ARTICLE 39. PERINATAL HOSPITAL SERVICES

Rule 1. Definitions

410 IAC 39-1-1 Applicability

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana Department of Health; 410 IAC 39-1-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-2 "Available at all times" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. "Available at all times" means available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance. *(Indiana Department of Health; 410 IAC 39-1-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-3 "Birth center" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 3. "Birth center" has the meaning set forth in 410 IAC 39-3-1. *(Indiana Department of Health; 410 IAC 39-1-3; filed Aug*

14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-1-4 "Board certified" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 4. "Board certified" means a physician certified by an American Board of Medical Specialties Member Board or the American Osteopathic Association. *(Indiana Department of Health; 410 IAC 39-1-4; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-5 "Delivering facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 5. "Delivering facility" means any hospital that has either an obstetric unit intended to care for pregnant women or a neonatal unit intended to care for newborns. *(Indiana Department of Health; 410 IAC 39-1-5; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-6 "Department" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 6. "Department" means the Indiana department of health. *(Indiana Department of Health; 410 IAC 39-1-6; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA; errata filed Jul 28, 2021, 3:27 p.m.: 20210811-IR-410210333ACA)*

410 IAC 39-1-7 "Hospital" defined

Authority: IC 16-21-13-5
Affected: IC 16-18-2-179; IC 16-21-13

Sec. 7. "Hospital" has the meaning set forth in IC 16-18-2-179(a). *(Indiana Department of Health; 410 IAC 39-1-7; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-8 "Immediately available at all times" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 8. "Immediately available at all times" means in the building where the perinatal care is provided, in a building that is physically connected to the building where the perinatal care is provided, or in a building adjacent to the building where the perinatal care is provided, twenty-four (24) hours a day, seven (7) days a week. *(Indiana Department of Health; 410 IAC 39-1-8; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-9 "Level of care" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 9. "Level of care" means the certified classification given to hospital neonatal and obstetric units that indicate expected capabilities as set forth in this article. *(Indiana Department of Health; 410 IAC 39-1-9; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-10 "Neonatal Level I facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 10. "Neonatal Level I facility" has the meaning set forth in 410 IAC 39-5-1. *(Indiana Department of Health; 410 IAC 39-1-10; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-11 "Neonatal Level II facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 11. "Neonatal Level II facility" has the meaning set forth in 410 IAC 39-5-2. *(Indiana Department of Health; 410 IAC 39-1-11; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-12 "Neonatal Level III facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 12. "Neonatal Level III facility" has the meaning set forth in 410 IAC 39-5-3. *(Indiana Department of Health; 410 IAC 39-1-12; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-13 "Neonatal Level IV facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 13. "Neonatal Level IV facility" has the meaning set forth in 410 IAC 39-5-4. *(Indiana Department of Health; 410 IAC 39-1-13; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-14 "Obstetric Level I facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 14. "Obstetric Level I facility" has the meaning set forth in 410 IAC 39-4-1. *(Indiana Department of Health; 410 IAC 39-1-14; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-15 "Obstetric Level II facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 15. "Obstetric Level II facility" has the meaning set forth in 410 IAC 39-4-2. *(Indiana Department of Health; 410 IAC 39-1-15; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-16 "Obstetric Level III facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 16. "Obstetric Level III facility" has the meaning set forth in 410 IAC 39-4-3. *(Indiana Department of Health; 410 IAC 39-1-16; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-17 "Obstetric Level IV facility" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 17. "Obstetric Level IV facility" has the meaning set forth in 410 IAC 39-4-4. *(Indiana Department of Health; 410 IAC 39-1-17; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-18 "Perinatal center" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 18. "Perinatal center" has the meaning set forth in 410 IAC 39-8-1. *(Indiana Department of Health; 410 IAC 39-1-18; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-19 "Physically present at all times" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 19. "Physically present at all times" means onsite in the building where the perinatal care is provided or in a building that is physically connected to the building where the perinatal care is provided, twenty-four (24) hours a day, seven (7) days a week. *(Indiana Department of Health; 410 IAC 39-1-19; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-1-20 "Readily available at all times" defined

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 20. "Readily available at all times" means available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance, and able to be physically present onsite within a time frame that incorporates maternal and newborn risks and benefits with the provision of care. *(Indiana Department of Health; 410 IAC 39-1-20; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

Rule 2. Levels of Care Certification

410 IAC 39-2-1 Certification process

Authority: IC 16-21-13-5
Affected: IC 4-21.5; IC 16-21-13

Sec. 1. (a) Each delivering facility that provides birthing services in Indiana must be certified for a level of care based on the services provided as follows:

(1) The obstetric level of care and the neonatal level of care must either match or be no more than one (1) level apart, unless a neonatal unit does not have a corresponding obstetric unit.

(2) Facilities should only accept mothers and newborns appropriate to the facility's level of care except in case of emergency. Risk appropriate care requires consideration of maternal risk factors and the gestational age and risk factors of her unborn infant.

(b) Each facility shall complete an application and specify at which level of care the facility seeks certification as follows:

(1) Facilities applying for either a Level III or Level IV certification must submit a completed application to the department not later than six (6) months after the effective date of this rule.

(2) Facilities applying for Level II certification must submit a completed application to the department not later than twelve

(12) months after the effective date of this rule.

(3) Facilities applying for Level I certification must submit a completed application to the department not later than twenty-four (24) months after the effective date of this rule.

(4) Birth centers must submit verification of accreditation within twenty-four (24) months after the effective date of this rule.

(5) Facilities that open new obstetric or neonatal services after the effective date of this rule must apply for certification not later than six (6) months prior to offering services. A formal certification survey will take place not later than six (6) months after the facility begins providing obstetric or neonatal services.

(c) Upon receipt of a facility's application, the department will review the application. As follows, the department:

(1) May request additional documents and the facility shall provide them.

(2) Shall conduct an onsite survey of the facility after the department has received and reviewed the application and any additional documents requested.

(3) Shall provide the facility with a written survey report within thirty (30) days of completing the onsite survey. The survey report shall include a description of any deficiencies.

(d) If the facility does not meet the requirements of the level of care for which it has applied, the facility will receive certification at the level of care for which it meets the minimum requirements.

(e) The department shall not deny a certification to a facility that meets the minimum requirements of this rule for certification.

(f) The certification granted through this rule shall be valid for three (3) years from the date of issuance as follows:

(1) The certification for a level of care may be removed within the three (3) years if the department determines that the facility no longer meets the level of care at which the department previously certified.

