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1) <u>Heading of the Part:</u> Regionalized Perinatal Health Care Code

2) <u>Code Citation</u>: 77 Ill. Adm. Code 640

3)	Section Numbers:	Proposed Action:
,	640.10	Repeal
	640.20	Amend
	640.25	Amend
	640.30	Amend
	640.40	Amend
	640.41	Amend
	640.42	Amend
	640.43	Amend
	640.44	Amend
	640.45	Amend
	640.50	Amend
	640.60	Amend
	640.70	Amend
	640.80	Amend
	640.90	Amend
	640.100	Repeal
	640.APPENDIX A	Amend
	640.APPENDIX B	Repeal
	640.EXHIBIT A	Repeal
	640.EXHIBIT B	Repeal
	640.APPENDIX C	Repeal
	640.EXHIBIT A	Repeal
	640.EXHIBIT B	Repeal
	640.APPENDIX F	Repeal
	640.EXHIBIT A	Repeal
	640.EXHIBIT B	Repeal
	640.APPENDIX G	Amend
	640.APPENDIX H	Amend
	640.EXHIBIT A	Amend
	640.EXHIBIT B	Amend
	640.EXHIBIT C	Amend
	640.EXHIBIT D	Amend
	640.APPENDIX I	Amend
	640.APPENDIX J	New

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New
New
New
New
New

- 4) <u>Statutory Authority</u>: Implementing and authorized by the Developmental Disability Prevention Act [410 ILCS 250]
- 5) <u>A Complete Description of the Subjects and Issues Involved</u>: Over the years the accepted standard of care has changed and the verbiage has become quite different. This change in the now accepted standard constitutes the need to update several Sections of Part 640.

Section 640.10 (Scope) is being repealed because the language is not regulatory and is not needed in the rules.

Section 640.20 (Definition) is being amended to add new definitions that reflect current acceptable standards in medical practice.

Section 640.25 (Incorporated Materials) is being amended to include current State statutes and rules and association standards that are referenced and incorporated in Part 640.

Section 640.30 (Perinatal Advisory Committee) is being amended to revise the composition and responsibilities of the Committee.

Section 640.40 (Standards for Perinatal Care) is being amended to include non-birthing center information, to update the current levels of perinatal care provided in Illinois, and to include a new provision that requires hospitals to inform the Department of a loss of essential resources.

Section 640.41 (Level I- Standards for Perinatal Care), Section 640.42 (Level II and Level II with Extended Capabilities – Standards for Perinatal Care), and Section 640.43 (Level III – Standards for Perinatal Care) are being amended to reflect the current accepted language, trends, practices and standards outlined at those levels of care, including continuing education requirements, the content of the letter of agreement with the hospital's Administrative Perinatal Center, and incorporation of the American College of Obstetricians and Gynecologists "Guidelines for Perinatal Care." Existing language is being revised for clarification and consistency. Application for Designation requirements

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are set forth. Provisions for designation with "exceptions" are being repealed. Hospitals must meet all requirements for the level of care for which they are applying.

Section 640.44 (Perinatal Center) is being amended to reflect changes in the name and the responsibilities of the Administrative Perinatal Center, including establishment of a Joint Mortality and Morbidity Review Committee.

Section 640.45 (Agency Action) is being amended to clarify the Department's responsibility for oversight of the designation process.

Section 640.50 (Designation and Re-designation of Level I, Level II, Level II with Extended Capabilities, and Level III Perinatal Facilities) is being amended to reflect changes in the Department's designation process.

Section 640.60 (Information for Facility Designation and Re-designation as Level I, Level II, Level II with Extended Capabilities, and Level III Perinatal Facilities and Assurance required of Applicants) is being amended to make technical changes in the application process requirements and to add procedural steps for a change in network affiliation.

Section 640.70 (Minimum Components for Letters of Agreements Between Level I, Level II, Level II with Extended Capabilities, or Level III Perinatal Facilities and Their Administrative Perinatal Center) is being amended to update the requirements for the letter of agreement.

Section 640.80 (Regional Perinatal Networks -- Composition and Funding) is being amended to reflect changes in funding for regional perinatal networks.

Section 640.90 (State Perinatal Reporting System) is being amended to reflect changes in reporting requirements.

Section 640.100 (High-Risk Follow-up Program) is being repealed because certified local health departments no longer perform this function.

Section 640.Appendix A (Standardized Perinatal Site Visit Protocol) is being amended to promote accuracy and collection of meaningful data and information without redundancy.

Section 640.Appendix B (Outcome Oriented Data Form) and its Exhibits are being repealed because these data are not longer being collected.

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Section 640.Appendix C (Maternal Discharge Record) and its Exhibits are being repealed because the data collection is not associated with any statistical or follow-up purpose.

Section 640.Appendix F (Report of Local Health, Infant) and its Exhibits are being repealed because resources are no longer available at the certified local health department level to do in-home follow-up.

Section 640.Appendix G (Sample Letter of Agreement) is being amended to reflect changes in the rules.

Section 640.Appendix H (Written protocol for Referral/Transfer/Transport) and its exhibits are being amended to reflect the changes in the rules.

Section 640.Appendix I (Perinatal Reporting System Data Elements) is being amended to reflect more current ethnicity and to include new neonatal complications.

Section 640.Appendix J (Guideline for application Process for Designation, Redesignation or Change in Designation) is being added to delineate to hospitals the steps to be taken in the application process for designation, re-designation, or change in designation as it applies to the Perinatal Program.

Section 640.Appendix K (Elements for Submission for Designation, Redesignation or Change in Designation) is being added to describe to hospitals the elements that must be included in applying for designation, re-designation, or change in designation of the perinatal program.

Section 640.Appendix L (Level I Resource Checklist), Section 640.Appendix M (Level II Resource Checklist), Section 640.Appendix N (Level II with Extended Neonatal Capabilities Resource Checklist), and Section 640.Appendix O (Level III Resource Checklist) are being added to outline areas of focus and to provide a means of describing institutional compliance.

- 6) <u>Published studies or reports, and sources of underlying data, used to compose this</u> <u>rulemaking</u>: None
- 7) <u>Will this rulemaking replace any emergency rulemaking currently in effect</u>? No
- 8) <u>Does this rulemaking contain an automatic repeal date</u>? No

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- 9) <u>Does this rulemaking contain incorporations by reference</u>? Yes
- 10) <u>Are there any other proposed rulemakings pending on this Part</u>? No
- 11) <u>Statement of Statewide Policy Objectives</u>: This rulemaking does not create or expand a State mandate.
- 12) <u>Time, Place and Manner in which interested persons may comment on this proposed</u> <u>rulemaking</u>: Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister Division of Legal Services Illinois Department of Public Health 535 W. Jefferson St., 5th floor Springfield, Illinois 62761

217/782-2043 E-mail: dph.rules@illinois.gov

- 13) <u>Initial Regulatory Flexibility Analysis</u>:
 - A) <u>Type of small businesses, small municipalities and not for profit corporations</u> <u>affected</u>: Perinatal centers
 - B) <u>Reporting, bookkeeping or other procedures required for compliance</u>: Reporting procedures are set forth in the proposed amendments.
 - C) <u>Types of professional skills necessary for compliance</u>: Medical, nursing, administrative
- 14) <u>Regulatory Agenda on which this rulemaking was summarized</u>: July 2009

The full text of the Proposed Amendments begins 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 Agency Action	
	640.50	Designation and Redesignation of Non-Birthing Center, Level I, Level II, Level II	
		with Extended Neonatal Capabilities, and Level III Perinatal Hospitals and	
		Administrative Perinatal CentersFacilities	
	640.60	<u>Application</u> for <u>Hospital</u> Facility Designation <u>or</u> Redesignation as	
		a Non-Birthing Center Level I, Level II, Level II with Extended Neonatal	
		Capabilities, and Level III Perinatal Hospital and Administrative Perinatal Center,	
		Facilities and Assurances Required of Applicants	
	640.70	Minimum Components for Letters of <u>AgreementAgreements</u> Between <u>Non-</u>	
		Birthing Center, Level I, Level II, Level II with Extended Neonatal Capabilities,	
		or Level III Perinatal Hospitals Facilities and Their Administrative Perinatal	
		Center	
	640.80	Regional Perinatal Networks – Composition and Funding	
	640.90	State Perinatal Reporting System	
	640.100	High-Risk Follow-up Program (<u>Repealed</u>)	
640.APPENDIX A Standardized Perinatal Site Visit Protocol		IX A Standardized Perinatal Site Visit Protocol	
640.APPENDIX B Outcome Oriented Data: Perinatal Facility Designation/Redesi		IX B Outcome Oriented Data: Perinatal Facility Designation/Redesignation	
		(Repealed)	
	640.E2	XHIBIT A Outcome Oriented Data Form (Repealed)	
	640.EXHIBIT B Data Collection Exception Form (<u>Repealed</u>)		
	640.APPEND	IX C Maternal Discharge Record (Repealed)	

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640.EXHIBIT	A	Maternal Discharge Record Form (Repealed)
640.EXHIBIT	В	Instructions for Completing Maternal Discharge Record
		(Repealed)
640.APPENDIX D	Report	of Local Health Nurse, Maternal – Prenatal (Repealed)
640.EXHIBIT	-	Local Health Nurse, Maternal – Prenatal Form (Repealed)
640.EXHIBIT	В	Instructions for Completing the Report of Local Health Nurse,
		Maternal – Prenatal (Repealed)
640.APPENDIX E	Report	of Local Health Nurse, Maternal – Postnatal (Repealed)
640.EXHIBIT		Local Health Nurse, Maternal – Postnatal Form (Repealed)
640.EXHIBIT		Instruction for Completing the Report of Local Health Nurse,
	_	Maternal – Postnatal (Repealed)
640.APPENDIX F	Report	of Local Health Nurse, Infant (Repealed)
640.EXHIBIT	1	Local Health Nurse, Infant Form (Repealed)
640.EXHIBIT		Instructions for Completing the Report of Local Health Nurse,
		Infant (Repealed)
640.APPENDIX G	Sample	e Letter of Agreement
		n Protocol for Referral/Transfer/Transport
640.EXHIBIT		Level I: Patients for consultation with (Level
		III <u>hospitalfacility</u> or <u>Administrative</u> Perinatal Center)
640.EXHIBIT	В	Level II: Patients for consultation with or transfer to
		(Level III hospital facility or Administrative
		Perinatal Center)
640.EXHIBIT	С	Level I: Maternal and neonatal Neonatal patients to be cared for at
		hospital (Level III hospitalfacility or
		Administrative Perinatal Center)
640.EXHIBIT	D	Level II: Maternal and <u>neonatal Neonatal patients</u> to be cared for
		at hospital (Level III hospitalfacility 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

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[410 ILCS 250].

SOURCE: Adopted at 5 Ill. Reg. 6463, effective June 5, 1981; amended at 6 Ill. Reg. 3871, effective March 29, 1982; emergency amendment at 8 Ill. Reg. 882, effective January 5, 1984, for a maximum of 150 days; amended and codified at 8 Ill. Reg. 19493, effective October 1, 1984; amended at 9 Ill. Reg. 2310, effective February 15, 1985; amended at 10 Ill. Reg. 5141, effective April 1, 1986; amended at 11 Ill. Reg. 1584, effective February 1, 1987; Part repealed and new Part adopted at 14 Ill. Reg. 12749, effective October 1, 1990; amended at 24 Ill. Reg. 12574, effective August 4, 2000; amended at 34 Ill. Reg. ______, effective ______.

Section 640.10 Scope (Repealed)

The "Regionalized Perinatal Health Care Code" is designed to coordinate and facilitate the use of ongoing efforts and existing resources in Illinois to improve perinatal health and to prevent perinatal mortality and conditions leading to developmental disabilities.

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

Section 640.20 Definitions

"Act" means the Developmental Disability Prevention Act [410 ILCS 250].

"Active Candidate" means having completed a residency in the appropriate medical discipline in a program approved by the Residency Review Committee or a program approved by the Council on Postdoctoral Training (COPT) for the American Osteopathic Association (AOA). Active candidates shall become board certified within five years after completion of an approved program.

"Administrative Perinatal Center" means a university or university-affiliated hospital that is designated by the Department as a Level III hospital, which receives financial support from the Department to provide leadership and oversight of the Regionalized Perinatal Healthcare Program.

"Affiliated Hospital" means an institution that has a letter of agreement with a specific Administrative Perinatal Center.

"Apgar" means the score devised in 1952 by Virginia Apgar to assess the health of newborn children immediately after birth. The five criteria are Activity (Muscle Tone), Pulse, Grimace (Reflex Irritability), Appearance (Skin Color), and Respiration.

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"Assisted Ventilation" means mechanical ventilation of any kind or Continuous Positive Airway Pressure (CPAP) of any kind.

"Bioethical or Infant Care Review Committee" means a hospital-based consultive group consisting of physicians and nonphysicians which can provide education, develop and recommend institutional policies, and offer consultation to providers and families facing a range of ethical problems or questions about the medical treatment of infants.

"Certified Local Health Department" means a local health department <u>thatwhich</u> receives program approval from the Department for all ten required basic health programs during required program and performance review.

"Congenital" means those intrauterine factors which influence the growth, development and function of the fetus. (Section 2(b) of the Act)

"Consultation" means <u>a health care provider an attending physician</u> obtaining information from <u>an obstetrician</u>, a maternal-fetal medicine <u>physician</u> or <u>neonatologyneonatalogy</u> specialist via the telephone, in writing, or in person for the purpose of making patient care decisions <u>and developing a care plan</u>.

"Continuous Quality Improvement" or "CQI" means a structured organizational process for involving personnel in planning and executing a continuous flow of improvements to provide quality health care that meets or exceeds expectations.

"Department" means the Department of Public Health. (Section 2(h) of the Act)

"Designated Local Health Agency" means an agency designated by the Department to provide maternal, infant, and family follow-up services to residents of a particular area. In areas served by a Certified Local Health Department, that department is the Designated Local Health Agency. For areas not served by a Certified Local Health Department, the designated Local Health Agency is a Certified Local Health Department for another county which has a contract with the Department to provide maternal, infant, and family follow-up services within the area or a county nurse or community nurse agency which has a contract with the Department to provide maternal, infant, and family follow-up services within the area.

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"Designation" means official recognition of a hospital facility by the Director of the Department as having met the standards contained in Section 640.40 and Section 640.50 for the level of care that the hospital will provide as a part of a regional perinatal network for all levels of perinatal care.

"Developmental Disability" means mental retardation, cerebral palsy, epilepsy, or other neurological handicapping conditions of an individual found to be closely related to mental retardation or to require treatment similar to that required by mentally retarded individuals, and the disability originates before such individual attains age 18, and has continued, or can be expected to continue indefinitely, and constitutes a substantial handicap of such individuals. (Section 2(f) of the Act)

"Dietitian" means a person who is licensed as a dietitian in accordance with the Dietetic and Nutrition Services Practice Act [225 ILCS 30].

"Disability" means a condition characterized by temporary or permanent, partial or complete impairment of physical, mental or psychological function. (Section 2(g) of the Act)

"Environmental" means those extrauterine factors which influence the adaptation, well being or life of the newborn and may lead to disability. (Section 2(c) of the Act)

"Family Centered Care" means the services of the health team that foster parentnewborn-family relationships such as those described in American College of Obstetricians and Gynecologists, Family Center Maternity/Newborn Care in Hospitals, and American Academy of Pediatrics and American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care.

"Full-time" means on duty a minimum of 36 hours, four days per week.

"Handicapping Condition" means a medically recognized birth defect that threatens life or has a potential for a developmental disability in accordance with Subpart C of the <u>Illinois</u> Health and Hazardous Substances Registry <u>Code</u> (77 Ill. Adm. Code 840.210).

"Health Care Provider" means an individual who provides medical services or treatments to patients within his or her scope of practice. This may include, but is

not limited to, physician, nurse, dietitian, social worker and respiratory care provider.

"High-Risk" means an increased level of risk of harm or mortality to the woman of childbearing age, fetus or newborn from congenital and/or environmental factors. (Section 2(d) of the Act)

"High-Risk Infant" means a live-born infant fitting the Adverse Pregnancy Outcomes Reporting <u>SystemSystems</u> (APORS) case definition. (See 77 Ill. Adm. Code 840.210.)

"High-Risk" means an increased level of risk of harm or mortality to the woman of childbearing age, fetus or newborn from congenital and/or environment factors. (Section 2(d) of the Act)

"Hospital" means a facility defined as a hospital in Section 3 of the Hospital Licensing Act [210 ILCS 85].

"Intermediate Care Nursery" or "ICN" means a nursery that provides nursing care to those infants convalescing or those sick infants not requiring intensive care.

"Joint Morbidity and Mortality Review" means the required review of maternal and neonatal cases attended by the Administrative Perinatal Center's maternalfetal medicine physician, neonatologist and the Perinatal Center administrator and/or obstetric and neonatal educators. The review is a quality improvement initiative under the Medical Studies Act [735 ILCS 5/8-2101] and consists of cases presented by the attending physician at the Regional Network Hospital. The review includes all maternal, fetal and neonatal deaths, as well as selected morbidities as determined by the Administrative Perinatal Center's Regional Quality Council or defined in the Regional Network Hospital's letter of agreement. The review provides evaluation and disposition of outcomes to guide educational program needs and quality improvement initiatives.

"Letter of Agreement" means a document executed between the Administrative Perinatal Center and the hospital, which includes responsibilities of each party in regard to the hospital's level of designation and the services to be provided.

"Maternity or Neonatal Complications" means those medically determined highrisk conditions, including, but not limited to, those explained in the Guidelines for Perinatal Care, American Academy of Pediatrics and American College of

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Obstetricians and Gynecologists.

"Maternity and Neonatal Service Plan" means the description required under Subpart O of the Hospital Licensing Requirements (77 Ill. Adm. Code 250) of the hospital's services for care of maternity and neonatal patients, and the way in which the services are part of an integrated system of perinatal care provided by designated perinatal facilities.

"Maternity or Neonatal Complications" means those medically determined highrisk conditions including but not limited to those explained in the Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists.

"Morbidity" means an undesired result or complication associated with a pregnancy, whether naturally occurring or as the result of treatment rendered or omitted.

"Neonatal Intensive Care Unit" or "NICU" means an intensive care unit for high risk neonates, directed by a board-certified pediatrician with subspecialty certification in neonatal medicine.

"Neonate" means an infant less than 28 days of age.

"Nurse" means a registered nurse or a licensed practical nurse as defined in the Nurse Practice Act [225 ILCS 65].

"Nurse Midwife, Certified" or "Certified Nurse Midwife" or "CNM" means an individual educated in the two disciplines of nursing and midwifery who possesses evidence of certification according to the requirements of the American College of Nurse-Midwives (ACNM).

"Perinatal" means the period of time between the conception of an infant and the end of the first month of life. (Section 2(a) of the Act)

"Perinatal Advisory Committee" or "PAC" means the advisory and planning committee established by the Department, which is referred to in Section 3 of the Act.

"Perinatal Center" means a referral facility intended to care for the high-risk patient before, during or after labor and delivery and characterized by

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sophistication and availability of personnel, equipment, laboratory, transportation techniques, consultation and other support services. (Section 2(e) of the Act)

"Pharmacist, Registered" or "Registered Pharmacist" means a person who holds a certificate of registration as a registered pharmacist, a local registered pharmacist or a registered assistant pharmacist under the Pharmacy Practice Act of 1987 [225] ILCS 85].

"Physician" means any person licensed to practice medicine in all its branches as defined in the Medical Practice Act of 1987 [225 ILCS 60].

"Preventive Services" means a medical intervention provided to a high risk mother and/or neonate in an effort to reduce morbidity and mortality. "Reactions, Skills and Abilities for Developmental Screening (RSA)" is an objective observation guide used to conduct developmental screening in children. "Regional Perinatal Management Group" means an organization of representatives of perinatal services, providers and service related agencies and organizations within a regional perinatal network that is responsible for the planning, development, evaluation and operation of the network and the establishment of regional priorities and policies for system support activities and staff.

"Regional Perinatal Network" means any number and combination of hospitalbased maternity and newborn facilities functioning at one <u>of fiveor three</u> levels of perinatal care.

"Regional Quality Council" or "RQC" means an organization of representatives of perinatal services, providers and service-related agencies and organizations within a regional perinatal network that is responsible for the planning, development, evaluation and operation of the network and the establishment of regional priorities and policies for system support activities and staff.

"Registered Nurse" means a person licensed as a registered professional nurse under the Nurse Practice Act.

"Respiratory Care Practitioner" means a person licensed as a respiratory care practitioner under the Respiratory Care Practice Act [225 ILCS 106].

"Social Worker" means a person who is a licensed social worker or a licensed clinical social worker under the Clinical Social Work and Social Work Practice Act [225 ILCS 20].

"Special Care Nursery" or "SCN" means a nursery that provides intermediate intensive care, directed by a board-certified pediatrician with subspecialty certification in neonatal medicine, to infants who weigh more than 1250 grams.

"State Perinatal Reporting System" means any system that requires data collection and submission of data to the Department. These systems include, but are not limited to, birth certificate submission, metabolic newborn screening, newborn hearing screening, perinatal HIV testing, and the Adverse Pregnancy Outcomes Reporting System (APORS) (see 77 Ill. Adm. Code 840).

"Statewide Quality Council" means the standing subcommittee established by the Perinatal Advisory Committee that is responsible for monitoring the quality of care and implementing recommendations for improving the quality of care being provided in the perinatal care system.

"Substantial Compliance" means meeting requirements, except for variance from the strict and literal performance that results in unimportant omissions or defects, given the particular circumstances involved.

"Substantial Failure" means the failure to meet requirements, other than unimportant omissions or defects, given the particular circumstances involved.

"Support Services" means the provision of current information regarding the identified handicapping conditions, referrals and counseling services, and the availability of additional consultative services.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.25 Incorporated <u>and Referenced</u> Materials

The following <u>regulations</u>, standards, <u>and</u> statutes <u>and rules</u> are incorporated or referenced in this Part.

a) State of Illinois Statutes:

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- 1) <u>Developmental Disability Prevention Act [410 ILCS 250]</u>"AN ACT relating to the prevention of developmental disabilities" (III. Rev. Stat. 1989, ch. 111¹/₂, par. 2101). (See Section 640.20).
- 2) Freedom of Information Act [5 ILCS 140](III. Rev. Stat. 1989, ch. 116, par. 201 et seq.). (See Section 640.90 (e)(1) and (3)).
- 3) Illinois Health Statistics Act [410 ILCS 520](Ill. Rev. Stat. 1989, ch. 1111/2, par. 5601 et seq.). (See Section 640.90(e)(2)).
- 4) Hospital Licensing Act [210 ILCS 85](III. Rev. Stat. 1989, ch. 1111/2, par. 142 et seq.). (See Section 640.90(e)(2)).
- 5) Section 8-2101 of the Code of Civil Procedure (Medical Studies Act) [735 <u>ILCS 5/8-2101](Ill. Rev. Stat. 1989, ch. 110, par. 8-2101).</u> (See Section 640.90(b)(3), (e)(1) and (2)).
- 6) State Records Act [5 ILCS 160](Ill. Rev. Stat. 1989, ch. 116, par. 43.4 et seq.). (See Section 640.90(e)(1)).
- 7) Illinois Health and Hazardous Substances Registry Act [410 ILCS 525]
- 8) Vital Records Act [410 ILCS 535]
- 9) Respiratory Care Practice Act [225 ILCS 106]
- 10) Dietetic and Nutrition Services Practice Act [225 ILCS 30]
- 11) Illinois Administrative Procedure Act [5 ILCS 100]
- 12) Nurse Practice Act [225 ILCS 65]
- 13) Pharmacy Practice Act of 1987 [225 ILCS 85]
- 14) Medical Practice Act of 1987 [225 ILCS 60]
- 15) Clinical Social Work and Social Work Practice Act [225 ILCS 20]
- b) State of Illinois <u>Rules</u>Regulations

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- Department of Public Health Illinois Health and Hazardous Substances Registry (77 Ill. Adm. Code 840). (See Sections 640.20, definition of "Handicapped Condition", 640.41 (c)(3), 640.90 (c)(1)).
- 2) <u>Department of Public Health –</u> Hospital Licensing Requirements (77 Ill. Adm. Code 250). (See Sections 640.20 definition of "Maternity and Neonatal Service Plan", 640.40, 640.41, 640.42, 640.43).
- Department of Public Health Rules of Practice and Procedure for Administrative Hearings (77 Ill. Adm. Code 100). (See Section 640.45 (b)).
- 4) <u>Department of Human Services –</u> Maternal and Child Health Services Code (77 Ill. Adm. Code 630). (See Sections 640.80 (b)).
- 5) <u>Department of Public Health –</u> Freedom of Information <u>Code</u> (2 Ill. Adm. Code 1126). (See Section 640.90 (e)(3)).
- c) Standards or Guidelines

1)Family Center Maternity/Newborn Care in Hospitals, American College of Obstetricians and Gynecologists (1978) (409-12th-Street, SW, Washington, DC 20024). (See Sections 640.20, definition of "Family Centered Care") 2)Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists (2007)(1988) (which may be obtained from the American Academy of PediatricsAAP, 141 Northwest Point Road, P.O. 927, Elk Grove Village, Illinois 60009-092760204). (See Sections 640.20, definition of "Family Centered Care," and "Maternity or Neonatal Complications", and (Section 640.43(d)(2);

- Fundamental Statistics in Psychology and Education, Guilford and Fruchter (1978) New York McGraw Hill. (See Section 640.80(b)(3)(E)
- All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulations and standards on the date specified and do not include any <u>amendments or editions</u>additions or deletions subsequent to the date specified.

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(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.30 Perinatal Advisory Committee

- a) The Perinatal Advisory Committee (PAC) is an advisory body to the Department in matters pertaining to the regionalization of perinatal health care. The purpose is to advise the Department on the establishment and implementation of policy.
- b) The duties of the <u>PACPerinatal Advisory Committee</u> shall be to advise the Department on and make recommendations concerning:
 - 1) <u>Healthhealth</u> policies <u>and quality of care issues</u> affecting perinatal health care services and implementation of the State's perinatal health care plan;
 - 2) <u>Thethe</u> needs of perinatal health care <u>consumers and</u> providers and consumers;
 - 3) <u>Methods</u> to seek a better understanding and wider support of regionalized perinatal health care within the local community;
 - 4) <u>Coordinating</u> and organizing regional networks or systems of perinatal health care;
 - 5) <u>Policies policies</u> relating to planning, operating and maintaining regional networks or systems of perinatal health care;
 - 6) <u>All proposals for rulemakingall proposed rules</u> affecting the provision of perinatal health care services under the Act; and
 - 7) <u>Hospitals</u>maternity hospitals seeking designation or redesignation as described in Sections 640.40 through 640.70.
- c) The <u>PACPerinatal Advisory Committee</u> shall consist of 22 members appointed by the Director of the Department and six ex-officio members as follows:
 - 1) Members
 - A) <u>10</u>Ten licensed physicians;

- B) Three hospital administrators;
- C) Two registered nurses;
- D) One licensed social worker;
- E) One registered dietitian;
- F) One registered respiratory <u>care practitioner</u>therapist;
- G) One health planner;
- H) Two consumers or representatives of the general public interested in perinatal health care; and
- I) One representative of a local health department;
- 2) Ex-Officio Members
 - A) <u>One representative of the Illinois Department of Healthcare and</u> <u>Family Services; One representative of the Perinatal Association of</u> <u>Illinois;</u>
 - B) <u>One representative of the Illinois Department of Human Services;</u> One representative of the Perinatal Centers of Illinois;
 - C) One representative of the Consortium of Perinatal Network Administrators;
 - D) One representative of the Chicago Department of Public Health;
 - E) One representative of the Chicago Maternal and Child Health Advisory Committee of the Chicago Department of <u>Public</u> Health; and
 - F) One representative of the Genetic and Metabolic Diseases Advisory Committee of the Department.
- d) Physician membership on the <u>PACPerinatal Advisory Committee</u> shall consist of

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four obstetrician-gynecologists, to include <u>a</u> subspecialist in maternal/fetal medicine, four pediatricians, to include <u>a</u> subspecialist in neonatal/perinatal medicine, and two family practice physicians.

