

## **Summary of Changes LSA #18-416**

The following identifies the changes between the proposed rule and final rule based on public comment for LSA #18-416. Comment reference numbers refer to the number on the summary of comments and agency response documents. Changes in text are noted in red.

### **410 IAC 39-1-19 and 410 IAC 39-4-1(b)(1)(F)**

**Proposed Rule language:** 410 IAC 39-1-19: "Physically present at all times" means onsite in the building where the perinatal care is provided, twenty-four (24) hours a day, seven (7) days a week.

410 IAC 39-4-1(b)(1)(F) - (1) Each Obstetric Level I facility shall have all of the following facility capabilities:

(F) Hospitals offering a trial of labor for patients with a prior cesarean delivery shall have appropriate facilities and personnel physically present 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).

**Comment #7:** IHA requests further clarification on the definition of physically present at all times. The unique nature of hospital buildings and campuses creates an environment where a provider can be in close proximity of the patient while not being physically located in the same building with the L&D department. IHA would suggest physically present extend to all buildings located immediately adjacent to the main hospital building in which the L&D services are provided.

**Comment #24:** Complying with this rule will limit the ability of Level 1 to do TOLAC even though the provider could be located in close proximity – just not “in the building”. This rule could potentially increase repeat cesarean section rates and/or cause women to unnecessarily travel greater distances to find a facility that meets this criteria. ACOG states in its Practice Bulletin Number 184, published in November 2017 that a provider should be readily available as opposed to physically on site. (There are several similar comments on this topic).

**Change:** ISDH reviewed the definition of “physically present at all times” and its uses in the rule. ISDH is changing the rule by expanding “physically present at all times” to include buildings attached to the building where the care is provided. Additionally, ISDH created a new definition “immediately available at all times” that allows for providers to also be located in adjacent buildings. ISDH also removed the phrase “immediately” from another location so there would not be confusion with the new definition. SDH updated the requirements as described below.

**Immediately available at all times:**

- Obstetric Level I – appropriate personnel for trial of labor with prior cesarean
- Obstetric Level II – blood bank technicians
- Obstetric Level III – Critical care specialists

Physically present at all times:

- Obstetric Level III
  - Obstetrician-gynecologist (OB-GYN)
  - Anesthesia services
- Neonatal Level I – Registered Nurse with demonstrated training and experience
- Neonatal Level II – Specialized personnel when infant is maintained on a ventilator
- Neonatal Level III
  - Pediatrician or advance practice nurse meeting the requirements of the rule
  - Respiratory therapists who can supervise the assisted ventilation of newborn infants

New rule language:

410 IAC 39-1-8 (new addition): “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.

410 IAC 39-1-19: "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.

410 IAC 39-4-1(b)(1)(F): (1) Each Obstetric Level I facility shall have all of the following facility capabilities:

(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).

410 IAC 39-4-2(c)(4): (c) Each Obstetric Level II facility shall ensure the following staffing requirements are met (Obstetric Level I plus the following):

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

410 IAC 39-4-3(b)(1): (1) Each Obstetric Level III facility shall have all of the following facility capabilities:

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

410 IAC 39-5-1(b)(3)(C) - (3) Each Neonatal Level I facility shall have the following medications:

(C) Emergency medications, as listed in the NRP, shall be available in the delivery area and neonatal units.

**410 IAC 39-2-2**

**Proposed Rule language:** Sec. 2. A hospital shall notify the department 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.

**Comment #13:** Clarification: When a facility “OB unit or NICU, or both, has physical changes made; or changes in administration; we need to notify the department”

- a. How do we inform the dept.: email, fill out a form on the ISDH website?
- b. is this labor and delivery and/or NICU units, does this include Mother-baby (postpartum) units

**Change:** Add an email address to the notification requirement.

**New rule language:**

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

#### **410 IAC 39-3-1(c)(3)**

**Proposed Rule language:** (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 transfer high-risk women and newborns.

**Comment #15:** Rule insert "Make preparations to transfer"

**Change:** Change the language to “make preparations to transfer” in 410 IAC 39-3-1 and throughout rule for consistency.

**New rule language:**

410 IAC 39-3-1(c) - (c) Each birth center shall ensure the following staffing requirements are met:

- (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.

410 IAC 39-4-1(c)(2)(A) - (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.

410 IAC 39-4-2 (c)(2)(B) - (2) Nursing services, as follows:

(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.

410 IAC 39-4-3(c)(2)(D) - (2) Nursing services, as follows:

(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.

410 IAC 39-5-1(c)(2)(B) - (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.

410 IAC 39-5-3(c)(2)(B) - (2) Nursing services, as follows:

(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.

#### **410 IAC 39-4-1(b)(1)(E)**

**Proposed Rule language:** (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:

(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, and either ABO-Rh-specific or O-Rh-negative blood and fresh frozen plasma and cryoprecipitate at the facility at all times.