(2) An application for recertification must be submitted not later than three (3) months before the expiration of the current certification.

(3) A facility may submit a new application for lower certification at any time. A facility shall submit a new application for lower certification any time there is a permanent substantial change that would affect the ability to meet the standards of the current level of care certification.

(g) A decision by the department under this article is subject to review under IC 4-21.5.

(h) The department, at its discretion, may request documents, conduct surveys, or both, if it has reason to believe that a facility may not be meeting the requirements of its current certification.

(i) A certification issued under this article must be conspicuously posted on the premises in an area open to and frequently accessed by patients. *(Indiana Department of Health; 410 IAC 39-2-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-2-2 Notification to department

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. A hospital shall notify the department via email (perinatalloc@isdh.in.gov) if any of the following occur in the obstetrical unit, neonatal unit, or both:

(1) Full or partial replacement of the physical unit.

(2) Addition or renovation to the physical unit.

(3) Operational changes.

(4) Administrative changes that may affect compliance with this article.

(Indiana Department of Health; 410 IAC 39-2-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 3. Birth Center Requirements

410 IAC 39-3-1 Birth center requirements

410 IAC 39-3-1 Birth center requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-2; IC 16-21-13

Sec. 1. (a) A birth center is a facility that provides peripartum care of low-risk women with uncomplicated singleton term

pregnancies, a vertex presentation, and who are expected to have an uncomplicated birth. Birth centers must be accredited by the Commission for the Accreditation of Birth Centers. This does not include a hospital that is licensed as a hospital under IC 16-21-2.

(b) Each birth center shall meet the following physical and procedural requirements:

(1) Each birth center shall have all of the following facility capabilities:

(A) Capability and equipment to provide low-risk maternal care and a readiness at all times to initiate emergency procedures to meet unexpected needs of the woman and newborn within the center, and to facilitate transport to an acute care setting when necessary.

(B) Ability to initiate quality improvement programs that include efforts to maximize patient safety.

(C) Medical consultation available at all times.

(D) Ability to initiate emergency procedures to meet unexpected needs of the woman and newborn within the center, including cardiopulmonary resuscitation (CPR) and newborn resuscitation and stabilization.

(E) Understanding of its capability to provide maternal and neonatal care and the threshold at which it should transfer women or newborns to a facility with a higher level of care.

(2) Each birth center shall establish the following policies and procedures:

(A) Established agreement with a receiving hospital with policies and procedures for a timely transport, including determinations of conditions necessitating consultation and referral.

(B) Transfer plans that include risk identification; determination of conditions necessitating consultation; referral and transfer; and a reliable, accurate, and comprehensive communication system between participating facilities and transport teams.

(C) Policies and procedures for data collection, storage, and retrieval.

(c) Each birth center shall ensure the following staffing requirements are met:

(1) Every birth is attended by at least two (2) licensed clinical professionals, one (1) of whom is certified in Neonatal Resuscitation Program (NRP®).

(2) The primary maternal care provider who attends each birth (includes certified nurse midwives, family medicine physicians, and obstetricians-gynecologists (OB-GYN)) is educated, licensed, and legally recognized to practice within the jurisdiction of the birth center.

(3) Availability of adequate numbers of qualified professionals with competence in Obstetric Level I care criteria (as described in 410 IAC 39-4-1) and ability to stabilize and make preparations to transfer high-risk women and newborns.

(Indiana Department of Health; 410 IAC 39-3-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 4. Obstetrical Levels of Care Requirements

410 IAC 39-4-1 Obstetric Level I facility requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. (a) An Obstetric Level I facility is a facility that provides care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility at which specialty maternal care is available.

(b) An Obstetric Level I facility shall demonstrate its capability of providing uncomplicated and complicated obstetrical care through written standards, protocols, guidelines, and training, including the following:

(1) Each Obstetric Level I facility shall have all of the following facility capabilities:

(A) Ability to begin emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

(B) Ensuring availability of support services, including anesthesia, obstetric ultrasonography, laboratory testing, radiology, and blood bank supplies readily available at all times.

(C) Ability to initiate education and quality improvement programs to maximize patient safety, collaborate with higher level facilities to do so, or both.

(D) Selecting and managing obstetrical patients at a maternal risk level appropriate to its capability.

(E) Access to the hospital's laboratory services including twenty-four (24) hour capability to provide blood group, Rhesus factor (Rh) type, cross-matching, antibody testing, and basic emergency laboratory evaluations. The facility must have:

(i) ABO-Rh-specific or O-Rh-negative blood;

(ii) fresh frozen plasma; and

(iii) cryoprecipitate;

at the facility at all times.

(F) Hospitals offering a trial of labor for patients with a prior cesarean delivery shall have appropriate facilities and personnel immediately available at all times during the trial of labor including:

(i) anesthesia provider;

(ii) provider capable of performing cesarean delivery; and

(iii) personnel certified in Neonatal Resuscitation Program (NRP).

(2) Each Obstetric Level I facility shall obtain and maintain current equipment and technology, including, but not limited to, the following:

(A) Obstetric ultrasonography.

(B) Nonstress and stress testing.

(C) Cardioversion and defibrillation capability for mothers.

(D) Resuscitation equipment for mothers.

(E) Oxygen and air outlets.

(F) Emergency call system.

(G) Laboratory testing supplies.

(H) Blood bank supplies.

(I) Fetal monitoring equipment.

(3) Each Obstetric Level I facility shall have the following medications:

(A) The following medications shall be readily available at all times to the delivery room:

(i) Uterotonics.

(ii) Narcotics.

(iii) Antibiotics.

(iv) Anticonvulsants.

(v) Antihemorrhagic medications.

(vi) Narcotic reversal medications.

(vii) Antihypertensive medications.

(viii) Medications to support the provision of anesthesia services.

(B) All emergency resuscitation medications needed to initiate and maintain resuscitation shall be readily available at all times in accordance with Advanced Cardiac Life Support (ACLS) and NRP training.

(4) Each Obstetric Level I facility shall establish and maintain the following policies and procedures:

(A) Protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple blood component therapy.

(B) Formal transfer plans in partnership with a higher-level facility that include, but are not limited to, the following:

(i) Risk identification.

(ii) Determination of conditions necessitating consultation.

(iii) Referral and transfer.

(iv) A reliable, accurate, and comprehensive communication system between participating hospitals and transport teams.