- e) Recommendations for physicians shall be solicited from the Illinois State Medical Society, the Illinois Section of the American College of Obstetricians and Gynecologists, the Illinois Chapter of the American Academy of Pediatrics, and the Illinois Chapter of the American Academy of Family Practice.
 Recommendations for hospital administrators and <u>a</u> health planner shall be solicited from the Illinois Hospital Association. Recommendations for nurses shall be solicited from the Illinois Nurses Association, the Illinois Nurses Section of the American College of Obstetricians and Gynecologists, and the American College of Nurse-Midwives. Recommendations for <u>a</u> social worker, <u>a</u> dietitian and <u>a</u> respiratory <u>care practitionertherapist</u> shall be solicited from the Illinois Perinatal Social Work Association, the Illinois Dietetics Association and the Illinois Society of Respiratory Care. Recommendations for <u>a</u> representative of a <u>certified</u> local health department shall be solicited from the Illinois Association of Public Health Administrators.
- f) Membership of the <u>PACPerinatal Advisory Committee</u> shall be selected to be representative of the levels of perinatal care described in Section 640.40, as well as of the different settings in which perinatal care is provided, both geographic and institutional.
- g) Members of the Perinatal Advisory Committee shall serve four_year terms. Exofficio Officio-members shall have no set term of service. Both members and exofficio members shall have full voting privileges.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.40 Standards for Perinatal Care

a) Levels of Perinatal Care
 Within each regional perinatal network there shall be three levels of perinatal care, and within Level II there shall be two categories of perinatal care: Level I or general care; Level II or intermediate care, or Level II with Extended Capabilities; and Level III or intensive care. Hospital licensing requirements Minimum licensing standards for all fivethree levels are described in Subpart O of the Hospital Licensing Requirements (77-III. Adm. Code 250). All hospitals

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providing obstetrical and neonatal services shall be designated in accordance with the provisions of this Part and have a letter of agreement with a designated Administrative Perinatal Center. (Section 640.70 describes the minimum components for the letter of agreement.)-

- 1) Non-Birthing Center hospitals do not provide perinatal services, but have a functioning emergency department. All licensed general hospitals that operate an emergency department shall have a letter of agreement with an Administrative Perinatal Center for referral of perinatal patients, regardless of whether the hospital provides maternity or newborn services. The letter of agreement shall delineate, but is not limited to, guidelines for transfer/transport of perinatal patients to an appropriate perinatal care hospital; telephone numbers for consultation and transfer/transport of perinatal patients; educational needs assessment for emergency department staff, and provision of education programs to maintain necessary perinatal skills.
- 2) Level I hospitals provide care to low-risk pregnant women and newborns, operate general care nurseries and do not operate an NICU or an SCN;
- 3) <u>Level II hospitals provide care to women and newborns at moderate risk,</u> operate intermediate care nurseries and do not operate an NICU or an <u>SCN.</u>
- 4) <u>Level II with Extended Neonatal Capabilities hospitals provide care to</u> women and newborns at moderate risk and do operate an SCN but do not operate an NICU.
- 5) Level III hospitals care for patients requiring increasingly complex care and do operate an NICU.
- b) Perinatal Network <u>Non-Birthing Center</u>, Level I, Level II, Level II with Extended <u>Neonatal</u> Capabilities and Level III <u>hospitalsfacilities</u> shall function within the framework of a regionally integrated system of services, <u>under the leadership of an</u> <u>Administrative Perinatal Center</u>, designed to maximize outcomes and to promote appropriate use of expertise and resources. <u>PrenatalRecognition of high risk</u> <u>conditions</u>, <u>prenatal</u> consultations, referrals, or transfers <u>and recognition of high</u> <u>risk conditions</u> are important to improve outcomes. Regional consultant

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relationships in maternal-fetal medicine and <u>neonatologyneonatalogy</u> referred to in this Part shall be detailed in the letter of agreement. <u>The hospital shall ensure</u> <u>that staffStaff</u> physicians and consultants <u>are familiar withshall be cognizant of</u> <u>the standards and the guidelines in</u> the letter of agreement.

- c) All hospitals shall inform the Department of any change in or loss of essential resources required by this Part within 30 days after the change and/or loss. The hospital shall then replace the required resource within 60 days. Failure to comply shall result in a review by the Department, with a potential loss of designation.
- c) Non-Maternity General Hospitals All licensed general hospitals that may provide emergent or urgent care shall have a letter of agreement with a Perinatal Center for referral of perinatal patients, regardless of whether they provide maternity or newborn services. The letter of agreement shall delineate but not be limited to: guidelines for transfer/transport of perinatal patients to an appropriate perinatal care facility, telephone numbers for consultation and transfer/transport of perinatal patients, educational needs assessment for Emergency Room staff, and provision of education programs to maintain emergency perinatal skills.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.41 Level I – Standards for Perinatal Care

Level I: To be designated as Level I, a <u>hospital</u>facility shall apply to the Department as described in Section 640.60-of this Part; shall and comply with all the conditions described in Subpart O of the Hospital Licensing Requirements <u>that(77 III. Adm. Code 250)</u> which are applicable to the level of care necessary for the patients served, and in addition shall comply with the following provisions (specifics regarding standards of care for both mothers and neonates as well as support services to be provided shall be defined in the hospital's letter of agreement with its Perinatal Center):

- a) <u>Level I General Provisions</u>
 - 1) The Maternity and Neonatal Service Plan of the Level I facility shall include:
 - <u>A)</u> <u>Aa</u> letter of agreement between the <u>hospital</u><u>facility</u> and its <u>Administrative</u> Perinatal Center <u>establishing criteria for maternal</u>

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and neonatalregarding plans for prompt 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.); with a maternal-fetal medicine subspecialist or neonatologist specific to high-risk women and those neonates with conditions or developmental disabilities requiring transfer, such as: acute surgical and cardiac difficulties, neonates born with handicapping conditions, managing high-risk pregnancies, genetic counseling, information, referral and counseling services for families of neonates born with a handicapping condition or for a high-risk mother or her spouse, and

- <u>B)</u> <u>Continuing continuing</u> education of staff in perinatal care; and, including family centered care for neonates with handicapping conditions.
- <u>C)</u> <u>Participation in the CQI program implemented by the</u> <u>Administrative Perinatal Center.(Section 640.70 describes the</u> <u>minimum components for the letter of agreement.) This agreement</u> <u>must include participation in a Continuous Quality Improvement</u> <u>program as defined by the Department and as designed and</u> <u>implemented by the Perinatal Center.</u>
- 2) The critical considerations in the care of patients anticipating delivery in these hospitals are as follows:
 - A) <u>Thethe</u> earliest possible detection of the high-risk pregnancy (risk assessment); and consultation with a maternal-fetal medicine subspecialist or neonatologist as specified in the letter of agreement₁₇ and transfer to the appropriate level of care; and
 - B) <u>Thethe</u> availability of trained personnel and facilities to provide competent emergency obstetric and newborn care. Included in the functions of this <u>hospital</u>facility are the stabilization of patients with unexpected problems, initiation of neonatal and maternal transports, patient and community education, and data collection and evaluation.

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- 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.
- <u>4)3</u> The Level I hospital shall maintain aA system of recording patient admissions, discharges, birth weight, outcome, complications, and transports tomust be maintained and meet the requirement requirements to support network CQIContinuous Quality Improvement activities described in the hospital's letter of agreement with the Administrative Perinatal Centeras developed by the Statewide Quality Council and must be consistent with that of the Perinatal Center. The hospital shall comply with the reporting requirements of the State Perinatal Reporting System Adverse Pregnancy Outcomes Reporting System (77 III. Adm. Code 840).

b) Level I – Standards for Maternal Care

- 1) The maternal patient with an uncomplicated current pregnancy and no previous history <u>that suggests</u>suggestive of potential difficulties is considered appropriate for Level I <u>hospitals; however, the hospital's letter</u> of agreement shall establish the specific conditions for the Level I <u>hospital.facilities.</u>
- 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 Appendix B and Appendix C of Guidelines for Perinatal Care. All maternal patients other than those identified in subsection (b)(1) above constitute potentially high-risk conditions for which consultation with a maternal fetal medicine subspecialist or neonatologist as specified in the letter of agreement is recommended. Consultation or transfer shall be considered for each of the following conditions:

A)

B)

Previo	Previous Pregnancy Problems:		
i)	Premature infant		
ii)	Perinatal death or mental retardation		
iii)	Isoimmunization		
iv)	Difficult deliveries		
v)	Congenital malformations		
vi)	Mid-trimester loss		
Currer	urrent Pregnancy Problems:		
i)	Any medical disorder (e.g., diabetes mellitus, hemoglobinopathy, chronic hypertension, heart disease, renal disease)		
ii)	Drug addiction		
iii)	Multiple gestation		
iv)	Intrauterine growth restriction		
v)	Preterm labor less than or equal to 36 weeks		
vi)	Postdate greater than or equal to 42 weeks		
vii)	Third trimester bleeding		

- viii) Abnormal genetic evaluation
- ix) Pregnancy induced hypertension
- 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

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

- 4) Hospitals shall have the capability of performing caesarean sections within 30 minutes after deciding to make an incision.
- c) Level I Standards for Neonatal Care
 - <u>Neonatal The neonatal</u> 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 <u>hospitalsfacilities</u>; however, the <u>hospital'sfacilities</u>' letter of agreement <u>shallmust</u> establish the specific conditions for Level I <u>hospitalsfacilities</u>.
 - 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:All neonatal patients other than those identified in subsection (c)(1) above constitute neonatal conditions for which a neonatology consultation as specified in the letter of agreement by the attending physician is recommended. Consultation or transfer is recommended for each of the following conditions:
 - A) Gestational age less than 36 weeks, birth weight less than 2500 grams
 - <u>A)</u>B) Small-for-gestational age (less than 10^{th} percentile)
 - <u>B)</u>C) <u>Documented sepsis</u>Sepsis
 - <u>C</u>) D Seizures
 - \underline{D} Congenital heart disease
 - \underline{E}) \underline{F} Multiple congenital anomalies

- <u>F)</u>G) Apnea
- <u>G)</u>H) Respiratory distress
- <u>H</u>+) Neonatal asphyxia
- <u>I)J)</u><u>Handicapping</u>Infants identified as having handicapping conditions or developmental disabilities <u>that</u>which threaten life or subsequent development
- <u>JK</u>) Severe anemia
- <u>K)</u> Hyperbilirubinemia, not due to physiologic cause
- <u>L)</u>M) Polycythemia

Specifics regarding consultation or transfer for each of these conditions must be detailed in the letter of agreement.

d) Level I – Resource Requirements

The following support services shall be available:

- 1) Capability for continuous electronic maternal fetal monitoring for patients identified at risk with staff knowledgeable in its use and interpretation available with evidence of completion of a yearly competence assessment in electronic fetal monitoring.
- 1)2) Blood bank technicians <u>shall be</u> on call and available within 30 minutes for performance of routine blood banking procedures.
- <u>2)</u>3) General anesthesia <u>services shall be</u> on call and available within 30 minutes to initiate caesarean sections.
- 4) Caesarean section capability within 30 minutes.
- <u>3)</u> Radiology <u>services shall beservice</u> available within 30 minutes-notice.
- 4)6) Clinical laboratory <u>services</u> shall include microtechnique for hematocrit

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within 15 minutes;, glucose, <u>blood urea nitrogen (BUN)</u>BUN, creatinine, blood gases, <u>and</u> routine urinalysis in <u>one</u>4 hour; <u>complete blood count</u> (<u>CBC)</u><u>CBC</u>, routine blood chemistries, type, cross, Coombs' test, and bacterial smear within <u>one hour</u><u>6 hours</u>; and capability for bacterial culture and sensitivity and viral culture.

- 5)7) A physician for the program shall be designated to assume primary responsibility for initiating, supervising and reviewing the plan for <u>managementmanagagement</u> of <u>distresseddepressed</u> infants<u>in the delivery</u> room. Policies and procedures shall assign responsibility for identification and resuscitation of distressed neonates to <u>individualsat least one</u> <u>individual</u> who <u>have completed a neonatal resuscitation program and areis</u> 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 licensed respiratory care practitioner. Individuals assigned to perform neonatal resuscitation shall have documented evidence of current completion of a neonatal resuscitation course. It is further recommended that physicians and/or advanced practice nurses who care for newborns have documented evidence of completion of a neonatal resuscitation course.
- 8) The Level I facility shall be responsible for provision of 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.
- e) Application for Designation, Redesignation or Change in Network
 - 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).

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- 2) The following information shall be submitted to the Department to facilitate the review of the hospital's application for designation or redesignation:
 - <u>A)</u> <u>Appendix A (fully completed);</u>
 - <u>B)</u> <u>Resource Checklist (fully completed);</u>
 - <u>C)</u> <u>A proposed letter of agreement between the hospital and the</u> <u>Administrative Perinatal Center (unsigned);</u>
 - 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 Administrative Perinatal Center (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:
 - <u>A)</u> <u>Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);</u>
 - B) Proposed letter of agreement between the applicant hospital and its Administrative Perinatal Center in accordance with Section 640.70;

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- <u>C)</u> 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
- <u>E)</u> <u>Recommendation of Department program staff.</u>

e) Exceptions to Level I Standards of Care

- 1) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes, and geography in the regional perinatal network. These exceptions are not intended to circumvent the Level II designation. The applicant facility or the Perinatal Center may seek the advice and consultation of the Department as well as the Perinatal Advisory Committee in regard to the conditions necessary for an exception.
- 2) Exceptions to the standards of care of this Part may be granted when the facility requesting an exception demonstrates that the resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level II facility. The resource requirements for these exceptions may be found in Section 640.42(d) for Level II facilities. The proposed exceptions shall be determined by the applicant facility and its Perinatal Center based primarily on outcomes.
- 3) If the applicant facility and its Perinatal Center cannot reach agreement on any aspect of the exceptions to the standards of care of this Part, the applicant facility or Perinatal Center shall seek the advice and consultation of the Perinatal Advisory Committee (i.e., subcommittee on facility designation). Any exception to the standards of care of this Part shall be clearly defined in the proposed letter of agreement and approved by the Department before implementing the exceptions or patient care services being requested. The Department shall permit a period of testing or trial (probation) to demonstrate that the applicant facility's resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level II facility.
- 4) If a dispute between the applicant facility and its Perinatal Center cannot

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be resolved after consultation with the Perinatal Advisory Committee (i.e., subcommittee on facility designation), then the applicant facility, the Perinatal Center, or the Perinatal Advisory Committee shall submit the dispute to the Department for settlement. The Department shall review all of the relevant information and documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care and the recommendations of the Perinatal Advisory Committee in deciding or settling a dispute. The Department shall inform the applicant facility, the Perinatal Center and the Perinatal Advisory Committee of its decision or judgment.

- 5) The following information shall be submitted to the Perinatal Advisory Committee (i.e., subcommittee on facility designation) to facilitate the review of the applicant facility's application for designation with exceptions to the standards of care of this Part:
 - A) A proposed letter of agreement (unsigned).
 - B) The curriculum vitae for all directors of patient care, i.e., OB, neonatal, nursing (OB and neonatal).
 - C) Appendices A and B (fully completed).
 - D) A letter from the Perinatal Center that includes the following information:
 - i) List of the exceptions being requested.
 - Sufficient data/information to demonstrate that the quality of care (outcomes) of the applicant facility are substantially equivalent to the appropriate standards as outlined in subsection (c) of this Section.
 - A description of the monitoring system used when a consultation occurs between the attending physician at the referring hospital and the physician consultant at the Perinatal Center or Level III facility and it is determined that the mother or newborn infant should stay in the community hospital for care.

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- iv) A description of any arrangements made between the applicant facility and the Perinatal Center to seek or insure quality improvement.
- 6) When the information described in Section 640.41(e) is submitted to the Perinatal Advisory Committee, it shall review the material for compliance with the Regionalized Perinatal Health Care Code, and shall make a recommendation for approval or disapproval of the applicant facility's application for designation with exceptions to the Department.
- 7) The medical co-directors of the Perinatal Center (or their designees) and the medical directors of obstetrics and maternal and newborn care and a representative of hospital administration from the applicant facility shall be present during the Perinatal Advisory Committee's review of the applicant facility's application for designation with exceptions.
- 8) The Department shall review the submitted materials and any other documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care, including quality of care (outcomes) data/information and the recommendation of the Perinatal Advisory Committee, and shall make a recommendation to the Director of Public Health concerning the approval or disapproval of the applicant facility's application for designation with exceptions.
- 9) The Director of Public Health shall make the final decision and inform the facility of the official determination regarding designation with exceptions to the standards of care of this Part. The Director's decision shall be based upon the recommendation of the Perinatal Advisory Committee and the facility's compliance with the Regionalized Perinatal Health Care Code, and may be appealed in accordance with Section 640.45. The Director of Public Health shall consider the following criteria or standards to determine if a facility is in compliance with the Code:
 - A) Maternity and Neonatal Service Plan (Subpart O of the Illinois Hospital Licensing Requirements).
 - B) Proposed letter of agreement between the applicant facility and its Perinatal Center in accordance with the provisions described in

Section 640.70.

- C) Appropriate outcome information contained in Appendices A and B.
- D) Other documentation that clearly substantiates a facility's compliance with particular provisions or standards of perinatal care.
- E) Recommendation of Department program staff.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.42 Level II and Level II with Extended <u>Neonatal</u> Capabilities – Standards for Perinatal Care

Level II: To be designated as Level II or Level II with Extended <u>Neonatal</u> Capabilities, a <u>hospitalfacility</u> shall apply to the Department as described in Section 640.60 of this Part<u>; shall</u> and comply with all <u>of</u> the conditions described in Subpart O of the Hospital Licensing Requirements <u>that(77 III. Adm. Code 250)</u> promulgated by the Department which are applicable to the level of care necessary for the patients served<u>i</u>; and <u>in addition</u> 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 <u>Administrative</u> Perinatal Center):

a) <u>Level II and Level II with Extended Neonatal Capabilities</u> – General Provisions

1)A Level II or Level II with Extended <u>Neonatal</u> Capabilities <u>hospital</u> <u>shall:facility is to</u>

- <u>1)</u> <u>Provide provide</u> all services outlined for Level I (Section 640.41(a)):
- 2) Provideas well as diagnosis and treatment of selected high-risk pregnancies and neonatal problems: Both the obstetrical service and the neonatal service must achieve the applicable capability of a Level II or Level II with Extended Capabilities facility for the applicable Level II designation. Further standards for Level II facilities are set out in subsections (b) through (h) with subsections (f) through (h) specifically applying to facilities that are Level II with Extended Capabilities.

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Included in the functions of this facility are education of allied health professionals and

- 3) <u>Acceptacceptance of selected maternal fetal and neonatal transports from</u> Level I or other Level II hospitals as identified in the <u>letterletters</u> of agreement with the <u>Administrative</u> Perinatal Center; <u>and</u>. <u>The letters of</u> agreement should include participation in a Continuous Quality Improvement program as defined by the Department and implemented by the Perinatal Center.
- <u>4)</u>2) <u>Maintain a</u>A system for recording patient admissions, discharges, birth weight, outcome, complications, and transports must be maintained and must meet requirements to support network <u>CQIContinuous Quality</u> <u>Improvement program</u> activities <u>described in the hospital's letter of</u> agreement with the Administrative Perinatal Center. The hospital shall comply with the reporting requirements of the State Perinatal Reporting <u>System as developed by the Statewide Quality Council.</u> The hospital must comply with the requirements of the Adverse Pregnancy Outcomes Reporting System (77 III. Adm. Code 840). For hospitals designated Level II with Extended Capabilities, participation in the Perinatal Reporting System is also required.
- b) Level II Standards for Maternal Care
 - The following maternal patients are considered to be appropriate for management and delivery by the primary physician at Level II <u>hospitalsfacilities</u> 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 (<u>see See Section 640.41(b)(1)</u>);
 - B) Normal current pregnancy although obstetric history may suggestbe suggestive of potential difficulties;
 - C) Selected medical conditions controlled with medical treatment such as_a: mild chronic hypertension, thyroid disease, illicit drug use, urinary tract infection, and non-systemic steroid_dependent reactive airway disease;

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- D) Selected obstetric complications that present after 32 weeks gestation, such as₁÷ 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 as₂: normal twin gestation, hyperemesis gravidium, suspected fetal macrosomia, or incompetent cervical os;
- F) Gestational diabetes, Class A1 (White's criteria).
- 2) <u>The attending health care provider shall consult</u>For the following maternal conditions, consultation with a maternal-fetal medicine subspecialist, as detailed in the <u>letterletters</u> of agreement <u>and outlined in the hospital's</u> obstetric department policies and procedures, for each of, but not limited to, the current pregnancy conditions listed in Appendix B and Appendix C of Guidelines for Perinatal Care, with subsequent management and delivery at the appropriate facility as determined by mutual collaboration is recommended.
 - A) Current obstetric history suggestive of potential difficulties such as: intrauterine growth restriction, prior neonatal death, two or more previous preterm deliveries less than 34 weeks, a single previous preterm delivery less than 30 weeks, birth of a neonate with serious complications resulting in a handicapping condition, recurrent spontaneous abortion or fetal demise, family history of genetic disease;
 - B) Active chronic medical problems with known increase in perinatal mortality, such as: cardiovascular disease Class I and Class II, autoimmune disease, reactive airway disease requiring treatment with systemic corticosteroids, seizure disorder, controlled hyperthyroidism on replacement therapy, hypertension controlled on a single medication, idiopathic thrombocytopenia pupura, thromboembolic disease, malignant disease (especially when active), renal disease with functional impairment, human immunodeficiency viral infection (consultation may be with

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maternal-fetal medicine or infectious disease subspecialist);

- C) Selected obstetric complications that present prior to 34 weeks gestation, such as: suspected intrauterine growth restriction, polyhydramnios, oligohydramnios, pre-eclampsia/pregnancyinduced hypertension, congenital viral disease, maternal surgical conditions, suspected fetal abnormality or anomaly, isoimmunization with antibody titers greater than 1:8, antiphospholipid syndrome;
- Abnormalities of the reproductive tract known to be associated with an increase in preterm delivery, such as uterine anomalies or diethyl stilbesterol exposure;
- E) Insulin dependent diabetes Class A2 and B or greater (White's criteria).
- 3) The attending health care provider shall refer patients For the following maternal conditions, referral to a maternal-fetal medicine subspecialist for evaluation based on the pregnancy conditions listed in Appendix B and Appendix C of Guidelines for Perinatal Care.shall occur. Subsequent patient management and site of delivery shall be determined by mutual collaboration between the patient's physician and the maternal-fetal medicine subspecialist as outlined in the letter of agreement with the Administrative Perinatal Center.÷
 - A) Selected chronic medical conditions with a known increase in perinatal mortality, such as: cardiovascular disease with functional impairment (Class III or greater), respiratory failure requiring mechanical ventilation, acute coagulopathy, intractable seizures, coma, sepsis, solid organ transplantation, active autoimmune disease requiring corticosteroid treatment, unstable reactive airway disease, renal disease requiring dialysis or with a serum creatinine concentration greater than 1.5 mg%, active hyperthyroidism, hypertension that is unstable or requires more than one medication to control, severe hemoglobinopathy;
 - B) Selected obstetric complications that present prior to 32 weeks gestation (prior to 30 weeks gestation for Level II with extended

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capabilities), such as: multiple gestation with more than two fetuses, twin gestation complicated by demise, discordancy, or maldevelopment of one fetus or by fetal-fetal transfusion, premature labor unresponsive to first-line tocolytics, premature rupture of membranes, medical and obstetrical complications of pregnancy possibly requiring induction of labor or non-emergent caesarean section for maternal or fetal indications, such as severe pre-eclampsia;

- C) Isoimmunization with possible need for intrauterine transfusion;
- D) Insulin-dependent diabetes mellitus Classes C, D, R, F, or H (White's criteria);
- E) Suspected congenital anomaly or abnormality requiring an invasive fetal procedure, neonatal surgery or postnatal medical intervention to preserve life, such as: fetal hydrops, pleural effusion, ascites, persistent fetal arrhythmia, major organ system malformation malfunction, or genetic condition.
- 4) 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 maternalfetal monitoring every two years.
- c) Level II Standards for Neonatal Care
 - 1) The following neonatal patients are considered appropriate for Level II <u>hospitals</u>facilities without a requirement for neonatology consultation:
 - A) Those listed for Level I- (see Section 640.41(c)(b)(1).);
 - B) Premature infants at 32 or more weeks gestation who are otherwise well;
 - <u>C)B)</u> Infants with mildMild to moderate respiratory distress (not requiring assistedmechanical ventilation in excess of six6 hours);-
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- D)C) Infants with suspected Suspected neonatal sepsis, hypoglycemia responsive to glucose infusion, and asymptomatic neonates of diabetic mothers-; and
- <u>E)</u>D) <u>InfantsNursery care of infants</u> with a birth weight greater than 1500 grams who are otherwise well.
- E) Nursery care of premature infants at 32 or more weeks gestation who are otherwise well.
- 2) <u>The attending physician shall consult a neonatologist for For the following neonatal conditions. Consultation shall be specified, neonatology consultation is recommended, as detailed in the letter of agreement with the Administrative Perinatal Center and outlined in the hospital's pediatric department policies and procedures for conditions including, but not limited to:, for each of the following:</u>
 - A) Premature birth with gestation less than 32 weeks, but greater than or equal to 30 weeks;
 - <u>A)</u>B) <u>BirthInfants with a birth</u> weight less than 1500 grams, but greater than 1250 grams;
 - <u>B)C)</u> Infants with 10 minute Apgar scores of 5 or less;
 - <u>C)</u>D) <u>Handicapping</u>Stable infants identified as having handicapping conditions or developmental disabilities that threaten subsequent development in an otherwise stable infant.
- 3) <u>Minimum conditions for transport shall be specified in the letter of agreement and outlined in the hospital's pediatric department policies and procedures for conditions including, but not limited to: Transfer shall occur upon recommendation of the Perinatal Center for each of the following neonatal conditions:</u>
 - A) Premature birth that is less than 3230 weeks gestation;
 - B) <u>Birth weight Birthweight</u> less than or equal to <u>15001250</u> grams;

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- C) <u>AssistedInfants requiring mechanical</u> ventilation beyond the initial stabilization period of <u>six6</u> hours;
- D) Infants who require a sustained inhaled oxygen concentration in excess of 50% in order to maintain a transcutaneous or arterial oxygen saturation greater than or equal to 92%;
- <u>D)</u>E) <u>Congenital</u>Infants with significant congenital heart disease associated with cyanosis, congestive heart failure, or impaired peripheral blood flow;
- <u>E)</u>F) <u>Major congenital</u>Infants with major congenital malformations requiring immediate comprehensive evaluation or neonatal surgery;
- <u>F)G</u> <u>NeonatalInfants requiring neonatal</u> surgery <u>required</u> with general anesthesia;
- <u>G)</u>H) <u>SepsisInfants with sepsis</u>, unresponsive to therapy, associated with persistent shock or other organ system failure;
- <u>H)</u><u>I)</u><u>Uncontrolled</u><u>Infants with uncontrolled</u> seizures;
- <u>I</u>)J) <u>StuporInfants with stupor</u>, coma, hypoxic ischemic encephalopathy Stage II or greater;
- <u>J)K)</u> <u>Double-volumeInfants requiring double-volume</u> exchange transfusion;
- <u>K)</u><u>L)</u><u>Metabolic</u><u>Infants with metabolic</u> derangement persisting after initial correction therapy;
- <u>L)M</u> <u>HandicappingInfants identified as having handicapping</u> conditions that threaten life for which transfer can improve outcome.
- Level II Resource Requirements Resources shall include all those listed for Level I (Section 640.41(d)) as well as the following:

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- Experienced blood bank technicians <u>shall be</u> immediately available in <u>the</u> hospital for blood banking procedures and identification of irregular antibodies. Blood component therapy <u>shall be</u> readily available.
- Experienced radiology technicians <u>shall be</u> immediately available in the hospital with professional interpretation available 24 hours a day. Ultrasound capability <u>shall be</u> 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 <u>services</u> shall include microtechnique blood gases in 15 minutes, <u>and</u> electrolytes and coagulation studies within <u>onean-hour</u>.
- 4) Personnel skilled in phlebotomy and <u>intravenous (IV)I.V.</u> placement in the newborn shall be available 24 hours a day.
- 5)4) Social work services provided by one licensed medical social worker, preferably with relevant experience and responsibility for perinatal patients, shall be available through the hospital social work department.
- 6)5) Protocols for discharge planning, routine follow-up care, and developmental follow-up shallmust be established.
- 6) General anesthesia on call available within 30 minutes to initiate caesarean section.
- 7) A licensed respiratory care practitioner with experience in neonatal care shall be available.
- 8) One registered 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 neonatal resuscitation program by medical, nursing and respiratory care staff or a hospital rapid response team.Continuous electronic maternal-fetal monitoring and staff knowledgeable in its use and interpretation, with evidence of completion of a yearly competence assessment in electronic fetal monitoring, shall be

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available 24 hours a day.

- 10) The Level II facility shall be responsible for provision of 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.
- 11) A physician for the program shall be designated to assume primary responsibility for initiating, supervising and reviewing the plan for management of depressed infants in the delivery room. Policies and procedures shall assign responsibility for identification and resuscitation of distressed neonates to an individual who is both specifically trained and available in the hospital at all times, such as another physician, a nurse with training and experience in perinatal care, or respiratory therapist. Individuals assigned to perform neonatal resuscitation shall have documented evidence of current completion of a neonatal resuscitation course. It is further recommended that physicians and/or advanced practice nurses who care for newborns have documented evidence of a neonatal resuscitation course.

