DEPARTMENT OF PUBLIC HEALTH
NOTICE OF ADOPTED AMENDMENTS

1) Heading of the Part: Regionalized Perinatal Health Care Code

2) Code Citation: 77 Ill. Adm. Code 640

3) Section Numbers: Adopted Actions:
   640.42    Amendment
   640.50    Amendment

4) Statutory Authority: Developmental Disability Prevention Act [410 ILCS 250]

5) Effective Date of Rulemaking:

6) Does this rulemaking contain an automatic repeal date? No

7) Does this rulemaking contain incorporations by reference? No

8) A copy of the adopted amendments, including any material incorporated by reference, is on file in the agency's principal office and is available for public inspection.

9) Notice of Proposed Amendments Published in Illinois Register: 40 Ill. Reg. 10728; August 12, 2016

10) Has JCAR issued a State of Objection to these amendments? No

11) Difference(s) between proposal and final version: In response to public comment, the proposed amendment to Section 640.41 was withdrawn by the Department. There were no changes made in response to comments or suggestions of JCAR.

12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreements issued by JCAR? Yes

13) Will this rulemaking replace an emergency rule currently in effect? No

14) Are there any amendments pending on this Part? No

15) Summary and Purpose of Rulemaking: This rulemaking clarifies the resource, personnel, and competence assessment requirements of the Regionalized Perinatal Health Care Code, provides for PAC members to participate remotely in hospital designation and redesignation site visits, and clarifies the number of members required to participate in a hospital designation or redesignation site visit.
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16) Information and questions regarding these adopted amendments shall be directed to:

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Illinois Department of Public Health
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The full text of the adopted amendments begin on the next page:
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TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER I: MATERNAL AND CHILDCARE

PART 640
REGIONALIZED PERINATAL HEALTH CARE CODE

Section 640.10 Scope (Repealed)
640.20 Definitions
640.25 Incorporated and Referenced Materials
640.30 Perinatal Advisory Committee
640.40 Standards for Perinatal Care
640.41 Level I – Standards for Perinatal Care
640.42 Level II and Level II with Extended Neonatal Capabilities – Standards for Perinatal Care
640.43 Level III – Standards for Perinatal Care
640.44 Administrative Perinatal Center
640.45 Department of Public Health Action
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
640.60 Application for Hospital Designation or Redesignation as a 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
640.70 Minimum Components for Letters of Agreement Between Non-Birthing Center, Level I, Level II, Level II with Extended Neonatal Capabilities, or Level III Perinatal Hospitals and Their Administrative Perinatal Center
640.80 Regional Perinatal Networks – Composition and Funding
640.85 Exceptions to Part 640
640.90 State Perinatal Reporting System
640.100 High-Risk Follow-up Program

640.APPENDIX A Standardized Perinatal Site Visit Protocol
640.APPENDIX B Outcome Oriented Data: Perinatal Facility Designation/Redesignation (Repealed)
640.EXHIBIT A Outcome Oriented Data Form (Repealed)
640.EXHIBIT B Data Collection Exception Form (Repealed)
640.APPENDIX C Maternal Discharge Record (Repealed)
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640.EXHIBIT A Maternal Discharge Record Form (Repealed)
640.EXHIBIT B Instructions for Completing Maternal Discharge Record (Repealed)

640.APPENDIX D Report of Local Health Nurse, Maternal – Prenatal (Repealed)
640.EXHIBIT A Local Health Nurse, Maternal – Prenatal Form (Repealed)
640.EXHIBIT B Instruction for Completing the Report of Local Health Nurse, Maternal – Prenatal (Repealed)

640.APPENDIX E Report of Local Health Nurse, Maternal – Postnatal (Repealed)
640.EXHIBIT A Local Health Nurse, Maternal – Postnatal Form (Repealed)
640.EXHIBIT B Instruction for Completing the Report of Local Health Nurse, Maternal – Postnatal (Repealed)

640.APPENDIX F Report of Local Health Nurse, Infant (Repealed)
640.EXHIBIT A Local Health Nurse, Infant Form (Repealed)
640.EXHIBIT B Instruction for Completing the Report of Local Health Nurse, Infant (Repealed)

640.APPENDIX G Sample Letter of Agreement

640.APPENDIX H Written Protocol for Consultation/Transfer/Transport
640.EXHIBIT A Level I: Patients for consultation with ______________________ (Level III hospital or Administrative Perinatal Center)
640.EXHIBIT B Level II: Patients for consultation with or transfer to ________________ (Level III hospital or Administrative Perinatal Center)
640.EXHIBIT C Level I: Maternal and neonatal patients to be cared for at __________________ hospital (Level III hospital or Administrative Perinatal Center)
640.EXHIBIT D Level II: Maternal and neonatal patients to be cared for at __________________ hospital (Level III hospital or Administrative Perinatal Center)

