

Comment #	Rule	Comment	Submitted	Discussion
1	General comment	There are multiple places in the proposed rule that use adjectives that are difficult to measure such as “skilled”, expertise, experience, adequate, adequate number, expertise in maternal and critical care”. We welcome the ability to interpret based upon professional judgement. However if the ISDH intends to validate, additional clarity will be required as interpretation of these words may vary.	Cindy Adams, PhD, RN, ANP-BC, NEA-BC System Chief Nursing Officer St. Vincent	RESPONSE: This language is offered in the <i>Guidelines for Perinatal Care, Eight Edition</i> and is, at times, intentionally vague to allow for flexibility and judgement by each delivering facility.  <i>NO CHANGE TO RULE LANGUAGE</i>
2	Repeated in Neo II oph., Neo III surgical	The term “prearranged consultative agreement” is used throughout the document, but it is not defined in the Proposed Rule. We recommend the Department clarify this term, and in so doing, define it to mean the contractual relationship between an affiliate hospital and perinatal center.	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	RESPONSE: The prearranged consultative agreement referred to throughout the rules <i>is not</i> the same as the memorandum of understanding between Perinatal Center and affiliate. The prearranged consultative agreement is an agreement entered into by two facilities where one offers consultation and/or services the other is unable to provide.  <i>NO CHANGE TO RULE LANGUAGE</i>
3	General comment	There is ambiguity throughout the Proposed Rule in terms and terminology. Examples include nursing staff versus all nursing staff, experts, expertise, and specialists, etc. The Department should provide consistency and/or definition for these terms/terminology.	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	RESPONSE: This language is offered in the <i>Guidelines for Perinatal Care, Eight Edition</i> and is, at times, intentionally vague to allow for some flexibility and judgement by each delivering facility.  <i>NO CHANGE TO RULE LANGUAGE</i>
4	General comment	The Levels of Care designation needs to include/ incorporate IPQIC’s Perinatal Substance Use Practice Bundle as part of the requirements for a given level. For example, for an OB unit to be Level 2 it should be required to fully implement this toolkit and provide this level of care for Moms/ neonates. This will off-set any disincentive to care for these patients for financial or medical/legal reasons. It would change the narrative to include Care for Maternal Substance Use Disorder as requisite for being a quality perinatal care institution. (?)	Rebecca Haak MD Hendricks GYN	RESPONSE: ISDH plans to offer a document of best practices guidelines. This document will encompass the PSU Toolkit and offer guidelines, but will not be added to the rule language. The IPQIC Perinatal Substance Use Practice Bundle is not part of the <i>Guidelines for Perinatal Care, Eight Edition</i> so it cannot be in the rule.  <i>NO CHANGE TO RULE LANGUAGE</i>

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5	410 IAC 39-1-2	<p>"Available at all times" means available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance.</p> <p><b>Comment</b> Please clarify and more clearly define this definition</p>	Deaconess The Women’s Hospital 4199 Gateway Blvd Newburgh, IN 47630	<p>RESPONSE: ISDH feels this term is well defined in the rules document, specifically in comparison to the definition of “readily available at all times” as well as “physically present at all times”.</p> <p>“Available at all times” is a person capable of offering consultation by telephone without parameters regarding physical availability onsite.</p> <p>“Readily available at all times” is a person capable of offering consultation who must also be obligated to come to the bedside as needed based on patient status and acuity.</p> <p>“Physically present at all times” is a person who remains onsite, inside the building where the care is provided to the patient, 24/7/365.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
6	410 IAC 39-1-5	<p>Per the Proposed Rule, “delivering facility” means any hospital that is either an obstetric unit intended to care for pregnant women or a neonatal unit intended to care for newborns.</p> <p>“Hospital” is defined as a hospital that is licensed under IC 16-21-2.</p> <p>Riley Hospital and IU Health Methodist are licensed under the same hospital license. For multiple hospitals that are under one license, we would suggest the “delivering facility” definition account for multiple hospitals that may be licensed under the same hospital license. As such, we recommend revising the definition of delivery facility as follows:</p> <p>“Delivering facility” means any hospital <b>or hospitals operating under a single license</b> that has/have either an obstetric unit intended to care</p>	Marissa G. Kiefer, MHA Vice President Riley Children’s Health	<p>RESPONSE: Delivering facility is not based on hospital licensure in the rule language. Each individual facility will require a separate application and level of care certification. There may be wide differences in the services offered among separate hospitals under the same licensure, which could lead to confusion and imbalance where certification is concerned. Each facility will be certified based on the scope of services provided.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		for pregnant women or a neonatal unit intended to care for newborns. (Emphasis added.)		
7	410 IAC 39-1-18	<p>“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.</p> <p><b>Comment</b> 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&amp;D department. IHA would suggest physically present extend to all buildings located immediately adjacent to the main hospital building in which the L&amp;D services are provided</p>	IHA	<p>RESPONSE: Thank you for your comment. The definition of physically present at all times will be edited to include a building connected the building where the perinatal care is provided. ISDH will also add a definition of “immediately available” that will include buildings that are adjacent to the building where services are provided.</p> <p><b><i>CHANGE TO RULE LANGUAGE:</i></b></p> <p><u>Rule 1, Section 8</u>                      “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.</p> <p><u>Rule 1, Section 18</u>                      “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, or in a building immediately adjacent to the building where the perinatal care is provided, twenty-four (24) hours a day, seven (7) days a week.</p> <p>List of other changes:  <u>Immediately available at all times:</u></p> <ul style="list-style-type: none"> <li>• Obstetric Level I – appropriate personnel for trial of labor with prior cesarean</li> <li>• Obstetric Level II – blood bank technicians</li> <li>• Obstetric Level III – Critical care specialists</li> </ul> <p><u>Physically present at all times:</u></p>