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:
 - <u>A)</u> <u>Appendix A (fully completed);</u>
 - B) Resource Checklist (fully completed) (Appendices L, M, N and <u>O);</u>
 - <u>C)</u> <u>A proposed letter of agreement between the hospital and the</u> <u>Administrative Perinatal Center (unsigned); and</u>

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- 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 Administrative Perinatal Center (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:
 - <u>A)</u> <u>Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);</u>
 - B) Proposed letter of agreement between the applicant hospital and its Administrative Perinatal Center, in accordance with Section 640.70;
 - <u>C)</u> 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
 - <u>E)</u> <u>Recommendation of Department program staff.</u>
- e) Exceptions to Level II Standards of Care

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- 1) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes, and geography in the regional perinatal network. These exceptions are not intended to circumvent the Level II with Extended Capabilities designation. The applicant facility or the Perinatal Center may seek the advice and consultation of the Department as well as the Perinatal Advisory Committee in regard to the conditions necessary for an exception.
- 2) Exceptions to the standards of care of this Part may be granted when the facility requesting an exception demonstrates that the resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level II facility with Extended Capabilities. The resource requirements for these exceptions may be found in subsection (d) of this Section for Level II with Extended Capabilities standards. The proposed exceptions shall be determined by the applicant facility and its Perinatal Center based primarily on outcomes.
- 3) If the applicant facility and its Perinatal Center cannot reach agreement on any aspect of the exceptions to the standards of care of this Part, the applicant facility or Perinatal Center shall seek the advice and consultation of the Perinatal Advisory Committee (i.e., subcommittee on facility designation). Any exception to the standards of care of this Part shall be clearly defined in the proposed letter of agreement and approved by the Department before implementing the exceptions or patient care services being requested. The Department shall permit a period of testing or trial (probation) to demonstrate that the applicant facility's resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level II with Extended Capabilities facility.
- 4) If a dispute between the applicant facility and its Perinatal Center cannot be resolved after consultation with the Perinatal Advisory Committee (i.e., subcommittee on facility designation), then the applicant facility, the Perinatal Center or the Perinatal Advisory Committee shall submit the dispute to the Department for settlement. The Department shall review all of the relevant information and documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care and the recommendations of the Perinatal Advisory Committee in deciding or settling a dispute. The Department shall inform

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the applicant facility, the Perinatal Center and the Perinatal Advisory Committee of its decision or judgment.

- 5) The following information shall be submitted to the Perinatal Advisory Committee (i.e., subcommittee on facility designation) to facilitate the review of the applicant facility's application for designation with exceptions to the standards of care of this Part:
 - A) A proposed letter of agreement (unsigned).
 - B) The curriculum vitae for all directors of patient care, i.e., OB, neonatal, nursing (OB and neonatal).
 - C) Appendices A and B (fully completed).
 - D) A letter from the Perinatal Center that includes the following information:
 - i) List of the exceptions being requested.
 - Sufficient data/information to demonstrate that the quality of care (outcomes) of the applicant facility are substantially equivalent to the appropriate standards as outlined in subsection (c) of this Section.
 - A description of the monitoring system used when a consultation occurs between the attending physician at the referring hospital and the physician consultant at the Perinatal Center or Level III facility and it is determined that the mother or newborn infant should stay in the community hospital for care.
 - iv) A description of any arrangements made between the applicant facility and the Perinatal Center to seek or insure quality improvement.
- 6) When the information described in subsection (e) is submitted to the Perinatal Advisory Committee, it shall review the material for compliance with the Regionalized Perinatal Health Care Code, and shall make a

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recommendation for approval or disapproval of the applicant facility's application for designation with exceptions to the Department.

- 7) The medical co-directors of the Perinatal Center (or their designees) and the medical directors of OB and neonatology and a representative of hospital administration from the applicant facility shall be present during the Perinatal Advisory Committee's review of the applicant facility's application for designation with exceptions.
- 8) The Department shall review the submitted materials and any other documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care, including quality of care (outcomes) information and the recommendation of the Perinatal Advisory Committee, and shall make a recommendation to the Director of Public Health concerning the approval or disapproval of the applicant facility's application for designation with exceptions.
- 9) The Director of Public Health shall make the final decision and inform the facility of the official determination regarding designation with exceptions to the standards of care of this Part. The Director's decision shall be based upon the recommendation of the Perinatal Advisory Committee and the facility's compliance with the Regionalized Perinatal Health Care Code, and may be appealed in accordance with Section 640.45. The Director of Public Health shall consider the following criteria or standards to determine if a facility is in compliance with the Code:
 - A) Maternity and Neonatal Service Plan (Subpart O of the Illinois Hospital Licensing Requirements).
 - B) Proposed letter of agreement between the applicant facility and its Perinatal Center in accordance with the provisions described in Section 640.70.
 - C) Appropriate outcome information contained in Appendices A and B.
 - Other documentation that clearly substantiates a facility's compliance with particular provisions or standards of perinatal care.

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- E) Recommendation of Department program staff.
- f) Level II with Extended <u>Neonatal</u> Capabilities Standards for <u>Special Care</u> <u>NurseryNeonatal Intensive Care</u> Services
 - 1) The following patients are considered appropriate for Level II with Extended <u>Neonatal</u> Capabilities <u>hospitals</u> with <u>SCNneonatal</u> <u>intensive care</u> services:
 - A) Those listed in subsection (c) <u>of this Section</u>for Level II care;
 - B) <u>Infants with Nursery care of</u> low birth weight infants greater than 1250 grams;
 - C) <u>Premature</u>Nursery care of premature infants of 30 or more weeksweeks gestation;
 - D) Infants on <u>assisted</u> wentilation.
 - 2) For each of the following neonatal conditions, a consultation shall occur between the Level II with Extended Neonatal Capabilities attending physician and the Administrative Perinatal Center or Level III neonatologist is required. The It is expected that the attending neonatologist at the Level II with Extended Neonatal Capabilities hospitalfacility and the attending neonatologist at the Administrative Perinatal Center or Level III hospitalfacility shall determine, by mutual collaboration, the most appropriate hospital facility to continue patient care-by mutual collaboration. The Level II hospitalfacility with Extended Neonatal Capabilities shall develop a prospective plan for patient care for those infants who remain at the Level II-hospitalfacility with Extended Capabilities. The plan shall include the following criteria that would trigger subsequent transfer to a Perinatal Center or Conditions that require transport to a Level III hospital shall be specified in the letter of agreement with the Administrative Perinatal Center and outlined in the hospital's department of pediatrics policies and procedures, including, but not limited tofacility:
 - A) Premature birth that is less than 30 weeks gestation;

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- B) Birth weight less than or equal to 1250 grams;
- C) <u>All conditions listed in subsection (c)(3) of this Section.</u> Infants with significant congenital heart disease associated with cyanosis, congestive heart failure, or impaired peripheral blood flow;
- D) Infants with major congenital malformations requiring immediate comprehensive evaluation or neonatal surgery;
- E) Infants requiring neonatal surgery with general anesthesia;
- F) Infants with sepsis, unresponsive to therapy, associated with persistent shock or other organ system failure;
- G) Infants with uncontrolled seizures;
- H) Infants with stupor, coma, hypoxic ischemic encephalopathy Stage II or greater;
- I) Infants requiring double-volume exchange transfusion;
- J) Infants with metabolic derangement persisting after initial correction therapy;
- K) Infants identified as having handicapping conditions that threaten life for which transfer can improve outcome.
- g) Level II with Extended <u>Neonatal</u> 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 <u>full-time</u> board_certified obstetrician or a subspecialty obstetrician certified by the American Board of Obstetrics and Gynecology in the subspecialty of maternal and fetal medicine or a licensed osteopathic physician with equivalent training and experience and certificationcertified by the American Osteopathic Board of

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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 <u>ana licensed</u> osteopathic physician with equivalent training and experience and <u>certificationcertified</u> 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 fulltime 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 licensed respiratory care practitioner with at least <u>three</u>³ years experience in all aspects of pediatric and neonatal respiratory therapy, preferably with a bachelor's degree and one successful completion of the neonatal/pediatric specialty examination of the National Board for Respiratory Care.
- F) Preventive services <u>shall be</u> 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 designated 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 <u>Illinois</u> Department <u>of Human Services willshall</u> identify and update referral resources for the area served by the unit.

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- H) Each Level II hospital with Extended Neonatal Capabilities shall develop, with the help of the Administrative Perinatal Center, Develop a referral agreement with a neonatal follow-up clinic to provide neuro-developmental assessment and outcome data on the neonatal population. HospitalInstitutional policies and procedures shallwill describe the at-risk population and referral procedure to be followed. Infants will be scheduled to be seen at regular intervals. Neurodevelopmental assessments will be communicated to the primary care physicians. Referrals will be made for interventional care in order to minimize neurologic sequelae. A system shall be established to track, record, and report neurodevelopmental outcome for the population, as required to support network CQI activities as developed by the Statewide Quality Council.
- If the Level II <u>hospital</u>facility with Extended <u>Neonatal</u> Capabilities transports <u>neonatal</u> patients, <u>the hospital shall comply</u>they must <u>comply</u> with <u>Guidelines for Perinatal Care</u>, <u>American Academy of</u> <u>Pediatrics and American College of Obstetricians and</u> <u>Gynecologists</u>the Level III transport resource requirements <u>delineated in Section 640.43(c)</u>.
- To provide for <u>assisted mechanical</u> ventilation of newborn infants beyond immediate stabilization, the Level II <u>hospitalfacility</u> with Extended <u>Neonatal</u> Capabilities shall also provide the following:
 - A) A pediatricianphysician 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; a pediatrician receiving postgraduate training in a neonatal-perinatal medicine fellowship program accredited by the Accreditation Council of Graduate Medical Education; 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. experienced in the management of mechanically

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ventilated infants present in the hospital during the entire time that the infant receives mechanical ventilation.

- B) Suitable <u>backupback-up</u> systems and <u>plans shall be in</u> <u>placeplanning</u> to prevent and respond appropriately to sudden power outage, oxygen system failure, and interruption of medical grade compressed air delivery.
- C) Nurses caring for mechanically ventilated infants who are receiving assisted ventilation shall have documented competence and experience in the care of those mechanically ventilated infants.
- D) A licensed respiratory care practitioner with documented competence and experience in the care of mechanically ventilated infants who are receiving assisted ventilation shallmust also be available to the nursery during the entire time that the infant receives assisted mechanical ventilation.
- <u>h)</u> <u>Application for Designation, Redesignation or Change in Network</u>
 - 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:
 - <u>A)</u> <u>Appendix A (fully completed);</u>
 - B) Resource Checklist (fully completed) (Appendices L, M, N and <u>O);</u>
 - <u>C)</u> <u>A proposed letter of agreement between the hospital and the</u> <u>Administrative Perinatal Center (unsigned); and</u>

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- 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 Administrative Perinatal Center (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 shall consider the following criteria or standards to determine if a hospital is in compliance with this Part:
 - <u>A)</u> <u>Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);</u>
 - B) Proposed letter of agreement between the applicant hospital and its Administrative Perinatal Center in accordance with Section 640.70;
 - <u>C)</u> 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
 - <u>E)</u> <u>Recommendation of Department program staff.</u>
- h) Exceptions to Level II with Extended Capabilities Standards of Care

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- 1) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes and geography in the regional perinatal network. These exceptions are not intended to circumvent the Level III designation. The applicant facility or the Perinatal Center may seek the advice and consultation of the Department as well as the Perinatal Advisory Committee in regard to the conditions necessary for an exception.
- 2) Facilities may request an exception to care for some subgroup of neonates listed in subsection (e)(2). The exceptions to the standards of care of this Part may be granted when the facility requesting an exception demonstrates that the resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Perinatal Center or Level III facility. The resource requirements for these exceptions may be found in Section 640.43(c) for Level III. The proposed exceptions shall be determined by the applicant facility and its Perinatal Center based primarily on outcomes.
- 3) If the applicant facility and its Perinatal Center cannot reach agreement on any aspect of the exceptions to the standards of care of this Part, the applicant facility or Perinatal Center shall seek the advice and consultation of the Perinatal Advisory Committee (i.e., subcommittee on facility designation) to settle the dispute. Any exception to the standards of care of this Part shall be clearly defined in the proposed letter of agreement and approved by the Department before implementing the exceptions or patient care services being requested. The Department shall permit a period of testing or trial (probation) to demonstrate that the applicant facility's resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Perinatal Center or Level III facility.
- 4) If a dispute between the applicant facility and its Perinatal Center cannot be resolved after consultation with the Perinatal Advisory Committee (i.e., subcommittee on facility designation), then the applicant facility, the Perinatal Center or the Perinatal Advisory Committee shall submit the dispute to the Department for settlement. The Department shall review all of the relevant information and documentation that clearly substantiates the facility's compliance with particular provisions or standards of

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perinatal care and the recommendations of the Perinatal Advisory Committee in deciding or settling a dispute. The Department shall inform the applicant facility, the Perinatal Center and the Perinatal Advisory Committee of its decision or judgment.

- 5) The following information shall be submitted to the Perinatal Advisory Committee (i.e., subcommittee on facility designation) to facilitate the review of the applicant facility's application for designation with exceptions to the standards of care of this Part:
 - A) A proposed letter of agreement (unsigned).
 - B) The curriculum vitae for all directors of patient care, i.e., OB, neonatal, nursing (OB and neonatal).
 - C) Appendices A and B (fully completed).
 - D) A letter from the Perinatal Center that includes the following information:
 - i) List of the exceptions being requested.
 - Sufficient information to demonstrate that the quality of care (outcomes) of the applicant facility are substantially equivalent to the appropriate standards as outlined in subsection (c) of this Section.
 - iii) A description of the monitoring system used when a consultation occurs between the attending physician at the referring hospital and the physician consultant at the Perinatal Center or Level III facility and it is determined that the mother or newborn infant should stay in the community hospital for care.
 - iv) A description of any arrangements made between the applicant facility and the Perinatal Center to seek or insure quality improvement.
- 6) When the information described in subsection (e) is submitted to the

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Perinatal Advisory Committee, it shall review the material for compliance with the Regionalized Perinatal Health Care Code, and shall make a recommendation for approval or disapproval of the applicant facility's application for designation with exceptions to the Department.

- 7) The medical co-directors of the Perinatal Center (or their designees) and the medical directors of OB and neonatology and a representative of hospital administration from the applicant facility shall be present during the Perinatal Advisory Committee's review of the applicant facility's application for designation with exceptions.
- 8) The Department shall review the submitted materials and any other documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care, including quality of care (outcomes) information, and the recommendation of the Perinatal Advisory Committee, and shall make a recommendation to the Director of Public Health concerning the approval or disapproval of the applicant facility's application for designation with exceptions.
- 9) The Director of Public Health shall make the final decision and inform the facility of the official determination regarding designation with exceptions to the standards of care of this Part. The Director's decision shall be based upon the recommendation of the Perinatal Advisory Committee and the facility's compliance with the Regionalized Perinatal Health Care Code, and may be appealed in accordance with Section 640.45. The Director of Public Health shall consider the following criteria or standards to determine if a facility is in compliance with the Code:
 - A) Maternity and Neonatal Service Plan (Subpart O of the Illinois Hospital Licensing Requirements).
 - B) Proposed letter of agreement between the applicant facility and its Perinatal Center under the provisions described in Section 640.70.
 - C) Appropriate outcome information contained in Appendices A and B.
 - D) Other documentation that clearly substantiates a facility's compliance with particular provisions or standards of perinatal

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care.

E) Recommendation of Department program staff.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.43 Level III – Standards for Perinatal Care

Level III: To be designated as Level III, a <u>hospitalfacility</u> shall apply to the Department for designation;, and shall comply with all of the conditions <u>prescribed in this Partdescribed</u> for intensive (Level III) perinatal care; of this Part and shall comply with all of the conditions <u>prescribeddescribed</u> in Subpart O of the Hospital Licensing Requirements (77 III. Adm. Code 250) promulgated by the Department which are applicable to the level of care necessary for the patients served;, and in addition 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 <u>its Administrativetheir</u> Perinatal Center):

- a) <u>Level III General Provisions</u>
 - A Level III <u>hospitalfacility</u> shall provide all services outlined for Level I and II (Sections 640.41(a) and 640.42(a)), <u>general</u>, intermediate and <u>specialintensive</u> care, as well as diagnosis and treatment of high-risk pregnancy and neonatal problems. Both the obstetrical and neonatal services <u>shallmust</u> achieve Level III capability for Level III designation. <u>The hospital shall and must</u> provide for the education of allied health professionals and <u>shall acceptacceptance of</u> selected maternal-fetal and neonatal transports from Level I or <u>Level II and Level II with Extended</u> Neonatal Capabilities hospitals.<u>facilities.</u>
 - 2) The Level III <u>hospital</u>facility 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 <u>hospitalfacility</u>, 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 <u>hospital'sfacility's</u>

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admissions, <u>and</u> which admissions include patients who are subsequently transferred, for the <u>three</u>² most recent calendar years, combined, for which data are available. The facility must demonstrate an adequate patient base to achieve an NICU average daily census to maintain the resources, expertise, and outcomes required.

- 4) A Level III <u>hospitalfacility</u> that elects not to provide all of <u>the advanced</u> <u>levelthese</u> services shall have established policies and procedures for transfer of these<u>mothers and</u> infants to a <u>hospitalfacility</u> that can provide the service needed.
- 5) Perinatal outcome statistics for the Level III facility must be substantially equivalent to those of the Perinatal Center and other designated Level III facilities.
- 6) This agreement should include participation in a CQI program as defined by the Department and implemented by the Perinatal Center.
- 5)7) The Level III hospital shall maintain aA system for recording patient admissions, discharges, birth weight, outcome, complications, and transports tomust be maintained and must meet requirements to support network CQI activities described in the hospital's letter of agreement with the Administrative Perinatal Center.as developed by the Statewide Quality Council. The hospital shallmust comply with the reporting requirements of the State Perinatal Reporting System.Adverse Pregnancy Outcomes Reporting System (77 III. Adm. Code 840).
- b) Level III Standards of Care
 - 1) The Level III <u>hospital</u>facility 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.
 - <u>The Level III hospital shall accept all medically eligible Illinois residents.</u> <u>Medical eligibility is to be determined by the obstetric or neonatal director</u> <u>or his/her designee based on the Criteria for High-Risk Identification</u> <u>(Guidelines for Perinatal Care, American Academy of Pediatrics and</u> <u>American College of Obstetricians and Gynecologists).</u>

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- 3) The Level III hospital shall provide or facilitate emergency transportation of patients referred to the hospital in accordance with guidelines for interhospital care of the perinatal patient (Guidelines for Perinatal Care)). If the Level III is unable to accept the patient referred, the Administrative Perinatal Center 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 maternalfetal monitoring every two years.

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- 10) The Level III hospital, in collaboration with the Administrative Perinatal Center, 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

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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.
 - <u>A)</u> 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 boardcertified 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

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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) <u>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.</u>
- 8) <u>A board-certified neonatologist, active candidate neonatologist or a</u> pediatrician receiving postgraduate training in a neonatal-perinatal medicine fellowship program accredited by the Accreditation Council of Graduate Medical Education shall be present and available in the hospital 24 hours a day to provide care for newborns in the NICU.
- 9) <u>Neonatal surgical services shall be supervised by a board-certified surgeon</u> 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) <u>Neonatal neurology services under the direct supervision of a board-</u> certified or active candidate pediatric neurologist shall be available for consultation in the NICU 24 hours a day.

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- 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,

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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 dedicated 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.
- 1) The Level III facility shall be responsible for provision of continuing education for medical, nursing, respiratory therapy, and other staff providing general, intermediate, and intensive care perinatal services with evidence of a yearly competence assessment appropriate to the patient population served.
- 2) The Level III facility shall accept all medically eligible Illinois residents. Medical eligibility is to be determined by the obstetrical or neonatal director or his/her designee based on the Department's standards for "Criteria for High Risk Identification (Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists)." If the facility is unable to accept the patient referred, the unit shall arrange for admission to another Level III facility or appropriate Level II facility.
- 3) The Level III facility shall provide or arrange emergency transportation of patients referred to the unit in accordance with guidelines for interhospital care of the perinatal patient (Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians and Gynecologists). Decisions relating to transportation shall be made by the appropriate neonatal or obstetric medical director or his/her designee. The director shall determine:
 - A) When to dispatch transportation from the facility or to use transportation facilities from the referring hospital;

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- B) When to use ground or air transportation;
- C) The kind of vehicle to be used;
- D) The staff who should accompany the patient (nurse, house staff, attending physician, respiratory therapist, or other related personnel) assuring that the staff selected is trained and prepared in emergency obstetrics or neonatology. The facility shall provide any staff attendants required to transport the patient when the trip is dispatched from the facility.;
- E) Whether transportation can be delayed;
- F) Priorities of need;
- G) Recommendations for support care to stabilize the patient until transport.
- 4) 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.
- 5) Medical director obstetrics: to direct the obstetric portion of the program. Level III 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 a licensed osteopathic physician with equivalent training and experience and certified by the American Osteopathic Board of Obstetricians and Gynecologists. 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 the obstetric services shall ensure the back-up supervision of their services when they are unavailable.

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- 6) An administrator/manager with a master's degree: to direct, in collaboration with the medical directors, the planning, development and operations of the non-medical aspects of the Level III facility and its programs and services.
- 7) Continuing education for health professionals.
- 8) Reporting program information: the Level III facility shall provide data relating to its activities and report information as required by the Department. Admission data, mortality, morbidity and other required data shall be reported on all admissions to this unit. This will include full compliance with the Adverse Pregnancy Outcomes Reporting System and the Perinatal Tracking System.
- 9) The Level III facility shall have a clearly identifiable telephone and facsimile number, 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.
- 10) The medical co-directors of the Perinatal Center shall be responsible for developing a system ensuring adequate physician to physician communications. Communications with referring physicians of patients admitted shall be sufficient to report patient progress before and at time of discharge.
- 11) Continuous electronic maternal-fetal monitoring and staff knowledgeable in its use and interpretation shall be available 24 hours a day. In addition, the Level III facility shall provide appropriate ultrasound available on the OB floor.
- 12) The Level III facility 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, to ensure appropriate enrollment in a developmental follow-up program, and to collect outcome information. 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 Department

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shall identify and update referral resources for the area served by the unit.

- 13) The Level III facility shall establish policies and procedures for the referral or transport of high risk mothers and infants who require specialized care or services not currently available at the Level III facility to the appropriate facility that can provide the service needed.
- 14) The Level III facility shall establish policies and procedures for the return transfer of high risk mothers and infants to the referring facility when they no longer require the specialized care and services of the Level III facility.
- 15) The pediatric-neonatal respiratory therapy services shall be directed by a full time licensed respiratory care practitioner with at least three years experience in all aspects of pediatric and neonatal respiratory therapy, preferably with a bachelor's degree and one successful completion of the neonatal/pediatrics specialty examination of the National Board for Respiratory Care.
- 16) A physician for the program shall be designated to assume primary responsibility for initiating, supervising and reviewing the plan for management of depressed infants in the delivery room. Policies and procedures shall assign responsibility for identification and resuscitation of distressed neonates to individuals who are both specifically trained and available in the hospital at all times, such as another physician, a nurse with training and experience in neonatal resuscitation or licensed respiratory care practitioner. Individuals assigned to perform neonatal resuscitation shall have documented evidence of current completion of a neonatal resuscitation course. It is further recommended that physicians and/or advanced practice nurses who care for newborns have documented evidence of completion of a neonatal resuscitation course.
- 17) To provide for mechanical ventilation of newborn infants beyond the immediate stabilization, a physician or advanced practice nurse experienced in the management of mechanically ventilated infants must be present in the hospital during the entire time that the infant receives mechanical ventilation. The Level III facility shall provide suitable backup systems and planning to prevent and respond appropriately to sudden power outage, oxygen system failure, and interruption of medical grade compressed air delivery.

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- 18) To care for the high risk pregnancy and for resulting infants whose birth weight is less than 1250 grams or whose gestational age is less than 30 weeks, the Level III facility shall have the perinatal leadership detailed above as well as the following resources:
 - A) A board certified or active candidate obstetrician shall be present and available in house, 24 hours a day. Maternal fetal medicine consultation must be available 24 hours a day. Obstetric anesthesia services under the direct supervision of a board certified anesthesiologist with extensive training or experience in maternal, fetal and neonatal anesthesia shall be available 24 hours a day.
 - B) Preventive services designated to prevent, detect, diagnose and 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 highrisk newborns.
 - C) A board certified or active candidate ophthalmologist with experience in the diagnosis and treatment of the visual problems of high-risk newborns (retinopathy of prematurity) shall be available to the nursery for appropriate examinations, treatment and followup care of high risk newborns.
 - D) Neonatal surgical (general), neonatal surgical anesthesia, and neonatal radiologic services detailed in subsections (c)(19)(A), (B), (C), and (D) of this Section.
 - E) Half of all neonatal intensive care direct nursing care hours shall be provided by licensed registered nurses who have two years or more nursing experience in a Level III neonatal intensive care unit. All neonatal intensive care direct nursing care hours shall be provided or supervised by licensed registered nurses who have advanced neonatal intensive care training and documented competence in neonatal pathophysiology and care technologies used in the Neonatal Intensive Care Unit. Evidence of current completion of a neonatal resuscitation course and a yearly competence assessment in neonatal intensive care nursing shall be

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required of all nursing staff working in the NICU.

- F) Licensed 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 licensed respiratory care practitioner for newborns on mechanical ventilators with additional staff provided as necessary to perform other neonatal respiratory care procedures. All direct respiratory care hours shall be provided or supervised by licensed respiratory care experience at a Level III Neonatal Intensive Care Unit. Evidence of completion of a neonatal respiratory care technology are required of all staff providing respiratory care in the NICU.
- G) Provide or develop a referral agreement with a follow-up clinic to provide neuro-developmental outcome data on the neonatal population. Institutional policies and procedures will describe the at-risk population and the referral neonatal procedure to be followed. Infants will be scheduled for assessments at regular intervals. Neurodevelopmental assessments will be communicated to the primary care physicians. Referrals will be made for interventional care in order to minimize neurologic sequelae. A system shall be established to track, record, and report neurodevelopmental outcome data for the population, as required to support network CQI activities as developed by the Statewide Quality Council.
- H) A protocol shall be established that defines the educational criteria necessary for commonly required home care modalities, including but not limited to continuous oxygen therapy, electronic cardiorespiratory monitoring, technologically assisted feeding and intravenous therapy.
- I) One registered pharmacist with experience in perinatal pharmacology shall be available for consultation on therapeutic pharmacology issues 7 days a week.

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- J) One or more full time licensed medical social workers with relevant experience shall be dedicated to the Level III perinatal facility. Time allotment should be based on the size of the unit and characteristics and needs of the patient population.
- 19) In order to provide comprehensive neonatal surgical services, including but not limited to infants with congenital anomalies or congenital heart disease, the Level III facility shall provide the following resources:
 - A) Neonatal surgical services shall be available 24 hours a day and shall be supervised by a surgeon board certified or board eligible in pediatric surgery appropriate for the procedures performed at the Level III facility.
 - B) Surgical specialists with specific training and extensive experience and/or subspecialty board certification or active candidacy (where applicable) shall be available 24 hours a day in the following subspecialties: pediatric urology, pediatric otolaryngology, neurosurgery, pediatric cardiothoracic surgery, pediatric orthopedics appropriate for the procedures performed at the Level III facility.
 - C) 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.
 - D) 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.
 - E) Neonatal neurology services under the direct supervision of a board certified or active candidate pediatric neurologist shall be available for consultation in the intensive care nursery 24 hours a day.
 - F) Neonatal cardiology services under the direct supervision of a

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pediatrician board certified or active candidate by the American Board of Pediatrics sub-board of pediatric cardiology shall be available to consult in the nursery 24 hours a day. In addition, cardiac ultrasound services and pediatric cardiac catheterization services by staff with specific training and experience shall be available as needed 24 hours a day.