(C) The hospital shall provide care to the maternal patient in accordance with acceptable standards of practice, as provided for by 410 IAC 15-1.6-9(a). The current Centers for Disease Control and Prevention (CDC) and American College of Obstetricians and Gynecologists (ACOG) recommendations related to the care of the maternal patient shall

be considered as authoritative sources of such acceptable standards of practice.

(c) Each Obstetric Level I facility shall ensure the following staffing requirements are met:

(1) Physician services. An obstetric provider, such as an obstetrician-gynecologist (OB-GYN), surgeon, or family medicine physician with additional training in obstetrics, with appropriate training and privileges to perform emergency cesarean delivery shall be readily available at all times to attend all deliveries.

(2) Nursing services, as follows:

(A) Adequate number of registered nurses (RNs) with competence in Level I care criteria and ability to stabilize and make preparations to transfer high-risk women, readily available at all times.

(B) Ensure minimum staffing according to Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) Guidelines for Professional Registered Nurse Staffing for Perinatal Units nurse-patient ratios, even when there are no perinatal patients.

(C) RN with demonstrated training and experience in the assessment, evaluation, and care of patients in labor present at all deliveries.

(D) Nursing staff shall be formally trained, certified, and competent in NRP.

(E) RN skilled in the recognition and nursing management of the complications of labor and delivery readily available at all times.

(F) On-duty RN whose responsibilities include the organization and supervision of antepartum, intrapartum, postpartum, and neonatal nursing services.

(G) Nursing leadership with expertise in perinatal nursing care.

(H) RN shall supervise licensed practical nurses and other licensed patient care staff who demonstrate knowledge and clinical competence in the nursing care of women, fetuses, and newborns during labor, delivery, and the postpartum and neonatal periods.

(I) Each delivering facility shall have a written plan for ensuring registered nurse-patient ratios as per current Guidelines for Perinatal Care, or AWHONN Guidelines for Professional Registered Nurse Staffing for Perinatal Units.

(3) Anesthesia services readily available at all times.

(4) Appropriately qualified medical staff readily available at all times to perform and interpret obstetric ultrasonography.

(5) At least one (1) person capable of initiating neonatal resuscitation shall attend every birth.

(6) Pharmaceutical services in accordance with 410 IAC 15-1.5-7.

(7) The hospital shall provide lactation support for the care of mothers and newborns per AWHONN and International Board Certified Lactation Consultant Staffing Recommendations for the Inpatient Setting Association (ILCA) recommendations on number of full-time equivalents per number of annual deliveries, based on the level of care at which the hospital is certified.

(8) Blood bank technicians shall be readily available at all times.

(Indiana Department of Health; 410 IAC 39-4-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-4-2 Obstetric Level II facility requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. (a) An Obstetric Level II facility is an Obstetric Level I facility plus care of appropriate high-risk antepartum, intrapartum, or postpartum conditions, both directly admitted and transferred from another facility. In addition to the requirements of an Obstetric Level I facility, an Obstetric Level II facility shall meet the requirements set forth in this section.

(b) An Obstetric Level II facility shall demonstrate as follows its capability of providing uncomplicated and complicated obstetrical care through written standards, protocols, guidelines, and training, including (Obstetric Level I plus the following):

(1) Each Obstetric Level II facility shall have all of the following facility capabilities:

(A) A policy in place for consultation referrals for genetic diagnostic and counseling services.

(B) Accept risk-appropriate maternal-fetal transports.

(2) Each Obstetric Level II facility shall obtain and maintain current equipment and technology, including, but not limited to, the following:

(A) Computed tomography (CT) scan.

(B) Magnetic resonance imaging (MRI).

(3) The medication requirements for Obstetric Level II are the same as Obstetric Level I.

(4) The policy and procedure requirements for Obstetric Level II are the same as Obstetric Level I, set forth in section 1 of this rule.

(c) Each Obstetric Level II facility shall ensure the following staffing requirements are met (Obstetric Level I plus the following):

(1) Physician services, as follows:

(A) An obstetrician-gynecologist (OB-GYN) or maternal-fetal medicine (MFM) specialist readily available at all times.

(B) An MFM specialist available at all times for consultation.

(C) Director of obstetric service is a board certified OB-GYN.

(D) Board certified anesthesiologist available at all times for consultation.

(E) Medical and surgical consultants available at all times for consultation.

(2) Nursing services, as follows:

(A) Nursing leadership and staff with formal training and experience in the provision of perinatal nursing care who are responsible for coordinating with respective neonatal care services.

(B) Adequate numbers of registered nurses with competence in Level II care criteria and ability to stabilize and make preparations to transfer high-risk women who exceed Level II care criteria, readily available at all times.

(3) Appropriately qualified medical staff to perform and interpret CT scans and MRI for maternal assessment.

(4) Blood bank technicians who are immediately available at all times.

(Indiana Department of Health; 410 IAC 39-4-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-4-3 Obstetric Level III facility requirements

Authority: IC 16-21-13-5

Affected: IC 16-21-13

Sec. 3. (a) An Obstetric Level III facility is an Obstetric Level II facility plus care of more complex maternal medical conditions, obstetric complications, and fetal conditions. In addition to the requirements of an Obstetric Level II facility, an Obstetric Level III facility shall meet the requirements set forth in this section.

(b) An Obstetric Level III facility shall demonstrate as follows its capability of providing uncomplicated and complicated obstetrical care through written standards, protocols, guidelines, and training, including (Obstetric Level II plus the following):

(1) Each Obstetric Level III facility shall have all of the following facility capabilities:

(A) Demonstrated experience and capability to provide comprehensive management of severe maternal complications.

(B) An onsite intensive care unit (ICU) should accept pregnant women and have critical care specialists, immediately available at all times.

(C) ICU collaborates actively with the maternal-fetal medicine (MFM) care team in the management of all pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions.

(2) Each Obstetric Level III facility shall obtain and maintain current equipment and technology, including, but not limited to, the following:

(A) Advanced imaging available at all times, including basic interventional radiology, maternal echocardiography, computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine imaging with interpretation.

(B) Ultrasonography with capability to perform Doppler studies.

(C) Appropriate equipment available to stabilize and monitor women in labor and delivery until they can be safely transferred to the ICU.

(3) The medication requirements for Obstetric Level III are the same as Obstetric Level I, set forth in section 1 of this rule.

(4) The policies and procedures for Obstetric Level III are the same as Obstetric Level I, set forth in section 1 of this rule.