**Comment #18:** Suggest clarifying whether the section regarding blood requirements is an either/or statement or an either/ and. Making the last line a sub-bullet would make this more clear. If this is an either/ and statement, there is concern with smaller facilities maintaining FFP at all times due to expiration and low usage rates. IHA would recommend allowing facilities to maintain blood components appropriate to the usage and type of patients served.

**Change:** Make the requirements a clear list to show that it is an “and” requirement.

#### **New rule language:**

410 IAC 39-4-1(b)(1)(E) - (1) Each Obstetric Level I facility shall have all of the following facility capabilities:

(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.

#### **410 IAC 39-4-1(c)(2)(F)**

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

(2) Nursing services, as follows:

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

**Comment #25:** The lack of reference to “postpartum” in nursing services which is inconsistent with the rest of the rule.

**Change:** Add “postpartum”.

#### **New rule language:**

410 IAC 39-4-1(c)(2)(F) - (2) Nursing services, as follows:

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

#### **410 IAC 39-4-2**

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

(4) Registered pharmacist readily available at all times.

**Comment #27:** We ask for further definition and consideration of the term “readily available” as it applies to this rule. Is the definition of “readily available” appropriate for pharmacy coverage? Is it essential to have a pharmacist physically present or is the rule there to be able to meet the patients’ medication needs? Courier services make medications available without having a pharmacist onsite.

Can this be added to section 410 IAC 39-4-2-c1(F) as Pharmacist available at all times for consultation as is MFM and anesthesia.

Many smaller facilities do not have coverage all the time but have created solutions to meet the patients’ needs. While wanting always to provide top care within these facilities, costs associated with that care needs consideration. The additional coverage required could result in having fewer facilities able to offer care at the level II.

**Change:** Remove the pharmacist requirement from Level II requirements. Also update the Level I requirements to match general hospital licensure requirements.

#### **New rule language:**

410 IAC 39-4-2(c)(4) - (c) Each Obstetric Level II facility shall ensure the following staffing requirements are met (Obstetric Level I plus the following):

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

(4) Blood bank technicians who are physically present at all times.

410 IAC 39-4-1(c)(6) - Each Obstetric Level I facility shall ensure the following staffing requirements are met:

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

410 IAC 39-5-1(c)(4) - (c) Each Neonatal Level I facility shall ensure the following staffing requirements are met:

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

### **410 IAC 39-4-3(c)(1)(B)**

**Proposed Rule language:** (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:

(B) MFM specialist readily available at all times.

**Comment #34 (represents several similar comments):** The Guidelines for Perinatal Care provided by the AAP and the American College of Obstetricians and Gynecologists lists in Table 1-2 of Chapter 1 that MFMs are to be available at all times onsite, defined as by telephone, or by tele-medicine with inpatient privileges. The Indiana state department of health defines “Readily available” to require MFM services to be available 24 (twenty-four) hours a day, 7 (seven) days a week for consultation and assistance, and able to be physically present onsite within a timeframe that incorporates maternal and newborn risks and benefits with the provision of care. This was a change from the previous standard available prior to the final rules stated (in regard to MFM coverage) which said:” a provider (or providers) board certified or board eligible in maternal-fetal medicine shall be: Available at all times onsite, by phone or by telemedicine with inpatient privileges.” The final rule changes this definition and in doing so, is no longer congruent with the published Guidelines for Perinatal Care.

**Change:** The MFM will only be required to be available onsite, by phone, or by telemedicine for Level III. The Level IV requirement will updated to require the MFM to be readily available. The proposed rule draft required this standard for Level IV facilities because it incorporated the Level III requirements, so this change is needed to maintain the Level IV standard.

### **New rule language:**

410 IAC 39-4-3(c)(1)(B) - (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:

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

410 IAC 39-4-4(c)(1)(C) - (1) Each Obstetric Level IV facility shall have all of the following facility capabilities:

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

### **410 IAC 39-5-1(c)(1)**

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

(1) Pediatricians, family physicians, nurse practitioners, or other advanced practice nurses readily available at all times.

**Comment #52 (similar to another comment):** We note inconsistency in the required staffing under neonatal services. One section suggests a pediatrician, or ‘nurse practitioner’ NP. Later in the neonatal services section it refers to a “neonatal nurse practitioner”.

**Change:** Will change that section and others for consistency to “advance practice provider”.

**New rule language:**

410 IAC 39-5-1(c)(1) – (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.

410 IAC 39-5-2(c)(3) - (c) Each Neonatal Level II facility shall ensure the following staffing requirements are met, including (Neonatal Level I plus the following):

(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.

410 IAC 39-5-3(c)(1)(B) - (c) Each Neonatal Level III facility shall ensure the following staffing requirements are met, including (Neonatal Level II plus the following):

(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.

**410 IAC 39-5-1(c)**

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

(1) Pediatricians, family physicians, nurse practitioners, or other advanced practice nurses 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 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) Registered pharmacist available at all times for consultation.