- G) The neonatal intensive care nursing and respiratory care resource requirements listed in subsections (c)(15) and (18) of this Section, respectively.
- H) Genetic counseling services for inpatients and outpatients and appropriate provisions for genetic laboratory testing, including but not limited to chromosomal analysis and banding, FISH, and selected allele detection.
- 20) The obstetric-newborn nursing services shall be directed by a full-time nurse experienced in perinatal nursing preferably with a master's degree.
- 21) One or more full-time licensed medical social workers with relevant experience shall be dedicated to the Level III perinatal facility. Time allotment will be based on the size of the unit and characteristics and needs of the patient population.
- 22) Respiratory therapists with experience in neonatal care should be available with staffing based on the respiratory care requirements of the patient population (minimum of 1 respiratory therapist for every 4 patients on mechanical ventilators with additional staff provided as necessary to perform other respiratory care procedures).
- 23) One registered dietitian with experience in perinatal nutrition and a certified diabetic educator shall be available to plan diets 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

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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:
 - <u>A)</u> <u>Appendix A (fully completed);</u>
 - <u>B)</u> Resource Checklist (fully completed) (Appendices L, M, N and <u>O);</u>
 - <u>C</u>) <u>A proposed letter of agreement between the hospital and the</u> <u>Administrative Perinatal Center (unsigned); and</u>
 - 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 Administrative Perinatal Center (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:
 - <u>A)</u> <u>Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);</u>

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- B) Proposed letter of agreement between the applicant hospital and its Administrative Perinatal Center in accordance with Section 640.70;
- <u>C)</u> <u>Appropriate outcome information contained in Appendix A and the Resource Checklist;</u>
- D) Other documentation that substantiates a hospital's compliance with particular provisions or standards of perinatal care set forth in this Part; and
- <u>E)</u> <u>Recommendation of Department program staff.</u>

d) Exceptions to Level III Standards of Care

- 1) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes, and geography in the regional perinatal network. These exceptions are not intended to circumvent the Level III capabilities designation. The applicant facility or the Perinatal Center may seek the advice and consultation of the Department as well as the Perinatal Advisory Committee in regard to the conditions necessary for an exception.
- 2) Exceptions to the standards of care of this Part may be granted when the facility requesting an exception demonstrates that the resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level III facility or Perinatal Center in its Regional Perinatal Network. The proposed exceptions shall be determined by the applicant facility and its Perinatal Center based primarily on outcomes.
- 3) If the applicant facility and its Perinatal Center cannot reach agreement on any aspect of the exceptions to the standards of care of this Part, the applicant facility or Perinatal Center shall seek the advice and consultation of the Perinatal Advisory Committee (i.e., subcommittee on facility designation). Any exception to the standards of care of this Part shall be clearly defined in the proposed letter of agreement and approved by the Department before implementing the exceptions or patient care services being requested. The Department shall permit a period of testing or trial

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(probation) to demonstrate that the applicant facility's resources and quality of care (outcomes) are substantially equivalent to the resources and quality of care for any Level III facility.

- 4) If a dispute between the applicant facility and its Perinatal Center cannot be resolved after consultation with the Perinatal Advisory Committee (i.e., subcommittee on facility designation), then the applicant facility, the Perinatal Center or the Perinatal Advisory Committee shall submit the dispute to the Department for settlement. The Department shall review all of the relevant information and documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care and the recommendations of the Perinatal Advisory Committee in deciding or settling a dispute. The Department shall inform the applicant facility, the Perinatal Center and the Perinatal Advisory Committee of its decision or judgment.
- 5) The following information shall be submitted to the Perinatal Advisory Committee (i.e., subcommittee on facility designation) to facilitate the review of the applicant facility's application for designation with exceptions to the standards of care of this Part:
 - A) A proposed letter of agreement (unsigned).
 - B) The curriculum vitae for all directors of patient care, i.e., OB, neonatal, nursing (OB and neonatal).
 - C) Appendices A and B (fully completed).
 - D) A letter from the Perinatal Center that includes the following information:
 - i) List of the exceptions being requested.
 - Sufficient data/information to demonstrate that the quality of care (outcomes) of the applicant facility are substantially equivalent to the appropriate standards as outlined in this Section.
 - iii) A description of the monitoring system used when a

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consultation occurs between the attending physician at the referring hospital and the physician consultant at the Perinatal Center or Level III facility and it is determined that the mother or newborn infant should stay in the community hospital for care.

- iv) A description of any arrangements made between the applicant facility and the Perinatal Center to seek or insure quality improvement.
- 6) When the information described is submitted to the Perinatal Advisory Committee, it shall review the material for compliance with the Regionalized Perinatal Health Care Code, and shall make a recommendation for approval or disapproval of the applicant facility's application for designation with exceptions to the Department.
- 7) The medical co-directors of the Perinatal Center (or their designees) and the medical directors of OB and neonatology and a representative of hospital administration from the applicant facility shall be present during the Perinatal Advisory Committee's review of the applicant facility's application for designation with exceptions.
- 8) The Department shall review the submitted materials and any other documentation that clearly substantiates the facility's compliance with particular provisions or standards of perinatal care, including quality of care (outcomes) information and the recommendation of the Perinatal Advisory Committee, and shall make a recommendation to the Director of Public Health concerning the approval or disapproval of the applicant facility's application for designation with exceptions.
- 9) The Director of Public Health shall make the final decision and inform the facility of the official determination regarding designation with exceptions to the standards of care of this Part. The Director's decision shall be based upon the recommendation of the Perinatal Advisory Committee and the facility's compliance with the Regionalized Perinatal Health Care Code, and may be appealed in accordance with Section 640.45. The Director of Public Health shall consider the following criteria or standards to determine if a facility is in compliance with the Code:
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- A) Maternity and Neonatal Service Plan (Subpart O of the Illinois Hospital Licensing Requirements).
- B) Proposed letter of agreement between the applicant facility and its Perinatal Center in accordance with the provisions described in Section 640.70.
- C) Appropriate outcome information contained in Appendices A and B.
- D) Other documentation that clearly substantiates a facility's compliance with particular provisions or standards of perinatal care.
- E) Recommendation of Department program staff.
- e) The Department, in conjunction with the Perinatal Advisory Committee, shall develop a plan for the evaluation of the Regionalized Perinatal Health Care Code to include, but not be limited to, morbidity and birthweight specific mortality indicators. A report shall be prepared annually.
- f) The Department shall develop a plan wherein the degree of compliance with these standards is determined on a periodic basis not to exceed three years.
- g) The standards identified throughout this Section do not apply to infants who, after having completed initial therapy, are transferred back to the referring hospital for continuing care. The capability of the hospital to provide necessary services for such infants is to be determined by mutual consent with the Perinatal Center and the issue addressed in the letter of agreement.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.44 Administrative Perinatal Center

a)To be designated <u>as an Administrative</u> Perinatal Center, a <u>hospital</u><u>facility</u> shall <u>submit an</u> <u>application apply</u> to the Department for <u>a grant to provide financial support to assist the</u> <u>Department in the implementation and oversight of the Regionalized Perinatal Health Care</u> <u>Program; the designation, and</u> shall comply with all of the conditions described for intensive (Level III) perinatal care in Section 640.43; and shall comply with all of the conditions described

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in Subpart O of the Hospital Licensing Requirements. <u>The Administrative Perinatal Center (77</u> <u>Ill. Adm. Code 250) promulgated by the Department which are applicable to the level of care</u> necessary for the patients served, and in addition shall comply with the following:

- <u>a)</u> <u>Administrative Perinatal Center General Provisions</u>
 - An AdministrativeA Perinatal Center shall be a university or university_affiliated hospital, having Level III hospital designation. An Administrative Perinatal Center may be composed of one or more institutions. The Administrative Perinatal Center shall be facility-responsible for the administration and implementation of the Department's regionalized perinatal health care program, including but not limited to:
 - <u>A)</u> <u>Continuingcontinuing</u> education for health <u>care</u> professionals:<u>- A Perinatal Center may be composed of one</u> or more institutions.
 - B) Leadership and implementation of CQI projects, including morbidity and mortality reviews at regional network hospitals;
 - <u>C)</u> <u>Maternal and neonatal transport services;</u>
 - <u>D)</u> <u>Consultation services for high-risk perinatal patients;</u>
 - E) Follow-up developmental assessment programs; and
 - <u>F)</u> <u>Laboratory facilities and services available to regional</u> <u>network hospitals.</u>
- 2) <u>An Administrative Perinatal Center shall</u><u>A Perinatal Center must</u> be capable of providing the highest level of care within a regional network appropriate to maternal and neonatal high-risk patients. The following services shall be available:
 - A) Consultants in the various medical-pediatric-surgical subspecialties including, but not limited to, cardiac, neurosurgery, genetics, and other support services;

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- B) Follow-up <u>developmental</u> assessment program;
- C) Maternal and neonatal transport services; and
- D) Laboratory facilities available to the hospitals within the regional perinatal network.
- b) <u>The Department will designate an Administrative Perinatal Center within</u> each regional perinatal network there shall be a Perinatal Center designated by the <u>Department</u> to be responsible for the administration and implementation of the Department's Regionalized Perinatal Health Care Program.
- c) The <u>Administrative</u> Perinatal Center will be responsible for providing leadership in the design and implementation of the Department's <u>Continuous Quality</u> <u>Improvement (CQI Program, including) program. This will include</u> the establishment and <u>regularly scheduled meetingsmaintenance</u> of a regional quality improvement structure (Regional Quality Council).<u>for the implementation of the</u> <u>Department's Quality Improvement in Perinatal Program, (QIPP).</u>
- The Administrative Perinatal Center shall establish a Joint Mortality and <u>d</u>) Morbidity Review Committee with the affiliated regional network hospitals. The Joint Mortality and Morbidity Review Committee shall review all perinatal deaths and selected morbidity, including, but not limited to, transports of neonates born with handicapping conditions, or developmental disabilities, or unique medical conditions. This review shall also include a periodic comparison of total perinatal mortality and the numbers attributable to categories of complications. Membership on the Joint Mortality and Morbidity Review Committee shall include, but not be limited to, pediatricians, obstetricians, family practice physicians, nurses, quality assurance, pathology, and hospital administration staff and representatives from the hospital's Administrative Perinatal Center. The network administrator shall prepare a yearly synopsis of the Regionalized Perinatal Network's perinatal deaths. This synopsis shall include statistical information, as well as an identification of the factors contributing to deaths that are identified as potentially avoidable. The synopsis shall be shared with the Regional Quality Council. The Regional Quality Council shall develop, for the Regional Perinatal Network, an action plan to address issues of preventability. The Regional Quality Council's action plan shall be forwarded to the Department.

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The membership of the Regional Quality Council shall include representatives from all levels and disciplines of perinatal health care providers.

<u>e)</u>d) <u>Perinatal Program OversightAgency Review</u>

- The Department shall work in conjunction with the Administrative <u>Perinatal Centers to conduct site visits at network hospitals to</u> <u>assuredevelop a plan that has the degree of</u> compliance with this <u>PartSection's standards determined</u> on a periodic basis not to exceed three years.
- 2) The <u>requirements of standards identified throughout</u> this <u>PartSection</u> do not apply to infants who, after having completed initial therapy, are transferred back to the referring hospital for continuing care. The capability of the hospital to provide necessary services for these infants <u>shallis to</u> be determined by mutual consent with the <u>Administrative</u> Perinatal Center and <u>the issue</u> addressed in the letter of agreement.
- 3) <u>Administrative Perinatal Centers shall provide information to the Department no less frequently than quarterly. These reports shall include, but not be limited to, network education activities; network meetings; overview of CQI activities; schedule of mortality and morbidity review meetings; and schedule of proposed and completed network hospital site visits. The Department shall develop a methodology for incorporating perinatal outcomes information into the perinatal facility designation, redesignation, and exception processes. The Department shall seek input on the development of this methodology from the Perinatal Advisory Committee. This input shall include, but not necessarily be limited to, the identification and selection of indicators, defining standards for each level of care and the methodology for applying the standards to the designation, redesignation and/or exception processes.</u>

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.45 Department of Public HealthAgency Action

a) <u>Department Review</u>

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- 1) The Department will develop a plan for determining the degree of compliance with this Part on a periodic basis not to exceed three years.
- 2) During the site visit, the hospital will receive, a determination of substantial compliance or substantial failure.

b) Department Oversight

<u>The Department may deny designation or redesignation or revoke designation of</u> <u>any hospital that</u><u>Any designated facility which</u> fails to <u>achieve substantial</u> <u>compliancecomply</u> with the requirements for its designation may have its <u>application</u> for designation <u>or redesignation set forth in this Part.denied or its</u> <u>designation revoked by the Department</u>. The Department <u>willshall</u> consider the following factors relevant in deciding whether <u>to deny designation or</u> <u>redesignation or to revoke designation:</u><u>failure to comply with the requirements for</u> <u>designation will result in denial or revocation:</u>

- 1) Failure to complete the letter of agreement within 90 days after receipt of the official site visit report;-
- 2) Failure to have <u>and to comply with an approved Maternal and Neonatal</u> Service Plan<u>:</u>-
- 3) Failure to complete the site visit and accompanying site visit report <u>documentation</u>, i.e., Standardized Perinatal Site Visit Protocol and <u>Outcome Oriented Data</u>:-
- 4) <u>Failure to complyApplicant facility has not demonstrated compliance</u> with all of the requirements <u>of this Part</u> for the level of designation.
- 5) <u>Failure to participateApplicant facility has failed to demonstrate adequate</u> participation in <u>and comply with ontinuous Quality Improvement (</u>CQI <u>programs) activities</u>, including the Regional Quality Council or other programs designed or <u>implemented by the Administrative Perinatal</u> <u>Centerimplemented by the Perinatal Center</u> or the Department<u>:</u>-
- 6) Failure to notify the Department of the loss of, or change in, an essential resource required for its level of designation;
- b) The circumstances under which an application or designation may be denied or

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revoked include:

- 1) failure to comply with the requirements for designation has been noted by the Department; and
- 2) when the institution has been notified by the Department as to the specific item or items not in compliance with the requirements for designation, and when the institution has not corrected the matter within a reasonable period of time (90 days).
- c) The Department will notify the hospital within 30 days after the site visit as to whether the hospital has achieved substantial compliance with this Part. The notification will include specific requirements with which substantial compliance has not been achieved. If the hospital has not achieved substantial compliance within 90 days after having received the notice, the Department will deny or revoke the designation. If progress toward substantial compliance is being made, per written documentation of the Administrative Perinatal Center, the Department will continue to work with the hospital and its Administrative Perinatal Center to achieve designation.
- <u>d)</u>e) The provisions of the Illinois Administrative Procedure Act [5 ILCS 100] and the Department's Rules of Practice and Procedure <u>infor</u> Administrative Hearings (77 Ill. Adm. Code 100) shall apply to all hearings challenging Department decisions, including those related to designation, redesignation, and denial or revocation of designation.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.50 Designation and Redesignation of <u>Non-Birthing Center</u>, Level I, Level II, Level II with Extended <u>Neonatal</u> Capabilities, and Level III Perinatal <u>Hospitals and</u> <u>Administrative Perinatal Centers</u> <u>Facilities</u>

a) The <u>hospital</u>facility shall declare by means of a letter of intent to the Department and the affiliated Administrative Perinatal Center that it seeks designation <u>as a</u> <u>hospital with no OB services</u>, or as a facility for the delivery of general perinatal care (Level I), or intermediate perinatal care (Level II, or Level II with Extended <u>Neonatal</u> Capabilities), or intensive care (Level III) in <u>a one of the</u> Regional Perinatal <u>Network.Networks of the Illinois Perinatal Health Care Program.</u>

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- b) The Department <u>willshall</u> acknowledge the letter of intent.
- The Administrative Perinatal Center shall arrange a site visit to the applicant c) hospitalfacility. 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 hospitalsfacilities shall consist of five5 members: three from the Administrative Perinatal Center of the hospital's Regional Perinatal Network, hospital network, including the Directors of Neonatology 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. The site visit team shall review the capabilities of the applicant hospitalfacility based on the requirements outlined in the letter of agreement between the applicant hospitalfacility and the Administrative Perinatal Center. The site visit team shall complete the Standardized Perinatal Site Visit Protocol (see Appendix A) and Outcome Oriented Data (see Appendix B) and submit these materials to the medical directors of the facility visited for their review and comment within 30 days from the date of the site visit. The Administrative Perinatal Center 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 <u>willshall</u> coordinate the site visit for <u>Administrative</u> Perinatal Centers. The team shall consist of <u>five5</u> members: one Director of Neonatology, <u>one Director of Maternal-Fetal Medicine and one Perinatal Network</u> <u>AdministratorNursing</u> from a non-contiguous Center; one representative from the PAC; and one representative of the Department. <u>The Department shall collaborate</u> 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. <u>The site visit team shall complete the Standardized Perinatal Site</u> Visit Protocol and Outcome Oriented Data and submit these materials to the Perinatal Center for their review and comment within 30 days from the date of the site visit.
- e) The complicated site visit report shall then be forwarded to the Department within 60 days from the date of the site visit. Department staff shall be available for technical and administrative consultation concerning the site visit.
- f) The Department, having received the information requested concerning the

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applicant facility, the site visit report and the letter of agreement between the applicant facility and the Perinatal Center, shall submit these materials to the Perinatal Advisory Committee for review. The applicant facility may request to appear or may be asked to appear before the Perinatal Advisory Committee during its review of the application.

- g) When the information described in Section 640.60 is submitted to the Perinatal Advisory Committee, it shall review the material, and the report of the site visit, for compliance with the Regionalized Perinatal Health Care Code; and shall make a recommendation for approval or disapproval of the facility's application for designation to the Department.
- e)h) The Department <u>willshall</u> review the submitted materials, any other documentation that clearly substantiates a <u>hospital'sfacility's</u> compliance with particular provisions or standards for perinatal care, and the recommendation of <u>the PAC. Perinatal Advisory Committee, and shall make a recommendation to the</u> <u>Director of Public Health concerning designation of the facility as an affiliated</u> <u>perinatal facility (Level I, Level II, Level II with Extended Capabilities, Level III)</u> to a designated Perinatal Center in the Statewide Regionalized Perinatal Health <u>Care Program.</u>
- f)i) The Department willDirector of Public Health shall make the final decision and inform the hospitalfacility of the official determination regarding designation. The Department'sDirector's decision willshall be based upon the recommendation of the PACPerinatal Advisory Committee and the hospital'sfacility's compliance with this Part, the Regionalized Perinatal Health Care Code, 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 DepartmentDirector of Public Health shall consider the following criteria or standards to determine if a hospitalfacility is in compliance with this Part: the Code:
 - 1) Maternity and Neonatal Service Plan (Subpart O of the Hospital Licensing Requirements);
 - 2) Proposed letter of agreement between the applicant hospital and its Administrative Perinatal Center in accordance with Section 640.70;

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- 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.
- 1) Confirmation of an approved Maternity and Neonatal Service Plan at the level of care for which the facility is seeking designation.
- 2) An approved letter of agreement between the applicant facility and its Perinatal Center in accordance with the provisions described in Section 640.70.
- 3) A completed Standardized Site Visit Protocol and Outcome Orientated Data report in accordance with the provisions described in Section 640.50(c) (e).
- 4) Other documentation that clearly substantiates a facility's compliance with particular provisions or standards for perinatal care.
- 5) Recommendation of Department program staff.
- <u>g)j</u>) <u>The Department will review allAll</u> designations <u>at leastshall be reviewed by the</u> Department every three years or when the Department may deem necessary to assure that the designated <u>hospitalsfacilities</u> continue to comply with the requirements of the perinatal plan. Circumstances <u>thatwhich</u> may influence the Department to review a <u>hospital'sfacility's</u> designation <u>more frequentlyother</u> than every three years could include:
 - 1) <u>A hospital's device</u> When a hospital wanted to expand or reduce services;-
 - 2) Poor perinatal outcomes
 - 3) Change in <u>Administrative</u> Perinatal Center or Network affiliation;-
 - 4) <u>Change in Availability of human resources that would have an impact on</u>

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the hospital's ability to comply with the required resources for the level of designation; orto complete Department site visit.

- 5) <u>An Administrative When a Perinatal Center finds and the Department</u> concurs or determines that a hospital is not appropriately participating in <u>and complying with Continuous Quality Improvement (CQI)</u> <u>programsactivities and/or the Quality Improvement in Perinatal Program</u> (QIPP).
- \underline{hk}) Existing designations shall be effective until redesignation is accomplished.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.60 <u>Application Information</u> for <u>Hospital Facility</u> Designation <u>orand</u> Redesignation as <u>a Non-Birthing Center</u>, Level I, Level II, Level II with Extended <u>Neonatal</u> Capabilities, and Level III Perinatal <u>Hospital Facilities</u> <u>and Administrative Perinatal</u> <u>Center</u>, and Assurances Required of Applicants

- a) Applicant <u>hospitals</u>facilities shall provide the Department <u>withthe following</u> information <u>based on standards and resources for the applicable level of</u> <u>designation. The information shall include, but not be limited to the following</u> <u>(see Appendix A):which may be included in its Maternity and Neonatal Service</u> <u>Plan or letter of agreement:</u>
 - 1) A definition of the geographic area the <u>hospital</u> facility currently serves or plans to serve.
 - A <u>physical</u> description of the <u>hospitalphysical facility</u>, compliance with Subpart O of <u>the Hospital Licensing Requirements</u>77 Ill. Adm. Code 250, and a description of the maternity and nursery units currently in place or in preparation for operation should the <u>hospitalfacility</u> be designated.
 - A <u>physical</u> description of the <u>hospital'sfacility's</u> staffing in accordance with <u>this Part</u> those additional standards or designation described in the <u>Regionalized Perinatal Health Care Code</u> as follows:
 - A) Social work and nutrition services shall be available through a hospital department for Level II and Level III designation.

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- B) Names, titles and contact numbers shall be provided for the Director or Chairman of Maternal-Fetal Medicine, Neonatology, Obstetrics, Pediatrics and Neonatal Services, Chief Nursing Supervisor, Nursing Supervisor of Maternity Unit; names and contact <u>numbersnumber</u> of medical staff members in maternal-fetal medicine, obstetrics and gynecology, neonatology, <u>obstetricOB</u> anesthesiology, family practice, anesthesiology; listing of anesthetists, staff for respiratory therapy, nurse-midwives, and involved house staff.
- C) A description of the current nurse/patient ratios in the nursery, delivery room, postpartum floor and intermediate or intensive care newborn nurseries for all shifts.
- D) A description of the qualifications of nursing personnel involved in the newborn nursery, delivery room and postpartum area.
- E) A description of the staff plans to assure that maternity/nursery staff are trained and prepared to stabilize infants prior to transfer, and are available 24 hours a day.
- A description giving evidence that the <u>hospital'sfacility's</u> laboratory, X-ray and respiratory therapy equipment and capabilities meet all <u>of</u> the conditions described in 77 III. Adm. Code 250, Subpart O <u>of the Hospital Licensing Requirements</u> and are available 24 hours a day in-house.
 - A) <u>Continuous</u>Evidence is required that continuous electronic maternal-fetal monitoring <u>shall beis</u> available, and staff <u>with</u> knowledge in its use and interpretation <u>shall beis</u> available 24 hours a day for Level I, Level II, Level II with Extended <u>Neonatal</u> Capabilities, and Level III designation applicants.
 - B) Level III and <u>Administrative</u> Perinatal <u>CentersCenter</u> shall provide Level II ultrasound available on the <u>obstetricOB</u> floor.
 - C) Level I ultrasound and staff knowledgeable in its use and interpretation shall be available at Level II <u>hospitalsfacilities</u> on a 24_hour_a_day basis.

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- 5) A description of the capabilities for or capabilities planned for (giving the start-up time), emergency neonatology surgery, listing specialists such as surgeons, trained or support staff for neonates, and a description of the capabilities for caesarean section and start-up time.
- 6) A description of the present plan for identification of high-risk maternity and neonatal patients and agreements for consultation with the <u>Administrative</u> Perinatal Center in cases of maternity and neonatal complications and neonates with handicapping conditions. This description shall include plans and agreements for providing:
 - A) Management of acute surgical or cardiac difficulties;
 - B) Genetic counseling <u>ifshould</u> a genetically related condition <u>isbe</u> diagnosed in the neonate, or <u>ifshould</u> a parent or a known carrier <u>requests therequest such</u> services;
 - C) Information, counseling and referral for parents of neonates with handicapping conditions or developmental disabilities to ensure informed consent for treatment;
 - D) Counseling and referral services to assist these patients in obtaining habilitation and rehabilitation services;
 - E) A description of the types of patients the <u>hospitalfacility</u> will care for and the types of patients it will refer to the <u>Administrative</u> Perinatal Center.
- A description of the history and current level of involvement with <u>CQI</u> <u>Continuous Quality Improvement</u> activities as designed and implemented by the <u>Administrative</u> Perinatal Center.
- 8) All of the information required for <u>hospital</u><u>facility</u> designation or redesignation to the <u>Administrative</u> Perinatal Center with which it is seeking affiliation.
- b) The following <u>proceduresguidelines</u> shall govern the review of perinatal <u>hospitals</u> facilities applying for designation or redesignation:

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- Hospitals applying for perinatal designation or redesignation shall provide all <u>of</u> the information contained in <u>the</u> Standardized Perinatal Site Visit Protocol (Appendix A) <u>and the Resource Checklist (see Appendices L, M,</u> <u>N and O).and Outcome Oriented Data (Appendix B).</u>
- 2) <u>The completed written documentation The completed Standardized</u> Perinatal Site Visit Protocol and Outcome Oriented Data shall be submitted to the Department three weeks in advance of the scheduled site visit, along with the site visit report, and the letter of agreement.
- 3) The Department will send the completed site visit documentation Standardized Perinatal Site Visit Protocol and Outcome Oriented Data shall be sent by the Department to the PAC members, no less than two weeksone week in advance of the PAC meeting, to facilitate PAC their review of the applicant hospital facility.
- 4) A representative of the <u>Administrative</u> Perinatal Center <u>and</u> representatives of the hospital for which the application is being considered shall be present at the PAC meeting to respond to questions or concerns of PAC members regarding the <u>hospital'sfacility's</u> application for designation or redesignation. The representative may also be asked to present an oral summary of the applicant <u>hospital'sfacility</u> and the <u>Administrative</u> Perinatal Center's reasons for recommending/not recommending designation or redesignation to the PAC. <u>A 12- to 18-</u> month follow-up will be scheduled for any increase in designation to assess compliance with the new level of designation.
- 5) The Department <u>will request that shall ask</u> the <u>Administrative</u> Perinatal Center to-conduct a follow-up site visit to the <u>hospital facility</u> for review for designation or redesignation if the initial site visit is more than <u>six6</u> months prior to submission to the <u>PAC</u>.for review by <u>PAC</u> for designation or redesignation. <u>Approval In such cases</u>, approval shall be contingent upon receiving the findings of the follow-up site visit.
- c) The following procedure shall be followed to change network affiliation for an individual hospital:

1) <u>The hospital requesting a change in affiliation shall submit a</u> written request to the Department. The existing Administrative Perinatal

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<u>Center shall provide information for the site visit and review, as requested.</u> <u>The receiving Administrative Perinatal Center shall conduct the site visit</u> <u>in preparation for a change in network.</u>

<u>Representatives from the hospital and receiving Administrative</u>
 <u>Perinatal Center shall appear before the PAC and shall present appropriate</u>
 <u>documentation as described in Appendix A.</u>

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.70 Minimum Components for Letters of <u>AgreementAgreements</u> Between <u>Non-Birthing Center</u>, Level I, Level II, Level II with Extended <u>Neonatal</u> Capabilities, or Level III Perinatal <u>Hospitals</u>Facilities and Their <u>Administrative</u> Perinatal Center

The following components, at a minimum, shall be addressed in a letter of agreement between the applicant <u>hospitalfacility</u> and its <u>Administrative</u> Perinatal Center:

- a) A description of how maternal and neonatal patients with <u>potential</u> <u>complicationsproblems</u>, including handicapping conditions or developmental disabilities, will be identified.
- b) A description of the types of maternal and neonatal cases in which consultation from the <u>Administrative</u> Perinatal Center or Level III <u>hospitalfacility shallwill</u> be sought and from which patients <u>shallwill</u> be selected for transfer. This description shall address those high-risk mothers or neonates with:
 - 1) Handicapping conditions, developmental disabilities, or medical conditions that are life threatening and require transport to a Perinatal Center or a Level III facility.
 - 2) <u>handicappingHandicapping</u> conditions, developmental disabilities, or medical conditions that may require additional medical and surgical treatment and support services, but would not, however, require transport to <u>ana Administrative</u> Perinatal Center or Level III <u>hospitalfacility</u>.
- c) A description of how the <u>Administrative</u> Perinatal Center or Level III <u>hospitalfacility</u> will report <u>a patient'spatients'</u> progress to the referring physicians, and the criteria for return of <u>the patientpatients</u> from the <u>Administrative</u> Perinatal Center or Level III <u>hospitalfacility</u> to an affiliated <u>hospitalfacility</u> closer to the

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patient's patients' home.

- d) A description of the methods for transporting high-risk mothers and neonates with physiological support in transit.
- e) A description of the information, counseling and referral services available within the local community and the regional network for parents or potential parents of neonates with handicapping conditions or developmental disabilities.
- f) A description of the professional educational outreach program for the regional network, including how efforts will be coordinated.
- A provision requiring the establishment of a Joint Mortality and Morbidity g) Review Committee to review all perinatal deaths and selected morbidity. The review shall include the births of children born with handicapping conditions or developmental disabilities, utilizing criteria of case selection developed by the PAC to determine the appropriateness of diagnosis and treatment of neonates born with a handicapping condition or developmental disability and the adequacy of procedures to prevent such disabilities or the loss of life (Section 3(g) of the Act). This review shall also include a periodic comparison of total perinatal mortality and the relative numbers attributable to various categories of complications. Membership on the Committee should include pediatricians, obstetricians and representation from their designated Perinatal Center. Membership on the Committee may also include general family practitioners, with specified support staff of the hospital. A yearly synopsis of the Perinatal Network's perinatal deaths will be prepared by the Network Administrator. This synopsis will include statistical information, as well as an identification of the factors contributing to deaths assigned a disposition of potentially avoidable. The synopsis will be shared with the Regional Quality Council. An action plan to address issues of preventability will be developed, for the Network, by the Regional Quality Council. The Regional Quality Council's action plan will be forwarded to the State-Wide Ouality Council. The membership of the Regional Quality Council shall include representatives from all levels and disciplines of perinatal healthcare providers.
- **gh**) A description of the regional perinatal network's program for medical and home nursing follow-up, describing systems of liaisons, with a letter of agreement from the agency providing the home nursing follow-up services.