(c) Each Obstetric Level III facility shall ensure the following staffing requirements are met (Obstetric Level II plus the following):

(1) Physician services, as follows:

(A) An obstetrician-gynecologist (OB-GYN) physically present at all times.

(B) MFM specialist available at all times onsite, by telephone, or by telemedicine with inpatient privileges.

(C) Director of MFM service who is a board certified MFM specialist.

(D) Director of anesthesia service is a board certified anesthesiologist.

(E) Full complement of subspecialists readily available at all times for consultation, including critical care, general surgery, infectious disease, hematology, cardiology, nephrology, neurology, and neonatology.

(2) Nursing services, as follows:

(A) All nurses working with antepartum patients at high risk shall have evidence of continuing education in maternal-fetal nursing and special training and experience in the management of women with complex maternal illnesses and obstetric complications.

(B) A director of perinatal nursing services, master's prepared or actively seeking a master's degree, who has overall responsibility for inpatient activities in the obstetric area. This registered nurse (RN) shall have demonstrated expertise in perinatal care as well as in the care of patients at high risk.

(C) A RN who is master's prepared or is actively seeking a master's degree shall coordinate education.

(D) Adequate numbers of nursing leaders and RNs with competence in Level III care criteria and ability to stabilize and make preparations to transfer high-risk women who exceed Level III care criteria, readily available at all times.

(3) Anesthesia services physically present at all times.

(4) Registered pharmacist with experience in perinatal-neonatal pharmacology readily available at all times.

(5) At least one (1) registered dietitian or nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of women at high risk.

(6) Social services, pastoral care, and bereavement services provided as appropriate to meet the needs of the population served.

(Indiana Department of Health; 410 IAC 39-4-3; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-4-4 Obstetric Level IV facility requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 4. (a) An Obstetric Level IV facility is an Obstetric Level III facility plus onsite medical and surgical care of the most complex maternal conditions and critically ill pregnant women and fetuses throughout antepartum, intrapartum, and postpartum care. In addition to the requirements of an Obstetric Level III facility, an Obstetric Level IV facility shall meet the requirements set forth in this section.

(b) An Obstetric Level IV facility shall demonstrate as follows its capability of providing uncomplicated and complicated obstetrical care through written standards, protocols, guidelines, and training, including (Obstetric Level III plus the following):

(1) Each Obstetric Level IV facility shall have all of the following facility capabilities:

(A) Onsite medical and surgical care of complex maternal conditions (including congenital maternal cardiac lesions, vascular injuries, neurosurgical emergencies, and transplants) with the availability of critical care unit or intensive care unit (ICU) beds.

(B) Provide seamless communication between maternal-fetal medicine (MFM) specialists and other subspecialists in the planning and facilitation of care for women with the most high-risk complications of pregnancy.

(C) Institutional support for the routine involvement of a MFM care team with the critical care units and specialists.

(D) MFM care team with expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. This includes co-management of ICU-admitted obstetric patients.

(2) The equipment requirements for Obstetric Level IV are the same as Obstetric Level III, set forth in section 3 of this rule.

(3) The medication requirements for Obstetric Level IV are the same as Obstetric Level I, set forth in section 1 of this rule.

(4) The policies and procedures requirements for Obstetric Level IV are the same as Obstetric Level I, set forth in section 1 of this rule.

(c) Each Obstetric Level IV facility shall ensure the following staffing requirements are met (Obstetric Level III plus the following):

(1) Physician services, as follows:

(A) Director of obstetric service is board certified in MFM or obstetrics and gynecology, with expertise in critical care obstetrics.

(B) Adult medical and surgical specialty and subspecialty consultants readily available at all times to collaborate with

MFM care team and advanced neurosurgery, transplant, or cardiac surgery.

(C) MFM specialist readily available at all times for onsite consultation and management, with full privileges.

(2) Nursing services, as follows:

(A) Adequate numbers of registered nurses (RNs) who have experience in the care of women with complex medical illnesses and obstetric complications; this includes competence in Level IV care criteria, readily available at all times.

(B) An advanced practice RN available to staff for consultation, education, and support on nursing care issues.

(3) Physician and nursing leadership with expertise in maternal intensive and critical care.

(Indiana Department of Health; 410 IAC 39-4-4; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 5. Neonatal Levels of Care Requirements

410 IAC 39-5-1 Neonatal Level I facility requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. (a) A Neonatal Level I facility is a facility that offers a basic level of newborn care to infants at low risk. These units have personnel and equipment available to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy term newborn infants. In addition, Level I neonatal units have personnel who can care for physiologically stable infants who are born at thirty-five (35) weeks of gestation or more and can stabilize ill newborn infants who are born at less than thirty-five (35) weeks of gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided.

(b) A Neonatal Level I facility shall demonstrate its capability of providing neonatal care through written standards, protocols, guidelines, and training, including the following:

(1) Each Neonatal Level I facility shall have the following facility capabilities:

(A) Appropriately detect, stabilize, and initiate management of unanticipated neonatal problems that occur until the patient can be transferred to a facility at which specialty neonatal care is available.

(B) Ability to initiate education and quality improvement programs to maximize patient safety, collaborate with higher-level facilities to do so, or both.

(C) Provide resuscitation and stabilization of unexpected neonatal problems according to the most current Neonatal Resuscitation Program (NRP) training.

(D) Select and manage neonatal patients at a neonatal risk level appropriate to its capability.

(E) Access to laboratory testing and blood bank supplies at all times.

(2) Each Neonatal Level I facility shall obtain and maintain current equipment and technology, including, but not limited to, the following:

(A) Portable x-ray.

(B) Phototherapy unit.

(C) Emergency call system.

(D) Intravenous infusion pump with drug library.

(E) Cardiac monitor.

(F) Radiant heat warmer.

(G) Bowel bags.

(H) Compressed air and oxygen source.

(I) Oxygen blender with flow meter and tubing.

(J) Equipment for examination, immediate care, and identification of the newborn.

(K) All equipment necessary to provide resuscitation and stabilization of unexpected neonatal problems according to the NRP training.

All equipment necessary to provide resuscitation and stabilization of the unexpected neonatal problems must be located within the delivery area. All other equipment may be located in the facility.

(3) Each Neonatal Level I facility shall have the following medications:

(A) Antibiotics.

(B) Anticonvulsants.

(C) Emergency medications, necessary to provide resuscitation and stabilization of unexpected neonatal problems according to NRP training, shall be available in the delivery area and neonatal units.

(4) Each Neonatal Level I facility shall establish and maintain the following policies and procedures:

(A) Formal transfer plans in partnership with a higher level of care facility that include, but are not limited to, the following:

(i) Risk identification.