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				<ul style="list-style-type: none"> <li>• Obstetric Level III                             <ul style="list-style-type: none"> <li>○ Obstetrician-gynecologist (OB-GYN)</li> <li>○ Anesthesia services</li> </ul> </li> <li>• Neonatal Level I – Registered Nurse with demonstrated training and experience</li> <li>• Neonatal Level II – Specialized personnel when infant is maintained on a ventilator</li> <li>• Neonatal Level III                             <ul style="list-style-type: none"> <li>○ Pediatrician or advance practice nurse meeting the requirements of the rule</li> <li>○ Respiratory therapists who can supervise the assisted ventilation of newborn infants</li> </ul> </li> </ul>
8	410 IAC 39-1-19	<p>Sec. 2. "Available at all times" means available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance.</p> <p>Sec 19 "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.</p> <p><b>Comment</b> Please more clearly define the distinction between “available at all times” and “readily available at all time”.</p>	Deaconess The Women’s Hospital	<p>RESPONSE: ISDH feels this term is well defined in the rules document, specifically in comparison to the definition of “readily available at all times” as well as “physically present at all times”.</p> <p>“Available at all times” is a person capable of offering consultation by telephone without parameters regarding physical availability onsite.</p> <p>“Readily available at all times” is a person capable of offering consultation who must also be obligated to come to the bedside as needed based on patient status and acuity.</p> <p>“Physically present at all times” is a person who remains onsite, inside the building where the care is provided to the patient, 24/7/365.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
9	410 IAC 39-2-1	We are especially grateful to see a linkage between obstetric and neonatal levels. We feel that linking obstetric and neonatal levels of care is vitally important in protecting the health of both mom and baby."	March of Dimes, Jeena Seila	<p>RESPONSE: Thank you for your comment.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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10	410 IAC 39-2-1(b)	IU Health and Riley would urge the Department to clarify the timing and process for applying for a Perinatal Center designation as it unclear from the Proposed Rule the nature of those obligations. In addition, we would ask the Department to clarify the timing for submission when a hospital is applying for a split level designation.	Marissa G. Kiefer, MHA Vice President Riley Children’s Health	<p>RESPONSE: For facilities wishing to split levels, the application will be due based on the timeline in the rules document for the highest level of care the facility is applying for.</p> <p>ISDH will offer notification to delivering facilities once it is determined that initial applications for Perinatal Centers have been certified. Hospitals will be offered 12 months from that date to select a Perinatal Center and enter into a memorandum of understanding. The change to language is addressed in Comment #72.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
11	410 IAC 39-2-1(c)(3)	As hospitals go through the survey process, will areas of deficiency (those deemed non-critical) be given an opportunity to fix these deficiencies? Will there be action plans given with a timeframe to complete the action plan? Deaconess	Deaconess The Women’s Hospital	<p>RESPONSE: Certification will be determined based upon the services being offered at the time of the facility’s survey. The rule does not prohibit reapplication for a different level of care at any time. If the delivering facility has questions regarding compliance with a particular rule the team of chief nurse consultants are available for collaboration and discussion prior to application.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
12	410 IAC 39-2-1(f)(3)	<b>Comment</b> Can a facility submit for a higher level of designation at any time as well or do they have to wait 3 years to resubmit?	Deaconess The Women’s Hospital	<p>RESPONSE: The rule does not prohibit reapplication for a different level of care at any time.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
13	410 IAC 39-2-2	Clarification: When a facility “OB unit or NICU, or both, has physical changes made; or changes in administration; we need to notify the department” <ul style="list-style-type: none"> <li>a. How do we inform the dept.: email, fill out a form on the ISDH website?</li> <li>b. is this labor and delivery and/or NICU units, does this include Mother-baby (postpartum) units</li> </ul>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	<p>RESPONSE: Thank you for your comment. The department will alter the rule language to provide clarification. Notification to the department shall occur for any changes made within any perinatal area, including postpartum units.</p> <p><b><i>CHANGE TO RULE LANGUAGE:</i></b> <u>Rule 2, Section 2</u></p>

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				<p>“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:</p>
14	410 IAC 39-3-1(b)(2)	Rule 3 Sec 1b2: Guidance needed re: data elements required	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: The collection of these data elements will be determined by the individual birthing centers. This rule is not requiring specific data elements, it is requiring policies and procedures regarding data collection.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
15	<p>410 IAC 39-3-(1)(c)(3)</p> <p><b>Repeated</b> 410 IAC 39-4-1(c)(2)(A)</p> <p>410 IAC 39-4-2(c)(2)(B)</p>	Rule insert "Make preparations to transfer"	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: This language may have been taken to mean the facility would be the one actually completing the transfer, but they are not. The facility transferring out will only be preparing the patient for transfer, not actually transferring themselves. The department agrees this rule requires clarification and will make an alteration to the rules document.</p> <p><b><i>CHANGE TO RULE LANGUAGE:</i></b></p> <p><u>Rule 3, Section 1, c, 3</u> “Availability of adequate numbers of qualified professionals with competence in obstetric level one care criteria (as described in 410 IAC 39-4-1) and ability to stabilize and make preparations to transfer high risk women and newborns”</p> <p><u>Rule 4, Section 1, c, 2, A</u> “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.”</p> <p><u>Rule 4, Section 2, c, 2, B</u> “Adequate numbers of registered nurses with competence in Level II care criteria and ability to stabilize and make</p>

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				<p>preparations to transfer high risk women who exceed Level II care criteria, readily available at all times.”</p> <p><u>Rule 4, Section 3, c, 2, D</u>                      “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.”</p> <p><u>Rule 5, Section 1, c, 2, B</u>                      “Adequate numbers of RN’s 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”</p> <p><u>Rule 5, Section 3, c, 2, B</u>                      “Adequate numbers of nursing leaders and RNs with competency 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.”</p>
16	410 IAC 39-4-1(b)(1)(C)	Insert “and improve patient care” after safety	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: Thank you for your comment. This rule language is taken from the <i>Guidelines for Perinatal Care, Eighth Edition</i>.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
17	410 IAC 39-4-1(b)(1)(E)	(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.	Anna M. Telligman MSN, RN, CNML Director of OB/OR/2W Clinic Greene County General Hospital	<p>RESPONSE: The department supports the rule language as currently written in order to ensure all facilities have rapid availability of blood products to support massive transfusion and multiple blood component therapy. The surveyor team has worked with facilities that do not currently have cryoprecipitate and will continue connecting these hospitals with trauma centers or the</p>

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		<p>Our Rural Critical Access Hospital has access to RBCs only. We give FFP and cryoprecipitate so infrequently that the risk for the products expiring before use is very high (our lab director does not recall that we have transfused cryoprecipitate during her career here of over a decade). We have arrangements with other facilities to provide these products to us when needed.</p> <p>Please consider changing this requirement to having access to these products through MOUs with other facilities.</p>		<p>blood bank to ensure that cryoprecipitate is available at each facility at all times.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
18	410 IAC 39-4-1(b)(1)(E)	<p><b>Comment</b> 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.</p>	IHA	<p>RESPONSE: Thank you for your comment. The department plans to edit this rule to provide clarity.</p> <p><b><i>CHANGE TO RULE LANGUAGE:</i></b>  <u>Rule Section 1, b, 1, E</u>                      “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 at all times:                      (i) ABO-Rh specific or O-Rh negative blood; and                      (ii) fresh frozen plasma; and                      (iii) cryoprecipitate.”</p>
19	410 IAC 39-4-1(b)(1)(F) <b>6 comments</b>	<p>As a Level 1 OB/Level 2 Neonatal applicant, I would suggest the rule for TOLAC (Rule 4, Sec. 1(b)1.(F)(i) which states the provider to be “in the building” be changed “readily available at all times” or “immediately available upon request”. Complying with this rule will limit the</p>	Patty Scherle Director of Women and Infant Services Memorial Hospital and Health Care Center	<p>RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the Guidelines.</p>