640.APPENDIX I Perinatal Reporting System Data Elements
640.APPENDIX J Guideline for Application Process for Designation, Redesignation or Change in Designation
640.APPENDIX K Elements for Submission for Designation, Redesignation or Change in Designation
640.APPENDIX L Level I Resource Checklist
640.APPENDIX M Level II Resource Checklist
640.APPENDIX N Level II with Extended Neonatal Capabilities Resource Checklist
640.APPENDIX O Level III Resource Checklist

AUTHORITY: Implementing and authorized by the Developmental Disability Prevention Act [410 ILCS 250].
Section 640.42  Level II and Level II with Extended Neonatal Capabilities – Standards for Perinatal Care

To be designated as Level II or Level II with Extended Neonatal Capabilities, a hospital shall apply to the Department as described in Section 640.60 of this Part; shall comply with all of 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 (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 II and Level II with Extended Neonatal Capabilities – General Provisions

   A Level II or Level II with Extended Neonatal Capabilities hospital shall:

   1)  Provide all services outlined for Level I (Section 640.41(a));

   2)  Provide diagnosis and treatment of selected high-risk pregnancies and neonatal problems;

   3)  Accept selected neonatal transports from Level I or other Level II hospitals as identified in the letter of agreement with the APC; and

   4)  Maintain a system for recording patient admissions, discharges, birth weight, outcome, complications and transports 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 II – Standards for Maternal Care
1) The following maternal patients are considered to be appropriate for management and delivery by the primary physician at Level II hospitals without requirement for a maternal-fetal medicine consultation; however, the hospital's letter of agreement shall establish the specific conditions for the Level II hospital:

A) Those listed for Level I (see Section 640.41(b));

B) Normal current pregnancy although obstetric history may suggest potential difficulties;

C) Selected medical conditions controlled with medical treatment such as, mild chronic hypertension, thyroid disease, illicit drug use, urinary tract infection, and non-systemic steroid-dependent reactive airway disease;

D) Selected obstetric complications that present after 32 weeks gestation, such as, mild pre-eclampsia/pregnancy induced hypertension, placenta previa, abrupto placenta, premature rupture of membranes or premature labor;

E) Other selected obstetric conditions that do not adversely affect maternal health or fetal well-being, such as, normal twin gestation, hyperemesis gravidum, suspected fetal macrosomia, or incompetent cervical os;

F) Gestational diabetes, Class A1 (White's criteria).

2) The attending health care provider shall consult a maternal-fetal medicine subspecialist, as detailed in the letter of agreement with the APC and outlined in the hospital's obstetric department policies and procedures, for each of, but not limited to, the current pregnancy conditions listed in Section 640.Appendix H.Exhibit B. Subsequent patient management and site of delivery shall be determined by mutual collaboration between the patient's physician and the maternal-fetal medicine subspecialist.

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

c) Level II – Standards for Neonatal Care

1) The following neonatal patients are considered appropriate for Level II hospitals without a requirement for neonatology consultation:

A) Those listed for Level I (see Section 640.41(c));

B) Premature infants at 32 or more weeks gestation who are otherwise well;

C) Infants with mild to moderate respiratory distress (not requiring assisted ventilation in excess of six hours);

D) Infants with suspected neonatal sepsis, hypoglycemia responsive to glucose infusion, and asymptomatic neonates of diabetic mothers; and

E) Infants with a birth weight greater than 1500 grams who are otherwise well.

2) The attending physician shall consult a neonatologist for the following neonatal conditions. Consultation shall be specified in the letter of agreement with the APC and outlined in the hospital's pediatric department policies and procedures for conditions including, but not limited to:

A) Birth weight less than 1500 grams;

B) 10 minute Apgar scores of 5 or less;

C) Handicapping conditions or developmental disabilities that threaten subsequent development in an otherwise stable infant.