(ii) Determination of conditions necessitating consultation.

(iii) Referral and transfer.

(iv) A reliable, accurate, and comprehensive communication system between participating hospitals and transport teams.

(B) The hospital shall provide care to the newborn in accordance with acceptable standards of practice, as provided for by 410 IAC 15-1.6-9(a). The current Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics (AAP), and American College of Obstetricians and Gynecologists (ACOG) recommendations related to the care of the newborn shall be considered as authoritative sources of such acceptable standards of practice.

(c) Each Neonatal Level I facility shall ensure the following staffing requirements are met:

(1) Pediatricians, family physicians, or advanced practice providers readily available at all times.

(2) Nursing services, as follows:

(A) Registered nurse (RN) with demonstrated training and experience in the assessment, evaluation, and care of normal newborns, physically present at all times.

(B) Adequate numbers of RNs with competence in Level I care criteria and ability to stabilize and make preparations to transfer high-risk neonates who exceed Level I care criteria, readily available at all times.

(C) Nursing care under the leadership of a RN.

(D) All nursing staff formally trained, certified, and competent in NRP.

(E) Each delivering facility shall have a written plan for ensuring registered nurse-patient ratios as per Guidelines for Perinatal Care, or Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) Guidelines for Professional Registered Nurse Staffing for Perinatal Units.

(3) NRP trained professionals readily available at all times to the delivery and neonatal units.

(4) Pharmaceutical services in accordance with 410 IAC 15-1.5-7.

(5) Blood bank technicians readily available at all times.

(6) A radiologic technician readily available at all times to perform portable x-rays.

(7) The hospital shall provide lactation support for the care of mothers and newborns per AWHONN and International Board Certified Lactation Consultant Staffing Recommendations for Inpatient Setting Association (ILCA) recommendations on number of full-time equivalents per number of annual deliveries, based on the level of care at which the hospital is certified.

(Indiana Department of Health; 410 IAC 39-5-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-5-2 Neonatal Level II facility requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. (a) A Neonatal Level II facility is a Neonatal Level I facility plus the ability to provide specialty care for infants born at thirty-two (32) weeks gestation or more and weighing one thousand five hundred (1,500) grams or more at birth who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis. Level II facilities can stabilize ill newborn infants who are born at less than thirty-two (32) weeks gestation until they can be transferred to a facility where the appropriate level of neonatal care is provided. In addition to the requirements of a Neonatal Level I facility, a Neonatal Level II facility shall meet the requirements set forth in this

section.

(b) A Neonatal Level II facility shall demonstrate as follows its capability of providing neonatal care through written standards, protocols, guidelines, and training, including (Neonatal Level I plus the following):

(1) Each Neonatal Level II facility shall have the following facility capabilities:

(A) Provide care for infants convalescing after intensive care.

(B) Accept risk-appropriate neonatal transports.

(C) Provide either:

(i) mechanical ventilation for brief duration (less than twenty-four (24) hours);

(ii) continuous positive airway pressure (CPAP); or

(iii) both.

(2) Each Neonatal Level II facility shall have the equipment necessary to provide CPAP or mechanical ventilation.

(3) The medication requirements for Neonatal Level II are the same as for Neonatal Level I.

(4) Each Neonatal Level II facility shall have a written plan for accepting neonates as back transports for ongoing convalescent care, including accepting patient information on the required case.

(c) Each Neonatal Level II facility shall ensure the following staffing requirements are met, including (Neonatal Level I plus the following):

(1) Physician services, as follows:

(A) Provider board certified in pediatrics or in neonatal-perinatal medicine shall be a member of the medical staff, have privileges for neonatal care, and have responsibility for neonatal unit services.

(B) The hospital shall have consulting relationships in place with a pediatric cardiologist, a surgeon, and an ophthalmologist who has experience and expertise in neonatal retinal examination.

(2) Nursing services, as follows:

(A) Nursing care shall be under the leadership of a registered nurse (RN) with demonstrated expertise in perinatal care.

(B) RN skilled in the recognition and nursing management of the neonate with complications readily available at all times.

(3) Care of newborn infants at high risk shall be provided by appropriately qualified personnel including pediatricians, neonatologists, pediatric hospitalists, or advance practice providers. This specialized personnel shall be physically present at all times when an infant is maintained on a ventilator.

(4) Personnel, such as physicians, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians, readily available at all times to provide ongoing care and to address emergencies.

(5) Respiratory therapist experienced in the delivery of CPAP, mechanical ventilation, or both, readily available at all times.

(Indiana Department of Health; 410 IAC 39-5-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-5-3 Neonatal Level III facility requirements

Authority: IC 16-21-13-5

Affected: IC 16-21-13

Sec. 3. (a) A Neonatal Level III facility is a Neonatal Level II facility plus the ability to provide acute and comprehensive neonatal intensive care for infants who are born at less than thirty-two (32) weeks gestation or less than one thousand five hundred (1,500) grams at birth or have medical or surgical conditions regardless of gestational age. In addition to the requirements of a Neonatal Level II facility, a Neonatal Level III facility shall meet the requirements set forth in this section.

(b) A Neonatal Level III facility shall demonstrate as follows its capability of providing neonatal care through written standards, protocols, guidelines, and training, including (Neonatal Level II plus the following):

(1) Each Neonatal Level III facility shall have the following facility capabilities:

(A) Provide sustained neonatal life support.

(B) Pediatric ophthalmology services for the monitoring of ROP. The facility shall have an organized program for or consultative agreement for the treatment and follow-up of ROP that incorporates neonatal risks and benefits with the provision of care.

(C) Pediatric surgical specialists (including anesthesiologists with pediatric experience) readily available at all times, or at another facility through prearranged consultative agreement, and shall perform all procedures in newborn infants

within a time interval that incorporates neonatal risks and benefits with the provision of emergency care.

(D) Pediatric medical subspecialty services must be provided onsite or through prearranged consultative agreement, which allows for emergency transport between institutions within a time interval that incorporates neonatal risks and benefits with the provision of emergency care.

(E) Capability to perform major surgery onsite or through a prearranged consultative agreement with a risk appropriate institution.

(2) Each Neonatal Level III facility shall obtain and maintain current equipment and technology, including, but not limited to, the following:

(A) Advanced imaging with interpretation on an urgent basis, including, but not limited to, computed tomography (CT), magnetic resonance imaging (MRI), and echocardiography.