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- <u>h</u>i) A description of the methodologies used to monitor, evaluate, and improve the quality of health care services provided <u>byunder the auspices of</u> the applicant <u>hospitalfacility</u>, including <u>a clear set of</u> expectations of both the <u>Administrative</u> Perinatal Center and applicant <u>hospitalfacility</u> on joint participation in <u>CQIcontinuous quality improvement</u> activities.
- ij) A requirement that the hospital shall provide stipulation requiring the provision of information, counseling and referral services to parents or potential parents of neonates with handicapping conditions or developmental disabilities upon the identification of the handicapping conditions and developmental disabilities, to assist in obtaining habilitation, rehabilitation, and special education services.
- jk) A requirement for provision requiring evaluation and consultation with the Administrative Perinatal Center or Level III hospitalfacility and referral to the Administrative Perinatal Center or Level III hospitalfacility, when determined appropriate by the perinatal conditions or developmental disabilities, within 24 hours after the identification of the conditions (specific conditions shallmust be defined in the letter of agreement).
- <u>k</u>l) A requirement that provision requiring the establishment of procedures for referral to appropriate state and local education service agencies of children having an identified handicapping condition or developmental disability requiring evaluation and assessment under such agencies <u>shall be established</u>. The procedures shall include <u>a provision for</u> obtaining parental consent prior to release of information to the appropriate state and local educational service agencies.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.80 Regional Perinatal Networks – Composition and Funding

a) Regional Perinatal Networks, as defined in Section 640.20, may include any number and combination of hospital-based maternity and newborn facilities functioning at one of the <u>fivethree</u> levels of perinatal care, according to policies and practices described in their letters of agreement. Where more than one Level III <u>hospitalfacility</u> provides services within a <u>Regional Perinatal Networkregional</u> perinatal network, a letter of agreement with the <u>Administrative</u> Perinatal Center shall describe how each will participate in the provision of services included in Section 640.40(c) of this Part. <u>Regional Perinatal NetworksSuch regional</u> perinatal networks may also include other agencies, institutions and individuals

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providing a complete range of perinatal health services, including preconceptional, prenatal, perinatal and family follow-up care services, as part of the regional network.

- b) The Department <u>willmay</u> allocate funds for perinatal health services provided through Regional Perinatal Networks.
 - Sections 630.30 through 630.70 of the Department's "Maternal and Child Health Services Code" (77 Ill. Adm. Code 630) describes categories of maternal and child health services project activity that are eligible for funding. Requirements for Maternal and Child Health (MCH) Project grant applications are included in 77 Ill. Adm. Code 630.80 through 630.200.
 - <u>1</u>2) Funds <u>willavailable to the Department for funding of regional perinatal</u> <u>networks may</u> be awarded <u>to Regional Perinatal Networks</u> under the following mechanisms:
 - A) The Department <u>willmay</u> provide grants to designated <u>Administrative</u> Perinatal Centers responsible for the administration and implementation of the Department's regionalized perinatal health care program. Under this option, the <u>Administrative</u> "Perinatal Center" is the applicant for <u>Maternal and Child Health</u> (MCH) Project funds and will apply as specified in <u>the Department</u> of <u>Human Services' Maternal and Child Health Services Code (</u>77 Ill. Adm. Code 630.30 through 630.70].
 - B) The Department may provide grants to regional perinatal networks acting through a Regional Perinatal Management Group representing all participants in the regional network for systems management and perinatal services, including providers of preconceptional, prenatal, and family follow-up care, as well as providers of hospital based perinatal care services. Under this option the "Regional Perinatal Management Group" is the applicant for MCH Project funds and will apply as specified in 77 Ill. Adm. Code 630 and this Part.
 - <u>BC</u>) Grant applications by regional perinatal networks may include services and responsibilities assigned to <u>Administrative</u> Perinatal

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Centers and Level III <u>hospitals</u> facilities in Section 640.40(c) of this Part in addition to the perinatal care services included in 77 Ill. Adm. Code 630.30 through 630.70.

D) The Department may reimburse Perinatal Centers, providers of high-risk services at Level III facilities and health care agencies providing follow-up services where no local health department exists through contracts developed directly with these agencies, institutions and individuals for costs incurred in providing perinatal care services.

<u>2</u>3) Preventive Services

- A) A portion of funds available to the Department for funding regional perinatal networks shall be targeted for <u>preventive</u> <u>services</u>. Preventive Services. These funds may be distributed or allocated to perinatal centers or regional perinatal networks according to a needs based formula. The formula for determining the Preventive Services allocation is based upon the following need factors:
 - i) Number of live births by Regional Perinatal Network
 - ii) Fetal death rate by Regional Perinatal Network (Number of fetal deaths per 1,000 live births plus fetal deaths)
 - iii) Low birthweight rate by Regional Perinatal Network (Number of live births less than 2500 grams per 1,000 live births)
 - iv) Low or no prenatal care rate by Regional Perinatal Network (Number of live births to females receiving prenatal care during the third trimester or no care per 1,000 live births)
 - v) Number of hospitals in Regional Perinatal Network
- B) The rates, based on occurrences at hospital of birth are calculated for each Regional Perinatal Network using vital statistics for the latest three years combined for which data is available. Total live

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births for these years also are considered. The most current Regional Perinatal Network affiliation is used to aggregate the occurrences and determine the number of hospitals in each network.

- C) The formula gives equal importance to each of the five need factors. Higher rates and absolute numbers indicate greater need. The values of each factor for each Regional Perinatal Network are standardized (Z-scores),* transformed into stanine scores,** and summed. The sum represents each Regional Perinatal Network's need indicator score. The indicator score is summed across all networks, and each network's relative proportion to that total is computed.
- D) The resulting percentage for each Regional Perinatal Network is applied to the total Preventive Services funds available to determine the allocation for each Regional Perinatal Network.

E) <u>* denotes Standardized Score (z Score)</u>

$$z = X - \overline{X} - \frac{X}{s.d.}$$

Where	Z	=	The standardized score for a particular perinatal
			network on a particular need factor

- X = The rate/number for a particular perinatal network on a particular need factor
- X = The mean for a particular need factor
- s.d. = The standard deviation for a particular need indicator ** denotes Transformation of Z scores to stanines.

Greater	than	+	1.75	=	9
+1.75	ŧo	+	1.5	=	8
+1.25	ŧo	+	0.25	=	7
+0.75	ŧo	+	0.25	=	6

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+0.25	ŧo	-	0.75 = 5
-0.25	ŧo	-	1.25 = 4
-0.75	ŧo	-	1.75 = 3
-1.25	ŧo	-	1.75 = 2
less	than	-	1.75 = 1

(Guilford and Fruchter Fundamental Statistics in Psychology and Education. New York: Mcgraw Hill)

 4) Requirements for Perinatal Centers and Level III facilities are included in Section 640.40(c) of this Part and include standards for medical eligibility for services.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.90 State Perinatal Reporting System

a) Purpose

The Department will maintain a <u>State</u> Perinatal Reporting System to follow selected high-risk perinatal patients, to <u>ensureinsure</u> that those patients are assessed at appropriate intervals, receive intervention as needed, and are referred for needed support services.

- b) Identification and Referral of High-<u>Riskrisk</u> Maternal Patients-
 - Each designated <u>Administrative</u> Perinatal Center and Level III <u>hospitalfacility thatwhich</u> provides obstetrical care shall establish criteria and procedures for identifying high-risk pregnant and postpartum patients. A statement describing <u>thesuch</u> criteria and procedures shall be on file and shall be provided to the Department on request.
 - 2) Each designated Perinatal Center and Level III facility shall prepare and distribute a Maternal Discharge Record (see Appendix C), to be provided by the Department, for each high-risk pregnancy or postpartum patient treated in the facility who requires public health nursing follow-up. If a patient is readmitted during the same or subsequent pregnancies and is deemed to be high-risk, another Maternal Discharge Record shall be prepared and distributed if public health nursing follow-up is needed.

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- 23) The hospital's Perinatal Review Committee-established pursuant to Section 640.70, or other committee established for the purpose of internal quality control or medical study for the purpose of reducing morbidity or mortality or improving patient care, shall collect and submit the required information required in subsection (b)(1) to the Department. These data will be considered confidential under Section 8-2101 of the Code of Civil Procedure [735 ILCS 5/8-2101].
- 4) The Maternal Discharge Record shall be completed and distributed within seven days after the patient's discharge from the facility. Instructions for proper completion of the Maternal Discharge Record are contained in Appendix C. Additional pages may be attached when there is insufficient space on the form for all needed information.
- 5) Copies of the Maternal Discharge Record shall be distributed as follows:
 - A) The original form (white copy) of the Maternal Discharge Record shall be sent to the Department of Public Health, 535 West Jefferson, Springfield, Illinois 62761;
 - B) The yellow copy shall be sent to the Local Health Department or other local health agency designated by the Department to provide follow up services in the county or area in which the patient resides;
 - C) The pink copy shall be retained by the reporting facility.
- 6) The hospital staff is encouraged to contact the designated local health agency by telephone when there is a need for additional information to be communicated to the local health nurse, or when a pre-discharge visit by the local health nurse is needed.
- 7) The Department will provide to the hospitals a list of Local Health Departments and other local health agencies designated to provide followup services to high risk maternal patients. The list will be updated as needed, at least annually.
- c) Identification of Perinatal Patients

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- <u>All The Department requires that all</u> Illinois hospitals licensed to provide obstetrical and newborn services <u>shall</u> report information on all perinatal patients. The Department requests, but does not require, reports on perinatal patients from hospitals outside Illinois<u>, except the (The</u> <u>Department does request reports from the St. Louis administrative</u> perinatal centers <u>or</u>, and hospitals maintained by the <u>federal government</u> <u>Federal Government</u> or other governmental agencies within the United States.)
- Each hospital <u>shallwill</u> prepare a Perinatal Report record (see Appendix <u>IH</u>), to be provided by the Department, for patients meeting one of the following conditions:
 - A) Live-birth<u>; or</u>.
 - B) Diagnosed prior to discharge from newborn hospitalization as a perinatal or neonatal death.
- 3) AGENCY NOTE: Women <u>whothat</u> present with spontaneous abortion, ectopic pregnancy or <u>hydatidiformhydatid</u> mole are perinatal patients and <u>shallmust</u> be reported. <u>TheIn addition, the</u> products of induced abortions shall not be reported to the <u>State</u> Perinatal Reporting System.
- <u>AGENCY NOTE:</u> Fetal death (gestation greater than 20 weeks) is considered a reportable perinatal outcome and will be included in the <u>State</u> Perinatal Reporting System. However, fetal deaths do not have to be reported through the <u>State</u> Perinatal Reporting System, because these deaths are already reported and compiled in the <u>Department's</u> <u>Departments's</u> Vital Records database.
- 53) Every hospital shall provide representatives of the Department with access to information from all medical, pathological, and other pertinent records and logs related to reportable registry information. The mode of access and the time during which this access will be provided shall be by mutual agreement between the hospital and the Department.
- 64) The <u>State</u> Perinatal Reporting System also will be complemented with information from the Department's Vital Records live birth database under the Vital Records Act[410 ILCS 535], the Adverse Pregnancy Outcomes

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Reporting System under the Illinois Health and Hazardous Substances Registry Act [410 ILCS 525] and other Maternal and Child Health Reports and submissions.

- 75) The Perinatal Reporting System consists of two forms of reporting. This reporting shall be on the forms provided by the Department or through electronic means that meets the exact specifications of the Department's data processing system. Complete perinatal reporting information shallmust be reported to the Department within 14 days after infant discharge, regardless of the method of reporting.
- 6) The Perinatal Report record shall be distributed in the following manner:
 - A) Two copies of the Perinatal Reporting System record must be sent to the Department of Public Health's Office of Epidemiology and Health Systems Development, 605 West Jefferson, Springfield, Illinois 62761.
 - B) A pink copy may be retained by the reporting facility.
 - C) A copy must be forwarded to the Local Health Nurse.
 - D) A copy must be forwarded to the Primary Care Physician.
- d) Report of Local Health Nurse
 - The Local Health Department or other designated local health agency providing follow-up services to high-risk infants shall prepare and distribute a Report of Local Health Nurse for each visit made; a Report shall also be distributed when a case is closed without a visit.
 - 2) Copies of the Report of Local Health Nurse shall be distributed as follows:
 - A) The original form (white copy) of the Report of Local Health Nurse shall be sent to the Department of Public Health, 535 West Jefferson, Springfield, IL 62761.
 - B) The canary copy shall be sent to the hospital which referred the patient for follow up services.

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- C) The pink copy shall be retained at the appropriate Local Health Nurse Agency.
- D) The goldenrod copy shall be sent to the patient's primary care physician.
- 3) The Local Health Department or other designated local health agency providing follow up services to high risk pregnant and postpartum women should send a copy of the progress notes to the referring hospital.

de) Availability of Information

- 1) The patient and <u>hospitalfacility</u>-identifying information submitted to the Department or <u>certified</u> local health <u>departmentagency</u> under the Act and this Part shall be privileged and confidential and shall not be available for disclosure, inspection or copying under the Freedom of Information Act or the State Records Act, except as described in this Section. These data shall also be considered confidential under Section 8-2101 of the Code of Civil Procedure.
- 2) Aggregate <u>summaries</u> and reports of follow-up activities may be provided upon request to hospitals, to <u>Administrative</u> Perinatal Centers, and to the <u>certified</u> local health <u>departmentagency</u> designated by the Department to provide follow-up services to the patients. <u>TheseSuch</u> reports may contain information provided by the referring hospital and information provided by the follow-up <u>certified local health</u> <u>departmentagency</u>. Patient or <u>hospitalfacility</u> specific data provided to the appropriate designee under this Section <u>areis</u> confidential and shall be handled in accordance with the provisions of the Illinois Health Statistics Act [410 ILCS 520] and Section 9 of the Hospital Licensing Act-[210 ILCS 85/9]. These data shall also be considered confidential under Section 8-2101 of the Code of Civil Procedure [735 ILCS 5/8-2101].
- 3) All reports issued by the Department in which the data <u>areis</u> aggregated so that no patient or reporting <u>hospitalfacility</u> may be identified shall be available to the public pursuant to the Department's Freedom of Information <u>Coderules (2 III. Adm. Code 1126)</u> and the Freedom of Information Act [5 ILCS 140].

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ef) Quality Assurance and Continuous Quality Improvement

- Reporting facilities (i.e., hospitals, <u>certified local health departmentsLocal Health Departments</u>, <u>and</u> managed care entities (<u>MCEsMCE</u>), <u>and</u> <u>designated local health agencies</u>) shall be subject to review by the Department to assess the timeliness, correctness and completeness of the reports submitted by the <u>hospitalfacility</u>.
- 2) Reporting facilities (i.e., hospitals, <u>certified local health departmentsLocal Health Departments and MCEs</u>, <u>managed care entities (MCE)</u>, and <u>designated community health agencies</u>) shall supply <u>additional</u> <u>information</u> to the Department at the Department's request <u>when</u> additional information <u>iswhen</u> needed to confirm the accuracy of reports previously submitted, or to clarify information previously submitted. The Department <u>willshall</u> not request data that are more than two years old.
- 3) Monthly reports will be compiled by the Department, listing all hospital referrals to each health department/agency. The reports will be used for audits and assistance to health departments.
- 4) Managed Care Entities must submit their Quality Assurance Plan (QAP) to the Department for review and use in state wide Quality Improvement in Perinatal program efforts.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 640.100 High-Risk Follow-up Program (Repealed)

- a) Local Health Nursing Follow-up for the High-Risk Mother
 - Purpose
 Home visits to families of high-risk/pregnant and postpartum women have a two-fold purpose: assessment of the woman and the family/environment and facilitation of early intervention for identified problems.
 - 2) Agencies to Provide Services
 - A) All Local Health Departments should provide follow-up services to

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residents of their counties.

- B) The Department may contract with a local health agency or county nurse to provide follow-up services to residents of areas without a Local Health Department.
- 3) Eligibility for Services

Any pregnant or postpartum patient identified as high risk by a Level III hospital and referred to a Local Health Department or other designated local health agency should be offered follow-up services. The patient may decline such services.

- 4) Services to be Provided
 - A) Home visits to high-risk pregnant women should be scheduled as often as the client's condition warrants or as requested by the attending physician. A post-discharge visit should be made as soon as possible after discharge. Additional visits may be made during the postpartum period (i.e., 6 weeks following the date of delivery) for pregnancy-related conditions as indicated or as requested by the attending physician. If additional visits are for chronic health conditions (e.g., chronic hypertension, CVA, advanced cardiac disease), the patient should be referred to the licensed home health agency in the area for long-term follow-up.
 - B) Local health agencies which provide services must adhere to the provisions of the Maternal and Child Health Services Code (77 III. Adm. Code 630).
- b) Local Health Nursing Follow-up for High-risk Infants
 - 1) Purpose

The purpose of the infant follow up program is to minimize disability in high risk infants by identifying as early as possible conditions requiring further evaluation, diagnosis, and treatment and by assuring an environment that will promote optimal growth and development.

2) Agencies to Provide Services

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- A) All Local Health Departments should provide follow-up services to residents of their counties.
- B) The Department may contract with a local health agency to provide follow-up services to residents of areas without a Local Health Department.

3) Eligibility for Services

Any infant eligible for the Adverse Pregnancy Outcomes Reporting System (APORS) and referred to a Local Health Department or other designated local health agency should be offered follow-up services. The family may decline such services.

4) Services to be Provided

- A minimum of 6 visits should be made by the follow-up nurse: as soon as possible after newborn hospital discharge, and at infant chronological ages 2, 6, 12, 18, and 24 months. Infants and their families having actual or potential health problems identified by the nurse should be visited more frequently for health monitoring, teaching, counseling and/or referral for appropriate services. Occasionally, when an infant is receiving services at the health department, a follow-up visit may be conducted by the nurse at that time.
- B) Follow-up services should include:
 - i) Health History including: prenatal and natal history; parental concerns; family history of genetic disease or unexplained mental retardation; compliance with medical regimen, if any, including medications, treatments, and visits to the physician; infant care, including nutrition, elimination, and sleep activity; and family/infant interaction, family coping and parental knowledge of injury prevention.
 - Physical assessment, developmental assessment, and age specific anticipatory guidance based on the American College of Obstetricians and Gynecologists guidelines or

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current recommendations of the State that are found in subsection (b)(5) of this Section.

- iii) Based on the results of the health history and physical assessment, the nurse will identify problems and nursing diagnoses and arrange for intervention. Intervention may include: counseling the family as to the importance of regular primary health care by the family physician, pediatrician, or clinic; encouraging scheduled return visits to Perinatal Center; family teaching/counseling by the follow-up nurse; referral to the physician or other screening, diagnostic or support services depending on the nature of the problem; and follow-up on referrals.
- 5) Local health agencies must adhere to the provisions of the Maternal and Child Health Services Code (77 Ill. Adm. Code 630) and the Department's High Risk Infant Tracking Supplement for Local Health Departments, which may be obtained from the Department's Office of Family Health.

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX A Standardized Perinatal Site Visit Protocol

Standardized Perinatal Site Visit Protocol

<u>Components of site visit tool – information to be completed by applicant hospital prior to site visit and reviewed and approved at time of site visit by site visit team.</u>

 HOSPITAL:
 CITY:
 , Illinois

 Level of Designation Applied for:
 Level I
 Level II
 Level II with Extended

 Neonatal Capabilities
 Level III
 Administrative Perinatal Center

ADMINISTRATIVE PERINATAL CENTER:

DATE OF SITE VISIT:

GEOGRAPHIC AREA SERVED (Provide description):

MEMBERS (titles and affiliated institutions) OF SITE VISIT TEAM:

I. HOSPITAL DATA Please use data from most recent three calendar years

A. MATERNAL DATA

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1. Number of Obstetrical Beds:	<u>Current</u> <u>RN/Patient</u>
<u>a.</u> <u>Ante-partum</u>	ratio
b. Labor / Delivery LDR	
C/Section Rooms	
Delivery Rooms (LDR)	
<u>c.</u> <u>Postpartum</u>	(mother/baby couplets)
2. Total Number of Deliveries	
3. Number of Vaginal Deliveries:	
<u>Spontaneous</u>	
Forceps	
Vacuum Extraction	
4. Number of C/Sections:	
Total	
Primary	
Repeat	
5. Number of Vaginal Births After Cesarean	
6. Number of inductions 7. Number of augmentations	
7. Tumoer of augmentations	

B. NEONATAL DATA

1. Number of nursery beds:		Current <u>RN/Patient</u> <u>Ratio</u>
Normal newborn		

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Intermediate/Special care		
NICU/Level III only		
2. Average daily census in the SCN		
3. Average daily census in the NICU		

<u>C.</u> <u>LIVE # BIRTH DATA</u>

 $\frac{1.}{10/2}$ Birth Weight Specific Data – indicate # born & died in each category (example $\frac{10/2}{10}$

(Use Electronic Birth Certificate data for live births)

<u>< 500 grams</u>		
<u>501 - 750</u>		
<u>751 - 1000</u>		
<u>1001 – 1250</u>		
<u>1251 - 1500</u>		
<u>1501 – 2000</u>		
2001 - 2500		
<u>2501 – 3000</u>		
<u>3001 – 3500</u>		
<u>3501 - 4000</u>		
4001 - 4500		
4501 - 5000		
<u>5001 – PLUS</u>		
Total Live Births/Neonatal		
Deaths		
	•	

2. Incidence of Neonatal complications (Occurrences at hospital of birth)

Pulmonary air leaks		
Necrotizing enterocolitis		
Retinopathy of prematurity		
Intraventricular hemorrhage – Grade III & IV		
Peri-ventricular leukomalacia		

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Bronchopulmonary dysplasia		
Respiratory Distress Syndrome		
Persistent Pulmonary Hypertension of the Newborn		
Meconium Aspiration Syndrome		
Neonatal Surgeries		
Seizures		
<u>5 minute Apgar <5</u>		

FETAL DEATHS <u>D.</u>

Birth weight Specific Data - # per weight category

<u><500 grams</u>	 	
<u>501 - 750</u>		
<u>751 – 1000</u>		
<u>1001 – 1250</u>		
<u>1251 – 1500</u>		
<u>1501 – 2000</u>		
<u>2001 – 2500</u>		
<u>2501 - 3000</u>		
<u>3001 – 3500</u>		
<u>3501 - 4000</u>		
<u>4001 - 4500</u>		

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<u>4501 – 5000</u>		
Total Fetal Deaths		

E. MORTALITY DATA

<u>1.</u> <u>Ma</u>	tternal Deaths (Hospital of Delivery)		
<u>2.</u> <u>Per</u>	inatal Deaths		
<u>a.</u>	Fetal Deaths (complete attached chart FD)		
<u>b.</u>	Neonatal Deaths (complete attached		
	<u>chart ND)</u>		

<u>F.</u> TRANSPORT DATA

1. Number of maternal transfer/transports		
(Do not include return transfers/transports)		
Into institution		
Out of institution		

2. Number of neonatal transfers (Do not include return transfers/transports)		
Into institution		
Out of institution		

3. <u>Provide maternal and neonatal transport information. Include previous calendar year</u> <u>and current year to date.</u>

II. RESOURCE REQUIREMENTS

Complete attached Resource Checklist for the appropriate level of care - current level and level being applied for if different.

III. ADMINISTRATIVE PERINATAL CENTERS

A. Provide documentation of educational activities sponsored by the Administrative Perinatal Center for network hospitals and local health departments.

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B. Provide evidence of morbidity and mortality reviews with network hospitals.

<u>C.</u> <u>Provide written documentation of Regional Perinatal Network CQI Activities</u>.

Components of site visit tool — information to be completed by applicant facility prior to site visit and reviewed and approved at time of site visit.

(By site visit team) Initial/Date

I. PROGRAM DOCUMENTATION:

- <u>Updated maternity service plan with current staffing pattern appropriate for</u> level of care.
- *f* Documentation of orientation program for nursing staff.
- *4* **Documentation of ongoing continuing education program.**
- A Documentation of Continuous Quality Improvement (CQI) Activities.
- *Updated, comprehensive procedure manual.*
- Appropriate resources checklist.

H. STAFF PERFORMANCE:

- *Chart review (site visit team).*
- A Discussion of patient care with staff selected at random by the site visit team.

HI. COMMENTS:

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Director of Site Visit Team:

Title: _____

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX B Outcome Oriented Data: Perinatal Facility Designation/ Redesignation (<u>Repealed</u>)

Section 640.EXHIBIT A Outcome Oriented Data Form (Repealed)

Level of Designation Applied for:	Level II Level II Level II (with extended capabilities)			
HOSPITAL:	CITY:			
DESCRIPTION OF GEOGRAPHIC AREA SERVED:				
PERINATAL CENTER:	DATE OF SITE VISIT:			
MEMBERS (titles and affiliated institution) OF SITE VISIT TEAM:				
Please use data from previous 3 calendar years: YEAR				
I. STATISTICS				
A. Maternal Data				
1. Number of obstetrical	beds:			
a. Antepartum				
b. Labor / Deliv LDR / DR C/Section Delivery I	Rep			
e. Intensive Car	re Beds			
	d. Postpartum			
----------------	--	----------------	---------------	--------------------
2.	Total number of deliveries:			
3.	Percent of vaginal deliveries: Spontaneous Forceps Vacuum Extraction			
4 .	Percent of C/Sections: % Primary % Repeat			
5.	Number of VBACs: Attempts Successes			
6.	Percent of inductions:			
7.	Percent of augmentations:			
8.	Outcomes for Maternal Admiss	sions with the	following dia	gnosis:
	Diabetes			
	 # of maternal admission # transferred out for delivery # discharged undelivered # of neonatal deaths # of fetal deaths # of neonates transferred to a higher level facility 			
	Chronic Hypertension			

		higher level facility	 	
₿.	Neonatal	- Data		
	1.	Number of nursery beds:	 	
		Normal Newborn	 	
		Intermediate / Special care	 	
		NICU / Level III	 	
		Average daily census in the Special Care Nursery	 	
		(Level II or II with extended capabilities or Level III intermediate)		
		Average daily census in the NICU (Level III)	 	
C.	Fetal Mo	ortality		
	1.	Birthweight Specific Data:		
		<500 grams	 	
		501-750	 	
		751-1000	 	
		1001–1250	 	
		1251-1500	 	
		1501-2000	 	
		2001-2500	 	
		2501-3000	 	
		3001-3500	 	
		3501-4000	 	

	4001-4500	 	
	4501-5000	 	
	5001 PLUS	 	
2.	Live Birth Data:		
< 500 grams:	Number of infants born Number of infants ventilated beyond six hours Number of ventilated infants survived Ventilator days (total) Oxygen days (total) Length of stay (days)		
501-750 grams	Number of infants born Number of infants ventilated beyond six hours Number of ventilated infants survived	 	
	Ventilator days (total) Oxygen days (total) Length of stay (days)	 	
751-1000 grams:	Number of infants born Number of infants ventilated beyond six hours Number of ventilated infants survived Ventilator days (total) Oxygen days (total) Length of stay (days)		
1001-1250 grams:	Number of infants born Number of infants ventilated beyond six hours Number of ventilated infants survived	 	

Oxygen days (total)	1	Ventilator days (total)	 ·	
Length of stay (days)			 . <u></u>	
1251 1500 grams: Number of infants born Number of ventilated infants			 	
Number of infants ventilated beyond six hours		Lengui or stay (days)	 	
Number of infants ventilated beyond six hours	1251-1500 grams:	Number of infants born		
Number of ventilated infants	, v	Number of infants ventilated	 	
survived		beyond six hours		
Ventilator days (total)		Number of ventilated infants	 	
Oxygen days (total) Length of stay (days)		survived		
Oxygen days (total) Length of stay (days)		Ventilator days (total)	 	
Length of stay (days)			 	
Number of infants ventilated beyond six hours			 	
Number of infants ventilated beyond six hours	1501_2000 grams:	Number of infants born		
beyond six hours	1501 2000 gruins.		 	
Number of ventilated infants				
survived		•	 	
Oxygen days (total)				
Oxygen days (total)		Ventilator days (total)	 	
Length of stay (days)			 	
Number of infants ventilated beyond six hours			 	
Number of infants ventilated beyond six hours	2001_2500 grams.	Number of infants born		
beyond six hours	2001 2000 grains.		 	,
Number of ventilated infants survived Ventilator days (total)				
survived Ventilator days (total)		•	 ·	
Ventilator days (total)				
Oxygen days (total)			 	
Length of stay (days)	l	vontilition duys (totul)	 	
Length of stay (days)		Oxveen days (total)		
2501-3000 grams: Number of infants born Number of infants ventilated beyond six hours Number of ventilated infants			 	
Number of infants ventilated beyond six hours Number of ventilated infants survived Ventilator days (total) Oxygen days (total)	1		 	
beyond six hours	2501-3000 grams:		 	
Number of ventilated infants survived Ventilator days (total) Oxygen days (total)				
survived			 	
Ventilator days (total) Oxygen days (total)				
Oxygen days (total)			 	
Oxygen days (total)			 	
Length of stay (days)		Oxygen days (total)	 	
		Length of stay (days)	 	

3001-3500 grams:	Number of infants born			
Soor Sooo grams.	Number of infants ventilated			
	beyond six hours			
	Number of ventilated infants		. <u></u>	
	survived			
	Ventilator days (total)			
	Oxygen days (total)			
	Length of stay (days)			
3501-4000 grams:	Number of infants born			
	Number of infants ventilated			
	beyond six hours			
	Number of ventilated infants			
	survived			
	Ventilator days (total)			
	Oxygen days (total)			
	Length of stay (days)			
4001-4500 grams:	Number of infants born			
	Number of infants ventilated			
	beyond six hours			
	Number of ventilated infants			
	survived			
	Ventilator days (total)			
	Oxygen days (total)			
	Length of stay (days)			
4501-5000 grams:	Number of infants born			
	Number of infants ventilated			
	beyond six hours			
	Number of ventilated infants			
	survived			
	Ventilator days (total)			
	Oxygen days (total)			
	Length of stay (days)			
5001 PLUS:	Number of infants born			
	Number of infants ventilated			
	beyond six hours			
I		·		·

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4	Number of ventilated infants			
Ţ	survived Ventilator days (total)	<u> </u>	<u> </u>	
			<u> </u>	
	Dxygen days (total) Length of stay (days)			
t	<u>Cengur or stay (days)</u>			
Incidence of Neonatal Con	mplications:			
Ŧ	Pulmonary air leaks			
	Necrotizing enterocolitis			
Ŧ	Retinopathy of Prematurity			
1	ntraventricular hemorrhage			
	Grade I & II			
	Grade III & IV			
Ŧ	Periventricular leukomalacia			
Ŧ	Bronchopulmonary dysplasia			
4	Veonatal Sepsis			
Ŧ	Respiratory Distress Syndrome			
Ŧ	Persistent Pulmonary			
	Hypertension of the			
	Newborn			
₩	Ieconium Aspiration Syndrome			
N	leonatal Surgeries			
	eizures			
5	minute Apgar <7			

D. OUTCOME STATISTICS

All neonatal deaths are to be counted by the hospital of birth regardless of place of death. Neonates born in emergency rooms are to be counted by the hospital of birth.