3) Minimum conditions for transport shall be specified in the letter of agreement and outlined in the hospital's pediatric department policies and
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procedures for conditions including, but not limited to:

A) Premature birth that is less than 32 weeks gestation;
B) Birth weight less than 1500 grams;
C) Assisted ventilation beyond the initial stabilization period of six hours;
D) Congenital heart disease associated with cyanosis, congestive heart failure or impaired peripheral blood flow;
E) Major congenital malformations requiring immediate comprehensive evaluation or neonatal surgery;
F) Neonatal surgery requiring general anesthesia;
G) Sepsis, unresponsive to therapy, associated with persistent shock or other organ system failure;
H) Uncontrolled seizures;
I) Stupor, coma, hypoxic ischemic encephalopathy Stage II or greater;
J) Double-volume exchange transfusion;
K) Metabolic derangement persisting after initial correction therapy;
L) Handicapping conditions that threaten life for which transfer can improve outcome.

d) Level II – Resource Requirements

Resources shall include all those listed for Level I (Section 640.41(d)) as well as the following:

1) Experienced blood bank technicians shall be immediately available in the hospital for blood banking procedures and identification of irregular antibodies. Blood component therapy shall be readily available.
2) Experienced radiology technicians shall be immediately available in the hospital with professional interpretation available 24 hours a day. Ultrasound capability shall be available 24 hours a day. In addition, Level I ultrasound and staff knowledgeable in its use and interpretation shall be available 24 hours a day.

3) Clinical laboratory services shall include microtechnique blood gases in 15 minutes and electrolytes and coagulation studies within one hour.

4) Personnel skilled in phlebotomy and intravenous (IV) placement in the newborn shall be available 24 hours a day.

5) Social work services provided by one social worker, with relevant experience and responsibility for perinatal patients, shall be available through the hospital social work department.

6) Protocols for discharge planning, routine follow-up care, and developmental follow-up shall be established.

7) A respiratory care practitioner with experience in neonatal care shall be available.

8) One dietitian with experience in perinatal nutrition shall be available to plan diets to meet the needs of mothers and infants.

9) Capability to provide neonatal resuscitation in the delivery room shall be satisfied by current completion of a nationally recognized neonatal resuscitation program by medical, nursing and respiratory care staff or a hospital rapid response team.

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 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:
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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 care and nursing (both obstetrics and neonatal).

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 or standards 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;
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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.

f) Level II with Extended Neonatal Capabilities – Standards for Special Care Nursery Services

1) The following patients are considered appropriate for Level II with Extended Neonatal Capabilities hospitals with SCN services:

A) Those listed in subsection (c) of this Section;

B) Infants with low birth weight greater than 1250 grams;

C) Premature infants of 30 or more weeks gestation;

D) Infants on assisted ventilation.

2) For each of the following neonatal conditions, consultation between the Level II with Extended Neonatal Capabilities attending physician and the APC or Level III neonatologist is required. The attending neonatologist at the Level II with Extended Neonatal Capabilities hospital and the attending neonatologist at the APC or Level III hospital shall determine, by mutual collaboration, the most appropriate hospital to continue patient care. The Level II hospital with Extended Neonatal Capabilities shall develop a prospective plan for patient care for those infants who remain at the hospital. Both the letter of agreement with the APC and the hospital's department of pediatrics' policies and procedures shall identify conditions that might require transfer to a Level III hospital, including, but not limited to:

A) Premature birth that is less than 30 weeks gestation;

B) Birth weight less than or equal to 1250 grams;

C) Conditions listed in subsections (c)(3)(C) through (L) of this Section.
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Level II with Extended Neonatal Capabilities – Resource Requirements

1) Resources shall include all those listed in Section 640.41(d) for Level I care and in Section 640.42(d) for Level II care, as well as the following:

   A) Obstetric activities shall be directed and supervised by a full-time board-certified obstetrician certified by the American Board of Obstetrics and Gynecology or a licensed osteopathic physician with equivalent training and experience and certification by the American Osteopathic Board of Obstetricians and Gynecologists.

   B) 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.

   C) The directors of obstetric and neonatal services shall ensure the back-up supervision of their services when they are unavailable.

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

   E) The pediatric-neonatal respiratory therapy services shall be directed by a full-time respiratory care practitioner with at least three years experience in all aspects of pediatric and neonatal respiratory therapy, with a bachelor's degree and completion of the neonatal/pediatric specialty examination of the National Board for Respiratory Care.

   F) Preventive services shall be designated to prevent, detect, diagnose and refer or treat conditions known to occur in the high risk newborn, such as: cerebral hemorrhage, visual defects (retinopathy of prematurity), and hearing loss, and to provide appropriate immunization of high-risk newborns.

   G) A person shall be designated to coordinate the local health department community nursing follow-up referral process, to direct
discharge planning, to make home care arrangements, to track discharged patients, and to collect outcome information. The community nursing referral process shall consist of notifying the high-risk infant follow-up nurse in whose jurisdiction the patient resides. The Illinois Department of Human Services will identify and update referral resources for the area served by the unit.

H) Each Level II hospital with Extended Neonatal Capabilities shall develop, with the help of the APC, a referral agreement with a neonatal follow-up clinic to provide neuro-developmental assessment and outcome data on the neonatal population. Hospital policies and procedures shall describe the at-risk population and referral procedure to be followed.