(B) Provide a full range of evidence-based respiratory support for periods longer than twenty-four (24) hours.

(3) Each Neonatal Level III facility shall have medications required to support care of the Level III neonate.

(4) Each Neonatal Level III facility shall establish and maintain the following policies and procedures:

(A) Written plan for accepting or transferring neonates as back transports for ongoing convalescent care. Back transport needs to be done in consultation with the referring physician.

(B) Prearranged written plan with a neurodevelopmental follow-up clinic or neurodevelopmental practice.

(c) Each Neonatal Level III facility shall ensure the following staffing requirements are met, including (Neonatal Level II plus the following):

(1) Physician services, as follows:

(A) Director of the neonatal intensive care unit (NICU) shall be a full-time, board certified neonatologist.

(B) A pediatrician who has completed pediatric residency training, or an advance practice provider with adequate NICU training and experience, with privileges for neonatal care appropriate to the level of the nursery, shall be physically present at all times.

(C) A neonatologist shall be readily available at all times.

(2) Nursing services, as follows:

(A) All nurses working with neonates at high risk shall have evidence of continuing education in neonatal nursing and special training and experience in the management of neonates with complex illnesses and neonatal complications.

(B) Adequate numbers of nursing leaders and registered nurses (RNs) with competence in Level III care criteria and ability to stabilize and make preparations to transfer high-risk neonates who exceed Level III care criteria, readily available at all times.

(C) A director of perinatal nursing services, master's prepared or actively seeking a master's degree, who has overall responsibility for inpatient activities in the neonatal area. This RN shall have demonstrated expertise in perinatal care as well as in the care of patients at high risk.

(D) A RN who is master's prepared or actively seeking a master's degree shall coordinate education.

(3) Respiratory therapists who can supervise the assisted ventilation of newborn infants physically present at all times.

(4) Pharmacy personnel with pediatric expertise who can work to continually review their systems and processes of medication administration to ensure that patient care policies are maintained.

(5) Physical therapist or occupational therapist with additional continuing education units in the area of neonatal care, as a member of the interdisciplinary care team.

(6) Speech therapist, with additional continuing education units in the area of neonatal care, as a member of the interdisciplinary care team.

(7) At least one (1) registered dietitian or nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of neonates at high risk.

(8) Social services, pastoral care, and bereavement service provided as appropriate to meet the needs of the population served.

(Indiana Department of Health; 410 IAC 39-5-3; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-5-4 Neonatal Level IV facility requirements

Authority: IC 16-21-13-5

Affected: IC 16-21-13

Sec. 4. (a) A Neonatal Level IV facility is a Neonatal Level III facility plus the ability to provide comprehensive subspecialty neonatal care services, including acute neonatal intensive care for infants of all birth weights and gestational ages, and neonatologists who assist in the management of fetuses who are extremely premature or have complex problems that render significant risk of preterm delivery and postnatal complications. In addition to the requirements of a Neonatal Level III facility, a Neonatal Level IV facility shall meet the requirements set forth in this section.

(b) A Neonatal Level IV facility shall demonstrate as follows its capability of providing neonatal care through written standards, protocols, guidelines, and training, including (Neonatal Level III plus the following):

(1) Each Neonatal Level IV facility shall have the following facility capabilities:

(A) Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions.

(B) Facilitate transport and provide outreach education.

(C) Managing all neonatal patients including those requiring advanced modes of neonatal ventilation and life support.

(D) Pediatric medical subspecialty services.

(E) Pediatric subspecialty surgical services such as pediatric cardio-thoracic open-heart surgery and pediatric neurosurgery within the institution.

(F) A neurodevelopmental follow-up clinic or practice.

(2) Each Neonatal Level IV facility shall have all equipment required to provide advanced modes of neonatal ventilation and life support, including, but not limited to, the following:

(A) High frequency ventilation.

(B) Inhaled nitric oxide.

(C) Extracorporeal membrane oxygenation (ECMO).

(3) The medication requirements for Neonatal Level IV are the same as Neonatal Level III.

(4) The policies and procedures requirements for Neonatal Level IV are the same as Neonatal Level III.

(c) Each Neonatal Level IV facility shall ensure the following staffing requirements are met, including (Neonatal Level III plus the following):

(1) Physician services, as follows:

(A) Maintain a full range of pediatric medical subspecialists, including pediatric cardio-thoracic open-heart surgery and pediatric neurosurgery, and pediatric anesthesiologists at the site.

(B) Pediatric medical and pediatric surgical specialty consultants readily available at all times.

(2) Nursing services, as follows:

(A) Adequate numbers of registered nurses (RNs) who have experience in the care of newborns with complex medical illnesses, including competence in Neonatal Level IV care criteria, readily available at all times.

(B) An advanced practice RN shall be available to the staff for consultation, education, and support on nursing care issues.

(3) A pediatric cardiac catheterization laboratory and appropriate staff.

(Indiana Department of Health; 410 IAC 39-5-4; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 6. Obstetrical and Neonatal Universal Standards

410 IAC 39-6-1 Laboratory requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. Each delivering facility shall meet the following requirements for laboratory capacity:

(1) The programmatic leaders of the perinatal service, in conjunction with the hospital laboratory leaders, shall ensure appropriate processing and reporting times for samples drawn from obstetric and neonatal patients with specific consideration for the acuity of the patient and the integrity of the samples.

(2) The hospital laboratory shall demonstrate the capability to immediately receive, process, and report urgent and emergent obstetric and neonatal laboratory requests.

(3) The hospital laboratory shall have a process in place to report critical results to the obstetric and neonatal services.

(4) The hospital shall have available the equipment and trained personnel to perform newborn screening prior to discharge on all infants born at or transferred to the institution, as required by the department.

(5) The hospital shall have molecular, cytogenic, and biochemical genetic testing available or a written policy for consultation and referral in place.

(Indiana Department of Health; 410 IAC 39-6-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-6-2 Education requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. (a) Each delivering facility shall have identified minimum competencies for perinatal clinical staff, not otherwise credentialed, assessed prior to independent practice and on a regular basis thereafter.

(b) At a minimum annually, each delivering facility shall provide continuing education programs for physicians, nurses, and ancillary members of the perinatal team concerning the treatment and care of perinatal patients in the following areas:

(1) Conduct team training in perinatal areas to teach staff to work together and communicate effectively.

(2) Lactation and breastfeeding education for all members of the perinatal team.