1. Maternal Deaths: (Attach documentation of joint case review meeting and assigned disposition of mortality for each death.)

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(Standardized Neonatal Mortality Rate and Standardized Perinatal Mortality Rate. This information should be obtained from the most current Perinatal Health Status Reports.)

2. Standardized Neonatal Mortality Rate:

3. Standardized Perinatal Mortality Rate: (Attach documentation of joint case review meetings and assigned disposition of the mortalities. Give synopsis of action taken on deaths disposed as potentially avoidable.)

H. STAFF

A. List the names and titles of directors/chairperson: Attach CV of Medical Directors; where appropriate identify subspecialty board).

	Full Time	Board Certified	Sub-board Certified
Maternal – Fetal	Y/N	Y/N	Y/N
Neonatology	Y/N	Y/N	Y/N
Obstetric	Y/N	Y/N	
FP/GP	Y/N	Y/N	
Anesthesia	Y/N	Y/N	
Obstetric Anesthesia	Y/N	Y/N	

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Pediatric	Y/N	Y/N	
OB/Gyn Residency Program (if applicable)	¥/N		
Pediatric Residency Program (if applicable)	Y/N		
Perinatal Fellowship Program	Y/N		
Neonatal Fellowship program	Y/N		
Pediatric Surgery	Y/N	Y/N	Y/N
Pediatric Neurosurgery	Y/N	¥/N	
Pediatric Radiology	Y/N	¥/N	
Pediatric Cardiology	Y/N	¥/N	Y/N
Pediatric Cardiac Surgery	Y/N	Y/N	
Pediatric Anesthesiology	Y/N	Y/N	
Pediatric Ophthalmology	Y/N	Y/N	

Pediatric Nephrology	Y/N	Y/N	Y/N
Pediatric Medical Genetics	Y/N	Y/N	
Pediatric Orthopedics	¥/N	Y/N	
Pediatric Otolaryngology	Y/N	Y/N	
Pediatric Pulmonology	Y/N	Y/N	Y/N
Pediatric Hematology	Y/N	Y/N	Y/N
Pediatric Endocrinology	Y/N	Y/N	Y/N
Pediatric Gastroenterology	Y/N	Y/N	Y/N
B. Staff Available	On Call	In House	24 hours/day
Obstetrics			······································
OB Anesthesia			
Maternal / Fetal			

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C. Nursing

(List the names, titles, and credentials of nursing staff, as required for this section, with privileges in the Departments of Obstetrics and Pediatrics. Attach CB of Director of Nursing.)

Director of Nursing (Maternal / Child Nursing)

Director of Nursing (NICU / NBN)

Certified Nurse Midwife / Midwives

Clinical Specialist/Nurse Practitioners – Neonatal and Obstetrics

Transport Coordinators

Neonatal	¥	N
Maternal / Fetal	¥	N
Allied Health Staff		
Radiology Director	¥	N
Genetics Director	¥	N
Respiratory Therapy Director	¥	N
Licensed Social Worker	¥	N
Registered Dietitian	¥	N
Director of Laboratory	¥	N

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Family Care Coordinator Y N	
Dedicated Pharmacist Y N	
D. Transport Statistics	
YEARS	<u> </u>
1. Number of maternal transfers/transports do not include return transfers/transports):	
into institution	
out of institution	<u> </u>
in Network	<u> </u>
out of Network	
2. Number of neonatal transfers (do not include return transfers):	
into institution	
out of institution	
in Network	
out of Network	
3. Number of in-born infants less than	
1250 grams transferred out (state disposition of above infants not transferred):	
E. Transfer Information (Please attach the information requested in this sec	tion):
1. Maternal:	
a. List conditions for which maternal patients were transferre only):	ed (latest yea
b. List hospitals to which maternal patients were transferred	(latest year

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only):

- c. Number of maternal transfer patients refused and reasons for refusal:
- 2. Neonatal:
 - a. List conditions for which neonates were transferred (latest year only):
 - b. List hospitals to which neonates were transferred (latest year only):
 - e. Number of neonatal transfer patients refused and reasons for refusal (latest year only):
- F. Anesthesia
 - 1. Is 24-hour anesthesia available in-house? Y N

If yes, who (anesthesiologist, nurse anesthetist)

If anesthesia is on-call, response time?

2. Location C/Section performed

in OR suite on obstetrical level in OR suite on surgery level

3. Length of time required for start up of C/Section

G. Education

- 1. Documentation of in-service education programming provided: Y N Brief description, dates, and attendance:
- 2. Documentation of fetal monitoring and neonatal resuscitation programs provided. Brief description, dates, and attendance:
- 3. Documentation of C/Section Reviews:
- H. Developmental Follow-up Program

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Briefly describe your developmental follow-up program, and include the name of the Director of this program and the length of follow-up.

Explain arrangements for integrating Early Intervention Programs with the discharge planning process and developmental follow-up program.

I. Continuous Quality Improvement (CQI)

Briefly describe CQI Activities specific to Maternal/Fetal/Neonatal Medicine.

J. Perinatal Centers

- 1. Provide documentation of educational activities sponsored by the Center for Network hospital and community health agencies.
- 2. Provide documentation of morbidity and mortality reviews with Network hospitals.
- 3. Provide documentation of Network Continuous Quality Improvement (CQI) activities.

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX B Outcome Oriented Data: Perinatal Facility Designation/ Redesignation (<u>Repealed</u>)

Section 640.EXHIBIT B Data Collection Exception Form (Repealed)

Sample Data Collection Form for Hospitals Serving "Exception" Cases

Both maternal and neonatal data should be supplied for either a maternal or neonatal exception. However, if a maternal exception is transported to another hospital for delivery, the data relevant to the neonate will not be provided by the referring hospital.

Cases	A	Maternal Data			Neonat	al Admittin	g Date	Nec	onatal Outer	əme	
Name and Record #s	Admission:	Maternal Dx and Risk Factors:	Perinatal Center/ Level III Contact?	Birth		GAWeight	Perinatal Center/ Level III Contact?	Vent care?*		D/C Date	If death, H & H Disposition
Baby	Date Time		Name Date Time	Date Time		Admitting Dx:	Name Date Time	Hours			:
Mother			Transport? Date Time To Where?	APGARS	1 min 5 min 10 min		Transport? Date Time To Where?	Days (*positive pressure)			

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX C Maternal Discharge Record (Repealed)

Section 640.EXHIBIT A Maternal Discharge Record Form (Repealed)

	State of Illinois Department of Public Health MATERNAL DISCHARGE RECORD PERINATAL TRACKING SYSTEM									
÷	ONLY DISCHARGING HO	SPITAL								
	COMPLETES. COMPLETE ONLY ON PATIENTS REQUIRING REFERRAL					id Recipient # id Pending	<u>.</u>	Yes		
					Social	Security #		- No		
	Required REFERRING HOSPITAL A	ND CITY	CODI	<u>∃*</u> M	ED. REC		CORN	ERSTONE	.#	
С Е	DATE OF ADMISSION*	RACE* WHITE ORIENTAL		HISPANIC* BLACK YES NO		<u>NO</u>	COUNT	COUNTY OF RESIDENCE* CODE*		CODE*
ł	PATIENT'S LAST NAME*		FIRST NAM	ME*		M.I.		DATE O	F BIRTH*	
Ē	HUSBAND'S LAST NAME		FIRST NA	ME						
N T	PATIENT'S MAIDEN NAM	E	MARITIAL ST		MARR	IED	PATIENT'S	TELEPHC	ONE NUMBI	ER.
Ŧ	PATIENT'S STREET ADDRESS APT. NUMBER*	CITY	_				ST/	\TE	ZIP CODE	3
	GRAVIDA* PARA*			B SAG STAT] POS. 🗌 N		EDC*	PRENA	TAL CARI		PRENATAL VISITS# OF VISITS
M	REPRODUCTIVE HISTORY CHECK REASONS FOR REFERRAL									
E D I C A L	APPROPRIATE NUMBERS	ABRUPTIO - CHRONIC ALCOHOL ABUSE ASTHMA CANCER CHRONIC DISEASE (SPECIFY) CHRONIC RENAL DISEASE CONVULSIVE DISORDER* DIABETES PRUG ABUSE (SPECIFY) PETAL ANOMALY HEART DISEASE ABOGLOBINOPATHY INCLUDING SICKLE CELL HYPERTENSION 6 IDIOPATHIC THROMBOCYTOPENIA		17. 18. 20. 21. 22. 23. 24. 26. 27. 28. 29. 30. 31. 32. 33.	19. MULTIPLE GESTATION 20. NO PRENATAL CARE 21. PRE ECLAMPSIA 22. REMATURE LABOR 23. PREVIA 24. PREVIA 25. PSYCHIATRIC DISORDER 26. PULMONARY EMBOLUS 27. PYELONEPHRITIS 28. RH SENSTIZATION 29. SEXUALLY TRANSMITTED DISEASE 30. SIGNIFICANT SOCIAL PROBLEMS 31. TEEN PREGNANCY 32. THROMBO EMBOLIC DISEASE		CONTHERESTRICTION FION RE URE OF MEMBRANE ORDER OLUS * MITTED DISEASE FAL PROBLEMS 2 CODISEASE			
S	DISCHARGE DATE* BI	OOD PRESSURE	PURPU HEIGHT	URA (ITCP) ¥	VEIGHT	CURRENT)	<u>34</u> (lbs)	= OTHE FAMI	R .Y PLANNII	NG*
ө С	=	/	FTIN	=						REFERRED
I A	DURING THIS { ADMISSION?* {	YPE & DATE OF DE VAGINAL OTHER OATE	C-SECTION	WAS INF		T HIGH RISK	SEX	_	Male E] Female
F	YES DATE BIRTH WEIGHT* APGARS MAJOR TREATMENT OF MOTHER DURING HOSPITALIZATION & DISCHARGE TREATMENT/DIAGNOSIS/MEDICATIONS APGARS						· · · · · · · · · · · · · · · · · · ·			
F	OTHER CONCERNS:									
₽ ₽ ₽ ₽ ₽ ₽ ₽ ₽										

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PHYSICIAN PROVIDING FOLLOW-UP CARE:* (INC. ADDRESS & PHONE #)				HOSPITAL NURSE (CONTAC	£	TELEPHONE	
REFERRAL TO COMMUNITY SERVICES* USES NO	IF YES TO WIC MENT		e health DCFS	☐ SOCIAL SERVICE . ☐ OTHER (<i>PLEASE SI</i>			PRENATAL ED	
CONTACT PERSON'S NAME		RELATIONSHI	P TO PATIENT	*		TELI	EPHONE NUMBER*	L
STREET ADDRESS			CITY			S	FATE	ZIP CODE
2 ND -CONTACT PERSON'S NAME		RELATION	SHIP TO PATIE	INT		TELI	EPHONE NUMBER*	L
							/	
PATIENT INFORMED OF PUBLIC I NURSE VISIT? ☐ YES	HEALTH	PUBLIC HE	ALTH NURSE	AGENCY NAME	CODI	3	ADDRESS	

SEND ORIGINALS:	DEPARTMENT OF PUBLIC	HEALTH	
	535 WEST JEFFERSON		SIGNATURE*
	SPRINGFIELD, IL 62761		
COPIES: YELLOW	LOCAL HEALTH NURSE	PINK FACILITY	DATE*
IL444-4210 (N-10-98)			

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX C Maternal Discharge Record (Repealed)

Section 640.EXHIBIT B Instructions for Completing Maternal Discharge Record (Repealed)

The following Section describes the data elements to complete the Maternal Discharge Record.

Medicaid Recipient Number:	Enter client's existing Medicaid recipient number.
Medicaid Pending:	Check box (yes) if Medicaid has been applied for and is pending.
Social Security Number:	Enter clients social security number.
Referring Hospital Name and City:	Enter the name and city of the discharging hospital.
Hospital Code:	Enter the code of the referring hospital.
Medical Record Number:	Enter the patient number used by your hospital which number is unique to this patient. This number is usually assigned by the business office.
Cornerstone Number:	IDPH/Local Health Agency use.
Date of Admission:	Enter the date the patient was admitted to the hospital.
Race:	Check the appropriate box. If a patient does not consider herself as belonging to any of the three racial groups, type or write the preferred designation alongside "Race."

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Hispanic:	Check the appropriate box. Indicate "Hispanic" if the patient identifies herself with that ethnic group. NOTE: Mark both "Race" and "Hispanic" for all Hispanic patients. Hispanic persons may belong to any race.
County of Residence:	Print the name of the county in which the patient resides.
County Code:	Enter the county code, if known.
Patient's Last Name, First Name, M.I.:	Print the name of the patient.
Date of Birth:	Enter the birth date of the patient.
Husband's Last Name, First Name:	Print the name of the patient's husband if she is married.
Patient's Maiden Name:	Print the maiden name of the patient. Enter the maiden name even when it is identical with the last name.
Marital Status:	Check the appropriate box.
Patient's Telephone Number:	Enter the Patient's home telephone number, including area code.
Patient's Street Address:	Enter apartment number, if any, house number, street, city, state and zip code of the patient.
Gravida:	Enter the total number of pregnancies,

including the present pregnancy.

Para:	F: Number of full term births P: Number of premature births A: Number of abortions, spontaneous and induced L: Number of living children
Blood Type:	Enter the blood group (O, A, B, or AB) and the RH type (positive or negative).
HbsAG Status:	Indicate positive or negative for hepatitis B surface antigen. When positive, or reactive, indicates HBV infected at the present time with the ability to pass the disease to other people.
EDC:	Enter the estimated month, day, and year of confinement.
Prenatal Care Began:	Enter the number of completed weeks of gestation at which the patient began prenatal care. If prenatal records are not available, enter the estimated weeks of gestation based on patient recall.
Prenatal Visits:	Enter the total number of prenatal visits the patient had.
Reproductive History:	Check the box or boxes for all items that apply.
Reasons for Referral:	Check the box or boxes for all items that apply.
Discharge Date:	Enter the month, day, and year the patient was discharged from the hospital.
Blood Pressure:	Enter the blood pressure of the patient at discharge.

Height:	Enter the height in feet and inches of the patient.
Weight:	Enter the weight in pounds of the patient at discharge.
Family Planning:	Check the appropriate box.
Patient Delivered During This Admission:	Check the appropriate box.
Type and Date of Delivery:	If the patient delivered during this admission, indicate the date of delivery and whether the delivery, was a vaginal delivery, caesarean section, or other, i.e., ectopic, hydatidiform mole.
Was Infant High Risk:	If the patient delivered during this admission, indicate whether the infant required care other than normal newborn.
Infant's Condition:	If the patient delivered during this admission, indicate the infant's sex, birth weight and APGAR scores.
Major Treatment During Hospitalization:	List all major medical and/or surgical treatments that the patient underwent while hospitalized (i.e., C-Section, mechanical ventilation, etc.).
Discharge Treatments/	Briefly describe any treatments and
Diagnosis/Medications:	medications (i.e., prescriptions, diet,
	restricted activity) prescribed for the patient at discharge.
Other Concerns:	Enter any additional information that may assist the local health nurse in providing appropriate follow-up services to this patient.

Physician Providing	Physician providing follow-up care to
Follow-up Care:	mother, include address and telephone number.
Hospital Nurse Contact:	Enter name and telephone number of hospital nurse who can answer questions, if necessary.
Referral to Community Services:	If the patient has been referred to any community service agency, check appropriate box(es).
Contact Person's Name:	Print the name of a friend, relative or other person with a stable address who would know how to get in touch with the patient.
Relationship:	Describe the relationship (friend, mother, pastor, etc.) of the contact person to the patient.
Telephone Number:	Enter the telephone number of the contact person.
Street Address, City, Zip Code:	List the complete address of the contact person.
Second Contact Person, Relationship and Telephone Number:	Print name of another contact person who lives at a different address than above. Include name, relationship, and telephone number.
Patient Informed of LHN Visit:	If the patient has been informed that a local public health nurse will visit her home, check the "Yes" box, otherwise check the "No" box.

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Local Health Nurse Agency Name:	Enter the name of the local health nurse agency to which the patient was referred for follow-up services. The Department will provide a list of the agencies and the areas they serve.
Local Health Nurse Agency Code:	Enter code.
Street Address, City, Zip Code:	Complete address of LHN agency.
Signature:	The person completing the medical information should sign the form.
Date:	Enter date the form is completed.
(Source: Repealed at 34 Ill. Reg.	_, effective)

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Section 640.APPENDIX F Report of Local Health Nurse, Infant (Repealed)

Section 640.EXHIBIT A Local Health Nurse, Infant Form (Repealed)

Infant Report Report	t of Local Hea	lth Nurse	- Illinois I	Department of I	Public Health
Infant, Last Name	Infant, First Nat	me	Sex	Birth da	te Cornerstone
			M/F/U	· / /	4 I.D. #
Patient I.D. #	Infant Classifica	ation			
		Genetics E	Both		
Street Address		Apt. No.	City		Zip Code
Local Health Agency		L	1	Agency (Jode
Hospital of Delivery		Reporting	Hospital	Reporting	z Hospital Code
Chronological Age			ected Age	wks.	mos.
Mother, Last Name	Mothe	r, First Nam	÷	Mother, Maiden	Name
Date of Visit / /	Visit 0 No.	4 2	3 4	5 6 7	<u>8 9 10</u>
Date Case Closed / /	Case Closed		With V	/isit 🗌 W	Vithout Visit
Reason for Closure 1. Comp	leted Program	4. Refused	Visit	7. Other	
(Circle One) 2. Infant	-Died 4	5. Services			
3. Unabl	e to Locate	Longer N	leeded		
		6. Moved			
Discharge/Diagnoses/Additional	: (Please Print)		Code	Drug Toxicit	
		(for II	OPH use only	y) — If yes, che	eck all that apply:
+					
2				_ <mark> 0 Opioid</mark> 1 Barbitu	
3				= -2 Cocain	
5				- $ -$	
· · · · · · · · · · · · · · · · · · ·					
Newborn Screening	Genetic Screenin	ng 🗌 🤆	Genetic Cour	nseling	Physical Assessment
Additional Data					
Heightins. Weightlbsoz. Head Circumferencecms. Denver II NormalSuspect					
Hearing 🗌 Normal 🗌 Sue	spect 🗍 Impa	ired 🗌 Iı	n Treatment		Untestable
Vision Normal Sur		ired 🗌 🤆	Corrected Wi	th Surgery	
Corrected With L		Hy Blind			
Support Service Referrals (check	all that apply)	Constin co	unseling/diagr	nosis 🗖 Social -	comicos
<u> </u>		<u> </u>	unsenng/uidgi	iosis 🔄 Social S	SCI VICCS

Department of Children and Family Services (DCFS) Developmental testing Division of Specialized Care for Children Early Intervention	Home health Home health Occupational services Physical therapy	Support group WIC / nutrition Other			
Send original to Illinois Department of Human Services, Office of Family Health, 535 W. Jefferson					
St., Springfield, Illinois	Signature of Nurse	completing this form			
Canary Reporting Hospital					
Pink Local Health Agency Goldenrod Primary Care Physician					
(Source: Repealed at 34 Ill. Reg	g., effective)			

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Section 640.APPENDIX F Report of Local Health Nurse, Infant (Repealed)

Section 640.EXHIBIT B Instructions for Completing the Report of Local Health Nurse, Infant (Repealed)

INSTRUCTIONS FOR COMPLETION OF INFANT REPORT OF LOCAL HEALTH NURSE

Please Note:This form is only for statistical/tracking information for Illinois Department
of Public Health (IDPH).The Cornerstone Physical Assessment — Child and
Denver II will be the assessment tools.

Infant's last name:	Last name of infant.
Infant's first name:	First name of infant.
Sex: male/female/unknown	Unknown indicates sexual ambiguity
Birth Date:	Infant's date of birth.
Cornerstone ID #:	Number assigned to infant by Cornerstone
Patient ID number:	The patient number given by the hospital to each infant which number is unique to each admission. Found on the Infant Discharge Record (IDR).
Infant Classification:	
APORS:	Check box if infant discharge record (APORS) received from hospital.
Genetics:	Check box if referred to genetics/for genetics services.
Both:	Check box if both APORS and Genetics.
Street address, apartment, city, zip code:	Address of infant: house number, street, apartment, city, zip code.

Local health agency:	Name of health department or agency responsible for providing high risk follow-up.
Agency code:	IDPH code number of health department or agency responsible for providing high risk follow-up.
Hospital of delivery:	Hospital of infant's birth. Reporting hospital: Hospital providing the highest level of care and responsible for completing Infant Discharge Record.
Reporting hospital code:	IDPH code number of reporting hospital.
Chronological age:	Age of infant in weeks (during the first year of life) then in months, calculated from date of birth.
Corrected age:	Age of infant in weeks based on gestational age at birth (see (IDR). To determine corrected age at time of visit, subtract the gestational age from 40 weeks, then subtract this difference from the chronological age (weeks) at the time of the visit.
Mother, last name:	Last name of mother.
Mother, first name:	First name of mother.
Mother, maiden name:	Maiden name of mother.
Date of visit:	Date of visit to family by Local Health Nurse.
Visit number:	Number of times infant has been seen by Local Health Nurse.
Date case closed:	Enter date the Local Health Nurse closed the case for follow-up.
Case closed with visit: without visit:	Home visit made at closure. Closed without a home visit

Reason for closure:	Circle appropriate reason case closed for all infants closed with and without visit.
Completed program:	Infant received 6 visits or more during the first 24 months of life.
Infant died:	Infant died after discharge from hospital.
Unable to locate:	Three unsuccessful attempts were made to locate infant. Attempts may include telephone contact; seeking the client in the home, clinic, school; and least preferable, by mail.
Refused visit:	Family refused home visit by nurse.
Services no longer needed:	Infant has minor anomaly (i.e., skin tag, anomaly of nails) that does not require follow- up.
Moved:	Family has moved out of area served by local health department. Refer to health department in other area.
Other:	Case closed for reason other those listed above. Specify reason.
Discharge diagnoses/additional:	Record up to 5 diagnoses: IDR diagnoses first, then additional diagnoses, if any.
ICD-9 Code:	For IDPH use only. IDPH will enter ICD-9 Code for each diagnosis.
Drug toxicity:	Check box if infant was diagnosed with drug toxicity.
Opioid:	If positive for drug toxicity, check all that have been identified.
Barbiturate:	

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Cocaine:	
Cannabis:	
Mixed:	
Not stated:	
Other:	Include drug if known.
Newborn screening:	Check box if newborn genetic/metabolic screening has been completed.
Genetic screening:	Check box if infant was screened later for any genetic assessed condition.
Genetic counseling:	Check box if family received information concerning genetics.
Physical assessment: Additional data:	Check box if you (the nurse visiting the family) completed a physical assessment on this visit. The Cornerstone physical assessment is expected on each visit, and will be documented on your agency's records.
Height:	Height measured in inches.
Weight:	Weight measured in pounds and ounces.
Head circumference:	Circumference of head measured in centimeters.
Hearing:	Based on gross evaluation during physical exam or as a result of formal testing.
normal:	Within normal limits.
suspect:	Possible visual impairment.
impaired:	Definite impairment.

in treatment:	Active treatment for hearing impairment; or corrected with treatment.
Vision:	Based on gross evaluation during physical exam or as a result of formal testing.
normal:	Within normal limits.
suspect:	Possible visual impairment.
impaired:	Definite impairment.
corrected with surgery:	
corrected with lens:	
legally blind:	Determined by formal testing.
Denver II:	
normal:	No delays and a maximum of one caution.
suspect:	Two or more cautions and one or more delays.
untestable:	Refusal scores on one or more items completely to the left of the age line or on more than one item intersected by the age line on the 75% to 90% area. Prescreen in 1 to 2 weeks.
Support service referrals:	Infant referred to one or more services. Check as many as apply.
Audiology testing	
Department of Children and Family Services (DCFS)	
Developmental testing	
Division of Specialized Care for Children	
Early Intervention	

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Genetic counseling/diagnosis	
Home Health	
Nutritional services	
Occupational therapy	
Physical therapy	
Social services	
Support group	
WIC/nutrition	
Other	Please specify.
Signature of Nurse completing this form.	
Send original copy of form to:	
Illinois Department of Public Health 535 West Jefferson Street Springfield, IL-62761	
Copies Canary copy: reporting hospital Pink copy: local health agency Goldenrod copy: primary care physician	

(Source: Repealed at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX G Sample Letter of Agreement

<u>(nameName of Administrative</u> Perinatal Center) is recognized and designated by the Illinois Department of Public Health as a Level III <u>Administrative</u> Perinatal Center providing obstetrical and neonatal care. In order to serve as a <u>Non-Birthing Hospital</u>, Level I, II, <u>II with Extended Neonatal Capabilities or</u> III, affiliated <u>with an Administrative</u> <u>Perinatal Centerperinatal facility</u> designated by the Illinois Department of Public Health, <u>(nameName</u> and address of hospital) agrees to affiliate with the above <u>Administrative</u> Perinatal Center.

This agreement is consistent with the Adopted Rules of the Illinois Department of Public Health, Regionalized Perinatal Health Care Code (77 Ill. Adm. Code 640).

Components for Letter of Agreement

- I. Introductory Remarks: The <u>Administrative</u> Perinatal Center may list items of organization of the Center.
- II. <u>Administrative</u> Perinatal Center Obligations
 - A. A 24-hour obstetrical and neonatal "hot-line" for immediate consultation, referral or transport of perinatal patients is available.

Obstetrical		Neonatal	
Hospital	Telephone #	Hospital	Telephone #

- B. The <u>Administrative</u> Perinatal Center <u>shallwill</u> accept all medically eligible obstetrical/neonatal patients.
- C. If the above named <u>Administrative</u> Perinatal Center is unable to accept a referred maternal or neonatal patient because of bed unavailability, that Center <u>shallwill</u> assist in arranging for admission of the patient to another <u>hospitalfacility</u> capable of providing the appropriate level of care.
- D. Transportation of neonatal patients remains the responsibility of the <u>Administrative</u> Perinatal Center. Decisions regarding transport and mode of transport will be made by the <u>Administrative</u> Perinatal Center neonatologist in collaboration with the referring <u>health care providerphysician</u>.