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

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

**Comment #51:** "Add Lactation Consultants to the list of personnel "

Human milk use often requires support from trained, certified lactation consultants;

**Change:** Added the certified lactation consultants to the list.

**New rule language:**

410 IAC 39-5-1(c)(7) - (c) Each Neonatal Level I facility shall ensure the following staffing requirements are met:

(1) Pediatricians, family physicians, nurse practitioners, or other advanced practice nurses 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 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) Registered pharmacist available at all times for consultation.

(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.

**410 IAC 39-5-2(b)(1)(C)**

**Proposed Rule language:** (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:

(C) Provide mechanical ventilation for brief duration (less than twenty-four (24) hours) or continuous positive airway pressure (CPAP), or both.

**Comment #54 (similar to another comment):** I have a question about the Levels of Care Rules. We have people interpreting the following statement for Level II neonatal services differently: "Provide mechanical ventilation for brief duration (less than 24 hours) or continuous positive airway pressure, or both."

Some interpret that to mean that we can't provide either CPAP or mechanical ventilation for greater than 24 hours and others interpret it to mean that you can't provide mechanical ventilation for longer than 24 hours but you can CPAP.

**Change:** Will change the layout of the clause for clarity.

**New rule language:**

**410 IAC 39-5-2(b)(1)(C)** - (1) Each Neonatal Level II facility shall have the following facility capabilities:

(C) Provide either:

- (i) mechanical ventilation for brief duration (less than twenty-four (24) hours);
- (ii) continuous positive airway pressure (CPAP); or
- (iii) both.

**410 IAC 39-5-3(b)(4)(A)**

**Proposed Rule language:** (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):

(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 including accepting patient information on the required case.

**Comment #58:** Is phrase "including accepting patient information on the required case" needed  
Unclear rationale for inclusion

**Change:** Added language from the standard for clarification.

**New rule language:**

**410 IAC 39-5-3(b)(4)(A)** - (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.**

**410 IAC 39-5-3(b)(1)(C)**

**Proposed Rule language:** (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:

(C) Pediatric surgical specialists (including anesthesiologists with pediatric experience) readily available at all times 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.

**Comment #61:** Commenter questioned whether a pediatric surgical specialist was required to be at the hospital or whether a consultative agreement is sufficient for a Neonatal Level III.

**Change:** Update language for clarification that a consultative agreement is sufficient.

**New rule language:**

410 IAC 39-5-3(b)(1)(C) - (1) Each Neonatal Level III facility shall have the following facility capabilities:

(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.

**410 IAC 39-8-8(a)**

**Proposed Rule language:** (a) Any facility not certified by the department as a perinatal center shall affiliate with a perinatal center.

**Comment #73:** What do we anticipate the time line will be for application – as in Sec. 8. (b) - choosing 1 perinatal center to affiliate with will need to be a discussion – so is this something we anticipate will need to be decided at the time of application – and do Level 1 OB / Level 2 Neonatal have a year to apply after the Levels come into effect? Is that the time when the decision for perinatal center will need to be made? One of the issues will be the Perinatal Centers need to be designated first – for example – since we presently use both St Vincent’s Evansville and Deaconess for education and transfers, the rules presently say we will need to choose one for our Perinatal Center. We will not know who is designated until that process is complete on if one or both of these hospitals will be a Perinatal Center. Thank you for addressing this question/concern!

**Change:** Added new language to show a delay in the requirement for affiliation to allow for perinatal center certification and then additional time for facilities to enter into an agreement.

**New rule language:**

410 IAC 39-8-8(a) - (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.**

**410 IAC 39-8-8(c)**

**Proposed Rule language:** (c) Every perinatal center shall affiliate with at least one (1) hospital outside of its own network.

**Comment #74:** MOU’s Every PC shall affiliate with at least one hospital outside its network. (p.20)

This makes sense to increase support in a region, however as the landscape changes in the future, there will be fewer hospitals that remain independent. Will this wording jeopardize the status of a Center in the future if affiliates then become named members of the system? It really isn’t feasible to support a hospital more than 100 miles away from the center based on the

requirements of training, support, and transport of patients. For Centers that are not centrally located, much of the state is over 100 miles away. Some regions in Indiana have very few hospitals that are not already affiliated into systems. Will this be revised in the future, as the landscape evolves?

**Change:** Add language to be clear that the requirement will apply unless there are no non-network facilities available, but the change does not have a geographic limit.

**New rule language:**

410 IAC 39-8-8(c) - (c) Every perinatal center shall affiliate with at least one (1) hospital outside of its own network, **unless none are available**.

**410 IAC 39-8-1(b)**

**Proposed Rule language:** (b) A hospital must meet either of the following certification criteria to be a perinatal center:

- (1) Obstetric Level III facility, and either a:
  - (A) Neonatal Level III facility; or
  - (B) Neonatal Level IV facility.
- (2) Obstetric Level IV facility and a Neonatal Level IV facility.

**Comment #77:** I would recommend that the perinatal levels of care language reflect that hospitals with Level 3 or 4 OB units with Level 3 or 4 NICUs are able to apply to be a Perinatal Center.

**Change:** ISDH added Obstetric Level IV facility to the first subsection and removed the second subsection for clarity.

**New rule language:** (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.