(3) Conduct clinical drills to help staff prepare for high-risk, high complexity events with low rate of occurrence. Examples include, but are not limited to, shoulder dystocia, emergency cesarean delivery, maternal hemorrhage, and neonatal resuscitation.

(4) Conduct drill debriefings to evaluate team performance and identify areas for improvement for high-risk events.

(5) Educate nurses, residents, nurse midwives, and delivering physicians to use standardized terminology to communicate all categories of fetal heart rate monitor tracings.

(6) Identify specific triggers for responding to changes in the vital signs and clinical condition of the mother, fetus, and newborn, and develop and use protocols and drills for responding to changes such as preeclampsia, hemorrhage, or neonatal shock.

(Indiana Department of Health; 410 IAC 39-6-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-6-3 Staffing requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 3. Each delivering facility shall have a written plan for ensuring registered nurse-patient ratios as per Guidelines for Perinatal Care, or Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) Guidelines for Professional Registered Nurse Staffing for Perinatal Units. *(Indiana Department of Health; 410 IAC 39-6-3; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-6-4 Performance improvement requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 4. Each delivering facility shall meet the following requirements for performance improvement:

(1) Have a multidisciplinary continuous quality improvement program for improving maternal and neonatal health outcomes that has initiatives to promote patient safety including, but not limited to, the following:

(A) Safe medication practices.

(B) Universal protocol to prevent procedural errors.
(C) Educational programs to improve communication and team work.
(2) Conduct internal perinatal case reviews that include all of the following:
(A) Maternal deaths.
(B) Intrapartum fetal and neonatal deaths.
(C) Maternal and neonatal transports.
(3) Utilize a multidisciplinary forum to conduct periodic performance reviews of perinatal programs. This review shall include the following:
(A) A review of the following:
(i) Trends.
(ii) Deaths.
(iii) Transfers.
(iv) Very low birth weight infants.
(B) Problem identification and solutions.
(C) Issues identified from the quality management process.
(D) Systems issues.

(Indiana Department of Health; 410 IAC 39-6-4; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-6-5 Written policy and procedural requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 5. Each delivering facility shall establish and maintain the following written policies, protocols, or plans:
(1) Initial stabilization and continuing care of all obstetrical and neonatal patients appropriate to the level of care rendered at its facility.
(2) Obstetrical and neonatal resuscitation protocols.
(3) Medical staff credentialing process shall include documentation of competency to perform obstetrical and neonatal invasive procedures appropriate to its certified level of care.
(4) Plan for accepting or transferring mothers or neonates as "back transports" for ongoing convalescent care, including criteria for accepting the patient and necessary patient information.
(5) Policies that allow families, including siblings, to be together in the hospital following the birth of an infant and that promote parental involvement in the care of the neonate including care of the neonate in the neonatal intensive care unit (NICU).
(6) Appropriate newborn screening program in place according to federal and state law.
(7) Policies and protocols to address emergency preparedness for the obstetric and neonatal areas.
(8) Policies and procedures on local anesthesia.

(Indiana Department of Health; 410 IAC 39-6-5; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-6-6 Reporting requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 6. Each delivering facility shall submit data to the department or its designee as requested by the department. *(Indiana Department of Health; 410 IAC 39-6-6; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

Rule 7. Transport Requirements

410 IAC 39-7-1 Interhospital transfer requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. (a) Facilities who provide maternal-fetal or neonatal transport services must be certified as a Level III or Level IV facility for the patient population they wish to transfer.

(b) Facilities that own or contract for maternal-fetal transport services must comply with the Indiana emergency medical services commission rules on emergency medical services and the Indiana Perinatal Transport Standards issued by the Indiana Perinatal Quality Improvement Collaborative (IPQIC) dated October, 2018.

(c) Facilities that own or contract for neonatal transport services must comply with the Indiana emergency medical services commission rules on emergency medical services and the Indiana Perinatal Transport Standards issued by the Indiana Perinatal Quality Improvement Collaborative (IPQIC) dated October, 2018.

(d) Facilities that own or contract for perinatal transfer services shall participate in data collection with the Ground and Air Medical Quality in Transport (GAMUT) national database. *(Indiana Department of Health; 410 IAC 39-7-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-7-2 Receiving hospital requirements

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. A delivering facility that accepts maternal primary transports, neonatal primary transports, or both, shall provide the following to the referring hospital and providers:

(1) Guidance on indications for consultation and referral of patients at high risk.

(2) Information about alternative sources for specialized care not provided by the accepting hospital.

(3) Guidance on the pre-transport stabilization of patients.

(4) Feedback on the pre-transport care of patients.

(5) A process in place for communication between sending and receiving personnel, which may include updates on ongoing care, discharge planning, or the need for future referrals and follow-ups.

(6) Once the patient has reached the receiving hospital, information regarding the patient's condition, and care given during transport, shall be communicated to the referring provider and referring hospital staff.

(Indiana Department of Health; 410 IAC 39-7-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 8. Perinatal Centers

410 IAC 39-8-1	Qualifications for perinatal centers
410 IAC 39-8-2	Perinatal collaboration
410 IAC 39-8-3	Training for affiliate hospitals
410 IAC 39-8-4	Quality assurance
410 IAC 39-8-5	Support services
410 IAC 39-8-6	Back transport
410 IAC 39-8-7	Neonatal intensive care unit transition and developmental follow-up
410 IAC 39-8-8	Memorandum of understanding between perinatal center and affiliate hospitals

410 IAC 39-8-1 Qualifications for perinatal centers

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. (a) The purpose of perinatal centers is to coordinate perinatal care throughout the state by affiliating with delivering facilities. Perinatal centers will work with affiliate hospitals by providing the following:

(1) Training.

(2) Quality assurance review.

