions

1) The Maternity and Neonatal Service Plan shall include:

A) A letter of agreement between the hospital and its APC establishing criteria for maternal and neonatal consultation; criteria for maternal and neonatal transports; standards of care of mothers and neonates; and support services to be provided. (Section 640.70 establishes the minimum components for the letter of agreement.);

B) Continuing education of staff in perinatal care; and

C) Participation in the CQI program implemented by the APC.

2) The critical considerations in the care of patients anticipating delivery in these hospitals are as follows:

A) The earliest possible detection of the high-risk pregnancy (risk assessment); consultation with a maternal-fetal medicine subspecialist or neonatologist as specified in the letter of agreement; and transfer to the appropriate level of care; and

B) The availability of trained personnel and facilities to provide competent emergency obstetric and newborn care. Included in the functions of this hospital are the stabilization of patients with unexpected problems, initiation of neonatal and maternal transports, patient and community education, and data collection and evaluation.

3) The Level I hospital shall provide continuing education for medical, nursing, respiratory therapy, and other staff providing general perinatal services, with evidence of a yearly competence assessment appropriate to the patient population served.

4) The Level I hospital shall maintain a system of recording patient admissions, discharges, birth weight, outcome, complications, and transports to meet the requirement 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 I – Standards for Maternal Care

1) The maternal patient with an uncomplicated current pregnancy and no previous history that suggests potential difficulties is considered appropriate for Level I hospitals; however, the hospital's letter of agreement shall establish the specific conditions for the Level I hospital.

2) Other than those maternal patients identified in subsection (b)(1), pregnancies of fewer than 36 weeks gestation constitute potentially high-risk conditions for which the attending health care provider shall consult with a board-certified obstetrician or maternal-fetal medicine subspecialist to determine whether a transport or transfer to a higher level of care is needed. The letter of agreement shall specify policies for consultation and the hospital's obstetric policies and procedures for each of, but not limited to, the pregnancy conditions listed in Section 640.Appendix H. Exhibit A.

3) 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 fetal monitoring use and interpretation. Physicians and nurses shall complete a competence assessment in electronic maternal-fetal monitoring every two years.

4) Hospitals shall provide caesarean section decision-to-incision capabilities within 30 minutes.

c) Level I – Standards for Neonatal Care

1) Neonatal patients greater than 36 weeks gestation or greater than 2500 grams without risk factors and infants with physiologic jaundice are generally considered appropriate for Level I hospitals; however, the hospital's letter of agreement shall establish the specific conditions for Level I hospitals.

2) For all neonatal patients other than those identified in subsection (c)(1), consultation with a neonatologist is required to determine whether a transport to a higher level of care is needed. Consultation shall be specified in the letter of agreement and outlined in the hospital's pediatric policies and procedures for conditions including, but not limited to:

A) Small-for-gestational age (less than 10th percentile)

B) Documented sepsis

C) Seizures

D) Congenital heart disease

E) Multiple congenital anomalies

F) Apnea

G) Respiratory distress

H Neonatal asphyxia

I) Handicapping conditions or developmental disabilities that threaten life or subsequent development

J) Severe anemia

K) Hyperbilirubinemia, not due to physiologic cause

L) Polycythemia

1. Level I – Resource Requirements

 The following support services shall be available:

1) Blood bank technicians shall be on call and available within 30 minutes for performance of routine blood banking procedures.

2) General anesthesia services shall be on call and available within 30 minutes to initiate caesarean sections.

3) Radiology services shall be available within 30 minutes.

4) Clinical laboratory services shall include microtechnique for hematocrit, blood gases, and routine urinalysis within 15 minutes; glucose, blood urea nitrogen (BUN), creatinine, complete blood count (CBC), routine blood chemistries, type, cross, Coombs' test and bacterial smear within one hour; and capability for bacterial culture and sensitivity and viral culture.

5) A physician for the program shall be designated to assume primary responsibility for initiating, supervising and reviewing the plan for management of distressed infants. Policies and procedures shall assign responsibility for identification and resuscitation of distressed neonates to individuals who have completed a nationally recognized neonatal resuscitation program and are both specifically trained and immediately available in the hospital at all times, such as another physician, a nurse with training and experience in neonatal resuscitation, or a respiratory care practitioner.

e) Application for 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 (Designation and Redesignation of Non-Birthing Center, Level I, Level II, Level II with Extended Neonatal Capabilities, Level III Perinatal Hospitals, and Administrative Perinatal Centers) and Section 640.60 (Application for Hospital Designation and Redesignation as Non-Birthing Center, Level I, Level II, Level II with Extended Neonatal Capabilities, Level III Perinatal Hospital, and Administrative Perinatal Center, and Assurances Required of Applicants).

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);

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

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

3) When the information described in subsection (e)(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 (Appendices L, M, N and O);

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

E) Recommendation of Department program staff.

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