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		<p>ability of Level 1 to do TOLAC even though the provider is immediately available or a half a block away – just not “in the building”. I think it is important to realize that in a Level 1 OB unit, the obstetrician in his office across the street is likely closer to the laboring patient than an obstetrician “in the building” in a larger medical center. This rule could potentially increase repeat cesarean section rates and/or limit access to care for those patients having to receive care from an OB Level 2/3 who chose to TOLAC which would be a distance for the patient to travel and defer them from the attempt.</p> <p>While referencing the ACOG Practice Bulletin Number 184, November 2017 it states “Trial of labor after previous cesarean delivery should be attempted at facilities capable of performing emergency deliveries. The American College of Obstetricians and Gynecologists and the Society for Maternal–Fetal Medicine’s jointly developed Obstetric Care Consensus document, <i>Levels of Maternal Care</i> (which introduced uniform designations for levels of maternal care), recommends that women attempting TOLAC should be cared for in a level I center (i.e., one that can provide basic care) or higher <sup>(151)</sup>. Level I facilities must have the ability to begin emergency cesarean delivery within a time interval that best considers maternal and fetal risks and benefits with the provision of emergency care <sup>(151)</sup>.”</p> <p>I feel the rule has put an added burden on Level 1 OB units. I would highly encourage the committee to revisit this rule and change the verbiage to</p>	<p>Jasper, IN 47546</p>	<p><b>CHANGE TO RULE LANGUAGE:</b> See comment #7</p>

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		immediately available upon request or readily available at all times. Thank you for considering.		
20	410 IAC 39-4-1(b)(1)(F)	<p>I would like to know if “present at all times” is interpreted as at the bedside, in the L&amp;D unit or can it be broader to include areas within the facility but in other areas like Postpartum, surgery. What about in the office that is in the same building or in a connecting building with a skywalk?</p> <p>Is this requirement the same for primary trials of labor patients, as well as, those that have already had one successful VBAC?</p>	Margaret A. Suozzi MSN, RN Director Women’s, Children’s & Medical Nursing Good Samaritan	<p>RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the Guidelines.</p> <p><b>CHANGE TO RULE LANGUAGE:</b> See comment #7</p>
21	410 IAC 39-4-1(b)(1)(F)	<p>The rule states that a provider who is able to perform a cesarean section needs to be “on premises”. ACOG, in their Practice Bulletin #205 states that “trial of labor after previous cesarean delivery should be attempted at facilities capable of performing emergency deliveries”. ACOG and the Society for Maternal Fetal Medicine jointly stated that “women attempting a trial of labor after cesarean should be cared for in a level 1 center (I.e one that can provide basic care) or higher. Level 1 facilities must have the ability to begin emergency cesarean delivery within a time interval that best considers maternal and fetal risks and benefits with the provision of emergency care”. By their own admission the intent of policy regarding VABC is not to restrict access but much of the data provided regarding VBAC comes from larger centers where typically studies are performed. Proposed Level 1 facilities are nearly 50% of the delivering hospitals in Indiana! The requirement to be “on premises” is too restrictive and, in my opinion not in alignment with ACOG intentions, and will significantly</p>	Scott A. Beckman M.D. Cell 812-639-0451 IU School of Medicine - Evansville Memorial Hospital, Jasper	<p>RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the <i>Guidelines for Perinatal Care, Eight Edition</i>.</p> <p><b>CHANGE TO RULE LANGUAGE:</b> See comment #7</p>

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		<p>restrict access to this important service to our patients in Indiana.</p> <p>In our hospital, Memorial Hospital in Jasper, Indiana, our policy for VBAC is for the provider to be in-house (“on premises”) or within a reasonable proximity to respond in an emergency. Our private office is within 1 minute driving distance so during the day our physicians are either at the office providing care to patients or in house on the obstetrical unit. When office has concluded for the day we present to the hospital where we stay until delivery occurs. We are not at home as that would be too far from the hospital hampering our response to an emergency situation. From 2015 to the completion of 2018 we had 94 VBAC attempts and an 87% success rate with ZERO uterine ruptures. In addition, our data show that when an emergency cesarean is performed for any reason, our “decision to incision time” is about 10 minutes averaged over the past three years. Whether a patient is a VBAC or a routine labor patient the response time for emergency care is what matters most, not where the physician is actually located during the labor attempt.</p> <p>Providing VBAC services is something that we are proud to offer our community and feel it contributes significantly to the overall well-being of our pregnant patients. We have demonstrated our ability to safely provide this service and our ability to respond to any obstetrical emergency. By requiring the provider to be “on premises” we would have to cancel office patients or even surgeries that are scheduled to meet the</p>		

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		<p>requirement. This would seriously hamper the provision of medical services for other patients. If this proposed rule were to be in place we would no longer be able to provide VBAC services to our patients.</p> <p>ACOG encourages VBAC in a safe environment and we feel that we provide that proven by the statistics I quoted above. The availability of dedicated anesthesia services, massive transfusion protocol, use of staff drills and our own policy of proximity when a patient is undergoing a trial of labor after cesarean contribute to this safety culture. I feel that this rule would severely limit VBAC services around the state as many patients are not able to travel (nor would it be safe to travel a distance in labor) to go to a hospital capable of providing VBAC services based on the proposed rule requirements. Many of our patients would be relegated to multiple cesareans which increases other risks for future pregnancies.</p> <p>A proposed solution would be to require facilities to demonstrate the ability to respond to an emergency in a timely fashion. Requiring appropriate “decision to incision” time data, the availability of dedicated anesthesia providers for obstetrical services and a reasonable provider distance from the hospital requirement in order to respond quickly would provide a well rounded “program” of delivering emergent obstetrical services. Not all facilities applying for level 1 status have the same resources and therefore perhaps not all Level 1 facilities want to provide VBAC services. There is more to the point of</p>		