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- E. Transportation of the obstetrical patient remains the responsibility of the (Level I, Level II, Level II with Extended Neonatal Capabilities or Level III hospitalfacility). Decisions regarding transport, transfer and mode of transport or transfer shallwill be made by the Administrative Perinatal Center maternal-fetalMaternal-Fetal medicineMedicine physician in collaboration with the referring health care providerphysician.
- F. The <u>maternal-fetal medicine</u>Maternal-Fetal Medicine physician of the <u>Administrative</u> Perinatal Center, in collaboration with the referring <u>health care</u> <u>provider</u>, <u>shallphysician will</u> decide whether to have an obstetrical patient stabilized before transfer, kept in the affiliated unit or transferred immediately. The best possible alternatives and the staff needed for transport <u>shallwill</u> be determined.
- G. <u>The Administrative Perinatal Center shall distribute written Written</u> protocols for the mechanism of referral/transfer/transport will be distributed by the Perinatal <u>Center to the affiliated hospital physician</u>, administration and nursing service. <u>Protocols are This is</u> to include a mechanism for data recording of the time, date and circumstances of transfer so <u>that</u> this information can be <u>utilized as</u> part of the morbidity and mortality reviews. (See Appendix A.)
- H. <u>The Administrative Perinatal Center shall send a</u> A-written summary of patient management and outcome will be sent by the Perinatal Center to the referring health care providerphysician of record and to the hospital hospital's chart.
- I. The <u>Administrative</u> Perinatal Center <u>shallwill</u> conduct <u>quarterlyperiodic</u> mortality and morbidity conferences at ______ Hospital.
 - 1. The <u>Administrative</u>conference will be conducted by the Perinatal Center's <u>Perinatal Network Administrator, maternal-fetal medicine</u><u>Maternal-Fetal</u> <u>Medicine</u> physician, neonatologist, nursing coordinator and/or obstetrical and neonatal nurse educators <u>shall conduct the conference</u>.
 - 2. <u>Hospital shallwill</u> prepare written summaries of cases and statistics for discussion, to be available to the <u>Administrative</u> Perinatal Center at least one week prior to the conference.
 - 3. The content of the review will be determined by the Regional Quality

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<u>CouncilPerinatal Management Group</u> of each <u>Regional Perinatal</u> Network <u>shall determine the content of the review</u>. The review <u>shallmust</u> include, but not be limited to, stillbirths, neonatal deaths, maternal and/or neonatal transports.

- J. The <u>Administrative</u> Perinatal Center <u>shallwill</u> transfer patients back to the referring hospital when medically feasible, in accordance with physician to physician consultation.
- K. The <u>Administrative</u> Perinatal Center <u>shall</u> develop and offer Perinatal Outreach <u>Education programs</u> <u>Educations program</u> at a reasonable cost to include the following:
 - 1. On-site consultation by <u>Administrative</u> Perinatal Center physicians and nurse educators as needed.
 - 2. Periodic obstetrical and neonatal needs assessment of ______ Hospital.
 - 3. Provide ______ Hospital with protocols for patient management.
 - 4. Develop Continuing Medical Education programs for obstetricians, pediatricians and family practitioners either at ________ Hospital or at the <u>Administrative</u> Perinatal Center site.
 - 5. Mini-Fellowships at the <u>Administrative</u> Perinatal Center for ______ Hospital physicians and nurses.
 - 6. Programs based on needs assessment by outreach nurse educators at ______ Hospital for obstetrical and neonatal nursing staff.
- L. The <u>Administrative</u> Perinatal Center <u>shallwill</u> establish, maintain and coordinate the educational programs offered by and for all <u>Non-Birthing Centers</u>, Level I, Level II, <u>Level II with Extended Neonatal Capabilities</u>, and Level III <u>hospitals</u><u>Hospitals</u> that it serves.for which they serve.
- M. The <u>Administrative</u> Perinatal Center shall develop a Regional <u>Quality Council</u>, <u>Perinatal Management Group</u>, including, but not limited to, representatives of each

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hospital in the <u>Regional</u> Perinatal Network. This group shall meet at least quarterly to plan management strategies, evaluate morbidity and mortality reviews, evaluate the effectiveness of current programs and services and to set future goals. The Regional <u>Quality Council</u> Perinatal Management Group shall determine the data collection system to be used by the Regional Perinatal Network.

III.		Hospital Obligations	
	A.	Hospital <u>shall</u> utilize the "hot-line" established by the <u>Administrative</u> Perinatal Center for consultation, referral and transport.	
	В.	Hospital <u>shallwill</u> transfer to <u>Administrative</u> Perinatal Center obstetrical and neonatal patients who require the services of the <u>Administrative</u> Perinatal Center, including, but not limited to, patients outlined in the <u>Regionalized Perinatal Health Care Codeperinatal rules</u> and regulations (See Appendix H, Exhibits A and B) for patients to be included for consultation, treatment or transfer).	
	C.	Hospital (level of care) <u>shallwill</u> usually care for the following maternal and neonatal patients. (See Appendix H, Exhibits B and C)	
	D.	Hospital <u>shall</u> will develop an ongoing in-house continuing educational program for the obstetrical and neonatal medical staff and other disciplines as needed.	
	E.	Hospital <u>shall</u> will participate in continuing educational programs for both nurses and physicians developed by the <u>Administrative</u> Perinatal Center. Cost to be shared.	
	F.	Hospital <u>shall</u> designate representatives to serve on the Regional <u>Quality Council</u> . Perinatal Management Group.	
	G.	Hospital <u>shallwill</u> establish a Perinatal Development Committee composed of medical and nursing representatives from both neonatal and obstetrical areas, administration and any other individuals deemed appropriate.	
	H.	Hospital <u>shall</u> will maintain and share such statistics as the Regional <u>Quality Council</u> Perinatal Management Group	

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may deem appropriate.

- I. _____ Hospital <u>shallto</u> develop or to utilize programs at _____<u>Administrative</u> Perinatal Center for follow-up of neonates with handicapping conditions.
- IV. Joint Responsibilities
 - A. This agreement will be valid for one year, at which time it may be renewed or renegotiated.
 - B. If either ______ Hospital or the ______ <u>Administrative</u> Perinatal Center <u>wisheswish</u> to change an individualized portion of this agreement, either may initiate the discussion. If a change in the agreement is reached, <u>the change it</u> must be reviewed by the <u>Department.Perinatal Advisory</u> <u>Committee</u>. If the ______ Hospital wishes to make a change and <u>Administrative</u> Perinatal Center is not in agreement, <u>Hospital can request a hearing by the <u>DepartmentPerinatal</u> <u>Advisory Committee</u>.</u>
 - C. If any of the institutions wants to terminate the agreement, written notification <u>shallmust</u> be given to <u>the Department and</u> other participating institutions six months in advance.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX H Written Protocol for Referral/Transfer/Transport

Section 640.EXHIBIT A Level I: Patients for consultation with ______ (Level III hospitalfacility or Administrative Perinatal Center)

- 1) Maternal Conditions
 - A) Previous Pregnancy Problems:
 - i) Premature infant
 - ii) Perinatal death or mental retardation
 - iii) Isoimmunization
 - iv) Difficult deliveries
 - v) Congenital malformations
 - vi) Mid-trimester loss
 - B) Current Pregnancy Problems:
 - i) Any medical disorder (e.g., diabetes mellitus, hemoglobinopathy, chronic hypertension, heart disease, renal disease)
 - ii) Drug addiction
 - iii) Multiple gestation
 - iv) Intrauterine growth retardation
 - v) Preterm labor less than or equal to 36 weeks
 - vi) Postdate greater than or equal to 42 weeks
 - vii) Third trimester bleeding
 - viii) Abnormal genetic evaluation
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- ix) Pregnancy induced hypertension
- 2) Neonatal Conditions
 - A) Gestation less than or equal to 36 weeks, weight less than or equal to 2500 grams
 - B) Small-for-gestational age (less than 10th percentile)
 - C) Sepsis
 - D) Seizures
 - E) Congenital heart disease
 - F) Multiple congenital anomalies
 - G) Apnea
 - H) Respiratory distress
 - I) Neonatal asphyxia
 - J) <u>HandicappingInfants identified as having handicapping</u> conditions or developmental disabilities <u>thatwhich</u> threaten life or subsequent development
 - K) Severe anemia
 - L) Hyperbilirubinemia, not due to physiologic cause
 - M) Polycythemia
- 3) Consultation and transfer to a Level III or <u>Administrative</u> Perinatal Center shall occur for the following conditions:
 - A) Premature labor or premature birth less than 34 weeks gestation.
 - B) <u>Birth weightBirthweight</u> less than or equal to 2000 grams.

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4) Exceptions:

- A) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes, and geography in the regional perinatal network.
- B) Exceptions to the standards of care of this Part may be granted when the facility requesting an exception demonstrates that the staffing, equipment and quality of care (outcomes), are substantially equivalent to the standards and quality of care for any Level II or Level III facility in their Regional Perinatal Network.
- C) Such exceptions shall be negotiated between the applicant facility and their Perinatal Center. The applicant facility or the Perinatal Center shall seek the advice and consultation of the Department, as well as the Perinatal Advisory Committee, to facilitate negotiations regarding exceptions to these standards of care. Any exception to the standards of care of this Part must be defined in the letter of agreement.
- D) _The Department shall review all letters of agreement and modification of letters of agreement. The Department shall use the criteria described in Section 640.41(e)(2) in order to approve or deny approval of any provision of or any letter of agreement.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX H Written Protocol for Referral/Transfer/Transport

Section 640.EXHIBIT B Level II: Patients for consultation with or transfer to (Level III <u>hospitalfacility</u> or <u>Administrative</u> Perinatal Center)

- 1) Maternal Conditions (Consultation)
 - A) Essential hypertension on medication.
 - B) Chronic Renal disease.
 - C) Chronic medical problems with known increase in perinatal mortality or morbidity.
 - D) Prior birth of neonate with serious complication resulting in a handicapping condition.
 - E) Abnormalities of the reproductive tract known to be associated with an increase in preterm delivery.
 - F) Previous delivery of preterm infant 34 weeks gestation.
 - G) Insulin_dependent diabetes Class B or greater.
- 2) Maternal Conditions (Transfer)
 - A) Patients from the above consultation list, <u>for whom transfer iswhich</u> deemed advisable by mutual collaboration between <u>the maternal-fetal medicineMaternal-</u> Fetal Medicine physician at the Level III <u>hospitalfacility</u> and the obstetrician at the referring office of <u>the</u> hospital.
 - B) Isoimmunization with possible need for intrauterine transfusion.
 - C) Suspected congenital anomaly compatible with life.
 - D) Insulin-dependent diabetes mellitus.
 - E) Cardiopulmonary disease with functional impairment.

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- F) Multiple gestation, with exception of twins.
- G) Premature labor prior to 32 weeks.
- H) Premature rupture of membranes prior to 32 weeks.
- I) Medical and obstetrical complication of pregnancy, possibly requiring induction of labor or cesarean section for maternal or fetal conditions prior to 32 weeks gestation.
- J) Severe pre-eclampsia or eclampsia.
- 3) Neonatal Conditions (Consultation or transfer): Specify whether consultation or transfer will <u>occurbe done</u> for each of the following:
 - A) Gestation less than 32 weeks or less than 1800 grams.
 - B) Sepsis unresponsive to therapy.
 - C) Uncontrolled seizures.
 - D) Significant congenital heart disease.
 - E) Major <u>congenital</u> congenital malformations requiring surgery.
 - F) <u>Assisted ventilation required</u><u>Infants requiring ventilation</u> after initial stabilization (greater than 6 hours).
 - G) OxygenInfants with oxygen requirements in excess of 50% (greater than 6 hours).
 - H) <u>10-Infants with ten</u> minute Apgar scores of 5 or less.
 - I) <u>MajorAll neonates requiring major</u> surgery.
 - J) <u>ExchangeInfants requiring exchange</u> transfusion.
 - K) Persistent metabolic derangement (e.g., hypocalcemia, hypoglycemia, metabolic acidosis).

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- L) <u>HandicappingInfants identified as having handicapping</u> conditions or developmental disabilities <u>thatwhich</u> threaten life or subsequent development.
- 4) Consultation and transfer to a Level III <u>hospital</u> or <u>Administrative</u> Perinatal Center shall occur for the following conditions:
 - A) Premature labor or premature birth less than 34 weeks gestation.
 - B) <u>Birth weight</u>Birthweight less than or equal to 2000 grams.
 - C) <u>Assisted</u>Mechanical ventilation beyond the initial stabilization period (6 hours).

5) Exceptions:

- A) Exceptions to the standards of care set forth in this Part may be necessary based on patient care needs, current practice, outcomes, and geography in the regional perinatal network.
- B) Exceptions to the standards of care of this part may be granted when the facility requesting an exception demonstrates that the staffing, equipment and quality of care (outcomes), are substantially equivalent to the standards and quality of care for any Level II or Level III facility in their Regional Perinatal Network.
- C) Such exceptions shall be negotiated between the applicant facility and their Perinatal Center. The applicant facility or the Perinatal Center may seek the advice and consultation of the Department, as well as the Perinatal Advisory Committee, to facilitate negotiations regarding exceptions to these standards of care. Any exception to the standards of care of this part must be defined in the letter of agreement.
- D) The Department shall review all letters of agreement and modification of letters of agreement. The Department shall use the criteria described in Section 640.41(e)(2) in order to approve or deny approval of any provision of or any letter of agreement.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX H Written Protocol for Referral/Transfer/Transport

Section 640.EXHIBIT C Level I: Maternal and <u>neonatal Neonatal</u> patients to be cared for at ______ hospital (Level III <u>hospital</u>facility or <u>Administrative</u> Perinatal Center)

1) Maternal

The maternal patient with an uncomplicated current pregnancy.

2) Neonatal

The neonatal patient greater than 34 weeks gestation or greater than 2000 grams without risk factors and infants with physiologic jaundice.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX H Written Protocol for Referral/Transfer/Transport

Section 640.EXHIBIT D Level II: Maternal and neonatal patients to be cared for at hospital (Level III <u>hospitalfacility</u> or <u>Administrative</u> Perinatal Center)

- 1) Maternal
 - A) The maternal patient with uncomplicated current pregnancy.
 - B) <u>Patient with normal Normal current pregnancy</u>, although previous history may <u>suggestbe suggestive of potential difficulties</u>.
 - C) <u>Patient with selected Selected medical conditions</u>, such as mild hypertension or controlled thyroid disease, <u>whenwhere</u> there is no increase in perinatal morbidity.
 - D) <u>Patient with selected Selected</u> obstetric complications such as pre-eclampsia or premature labor greater than 34 weeks.
 - E) <u>Patient with an incompetent cervix Incompetent</u>.
 - F) Patient with gestational diabetes Gestational.
- 2) Neonatal
 - A) <u>Patients</u>Neonatal patients greater than 34 weeks gestation or greater than 1800 grams without risk factors.
 - B) <u>Patients with mildMild</u> to moderate respiratory distress (not requiring <u>assisted</u> ventilation in excess of 6 hours).
 - C) <u>Patients with suspected Suspected</u> neonatal sepsis, hypoglycemia, neonates of diabetic mothers and post-asphyxia without life_threatening sequelae.
 - D) <u>Premature</u>Nursing care of premature infants greater than 1800 grams who are <u>otherwise</u>other wise well.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX I Perinatal Reporting System Data Elements

- 1. Child's First Name
- 2. Child's Middle Name
- 3. Child's Last Name
- 4. Child's Suffix
- 5. AKA
- 6. Child's Date of Birth
- 7. Child's Time of Birth
- 8. Sex
 - A. Male
 - B. Female
 - C. Ambiguous

9. <u>Child of Hispanic OriginRace</u>

- <u>A.</u> <u>Yes</u> <u>Cuban</u> <u>Mexican</u> <u>Puerto Rican</u>
- B. No A. White
- B. Black
- C. Asian
- D. Other

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- 10. <u>RaceHispanic</u>
 - <u>A.</u> <u>Asian</u>
 - <u>B.</u> <u>Black</u>
 - <u>C.</u> <u>Caucasian</u>
 - D. Native American
 - <u>E.</u> <u>Other</u>
 - A. Yes
 - B. No
 - C. N/A
- 11. Place of Birth
- 12. City of Birth
- 13. County of Birth
- 14. Mother's First Name
- 15. Mother's Middle Name
- 16. Mother's Last Name
- 17. Mother's Maiden Name
- 18. Mother's Social Security Number
- 19. Mother's Date of Birth
- 20. Mother's Street Number

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- 21. Mother's Street Name
- 22. Mother's Street Direction
- 23. Mother's Street Type
- 24. Mother's Street Location
- 25. Mother's City
- 26. Mother's County
- 27. Mother's Zip Code
- 28. Mother's State
- 29. Mother's Telephone
- 30. Mother's Age
- 31. Mother's Birthplace
 - A. ____State
 - B. ____County
- 32. Mother of Hispanic Origin
 - A. Yes Cuban Mexican Puerto <u>RicanRico</u>
 - B. No
- 33. Mother's Race

<u>A.</u> <u>Asian</u>

<u>B.</u>	<u>Black</u>
<u>D.</u>	DIACK

- <u>C.</u> <u>Caucasian</u>
- D. <u>Native American</u>
- <u>E.</u> <u>Other</u>
- A. American Indian
- B. Black
- C. White
- 34. Mother's Education (specify highest grade <u>completed</u> completion)
- 35. Mother's Occupation
- 36. Mother's Business/Industry
- 37. Mother Employed During Pregnancy
 - A. Yes
 - B. No
 - C. Record Not Available (N/A)
 - D. Not Stated

38. <u>Marital</u>Martial Status

- A. Married
- B. Not Married
- 39. Father's Last Name

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- 40. Father's Middle Name
- 41. Father's First Name
- 42. Father of Hispanic Origin
 - A. Yes Cuban Mexican Puerto Rican
 - B. No
- 43. Father's Race
 - <u>A.</u> <u>Asian</u>
 - <u>B.</u> <u>Black</u>
 - <u>C.</u> <u>Caucasian</u>
 - D. <u>Native American</u>
 - <u>E.</u> <u>Other</u>
 - A. Indian American
 - B. Black
 - C. White
- 44. Father's Education (specify highest grade completed)
- 45. Father's Age
- 46. Father's Occupation
- 47. Father's Business/Industry

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- 48. Father Employed
 - A. Yes
 - B. No
 - C. Record N/A
 - D. Not Stated
- 49. Pregnancy History
- 50. Plurality (# this Birth)

If greater than 1, Birth Order of this Birth

- 51. Previous Live Births
- 52. Number Live Births Now Living
- 53. Number Live Births Now Dead
- 54. Date of Last Live Birth
- 55. Previous Terminations
- 56. Number of Other Terminations
- 57. Date of Last Other Termination
- 58. Date <u>of Last Normal Menses</u>
- 59. Month Prenatal Care Began
- 60. Number of Prenatal Care Visits
- 61. 1 Minute <u>ApgarAPGAR</u> Score

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- 62. 5 Minute <u>Apgar APGAR</u> Score
- 63. Estimate of <u>Number of Gestation Weeks</u>
- 64. Mother Transferred In Prior to Delivery
 - A. Yes
 - B. Name of <u>HospitalFacility</u> ______ Location of <u>HospitalFacility</u> _____
 - C. No
- 65. Infant Transferred (Out)
 - A. Yes
 - B. <u>NameNames</u> of <u>HospitalFacility</u> ______ Location of <u>HospitalFacility</u> _____
 - C. Transfer Code
 - D. No
- 66. Reporting Hospital
- 67. Reporting Hospital City
- 68. Tobacco Use During Pregnancy
 - A. Smoked during pregnancy Average cigarettes per day _____
 - B. Stopped smoking during pregnancy
 - C. Smoked during pregnancy

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C.D. Does not smoke

- D.E. Record N/A
- E.F. Not Stated
- 69. Alcohol Use During Pregnancy
 - A. Yes Average number drinks per day _____
 - B. No
 - C. Record N/A
 - D. Not Stated

70. Mother's Weight Gain

- A. Yes Pounds _____
- B. No
- C. Record N/A
- D. Not Stated

71. Mother's Weight Loss

- A. Yes Pounds _____
- B. No
- C. Record N/A
- D. Not Stated
- 72. Medical Risk Factors for this Pregnancy

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- A. Anemia
- B. Cardiac Disease
- C. Acute or Chronic Lung Disease
- D. Diabetes
- E. Genital Herpes
- F. Hydramnios/OligohydramniosOligohydraminos
- G. Hemoglobinapathy
- H. Hypertension, Chronic
- I. Hypertension, Pregnancy-related Pregnancy, related
- J. Eclampsia
- K. Incompetent Cervix
- L. Previous Infant 4000 + Grams
- M. Previous Preterm or <u>Small-for-Gestational-Age (SGA)</u>SGA Infant
- N. Renal Disease
- O. Rh Sensitization
- P. Uterine Bleeding
- Q. None
- R. Other, Specify
- 73. Obstetric Procedures

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- <u>A.</u> <u>Amniocenteses</u> <u>Aminocentesis</u>
- B. Electronic Fetal Monitoring Internal External Both Neither Record N/A Not Stated
- <u>C.</u> Induction of Labor
- D. Stimulation of Labor K. Yes Pitocin
 - Oxytocin _____
- L. No
- M. Record N/A
- N. Not Stated
- <u>E.</u>O. Tocolysis
- <u>F.P.</u> Ultrasound
- <u>G.Q.</u> None
- H.R. Other, Specify
- 74. Complications of Labor and/or Delivery
 - A. Febrile
 - B. Meconium
 - C. Premature Rupture
 - D. Abruptio Placenta
 - E. Placenta Previa

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- F. Other Excessive <u>Bleeding</u>bleeding
- G. Seizures <u>During Labor</u>during labor
- H. Precipitous <u>Labor</u>labor
- I. Prolonged <u>Laborlabor</u>
- J. Dysfunctional <u>Labor</u>labor
- K. Breech/Malpresentation
- L. Cephalopelvic Disportion
- M. Cord Prolapse
- N. Anesthetic Complications
- O. Fetal Distress
- P. None
- Q. Other, Specify
- 75. Method of Delivery
 - A. <u>Spontaneous</u>Spon. Vaginal
 - B. Mid Low Forceps
 - C. Vacuum Extraction
 - D. Vaginal Breech
 - E. <u>Caesarean</u>C. Section Primary
 - F. <u>Caesarean</u>C. Section Repeat

- G. Other <u>Type</u>type
- H. Record N/A
- I. Not Stated
- J. Vaginal <u>Birth</u> After Previous <u>Caesarean</u> Section (VBAC)
- K. Other <u>Caesarean</u>C Section
- 76. Abnormal Conditions of Newborn
- 77. Anemia

- 78. Birth Injury
- 79. Fetal Alcohol Syndrome
- 80. Hyaline Membrane Disease
- 81. Meconium Aspiration Syndrome
- 82. Assisted Ventilation > 30 min.
- 83. Assisted Ventilation = 30 min.
- 84. Seizures
- 85. <u>Human Immunodeficiency Virus (HIV)</u>None
- 86. Other, Specify
- 87. Congenital Anomolies of <u>NewbornChild</u>
- 88. <u>Anencephalous</u>Anacephalus
- 89. Congenital Syphilis
- 90. Hypothyroidism

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- 91. Adrenogenital Syndrome
- 92. Inborn Errors of Metabolism
- <u>93.</u> <u>Cystic Fibrosis</u>
- <u>94.</u> <u>Immune Deficiency Disorder</u>
- <u>95.</u> <u>Retinopathy of Prematurity</u>
- <u>96.</u> <u>Chorioretinitis</u>
- 97. Strabismus
- <u>98.</u> Intrauterine Growth Restriction
- <u>99.</u> <u>Cerebral Lipidoses</u>
- 100.89. Spina Bifida/Meningocele
- <u>101.90.</u>Hydrocephalus
- 102.91. Microcephalus
- <u>103.92.</u>Other CNS Anomalies, Specify
- <u>104.93.</u>Heart Malformations, Specify
- <u>105.94</u>. Other Circulatory/Respiratory Anomalies, Specify _____
- <u>106.95</u>.Rectal Atresia/Stenosis
- <u>107.96.</u>Tracheoesophageal Fistula/Esophageal Atresia
- <u>108.97</u>.Omphalocele/Gastrochisis
- <u>109.98.</u>Other Gastrointestinal Anomaly

<u>110.99.</u>Malformed Genitalia

- <u>111.100.</u> Renal Agenesis
- <u>112.101.</u> Other Urogenital Anomaly, Specify _____
- <u>113.402.</u> Cleft Lip/Palate, Specify
- <u>114.103.</u> Polydactyly/Syndactyly/<u>Adactyly</u>Adetyly
- <u>115.</u>104. Club Foot
- <u>116.</u> Diaphragmatic Hernia
- <u>117.106.</u> Other <u>Musculoskeletal</u>/Integumental Anomaly
- <u>118.107.</u> <u>Down's</u> Downs Syndrome
- <u>119.108.</u> Other Chromosomal Anomaly, <u>Specify</u> <u>Specify</u>
- <u>120.109.</u> None
- <u>121.110.</u> Other, Specify _____
- <u>122.</u>+++. Transfusion
- <u>123.112.</u> Anesthesia
 - A. Local/Pudenal
 - B. Regional
 - C. General
- <u>124.113.</u> Umbilical Cord Blood Gases Tested
 - A. Yes
 - B. No

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- <u>125.114.</u> Small-for-Gestational-Age (SGA)
- <u>126.115.</u> Infection of Newborn Acquired Before Birth
- <u>127.</u>116. Infection of Newborn Acquired During Birth
- <u>128.</u> Infection of Newborn Acquired After Birth
- <u>129.118.</u> Hereditary Hemolytic Anemias
- <u>130.119.</u> Hemolytic Diseases of the Newborn
- <u>131.120.</u> Due to Rh Incompatibility Only
- <u>132.121.</u> Due to ABO Incompatibility
- <u>133.122.</u> Due to Other Causes
- <u>134.123.</u> Drug Toxicity or Withdrawal
 - A. Yes, Specify _____
 - B. No
- <u>135.124.</u> Highest Bilirubin, <u>Total</u>
- <u>136.125.</u> Admit to Designated Patient Unit
 - A. Yes
 - B. No
- <u>137.126.</u> Genetic Screenings Conducted
- <u>138.127.</u> Rh Determination
 - A. Mother's Blood Type _____ Rh Factor _____ Immune Globulin Given

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<u>B.</u>	Yes
<u>C.</u>	No
<u>139.</u> 128.	Hepatitis B – Surface Antigen
А.	Positive
В.	Negative
<u>140.</u> 129.	Non-Obstetrical Infections
А.	Syphilis
В.	Gonorrhea
C.	Rubella
D.	Other
<u>141.</u> 130.	Obstetrical Infections
А.	Antepartum Amnionitis/Chioramnionitis Urinary Tract Infection
B.	Postpartum Endometritis Infection of Wound Urinary Tract Infection
<u>142.</u> 131.	Mother admitted within with 72 hours after of delivery
А.	Precipitous Delivery
B.	Planned Home Birth
<u>143.</u> 132.	Drug Use During Pregnancy

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- B. Heroin
- C. Marijuana
- D. Other Street DrugsDrug(s)
- E. None
- F. Record N/A
- G. Not Stated
- <u>144.</u>133. Transfusion
- <u>145.134.</u> Prenatal Screening Conducted for
 - A. Gestational Diabetes (Blood Glucose Tolerance Test)
 - B. Congenital/Birth Defects
 - A. Maternal Alpha Feta Protein
 - B. Chromosomal
 - C. Other

<u>146.135.</u> Number of Days Maintained on Ventilation Before Transfer to Level III Center-Days

- <u>147.136.</u> Prenatal Ultrasound
 - A. Yes
 - B. No

C.	Record N/A			
D.	Not Stated			
<u>148.137.</u>	Chorionic Villus Sampling			
<u>149.138.</u>	Were Newborn Screening Tests Conducted?			
А.	Yes			
B.	No			
<u>150.</u> 139.	Mother Transferred Out to Another Hospital After Delivery Destination Hospital Code			
<u>151.140.</u>	Mother Transferred From Emergency Room			
<u>152.141.</u>	Infant Transferred In Transfer Code			
<u>153.142.</u>	Consult Administrative Perinatal Center or Another Level III			
<u>154.143.</u>	Infant Maternal			
	А.	A.	Yes, <u>with</u> ₩/Transfer	
	В.	B.	Yes, No Transfer	
	C.	C.	No Consultation	
	D.	D.	Not Stated	
<u>155.144.</u>	Mother Died In Hospital			
<u>156.</u> 145.	Fetal Death			
<u>157.146.</u>	Infant Died in Hospital			
<u>158.</u> 147.	Extrauterine Pregnancy			

- <u>159.148.</u> Ectopic Pregnancy
- <u>160.149.</u> Admission Date Infant
- <u>161.</u> Admission Date Maternal
- <u>162.151.</u> Discharge Date Infant
- <u>163.</u> Discharge Date Maternal
- <u>164.153.</u> Payment Method
 - A. Yes

Medicaid Medicaid HMO HMO Medicare CHAMPUS Title V Health <u>Insurance</u>Ins. Self Pay <u>Record N/A</u> Not Stated <u>Health Ins/\$/</u> Other, Specify ____

- B. No
- <u>165.154.</u> Were prenatal records available prior to delivery?
 - A. Yes
 - B. No

<u>166.155.</u> Maternal Diagnosis (Specify up to 8 Diagnoses)

<u>167.</u> Mother's Medical Record Number _____

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	<u>168.</u> 157.	Infant Diagnoses (Including Congenital Anomalies); Specify up to 8 <u>Diagnoses</u> diagnosis		
	<u>169.158.</u>	Infant Released to:		
A. Home				
	B. Other Hospital		Name and Location	
	C. Long Term Care		Name and Location	
	D. 0	Other Child Care Agency	Name and Location	
<u>170.159.</u> Infant Patient ID		Infant Patient ID		
l	<u>171.</u> 160.	50. Infant Medical Record Number		
	<u>172.</u> 161. Referrals			
	А.	Community Social Service	ces	
	B.	Division of Specialized Services for Children (DSCC)		
	C.	DCFS		
	<u>C.</u>	Department of Healthcare and Family Services (HFS)		
	<u>D.</u>	Department of Children and Family Services (DCFS)		
	<u>E.</u> D.	Other, Specify		
	<u>F.E.</u>	None		
	<u>G.</u> F.	Early Intervention progra	m	
	<u>H.</u> G.	Other		
	<u>173.</u> 162.	Feedings		

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- 174.163. Breast Fedfed
- <u>175.</u>164. Bottle
- <u>176.165.</u> Tube
- <u>177.</u>166. Formula
- <u>178.</u>167. Frequency
- <u>179.</u>168. Amount
- <u>180.</u>169. Infant Medications
- <u>181.</u>^{170.} Birth Weight
- <u>182.171.</u> Birth Head Circumference
- <u>183.</u>172. Birth Length
- <u>184.</u>173. Discharge Weight
- <u>185.174.</u> Discharge Head Circumference
- <u>186.175.</u> Discharge Length
- <u>187.176.</u> Infant Discharge Treatment
- <u>188.</u>177. Other Concerns
- <u>189.</u>178. RN Contact at Hospital Phone Number
- <u>190.</u>179. Relative/Friend
- <u>191.180.</u> Relationship
- <u>192.</u>181. Address/Phone #

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- <u>193.182.</u> Family <u>Informed informed</u> of <u>Local Health NurseLHN</u> Visit
 - A. Yes
 - B. No
- <u>194.183.</u> Primary Care Physician's Name –
- <u>195.184.</u> Mother Gravida Para F_ P_ A_ L_
- <u>196.</u>185. Signature
- <u>197.186.</u> Title
- <u>198.</u>187. Report Date
- 188. Other Infant Diagnoses
- 189. Congenital Syphilis
- 190. Hypothyroidism
- 191. Adrenogenital Syndrome
- 192. Inborn Errors of Metabolism
- 193. Cystic Fibrosis
- 194. Immune Deficiency Disorder
- 195. Leukemia
- 196. Constitutional Aplastic Anemia
- 197. Coagulation Defects
- 198. Neurofibromatosis
- 199. Retinopathy of prematurity

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- 200. Chorioretinitis
- 201. Strabismus
- 202. Endocardial Fibroelastosis
- 203. Occlusion of Cerebral Arteries
- 204. Intrauterine Growth Retardation
- 205. Cerebral Lipidoses

(Source: Amended at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX J Guideline for Application Process for Designation, Redesignation or Change in Designation

Initial Process:

The hospital administration shall:

Send a Letter of Intent for change in status to the Department and affiliated Administrative Perinatal Center 6 to12 months before expected review by the PAC.