I) If the Level II hospital with Extended Neonatal Capabilities transports neonatal patients, the hospital shall comply with Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists.

2) To provide for assisted ventilation of newborn infants beyond immediate stabilization, the Level II hospital with Extended Neonatal Capabilities shall also provide the following:

A) Effective July 1, 2011, a pediatrician or advanced practice nurse whose professional staff privileges granted by the hospital specifically include the management of critically ill infants and newborns receiving assisted ventilation; or an active candidate or board-certified neonatologist shall be in the hospital the entire time the infant is receiving assisted ventilation. If infants are receiving on-site assisted ventilation care from an advanced practice nurse or a physician who is not a neonatologist, an active candidate or board-certified neonatologist shall be available on call to assist in the care of those infants as needed.

B) Suitable backup systems and plans shall be in place to prevent and respond appropriately to sudden power outage, oxygen system failure, and interruption of medical grade compressed air delivery.

C) Nurses caring for infants who are receiving assisted ventilation shall have documented competence and experience in the care of
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those infants.

D) A respiratory care practitioner with documented competence and experience in the care of infants who are receiving assisted ventilation shall also be available to the nursery during the entire time that the infant receives assisted ventilation.

h) 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 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 (h)(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.
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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 shall consider the following criteria or standards 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 41 Ill. Reg. _______, effective ____________)

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

a) The hospital shall declare by means of a letter of intent to the Department and the affiliated APC that it seeks designation as a hospital with no OB services, or as a Level I, Level II, Level II with Extended Neonatal Capabilities, or Level III in a Regional Perinatal Network.

b) The Department will acknowledge the letter of intent.

c) The APC shall arrange a site visit to the applicant hospital. The hospital shall prepare the designation/redesignation documents in accordance with Section 640.60. The site visit team for Level I, II, II with Extended Neonatal Capabilities, and III perinatal hospitals shall consist of sixfive members: three from the APC of the hospital's Regional Perinatal Network, including the Directors of Neonatology.
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and Maternal-Fetal Medicine or their designees and the Perinatal Network Administrator; a representative of nursing; one representative from the PAC; and one representative of the Department. When travel is not feasible, regardless of the reason, the PAC representative shall be permitted to participate in the site visit from a remote location via telephone, Voice over Internet Protocol (VoIP), or video conferencing. The site visit team shall review the capabilities of the applicant hospital based on the requirements outlined in the letter of agreement between the applicant hospital and the APC. The site visit team shall complete the Standardized Perinatal Site Visit Protocol (see Appendix A) and submit these materials to the medical directors of the hospital visited for their review and comment within 30 days after the date of the site visit. The APC shall collaborate with the Department to develop a summary site visit report within 60 days after the site visit. This report shall be sent to the hospital within 90 days after the site visit.

d) The Department will coordinate the site visit for APCs. The team shall consist of five members: one Director of Neonatology, one Director of Maternal-Fetal Medicine and one Perinatal Network Administrator from a non-contiguous Center; one representative from the PAC; and one representative of the Department. When travel is not feasible, regardless of the reason, the PAC representative shall be permitted to participate in the site visit from a remote location via telephone, Voice over Internet Protocol (VoIP), or video conferencing. The Department shall collaborate with the site visit team to develop a summary site visit report within 60 days after the site visit. This report shall be forwarded to the hospital within 90 days after the site visit.

e) The Department will review the submitted materials, any other documentation that clearly substantiates a hospital's compliance with particular provisions or standards for perinatal care, and the recommendation of the PAC.

f) 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. A 12-month to 18-month follow-up review will be scheduled for any increase in hospital designation to assess compliance with the requirements of this Part that are applicable to the new level of designation. The Department shall consider the following criteria to determine if a hospital is in compliance with this Part:
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1) Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);

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

3) Appropriate outcome information contained in Appendix A and the Resource Checklist (Appendices L, M, N and O);

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

5) Recommendation of Department program staff.

g) The Department will review all designations at least every three years to assure that the designated hospitals continue to comply with the requirements of the perinatal plan. Circumstances that may influence the Department to review a hospital's designation more frequently than every three years could include:

1) A hospital's desire to expand or reduce services;

2) Poor perinatal outcomes;

3) Change in APC or Network affiliation;

4) Change in resources that would have an impact on the hospital's ability to comply with the required resources for the level of designation; or

5) An APC finds and the Department concurs or determines that a hospital is not appropriately participating in and complying with CQI programs.

h) Existing designations shall be effective until redesignation is accomplished.

(Source: Amended at 41 Ill. Reg. ______, effective _____________)