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		<p>providing emergency delivery services than where the provider is located. Perhaps the provision of VBAC services can be an “add-on” certification that can be attained by providing the data necessary to demonstrate the ability to safely provide this service.</p>		
22	410 IAC 39-4-1(b)(1)(F)	<p>I do have concerns though over one point in the Guidelines regarding section 410 IAC 39-4-1 Sec. 1. (a) (1) (F). This section restricts Level I OB facilities in offering trial of labor patients to times when a provider is “physically present at all times”. This restriction is a contradiction from the ACOG Practice Bulletin November 2017 which states “that women attempting TOLAC should be cared for in level 1 center (ie, one that can provide basic care) or higher. Level I facilities must have the ability to begin emergency cesarean delivery with a time interval that best considers maternal and fetal risks and benefits with the provision of emergency care.” The main restriction is the ability to provide emergency care. Certainly not every Level 1 has the same capabilities; however, restricting all Level 1 facilities seems a bit all-inclusive when there is a great variety.</p> <p>One of my concerns about restricting Level 1 OB facilities is the access to care when over 50% of the delivering hospitals in Indiana are Level 1. By placing this restriction, most Level 1 facilities would be unable to continue to provide this service as maintaining a provider “in the building at all times” would be impossible during the work week</p>	<p>Erica Arthur, RNC, MSN                      Clinical Manager of Women and Infant Services                      Memorial Hospital and Health Care Center                      Jasper, Indiana 47546                      Office 812-996-7700</p>	<p>RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the <i>Guidelines for Perinatal Care, Eight Edition</i>.</p> <p><b>CHANGE TO RULE LANGUAGE:</b>                      See comment #7</p>

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		<p>without compromising many more patients’ care (ie office hours). This would necessitate patients being referred to higher Levels of Care. Patients in rural areas would struggle with these referrals. Additionally, there is no guarantee they would make that trip “in time” when delivery is imminent. For some that trip is 1-2 hours in length and labor may be short if this is not their first attempt. Is it truly better for them to TOLAC in the car to a Level 2-4 center of care or reach a high quality Level 1? Additionally, some patient populations may refuse to obtain care because of added travel cost and elect to deliver at home. Lastly, this may also result in additional unnecessary repeat cesarean sections which may cause complications in future pregnancies.</p> <p>I understand the concerns facing the committee considering our state’s Maternal and Infant mortality rates. I also understand that not all Level 1 are necessarily the ideal candidates to attempt trials of labors. Taking that into consideration, I would ask that you consider a wording changing in this rule. A verbiage change in the rule from provider being “physically present at all times” to “immediately available” would allow appropriate Level 1 OB facilities to continue trials of labor and still maintain a safety standard. However, if that is not an acceptable alternative, perhaps there is a way to allow Level 1 facilities to apply for exemptions if they meet a designated standard of</p>		

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		care as deemed by their associated Perinatal Center or something similar. Thank you for your consideration.		
23	410 IAC 39-4-1(b)(1)(F)	photo image TOLAC comment consider MD immediately available but not necessarily present. Hospital by hospital physical review of location of MD if not physically present. (office hours across the street). Review of location noted if physicians are close enough to the L&D unit to safely provide this service.  STATs 2015-2018 80-95% success rate which included 81 attempts	Megan Isaacs MD Jasper Memorial Hospital	RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the <i>Guidelines for Perinatal Care, Eight Edition</i> .  <b>CHANGE TO RULE LANGUAGE:</b> See comment #7
24	410 IAC 39-4-1(b)(1)(F)	<b>Comment</b> 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.	IHA	RESPONSE: Thank you for your comment. The definition of “physically present at all times” will be changed to “immediately available” as described in Comment #7 to reflect concerns expressed for provider availability during TOLAC. This will more closely match the <i>Guidelines for Perinatal Care, Eight Edition</i> .  <b>CHANGE TO RULE LANGUAGE:</b> See comment #7
25	410 IAC 39-4-1(c)(2)(F)	In obstetrical services/ nursing the rules call for an on duty RN whose responsibilities include the organization and supervision of antepartum, intrapartum, and neonatal nursing. there is no mention of postpartum, which is inconsistent with other areas of the document St. Vincent	Cindy Adams, PhD, RN, ANP-BC, NEA-BC System Chief Nursing Officer St. Vincent	RESPONSE: The department will alter the rule language to include postpartum.  <b>CHANGE TO RULE LANGUAGE:</b> <u>Rule 4, Section 1, c, 2, F</u> “On-duty RN whose responsibilities include the organization and supervision of antepartum, intrapartum, postpartum, and neonatal nursing services.”

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26	410 IAC 39-4-1(c)(2)(I)  <b>Repeats</b> 410 IAC 39-5-1(c)(2)(E)  410 IAC 39-6-3	A potential area of concern for our delivering hospitals (Levels 1-4) is possible discordance from the AWHONN staffing guidelines, which are outlined in several areas of the rules. We are concerned about the ability of facilities to consistently meet the AWHONN staffing guidelines in all circumstances. As systems work toward optimal staffing and productivity standards, it is important that we allow some room for professional judgement, rather than implementing rigid standards.	Cindy Adams, PhD, RN, ANP-BC, NEA-BC System Chief Nursing Officer St. Vincent	RESPONSE: The <i>Guidelines for Perinatal Care, Eight Edition</i> support the AWHONN staffing guidelines.  <i>NO CHANGE TO RULE LANGUAGE</i>
27	410 IAC 39-4-2(c)(4)	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.	Angela M. Bratina, MSN, RN, FNP-BC, NE-BC Franciscan Health Indianapolis Administrative Director, Center for Women & Children	RESPONSE: ISDH has removed this requirement and will instead use the standard in the hospital licensure rules for pharmaceutical standards.  CHANGE TO RULE LANGUAGE: 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.
28	410 IAC 39-4-3(b)(1)(B)	LOC III ICU We would recommend “physically present at all times” be modified to “readily available at all times”. This will accommodate	Marissa G. Kiefer, MHSA Vice President	RESPONSE: Thank you for your comment. Critical care specialists at an obstetric Level III facility must be physically present at all times in order to ensure risk