(3) Facilitation of transport of mother and newborn.
(4) Other support services as necessary.
(b) A hospital must meet the following certification criteria to be a perinatal center:
(1) Obstetric Level III facility or Obstetric Level IV facility, and either a:
(A) Neonatal Level III facility; or
(B) Neonatal Level IV facility.
(c) In addition to the requirements set forth in subsection (a), the hospital must have the following capacity to be a perinatal center:
(1) A maternal-fetal medicine (MFM) specialist readily available at all times for onsite consultation and management with full privileges.
(2) Director of obstetric service is board certified in MFM or obstetrician-gynecologist (OB-GYN) with expertise in critical care obstetrics.
(3) An advanced practice registered nurse shall be available to the staff for consultation, education, and support on nursing care issues.
(Indiana Department of Health; 410 IAC 39-8-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-8-2 Perinatal collaboration
Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 2. (a) Each perinatal center shall annually engage in a minimum of two (2) efforts sponsored by the department supporting improved outcomes for pregnant women and newborns.
(b) At least annually, perinatal centers and their affiliates shall review quality metrics recommended by the department and review and revise programs and activities to improve outcomes for pregnant women and newborns. *(Indiana Department of Health; 410 IAC 39-8-2; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-8-3 Training for affiliate hospitals
Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 3. Perinatal centers shall provide clinical training to address affiliate needs that augment routine training as outlined by the department, including the following:
(1) Obstetric training including fetal heart rate monitoring.
(2) Neonatal training including the following:
(A) Neonatal Resuscitation Program (NRP).
(B) Post-resuscitation and pre-transport stabilization care of sick infants.
(3) Universal training including the following:
(A) Discharge planning.
(B) Identification of high risk patients and appropriate transfer.
(C) Development of shared protocols with obstetrics and neonatology including the following:
(i) Perinatal hospice and bereavement.
(ii) Transport.
(iii) Safe sleep.
(iv) Car seat safety.
(v) Communication and patient safety.
(vi) Other topics that are jointly identified.
(Indiana Department of Health; 410 IAC 39-8-3; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-8-4 Quality assurance

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 4. In addition to data collected on birth and death certificates, perinatal centers will review and analyze quality metrics recommended by the department with their affiliates for identification of quality improvement initiatives. *(Indiana Department of Health; 410 IAC 39-8-4; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-8-5 Support services

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 5. Delivering facilities serving as perinatal centers shall provide the following support to affiliate hospitals at all times:
(1) Maternal-fetal medicine (MFM) specialist consultation by phone or telemedicine.
(2) Maternal-fetal transport including a reliable and comprehensive communication system to initiate transport.
(3) Communication with the discharging obstetrician-gynecologist (OB-GYN) or MFM specialist, and the referring OB-GYN or family medicine physician regarding the outcome of pregnancy, recommendations for postdelivery care or continued interpregnancy care, and management of the next pregnancy including, when appropriate, birth spacing.
(4) Neonatal consultation by phone or telemedicine.
(5) Neonatal transport, including a reliable and comprehensive communication system to initiate transport.
(6) Developmental follow-up program for high-risk newborns.

(Indiana Department of Health; 410 IAC 39-8-5; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-8-6 Back transport

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 6. Perinatal centers shall make every effort to transfer maternal-fetal or neonatal patients back to the affiliate hospital when risk appropriate and by mutual agreement with the affiliate hospital and family. *(Indiana Department of Health; 410 IAC 39-8-6; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

410 IAC 39-8-7 Neonatal intensive care unit transition and developmental follow-up

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 7. Perinatal centers shall support the following services:
(1) Retinopathy of prematurity screening.
(2) Assistance to affiliate hospitals in accessing subspecialty care as needed.
(3) Work with affiliate hospitals and primary care providers to establish medical homes to coordinate ongoing well child care.
(4) Implementation of a developmental follow-up screening program, with the following requirements:
    (A) Perinatal centers shall use a valid and reliable standardized screening tool.
    (B) The tool shall be administered at recommended intervals.
    (C) The developmental follow-up screening program shall serve high-risk infants including, but not limited to, those with the following conditions:
        (i) Newborns weighing less than or equal to one thousand five hundred (1,500) grams at birth.
        (ii) Hypoxic-ischemic encephalopathy (HIE).
        (iii) Neonatal seizures.
        (iv) Hypoxic cardiorespiratory failure.
        (v) Complex, multiple congenital anomalies.
        (vi) Neonatal abstinence syndrome (NAS).

(vii) All other high-risk infants with additional diagnoses at the discretion of the center.

(Indiana Department of Health; 410 IAC 39-8-7; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

410 IAC 39-8-8 Memorandum of understanding between perinatal center and affiliate hospitals

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 8. (a) Any facility not certified by the department as a perinatal center shall affiliate with a perinatal center. The department shall notify facilities when all initial perinatal centers have been certified. Facilities not certified by the department as perinatal centers will have twelve (12) months from notification to enter into a memorandum of understanding with a certified perinatal center.

(b) Nonperinatal centers may affiliate with only one (1) perinatal center.

(c) Every perinatal center shall affiliate with at least one (1) hospital outside of its own network, unless none are available.

(d) The department will assign unaffiliated hospitals to perinatal centers as needed.

(e) Each perinatal center and its affiliate hospitals shall enter into an agreement that defines the responsibilities of each partner as follows:

(1) Each perinatal center shall have the following responsibilities:

(A) Training to affiliates as specified in section 1 of this rule.

(B) Support services to affiliates as specified in section 1 of this rule.

(C) Sponsor and coordinate visits to affiliate hospitals related to outcomes and quality assurance at least annually.

(D) Support for transition of patients from perinatal specialty care to primary physician.

(2) Each affiliate hospital shall have the following responsibilities:

(A) Compliance with perinatal levels of care rules.

(B) Collection of quality improvement data.

(C) Attendance and participation in perinatal center and affiliate meetings.

(D) Collaboration with the perinatal center and provision of data for annual visit to evaluate outcomes.

(E) Collaboration with the perinatal center related to transition home and back transport of shared patients.

(Indiana Department of Health; 410 IAC 39-8-8; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)

Rule 9. Matters Incorporated by Reference

410 IAC 39-9-1 Matters incorporated by reference

410 IAC 39-9-1 Matters incorporated by reference

Authority: IC 16-21-13-5
Affected: IC 16-21-13

Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed and are hereby incorporated by reference:

(1) Indiana Perinatal Quality Improvement Collaborative (IPQIC), Indiana Perinatal Transport Standards (October 2018 Edition) available at: https://www.in.gov/laboroflove/files/perinatal-transport-guidelines-12-18.pdf.

(2) Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), Guidelines for Professional Registered Nurse Staffing for Perinatal Units (2010 Edition) available at: https://www.awhonn.org/.

(3) United States Lactation Consultant Association, International Board Certified Lactation Consultant Staffing Recommendations for the Inpatient Setting (July 2010) available at: https://uscla.org/.

(b) Documents incorporated by reference do not include any later amendments or editions than those specified in the incorporation citation. Documents incorporated by reference are available for review at the department at 2 North Meridian Street, Indianapolis, Indiana 46204. *(Indiana Department of Health; 410 IAC 39-9-1; filed Aug 14, 2019, 3:32 p.m.: 20190911-IR-410180416FRA)*

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