Prepare appropriate documents for site visit. Required documents and assistance with preparation are available through affiliate Administrative Perinatal Center. The site visit team will include, but not be limited to, Co-Directors of Administrative Perinatal Center and Network Administrator, Perinatal Advisory Committee and Department. The Department will assign the additional representatives required.

Send information three weeks in advance of the scheduled site visit to:

Illinois Department of Public Health Perinatal Program Administrator 535 West Jefferson Springfield, Illinois 62761

Assemble appropriate representation from the hospital on the day of the site visit to be available to present an overview of the hospital and to answer questions from the site visit team. Hospital representatives should include at a minimum:

- <u>Hospital administration</u>
- Chair of OB/GYN
- <u>Chair of Family Practice, if appropriate</u>
- <u>Chair of Pediatrics</u>
- <u>Director of Anesthesiology</u>
- Director of Maternal-Fetal Medicine, if appropriate
- Director of Neonatology, if appropriate
- <u>Director of Nursing</u>

Once the site visit has been completed and the hospital and Administrative Perinatal Center are satisfied that the application is complete, the Administrative Perinatal Center will contact the Department in writing to schedule application review before the Perinatal Advisory Committee.

On the day of the review, the following representatives must be present from the hospital to be reviewed:

- <u>Hospital administration</u>
- <u>Chair of OB/GYN</u>
- Chair of Family Practice, if appropriate
- <u>Chair of Pediatrics</u>
- Director of Maternal-Fetal Medicine, if appropriate
- <u>Director of Neonatology, if appropriate</u>
- Director of Nursing
- <u>Co-Directors of Affiliate Perinatal Network</u>
- Network Administrator from Affiliate Perinatal Network
- Other personnel as identified by hospital, Perinatal Advisory Committee or Sub-Committee

After reviewing the application, the PAC will present a formal outline of the issues and recommendations to the Department.

After review of the recommendations and deliberations, the Department will send a formal letter as to the status of the hospital.

The hospital and the Administrative Perinatal Center will work together to address the recommendation in the follow-up letter.

The Administrative Perinatal Center will be responsible for monitoring any indicators or required changes that are identified by the PAC.

In preparation for re-review, the hospital and Administrative Perinatal Center will prepare information only on issues addressed in the follow-up letter.

The Administrative Perinatal Center will contact the Department to schedule the re-review meeting.

The Administrative Perinatal Center will send appropriate documents, identified in the follow-up letter, to the Department three weeks before the re-review is scheduled.

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Only representatives from the Administrative Perinatal Center shall attend the re-review meeting to answer any questions the review committee may have concerning the identified items. Hospital representatives may attend the meeting if they choose.

The Illinois Department of Public Health will send a formal follow-up letter to the hospital and the Administrative Perinatal Center concerning the outcome of the meeting and any follow-up instructions.

(Source: Added at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX K Elements for Submission for Designation, Redesignation or **Change in Designation**

Level III Review

- Appendix A •
- **Resource Checklist for Level III**
- Evaluation letter from Administrative Perinatal Center
- Vita for co-directors
- Credentials for Obstetric (OB)/Family Practice (FP) physicians, Advance • Practice Nurses (APN), Neonatology & Anesthesia
- Copy of OB/Peds Departmental Rules
- Maternal-Fetal Medicine (MFM), Neonatology Consultation/referral tool/QA reports for 3 months
- Mortality and Morbidity (M&M) statistics and description of the • process/participation
- Transport statistics, both into and out of hospital •
- Listing of educational classes
- Description of educational classes
- Description of CQI
- 3 months of call schedules for OB, Maternal-Fetal Medicine and Neonatology (current and last 2 actual or 3 proposed schedules)

Level II with Extended Neonatal Capabilities Review

- Appendix A •
- Resource Checklist for Level II with Extended Neonatal Capabilities
- Evaluation letter from Administrative Perinatal Center
- Vita for Director of Neonatology, Maternal-Fetal Medicine (MFM), if appropriate
- Credentials for Obstetricians/Family Practice physicians, Advanced Practice Nurses (APN), Neonatology & Anesthesia
- Copy of OB/Peds Departmental Rules •
- Consultation/referral tool/QA reports for 3 months
- Mortality and Morbidity (M&M) statistics and description of process/participation
- Transport statistics, both into and out of hospital
- Listing of educational classes
- **Description of COI**
- 3 months of call schedules for OB, MFM and Neonatology as appropriate

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Level II Review

- Appendix A
- **Resource Checklist for Level II**
- Evaluation letter from Administrative Perinatal Center
- Credentials for Obstetrics (OB)/Family Practice (FP) physicians, Advance • Practice Nurses (APN), Neonatology & Anesthesia
- Copy of OB/Peds Departmental Rules •
- Consultation/referral tool/QA reports for 3 months •
- Mortality and Morbidity (M&M) statistics and description of process/participation •
- Transport statistics out of hospital
- Listing of educational classes
- **Description of CQI**

Level I Review

- Appendix A •
- Resource Checklist for Level I
- Evaluation letter from Administrative Perinatal Center
- Credentials for Obstetrics (OB)/Family Practice (FP) physicians, Advance Practice Nurses (APNs), Neonatology & Anesthesia
- Mortality and Morbidity (M&M) statistics and description of process/participation •
- Transport statistics out of hospital
- Listing of educational classes
- **Description of COI**

Administrative Perinatal Center

- Network description
- Educational programs
- Network projects
- Discussion with representatives from Regional Network Hospitals
- Network participation
- Network evaluation
- Network challenges
- Network M&M statistics •
- University integration

(Source: Added at 34 Ill. Reg. _____, effective _____)

Section 640.APPENDIX L Level I Resource Checklist

Level I Resource Checklist Briefly describe institutional compliance:

1. The hospital shall provide continuing education for medical, nursing, respiratory therapy and other staff who provide general perinatal services, with evidence of a yearly competence assessment appropriate to the population served.

RECOMMENDATIONS:

2. <u>The hospital shall provide documentation of participation in Continuous Quality</u> <u>Improvement (CQI) implemented by the Administrative Perinatal Center.</u>

RECOMMENDATIONS:

3. The hospital shall provide documentation of the health care provider's risk assessment and consultation with a maternal-fetal medicine sub-specialist or neonatologist as specified in the letter of agreement and hospital's policies and procedures, and transfer to the appropriate level of care.

RECOMMENDATIONS:

<u>4.</u> <u>The hospital shall provide documentation of the availability of trained personnel and facilities to provide competent emergency obstetric and newborn care.</u>

RECOMMENDATIONS:

5. The hospital shall maintain a system of recording admissions, discharges, birth weight, outcome, complications and transports to meet the requirement to support CQI activities described in the hospital's letter of agreement with the Administrative Perinatal Center. The hospital shall comply with the reporting requirements of the State Perinatal Reporting System.

RECOMMENDATIONS:

6. The hospital shall provide documentation of the capability for continuous electronic maternal-fetal monitoring for patients identified at risk with staff available 24 hours a day, including physicians and nursing, who are knowledgeable of electronic fetal
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monitoring use and interpretation. Staff shall complete a competence assessment in electronic maternal-fetal monitoring every two years.

RECOMMENDATIONS:

7. <u>The hospital shall have the capability of performing caesarean sections (C-sections)</u> within 30 minutes of decision-to-incision.

RECOMMENDATIONS:

8. The hospital shall have blood bank technicians on call and available within 30 minutes for performance of routine blood banking procedures.

RECOMMENDATIONS:

9. The hospital shall have general anesthesia services on call and available under 30 minutes to initiate C-section.

RECOMMENDATIONS:

<u>10.</u> <u>The hospital shall have radiology services available within 30 minutes.</u>

RECOMMENDATIONS:

<u>11.</u> <u>The hospital shall have the following clinical laboratory resources available:</u>

Microtechniques for hematocrit, within 15 minutes; glucose, blood urea nitrogen (BUN), creatinine, blood gases, routine urine analysis, complete blood count, routine blood chemistries, type & cross, Coombs test, bacterial smear within 1 hour; and capabilities for bacterial culture and sensitivity and viral culture.

RECOMMENDATIONS:

12. The hospital shall designate a physician to assume primary responsibility for initiating, supervising and reviewing the plan for management of distressed infants. Policies and procedures shall assign responsibility for the identification and resuscitation of distressed neonates to individuals who have successfully completed a neonatal resuscitation program and are both specifically trained and immediately available in the hospital at all times.

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RECOMMENDATIONS:

13. The hospital shall be responsible for assuring that staff physicians and consultants are aware of standards and guidelines in the letter of agreement.

RECOMMENDATIONS:

14. The hospital shall provide documentation of health care provider participation in Joint Mortality and Morbidity reviews.

RECOMMENDATIONS:

(Source: Added at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX M Level II Resource Checklist

Level II Resource Checklist Briefly describe institutional compliance:

The Level II hospital shall provide all of the services outlined for Level I general care.

1. The hospital shall provide continuing education for medical, nursing, respiratory therapy and other staff who provide general perinatal services, with evidence of a yearly competence assessment appropriate to the population served.

RECOMMENDATIONS:

2. The hospital shall provide documentation of participation in Continuous Quality Improvement (CQI) implemented by the Administrative Perinatal Center.

RECOMMENDATIONS:

3. The hospital shall provide documentation of the health care provider's risk assessment and consultation with a maternal-fetal medicine sub-specialist or neonatologist as specified in the letter of agreement and hospital's policies and procedures, and transfer to the appropriate level of care.

RECOMMENDATIONS:

4. The hospital shall provide documentation of the availability of trained personnel and facilities to provide competent emergency obstetric and newborn care.

RECOMMENDATIONS:

5. The hospital shall maintain a system of recording admissions, discharges, birth weight, outcome, complications and transports to meet the requirement to support CQI activities described in the hospital's letter of agreement with the Administrative Perinatal Center. The hospital shall comply with the reporting requirements of the State Perinatal Reporting System.

RECOMMENDATIONS:

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6. The hospital shall provide documentation of the capability for continuous electronic maternal-fetal monitoring for patients identified at risk with staff available 24 hours a day, including physicians and nursing, who are knowledgeable of electronic fetal monitoring use and interpretation. Staff shall complete a competence assessment in electronic maternal-fetal monitoring every two years.

RECOMMENDATIONS:

7. The hospital shall have the capability of performing caesarean sections within 30 minutes of decision to incision.

RECOMMENDATIONS:

8. The hospital shall have experienced blood bank technicians immediately available in the hospital for blood banking procedures and identification of irregular antibodies. Blood component therapy shall be readily available.

RECOMMENDATIONS:

9. The hospital shall have general anesthesia services on call and available under 30 minutes to initiate C-section.

RECOMMENDATIONS:

10. The hospital shall have experienced radiology technicians 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.

RECOMMENDATIONS:

<u>11.</u> <u>The hospital shall have the following clinical laboratory resources available:</u>

Micro-techniques for hematocrit and blood gases within 15 minutes; glucose, blood urea nitrogen (BUN), creatinine, blood gases, routine urine analysis, electrolytes and coagulation studies, complete blood count, routine blood chemistries, type & cross, Coombs' test, bacterial smear within 1 hour; and capabilities for bacterial culture and sensitivity and viral culture.

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RECOMMENDATIONS:

12. The hospital shall designate a physician to assume primary responsibility for initiating, supervising and reviewing the plan for management of distressed infants. Policies and procedures shall assign responsibility for the identification and resuscitation of distressed neonates to individuals who have successfully completed a neonatal resuscitation program and are both specifically trained and immediately available in the hospital at all times.

RECOMMENDATIONS:

13. The hospital shall ensure that personnel skilled in phlebotomy and IV placement in newborns are available 24 hours a day.

RECOMMENDATIONS:

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

RECOMMENDATIONS:

15. The hospital shall ensure that protocols for discharge planning, routine follow-up care, and developmental follow-up are established.

RECOMMENDATIONS:

16. The hospital shall ensure that a licensed respiratory care practitioner with experience in neonatal care is available 24 hours a day.

RECOMMENDATIONS:

17. The hospital shall ensure that a dietitian with experience in perinatal nutrition is available to plan diets to meet the needs of mothers and infants.

RECOMMENDATIONS:

18. The hospital shall ensure that staff physicians and consultants are aware of standards and guidelines in the letter of agreement.

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RECOMMENDATIONS:

<u>19.</u> <u>The hospital shall provide documentation of health care provider participation in Joint Mortality and Morbidity reviews.</u>

(Source: Added at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX N Level II with Extended Neonatal Capabilities Resource Checklist

Level II with Extended Neonatal Capabilities Resource Checklist

Briefly describe institutional compliance:

1. The hospital shall provide documentation that the obstetrical activities are directed and supervised by a full-time board-certified obstetrician or a licensed osteopathic physician with equivalent training and experience and certification by the American Osteopathic Board of Obstetricians and Gynecologists.

RECOMMENDATIONS:

2. The hospital shall provide documentation that the neonatal activities are 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.

RECOMMENDATIONS:

3. The directors of obstetrics and neonatal services shall ensure back-up supervision of their services when they are unavailable.

RECOMMENDATIONS:

4. The hospital shall provide documentation that the obstetric-newborn nursing service is directed by a full-time nurse experienced in perinatal nursing, preferably with a master's degree.

RECOMMENDATIONS:

5. <u>The hospital shall provide documentation that the pediatric-neonatal respiratory therapy</u> services are directed by a full-time licensed respiratory care practitioner with a bachelor's <u>degree</u>.

RECOMMENDATIONS:

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6. The hospital shall provide documentation that the practitioner responsible for the Special Care Nursery has at least three years experience in all aspects of pediatric and neonatal respiratory therapy and completion of the neonatal/pediatric specialty examination of the National Board for Respiratory Care.

RECOMMENDATIONS:

7. Preventive services shall be designed 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.

RECOMMENDATIONS:

8. The hospital shall ensure that a person is designated to coordinate the local health department community nursing follow-up 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 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.

RECOMMENDATIONS:

9. The hospital shall provide documentation that the Level II hospital with Extended Neonatal Capabilities has developed, with the assistance of the Administrative Perinatal Center, a referral agreement with a neonatal follow-up clinic to provide neurodevelopmental assessment and outcome data on the neonatal population. Institutional policies and procedures shall describe the at-risk population and referral procedure to be followed.

RECOMMENDATIONS:

10. The hospital shall ensure that if the Level II hospital with Extended Neonatal Capabilities transports neonatal patients, the hospital complies with Guidelines for Perinatal Care, American Academy of Pediatrics and American College of Obstetricians.

RECOMMENDATIONS:

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To provide for assisted ventilation of newborn infants beyond immediate stabilization:

1. The hospital shall provide documentation that 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, a pediatrician receiving post-graduate training in a neonatal-perinatal medicine fellowship program accredited by the Accreditation Council of Graduate Medical Education or an active candidate or board-certified neonatologist is present in the hospital the entire time that the infant is receiving assisted ventilation. If infants are receiving on-site assisted ventilation care from an advance practice nurse or a physician who is not a neonatologist, a board-certified neonatologist or active candidate neonatologist shall be available on call to assist in the care of those infants as needed.

RECOMMENDATIONS:

2. The hospital shall provide suitable backup systems and planning to prevent and respond appropriately to sudden power outage, oxygen system failure, and interruption of medical grade compressed air delivery.

RECOMMENDATIONS:

3. The hospital shall provide documentation that the nurses caring for infants who are receiving assisted ventilation have documented competence and experience in the care of such infants.

RECOMMENDATIONS:

4. The hospital shall provide documentation that the licensed respiratory care practitioner has documented competence and experience in the care of the infants who are receiving assisted ventilation and is also available to the Special Care Nursery during the entire time that the infant receives assisted ventilation.

RECOMMENDATIONS:

(Source: Added at 34 Ill. Reg. _____, effective _____)

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Section 640.APPENDIX O Level III Resource Checklist

Level III Resource Checklist

Briefly describe institutional compliance:

The Level III hospital shall provide all of the services outlined for Level I and Level II 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.

Level III General Provisions

1.The hospital shall provide documentation of participation in Continuous Quality
Improvement (CQI) implemented by the Administrative Perinatal Center.

RECOMMENDATIONS:

2. <u>The hospital shall provide documentation of health care provider participation in Joint</u> <u>Morbidity & Mortality Reviews.</u>

RECOMMENDATIONS:

3. The hospital shall have the following clinical laboratory resources available:

Microtechniques for hematocrit and blood gases within 15 minutes; glucose, blood urea nitrogen (BUN), creatinine, blood gases, routine urine analysis, electrolytes and coagulation studies, complete blood count, routine blood chemistries, type & cross, Coombs test, bacterial smear within one hour; and capabilities for bacterial culture and sensitivity and viral culture.

RECOMMENDATIONS:

4. The hospital shall ensure that experienced radiology technicians are immediately available in the hospital with professional interpretation available 24 hours a day. Ultrasound capability shall be available 24 hours a day with additional ultrasound availability on the OB floor and staff knowledgeable in its interpretation.

RECOMMENDATIONS:

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5. The hospital shall provide blood bank technicians immediately available in the hospital for blood banking procedures and identification of irregular antibodies. Blood components shall be readily available.

RECOMMENDATIONS:

6. The hospital shall ensure that personnel skilled in phlebotomy and IV placement in newborns are available 24 hours a day.

RECOMMENDATIONS:

Level III Standards

1. The Level III hospital shall provide documentation of a policy requiring health care professionals, in both obstetrics and pediatrics, to obtain consultation from or transfer of care to the maternal-fetal medicine or neonatology sub-specialists as outlined in the standards for Level II.

RECOMMENDATIONS:

2. The Level III hospital shall accept all medically eligible Illinois residents. Medical eligibility is to be determined by the obstetrical 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).

RECOMMENDATIONS:

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, American Academy of Pediatrics and American College of Obstetricians and Gynecologists). If the Level III hospital is unable to accept the patient referred, the Administrative Perinatal Center shall arrange for placement at another Level III hospital or appropriate Level II or Level II hospital with Extended Neonatal Capabilities.

RECOMMENDATIONS:

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4. The 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 as outlined in the letter of agreement.

RECOMMENDATIONS:

5. The Level III hospital shall have a clearly identifiable telephone number, facsimile number and/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.

RECOMMENDATIONS:

6. 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.

RECOMMENDATIONS:

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

RECOMMENDATIONS:

8. The hospital shall provide data relating to activities and shall comply with the requirements of the State Perinatal Reporting System.

RECOMMENDATIONS:

9. 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.

RECOMMENDATIONS:

10. The hospital shall provide documentation of the capability for continuous electronic maternal-fetal monitoring for patients identified at risk with staff available 24 hours a

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day, including physicians and nursing, who are knowledgeable of electronic fetal monitoring use and interpretation. Staff shall complete a competence assessment in electronic maternal-fetal monitoring every two years.

RECOMMENDATIONS:

11. The Level III hospital, in collaboration with the Administrative Perinatal Center, 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.

RECOMMENDATIONS:

12. The Level III hospital shall provide suitable backup systems and planning to prevent and respond to a sudden power outage, oxygen system failure, and interruption of medical grade compressed air delivery.

RECOMMENDATIONS:

13. The Level III hospital shall provide or develop a referral agreement with a 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 physicians. Referrals shall be made for interventional care in order to minimize neurological 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.

RECOMMENDATIONS:

<u>14.</u> <u>Neonatal surgical services shall be available 24 hours a day.</u>

RECOMMENDATIONS:

Level III Resource Requirements

1. The Level III hospital shall provide documentation that obstetrical activities shall be directed and supervised by a full-time subspecialty obstetrician certified by the American

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Board of Obstetrics and Gynecology in the subspecialty of maternal-fetal medicine or a licensed osteopathic physician with equivalent training and experience and certification by the American Osteopathic Board of Obstetricians and Gynecologists. The director of obstetric services shall ensure the back-up supervision of his or her services by a physician with equivalent credentials.

RECOMMENDATIONS:

2. The Level III hospital shall provide documentation that 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 shall ensure the backup supervision of his or her services by a physician with equivalent credentials.

RECOMMENDATIONS:

3. The Level III hospital shall provide documentation that 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.

RECOMMENDATIONS:

4. The Level III hospital shall provide documentation that the obstetric and newborn nursing services are directed by a full-time nurse experienced in perinatal nursing with a master's degree.

RECOMMENDATIONS:

5. The Level III hospital shall provide documentation that half of all neonatal intensive care direct nursing care hours are provided by registered nurses who have had two years or more nursing experience in a Level III NICU. All NICU direct nursing care hours shall be provided or supervised by licensed 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.

RECOMMENDATIONS:

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6. The Level III hospital shall provide documentation that obstetrical anesthesia services, under the supervision of a board-certified anesthesiologist with training in maternal, fetal and neonatal anesthesia, are available 24 hours a day. The director of obstetric anesthesia shall ensure the back-up supervision of his or her services when he or she is unavailable.

RECOMMENDATIONS:

7. The Level III hospital shall provide documentation that pediatric-neonatal respiratory therapy services are directed by a full time licensed respiratory care practitioner with a bachelor's degree.

RECOMMENDATIONS:

8. The Level III hospital shall provide documentation that the respiratory care practitioner responsible for the NICU has at least three years of experience in all aspects of pediatric and neonatal respiratory care at a Level III Neonatal Intensive Care Unit and completion of the neonatal/pediatrics specialty examination of the National Board for Respiratory Care.

RECOMMENDATIONS:

9. The Level III hospital shall provide documentation that respiratory care practitioners with experience in neonatal ventilatory care staff the NICU according to the respiratory care requirements of the patient population, with a minimum of one dedicated neonatal licensed respiratory care practitioner for newborns on assisted ventilation, and with additional staff provided as necessary to perform other neonatal respiratory care procedures.

RECOMMENDATIONS:

10. The Level III hospital shall provide documentation that a physician for the program assumes 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

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satisfied by current completion of a neonatal resuscitation program by medical, nursing and respiratory care staff or a rapid response team.

RECOMMENDATIONS:

11. The Level III hospital shall provide documentation that a board-certified or active candidate obstetrician is present and available in the hospital 24 hours a day. Maternal-fetal medicine consultation shall be available 24 hours a day.

RECOMMENDATIONS:

12. The Level III hospital shall provide documentation that a board-certified neonatologist, active candidate neonatologist or a pediatrician receiving postgraduate training in a neonatal-perinatal medicine fellowship program accredited by the Accreditation Council of Graduate Medical Education is present and available in the hospital 24 hours a day to provide care for newborns in the NICU.

RECOMMENDATIONS:

13. The Level III hospital shall provide documentation that neonatal surgical services are supervised by a board-certified surgeon or active candidate in pediatric surgery appropriate for the procedures performed at the Level III hospital.

RECOMMENDATIONS:

14. The Level III hospital shall provide documentation that neonatal surgical anesthesia services under the direct supervision of a board-certified anesthesiologist with extensive training or experience in pediatric anesthesiology are available 24 hours a day.

RECOMMENDATIONS:

15. The Level III hospital shall provide documentation that neonatal neurology services, under the direct supervision of a board-certified or active candidate pediatric neurologist, are available for consultation in the NICU 24 hours a day.

RECOMMENDATIONS:

16. The Level III hospital shall provide documentation that neonatal radiology services, under the direct supervision of a board-certified radiologist with extensive training or

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experience in neonatal radiographic and ultrasound interpretation, are available 24 hours a day.

RECOMMENDATIONS:

17. The Level III hospital shall provide documentation that neonatal cardiology services, under the direct supervision of an active candidate pediatrician or a pediatrician boardcertified by the American Board of Pediatrics Sub-Board of Pediatric Cardiology, are available for consultation 24 hours a day. In addition, cardiac ultrasound services and pediatric cardiac catherization services by staff with specific training and experience shall be available 24 hours a day.

RECOMMENDATIONS:

18. The Level III hospital shall provide documentation that a board-certified or active candidate ophthalmologist with experience in the diagnosis and treatment of the visual problems of high-risk newborns (retinopathy of prematurity) is available for appropriate examinations, treatment and follow-up care of high-risk newborns.

RECOMMENDATIONS:

19. The Level III hospital shall provide documentation that pediatric sub-specialists with specific training and extensive experience or subspecialty board certification or active candidacy (when applicable) are 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.

RECOMMENDATIONS:

20. The Level III hospital shall provide documentation that genetic counseling services are 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.

RECOMMENDATIONS:

21. <u>The Level III hospital shall designate at least one person to coordinate the community</u> nursing follow-up referral process, to direct discharge planning, to make home care

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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.

RECOMMENDATIONS:

22. The Level III hospital shall establish a protocol that defines 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.

RECOMMENDATIONS:

23. The Level III hospital shall provide documentation that one or more full-time licensed medical social workers with perinatal/neonatal experience are dedicated to the Level III hospital.

RECOMMENDATIONS:

24. The Level III hospital shall provide documentation that one registered pharmacist with experience in perinatal pharmacology is available for consultation on therapeutic pharmacology issues 24 hours a day.

RECOMMENDATIONS:

25. The Level III hospital shall provide documentation that one dietitian with experience in perinatal nutrition is available to plan diets and education to meet the special needs of high-risk mothers and neonates in both inpatient and outpatient settings.

RECOMMENDATIONS:

(Source: Added at 34 Ill. Reg. _____, effective _____)