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		rural communities that would benefit from a Level III but have critical care available within 30 minutes.	Riley Children’s Health	appropriate care for critical care maternal patients. In the blue book (page 24) it is clear that at a Level III the critical care specialists must be onsite, not on call offsite.  <i>NO CHANGE TO RULE LANGUAGE</i>
29	410 IAC 39-4-3(b)(1)(B)	(B) An onsite intensive care unit (ICU) should accept pregnant women and have critical care specialists, physically present at all times.  Please clarify the definition of a “specialist”? Does this include physicians, nurse practitioners (NP)/APRNs, and physician assistants (PA)?	Deaconess	RESPONSE: The rule does not specify provider type so it is up to each facility to determine which critical care specialists are appropriate to care for intensive care patients admitted to the intensive care unit. However, an advanced practice provider with training, experience, and expertise in critical care will be sufficient.  <i>NO CHANGE TO RULE LANGUAGE</i>
30	410 IAC 39-4-3(b)(1)(B)	Insert “when a critically ill mother is in the critical care unit or within 30 minutes of admission to the critical care unit” after times Critical care unit may not always have peripartum women present.	William A. Engle, MD Neonatologist, IUSM	RESPONSE: Thank you for your comment. Critical care specialists at an obstetric Level III facility must be physically present at all times in order to ensure risk appropriate care for critical care maternal patients.  <i>NO CHANGE TO RULE LANGUAGE</i>
31	410 IAC 39-4-3(c)(1)(B) 7 <b>comments</b>	As chief of Obstetrics at Union Health, I can attest to the need, for our community, to remain and Obstetric Level III facility. The central southwestern region has the worst infant mortality rate in the State of Indiana. We are focused on improving our outcomes and have worked for the past 2 years to better identify at-risk pregnant women and families to wrap OB navigation services around them.  My partners and I have worked closely with MFM providers at IU Health and St. Vincent whenever the care of our patients warranted it. The proposed amendment to the rule will enable our organization to (1) formalize these relationships, and (2) leverage our organization’s national expertise in	Thomas Yeagley MD Chief of OB Union Hospital Medical Group, Union Hospital support	RESPONSE: Thank you for your comment. The department will alter the rule language to coincide with requirements found in <i>Guidelines for Perinatal Care, Eighth Edition</i> . Altering the language for MFM in OB Level III leads to necessary changes in the rule language for OB Level IV and Perinatal Centers. Removing the MFM readily available at all times in OB III requires adding it to OB IV as well as Perinatal Centers to ensure appropriate MFM coverage for Level III Perinatal Centers and Level IV facilities.  <b>CHANGES TO RULE LANGUAGE:</b> <u>Rule 4, Section 3, c, 1, B</u> <b>REMOVE:</b> “MFM specialist readily available at all times.”

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		<p>telehealth to help overcome access barriers relating to the limited number of MFM providers locally.</p> <p>We are committed to meeting the needs of our patients and the proposed amendment will help us continue to do so.</p>		<p><b>CHANGE TO:</b> “MFM available at all times onsite, by telephone, or by telemedicine with inpatient privileges”</p> <p><u>Rule 4, Section 4, c, 1, (adding new point so you can choose whatever letter you please)</u></p> <p><b>ADD:</b> “A maternal-fetal medicine (MFM) specialist readily available at all times for onsite consultation and management, with full privileges.”</p>
32	410 IAC 39-4- 3(c)(1)(B)	<p>I am writing in regards to the ruling that Maternal Fetal Medicine be available to be “in house” when needed. I work for a large system and the MFM physician covers multiple hospitals while they are on call. They are available to consult on an as needed bases and are on call to reach by cell phone when needed. However, they may not be immediately available to come to the bedside. They also are more of a consult service than they are delivering physicians. They do not perform deliveries themselves as it is handed off to the primary OB. There is no standing evidence via ACOG or AWHONN that an MFM needs to be available to come in 24/7. I urge you to review this ruling and overturn or reword to include that they are available for consult, but not immediately available to come to the bedside. This is not based on evidence and is not a realistic expectation.</p>	<p>Emily McClelland MSN, RN, NE-BC, RNC-OB Clinical Operations Manager Labor and Delivery/Maternal Fetal Medicine IU Health North Hospital</p>	<p>SAME AS COMMENT #31</p>
33	410 IAC 39-4- 3(c)(1)(B)	<p>Sec 3 (c)(1)(B)“ We submit to clarify and remove any ambiguity associated with the current definition and staffing requirement for Maternal-Fetal Medicine specialist at Obstetric Level III facilities”. We respectfully request ISDH adopt the ACOG definition provided in the 8<sup>th</sup> edition ‘MFM with inpatient privileges available at all times, either onsite, by phone, or by telemedicine.’”</p>	<p>Rhonda Smith RN MSN VP &amp; CNO Union Hospital, Terre Haute IN</p>	<p>SAME AS COMMENT #31</p>

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34	410 IAC 39-4- 3(c)(1)(B)	<b>Comment:</b> 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 telemedicine 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.	IHA	SAME AS COMMENT #31
35	410 IAC 39-4- 3(c)(1)(B)	While not many concerns were voiced yesterday at the meeting, one proposed rule could negatively impact many organizations that have invested significant time and resources in earning Level III designation so we many continue to care for patients in our communities. Our organization supports the objection raised by the representatives from Union Hospital regarding rule 410 IAC 39-4-3 Sec C, 1 b “MFM specialist readily available at all times” the rule, as currently written conflicts with the recommendations from the Guidelines for Perinatal Care, 8 <sup>th</sup> Edition which reads that MFM specialists should be “available at all times onsite,	Carla Meyer Administrative Director, Patient Care Services Community Hospital, Munster IN	SAME AS COMMENT #31

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		<p>by phone or by telemedicine with inpatient privileges.” Our organization respectfully requests the additional clarifiers be added to the rule so it aligns with the current published recommendations from the ACOG and AAP.</p>		
36	410 IAC 39-4-3(c)(1)(B)	<p>Eskenazi Health has reviewed the Proposed Rule for Perinatal Hospital and Birthing Center Levels of Care and finds the guidance helpful in many respects, setting forth the specifications and guidance for obstetrics and neonatal certification. Eskenazi Health does, however, have concerns about the requirement that a maternal fetal medicine (MFM) specialist be readily available at all times for Level III Obstetrics Facilities. Eskenazi Health requests that ISDH clarify that MFM services need only be available for consultation by phone twenty-four hours a day, seven days a week, and not available to be on-site twenty-four hours a day, seven days a week. Consultation by an MFM can be provided effectively by phone. Even during complex labor and delivery cases, the OB/GYN continues to be the lead physician during and after MFM consultation. The requirement that an MFM be readily available at all times, to the extent it requires the MFM to be available to come on-site at all times, would be unnecessarily burdensome when the consultation can be achieved telephonically without compromising patient care.</p>	Elizabeth Ferries-Rowe, MD Director of Women’s Services Eskenazi Health Services	SAME AS COMMENT #31
37	410 IAC 39-4-3(c)(1)(B)	<p>We are concerned that the Level III requirement for MFM coverage “being readily available at all times: may cause unintentional restriction of access to care in geographically diverse areas of the state.</p>	Cindy Adams, PhD, RN, ANP-BC, NEA-BC System Chief Nursing Officer St. Vincent	SAME AS COMMENT #31

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38	410 IAC 39-4- 3(c)(1)(C) 410 IAC 39-4- 4(c)(1)(A)	<p>We believe there is lack of clarity and consistency around the MFM requirements for Level III and Level IV facilities. For example Level IV facility requirements call for a Director of obstetric service is board certified in MFM or obstetrics and gynecology, with <b>expertise in critical care obstetrics</b>. General obstetricians are rarely critical care specialists. In addition, to find a board certified MFM with critical care expertise is rare.</p> <p><b>Comment</b> St. Vincent is asking for clarity of the statement “expertise in critical care obstetrics”</p>	Cindy Adams, PhD, RN, ANP- BC, NEA-BC System Chief Nursing Officer St. Vincent	<p>RESPONSE: This language is offered in the <i>Guidelines for Perinatal Care, Eight Edition</i> and is, at times, intentionally vague to allow for some flexibility and judgement by each delivering facility.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
39	410 IAC 39-4- 3(c)(2)(B)	Hospitals across the state vary with respect to nursing leadership titles. The current language strictly requires a director. We would suggest that the nursing leader be referred to as manager or director of perinatal nursing.	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	<p>RESPONSE: Thank you for your comment. The team of nurse surveyors will discuss individual nursing leadership structures with each facility at the time of certification. Different facilities utilize various words to identify their nursing leaders: managers, directors, supervisors, specialists, etc. It would be impossible to encompass every word into the rule language that may be utilized at each individual facility. The blue book uses the word “director”, which is why it is used in the rule language. Surveyors are aware of the structure in each facility, and have offered guidance regarding the education requirements of nursing leaders. This is a requirement for only Level III and IV facilities, as indicated in the blue book.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
40	410 IAC 39-4- 3(c)(2)(B)	The rules note that the Perinatal Director of Nursing must have expertise in perinatal care whereas the ACPG guidelines call for “obstetrics, neonatal, or both” this should apply to both the obstetric and neonatal services	Cindy Adams, PhD, RN, ANP- BC, NEA-BC System Chief Nursing Officer St. Vincent	RESPONSE: Thank you for your comment. The word “perinatal” is meant to encompass nursing leaders who may have obstetric experience, neonatal experience, or both. The intention of using the word “perinatal” is to allow flexibility in the type of experience this nursing leader may have. It is rare to find a facility that has an

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				<p>individual director for obstetrics with obstetric experience and a master’s degree, as well as an additional individual director for the neonatal unit with neonatal experience and a master’s degree. Almost all facilities have one director who oversees both the obstetric and neonatal units. This individual may have obstetric experience, or neonatal experience, but rarely has both. We utilized “perinatal” to encompass all levels of experience we see in Indiana facilities.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
41	410 IAC 39-4-3(c)(2)(C)	<p>I have reviewed Standard 8.20.c which states “Nursing care should be under the leadership of a registered nurse, Master’s prepared or actively seeking a Master’s degree, with experience and training in neonatal nursing, as well as in the care of patients at high risk.”</p> <p>In regards to this standard it is my contention that 18 years of clinical bedside experience in a Level III NICU and 17 years of proven leadership in Maternal Child Nursing should be considered as meeting this requirement. I understand as healthcare Changes future leaders should have advanced education <u>along</u> with experience. However, I have found no research supporting advanced education as a quality for good nurse leadership.</p>	<p>Elaine Johnson-Merkel BSN, RN, CLC  Director of Women and Children’s Pavilion   85 E. Hwy 6. Valparaiso In 46383   Phone: 219-983-8541</p>	<p>RESPONSE: Thank you for your comment. The <i>Guidelines for Perinatal Care, Eighth Edition</i> addresses the education level of the director in addition to the type of experience required. This rule requirement will need to be in place at the time the facility submits their application for certification.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
42	410 IAC 39-4-3(c)(4)	<p>So, we have a level 3 NICU currently at The Womens Hospital in Newburgh Indiana. The pharmacy in that hospital is NOT 24 hours. HOWEVER we have Deaconess Gateway Hospital within walking distance of about 7 minutes to The Womens Hospital. They make whatever they need emergently and take it over there during off hours.</p>	<p>Meredith Petty, PharmD Clinical Manager/Residency Director Deaconess Health System</p>	<p>RESPONSE: Thank you for your comment. The requirement is met as long as the two buildings are physically attached.</p>

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		<p>If they were to submit to trying to get the Indiana Perinatal Designation, is that OK for pharmacy services? Or does a Pharmacist have to be ON SITE- i.e. physically in the building? Or is a neighboring (gateway ) pharmacy that is 24 hours and offers coverage OK (even though it is a little hike)?</p> <p><b>Neonatal pharm</b> is covered in the OB LOC II &amp; III rules “Readily available at all times” means 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. Does Pharm services need to be added to Neonatal Rules or covered under OB rules?</p>		
43	General Comment	Dr. Engle request Social service, pastoral care and bereavement services should be available to all patients in hospital facilities, especially those with level 1 -4 maternity and neonatal service facilities.	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: ISDH plans to offer a document of best practice guidelines. This document will encompass these types of support services and offer guidelines, but will not be added to the rule language because it is not in the <i>Guidelines for Perinatal Care, Eighth Edition</i>.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
44	410 IAC 39-4-4(a)	<p><i>B) Adult medical and surgical specialty and subspecialty consultants <b>readily available at all times</b> to collaborate with MFM care team and advanced neurosurgery, transplant, or cardiac surgery. (Emphasis added.)</i></p> <p>There is inconsistent use of language within the Obstetrical Level IV facility provisions pertaining to “onsite” and “readily available at all times”. Unlike “Readily available at all times”, “Onsite” is not defined in the</p>	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	<p>RESPONSE: Thank you for your comment. The medical and surgical <i>care</i> must be provided onsite. However, the personnel <i>capable of performing</i> these services must be readily available at all times. One of the rules is referring to facilities capabilities onsite (410 IAC 39-4-4 a); the other rule is referring to physician services (410 IAC 39-4-4 c).</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		<p>definitions section of the Proposed Rule. At 410 IAC 39-4-4(a), the term “onsite” is used when discussing the availability of “medical and surgical care of the most complex maternal conditions . . . .” However, later in this same section, the Proposed Rule utilizes “readily available at all times” when referring to adult medical and surgical specialty and subspecialty consultants. Consequently, <b>we would recommend</b> the Department strike the use of “onsite” in this provision and, alternatively, use the phrase “readily available at all times” to avoid any undue confusion in the application of this section.</p>		
45	410 IAC 39-5-1(a)	<p>Insert “or physically and physiologically appear to be” after born at ...                      Physiologic and physical maturity varies at each gestational age; it is possible that a NB born at 34 weeks’ gestation is as mature as one born at 35 weeks’ gestation. Should the stable 34 weeks’ gestation NB who eats well be separated from her mother simply because she is declared to be 34 weeks’ gestation at birth.</p>	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: Thank you for your comment. The definition of a Neonatal Level I is taken from the <i>Guidelines for Perinatal Care, Eighth Edition</i>. The department feels the definition is clear in delineating the gestational age appropriate for care within a Neonatal Level I facility.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
46	410 IAC 39-5-1(a)	<p>Dr. Engle                      If the rules need to be precise, either use of the term “completed” weeks of gestation (e.g. 35 weeks 0 days for 35 weeks’ gestation) or use 35 weeks plus 0 days rather than 35 weeks alone</p>	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: Thank you for your comment. The definition of a Neonatal Level I is taken from the <i>Guidelines for Perinatal Care, Eighth Edition</i>. The department feels the definition is clear in delineating the gestational age appropriate for care within a Neonatal Level I facility.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
47	410 IAC 39-5-1	<p>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) states “A Neonatal Level I facility is a facility that offers a basic level of newborn care to</p>	Kimberly Flora, RN, MSN Director of Obstetrics	<p>RESPONSE: The <i>Guidelines for Perinatal Care, Eighth Edition</i> discusses respiratory support such as mechanical ventilation and CPAP for Neonatal Level II, but not for Neonatal Level I.</p>

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		<p>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. “ Sec. 1. (1) (D) states “Select and manage neonatal patients at a neonatal risk level appropriate to its capability.”</p> <p><b>Comment</b> We are requesting a clarification statement in this section to include, if the use of Continuous Positive Airway Pressure (CPAP), Intravenous (IV) therapy and Oral/Nasogastric tube is allowed for a Level I nursery and the duration of time allowed for this type of care provided. If the previously stated is not allowed for use in a Level 1 nursery, please further explain. For example, 410 IAC 39-5-2 Neonatal Level II facility requirements Authority: IC 16-21-13-5 Affected IC 16-21-13 Sec. 2. (1) (C) states “Provide mechanical ventilation for brief duration (less than twenty-four (24) hours) or continuous positive airway pressure (CPAP) or both.</p> <p>Further clarification of the extent of care to be included for the neonate at a Level I nursery would be beneficial to provide the care within the standards of the determined level. Our facility has board certified pediatricians and qualified nurses to perform brief/limited CPAP/IV/OG-NG care for stabilization of newborns and request that this be</p>	<p>Woodlawn Hospital 1400 E 9th St Rochester, In 46975 kflora@woodlawnhospital.com</p>	<p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		<p>added to the Level I criteria. We are able to provide further information on this request if needed. Thank you for the consideration.</p>		
48	410 IAC 39-5-1(b)(2)	<p>Dr. Engle Add Oxygen Saturation monitor to the list</p>	<p>William A. Engle, MD Neonatologist, IUSM</p>	<p>RESPONSE: The oxygen saturation monitor is included as a requirement under “all equipment necessary to provide resuscitation and stabilization of unexpected neonatal problems according to the most current NRP guidelines”, which is found under the equipment requirements of a Neonatal Level I facility. This would additionally be required by the Obstetric and Neonatal Universal Standards, Laboratory requirements regarding equipment necessary to perform newborn screening.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
49	410 IAC 39-5-1(b)(4)	<p>410 IAC 39-5-1, this provisions seems to imply that a formal relationship may exist between an affiliate hospital and some other higher level of care facility as it relates to transfer plans. We would argue that to avoid any conflict with the partnership agreement that must exist between an affiliate hospital and the perinatal center, any transfer plans between an affiliate hospital and some other higher level of care facility should only occur within the context of the partnership agreement between the perinatal center and an affiliate hospital. Transfer plans should not be developed outside of that agreement. To do otherwise, could result in conflicts between the affiliate hospital and the perinatal center, as stated elsewhere in the rule in which non-perinatal centers may affiliate with only one (1) perinatal center.</p>	<p>Marissa G. Kiefer, MHSA Vice President Riley Children’s Health</p>	<p>RESPONSE: The memorandum of understanding between Perinatal Center and affiliate is entirely separate from a transfer agreement between any two facilities. Hospitals may choose to transfer patients to any facility outside of their Perinatal Center.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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50	410 IAC 39-5-1(b)(4)	Hepatitis B vaccine/treatment is universally recommended beginning at birth; Human Milk use is also universally recommended and management skills by staff and lactation consultants are important assets to require	William A. Engle, MD Neonatologist, IUSM	RESPONSE: ISDH plans to offer a document of best practice guidelines. This document will encompass these types of guidelines, but will not be added to the rule language.  <i>NO CHANGE TO RULE LANGUAGE</i>
51	410 IAC 39-5-1(c)	Dr. Engle "Add Lactation Consultants to the list of personnel ". Human milk use often requires support from trained, certified lactation consultants;	William A. Engle, MD Neonatologist, IUSM	RESPONSE: The department will add language to Neonatal Level I facilities regarding lactation support services.  <b><i>CHANGES TO RULE LANGUAGE:</i></b> <u>Rule 5, Section 1, c, 7</u> <b>ADD:</b> "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."
52	410 IAC 39-5-1(c)(1)  <b>Repeat</b> 410 IAC 39-5-2(c)(3)  410 IAC 39-5-3(c)(1)	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".	Cindy Adams, PhD, RN, ANP- BC, NEA-BC St. Vincent	RESPONSE: Thank you for your comment. The department will alter the rule language to provide clarification.  <b><i>CHANGES TO RULE LANGUAGE:</i></b> <u>Rule 5, Section 1, c, 1</u> "Pediatricians, family physicians, or advanced practice providers, readily available at all times."  <u>Rule 5, Section 2, c, 3</u> "Care of newborn infants at high risk shall be provided by appropriately qualified personnel including, pediatricians, neonatologists, pediatric hospitalists, or advanced practice providers. This specialized personnel shall be physically present at all times when an infant is maintained on a ventilator."

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				<p><u>Rule 5, Section 3, c, 1, B</u>                      “A pediatrician who has completed pediatric residency training, or an advanced 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.”</p>
53	410 IAC 39-5-2(c)(3)	Change NNP to Advanced Practice Providers (LOC III)	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: Thank you for your comment. The department will alter the rule language to provide clarification.</p> <p><b><i>CHANGES TO RULE LANGUAGE:</i></b>  <u>Rule 5, Section 1, c, 1</u>                      “Pediatricians, family physicians, or advanced practice providers, readily available at all times.”</p> <p><u>Rule 5, Section 2, c, 3</u>                      “Care of newborn infants at high risk shall be provided by appropriately qualified personnel including, pediatricians, neonatologists, pediatric hospitalists, or advanced practice providers. This specialized personnel shall be physically present at all times when an infant is maintained on a ventilator.”</p> <p><u>Rule 5, Section 3, c, 1, B</u>                      “A pediatrician who has completed pediatric residency training, or an advanced 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.”</p>
54	410 IAC 5-2(b)(1)(C)	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	Michaela Nufer, MSN, NNP-BC, CCD Director of Nursing Women	<p>RESPONSE: The department will edit the rule language to offer clarification. Thank you for your comment.</p> <p><b><i>CHANGES TO RULE LANGUAGE:</i></b>  <u>Rule 5, Section 2, b, 1, C</u></p>

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		(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.	and Children Services Elkhart General Hospital \	<b>CHANGE TO:</b> “Provide either: (i) mechanical ventilation for brief duration (less than 24 hours); or (ii) continuous positive airway pressure (CPAP); or (iii) both.”
55	410 IAC 5- 2(b)(1)(C)	<b><i>A) Provide mechanical ventilation for brief duration (less than twenty-four (24) hours) or continuous positive airway pressure (CPAP), or both. (Emphasis added.)</i></b>  Based on the aforementioned, it is unclear whether CPAP is subject to the same ‘less than 24 hours’ restriction. In addition, the rule does not consider the use of high-flow nasal cannula at flows > 2LPM for CPAP-effect, a common practice at many facilities. In an attempt to clarify, we would suggest that the 24-hour limit be restricted to mechanical ventilation only. To further clarify, the use of high-flow nasal cannula for CPAP-effect should be included when discussing the use of CPAP.	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	RESPONSE: The department will alter the rule language to offer clarification. Thank you for your comment. The <i>Guidelines for Perinatal Care, Eighth Edition</i> offers this statement in regards to mechanical ventilation and CPAP, but does not address high-flow nasal cannula for Level II facilities.  <b>CHANGES TO RULE LANGUAGE:</b> <u>Rule 5, Section 2, b, 1, C</u> <b>CHANGE TO:</b> “Provide either: (i) mechanical ventilation for brief duration (less than 24 hours); or (ii) continuous positive airway pressure (CPAP); or (iii) both.”
56	410 IAC 5- 2(b)(1)(C)	Insert “High Flow Nasal cannula” before CPAP HFNC is regularly used in many neonatal units. Alternatively, phrasing to include “mechanical respiratory support devices or technologies” could replace the list	William A. Engle, MD Neonatologist, IUSM	RESPONSE: Thank you for your comment. The <i>Guidelines for Perinatal Care, Eighth Edition</i> offers this statement in regards to mechanical ventilation and CPAP, but does not address high-flow nasal cannula for Level II facilities.
57	410 IAC 39-5- 2(b)(4)  Repeat	Insurers have an important part to play in back transfers; should the rules incorporate responsibility of payers to support such back transports Back transport delays/denials caused by 3 <sup>rd</sup> party payer decision processes	William A. Engle, MD Neonatologist, IUSM	RESPONSE: The department does not have authority to regulate payer issues. Thank you for your comment.  <i>NO CHANGE TO RULE LANGUAGE</i>

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	410 IAC 39-5-3(b)(4)(A)  410 IAC 39-6-5			
58	410 IAC 39-5-3(b)(4)(A)	Is phrase “including accepting patient information on the required case” needed Unclear rationale for inclusion	William A. Engle, MD Neonatologist, IUSM	<p>RESPONSE: Thank you for your comment. The department will edit the rule language to provide clarification based on language in the <i>Guidelines for Perinatal Care, Eight Edition</i>.</p> <p><b>CHANGES TO RULE LANGUAGE:</b> <u>Rule 5, Section 3, b, 4, A</u> <b>CHANGE TO:</b> “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.”</p>
59	410 IAC 39-5-2(c)(1)(B)	<p>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.</p> <p><b>Comment</b> Please consider adding a definition of “consulting relationship: to clarify that the intent is that the hospital staff shall know whom to call for a specific issue, not that the hospital is required to have someone who is available to attend to the patient in person</p>	IHA	<p>RESPONSE: The consultative agreement may require the presence of the provider onsite, or may require the transfer of the patient to the facility where the service is provided. This is dependent upon the patient status, service provided, and agreement between facilities.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

Comment #	Rule	Comment	Submitted	Discussion
60	410 IAC 39-5- 2(c)(1)(B)	Neonatal Level II facility requirements Sec. 2 (c) (1) (B) "The hospital shall have consulting relationships in place with a pediatric cardiologist, a surgeon, and an ophthalmologist..."  Please consider adding a definition of "consulting relationship" to clarify that the intent is that the hospital staff shall know whom to call for a specific issue, not that the hospital is required to have someone who is available and willing to come see the baby in person.	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	RESPONSE: The consultative agreement may require the presence of the provider onsite, or may require the transfer of the patient to the facility where the service is provided. This is dependent upon the patient status, service provided, and agreement between facilities.  <i>NO CHANGE TO RULE LANGUAGE</i>
61	410 IAC 39-5- 3(b)(1)(C)	Since it is not required to perform surgeries onsite for a Neonatal Level III facility as long as a prearranged consultative agreement is made, is it acceptable to have pediatric surgical specialists available at a Children’s Hospital that does offer these services through an established agreement? Would this structure then meet the requirements in the above statement for “readily available at all times”?	Deaconess	RESPONSE: The facility will require an agreement with a risk appropriate institution that will accept the transfer of surgical patients who require surgical services beyond what your facility is capable of providing. The rule language will be amended to provide clarification.  <b><i>CHANGE RULE LANGUAGE:</i></b> <u>Rule 5, Section 3, b, 1, C</u> CHANGE TO: “Pediatric surgical specialists (including anesthesiologists with pediatric experience) readily available at all times, or at another facility through prearranged consultative agreement, shall perform all procedures in newborn infants within a time interval that incorporates neonatal risks and benefits with the provision of emergency care.”
62	410 IAC 39-5- 4(b)(2)	Add Therapeutic Hypothermia to list Therapeutic hypothermia is standard of care for moderate/severe HIE	William A. Engle, MD Neonatologist, IUSM	RESPONSE: Thank you for your comment. The <i>Guidelines for Perinatal Care, Eighth Edition</i> do not include this.  <i>NO CHANGE TO RULE LANGUAGE</i>
63	410 IAC 39-6-2(b)	This annual requirement is not in keeping with other programs such as ACLS, NRP, BLS and PALS which are provided on a biannual basis. We	Cindy Adams, PhD, RN, ANP- BC, NEA-BC St. Vincent	RESPONSE: Thank you for your comment. The programs mentioned are certifications (ACLS, NRP, BLS, PALS). The frequency of recertification is determined by the individual certifying body. Fetal monitoring education

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		believe that fetal monitoring education should not differ from the other programs. St Vincent		does not necessarily require a formal certification; this education is required annually.  <i>NO CHANGE TO RULE LANGUAGE</i>
64	410 IAC 39-6-6	Reporting requirements a. Sec. 6 “each delivering facility shall submit data ...” i. What data and to whom? ii. How far in advance? iii. Where do we submit? ISDH website? iv. Or, is this by request by the dept?	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	RESPONSE: Requests for data will be made by ISDH and the facility will submit the information that they have available. There are currently no specific data elements that must be gathered so the facilities will not be required information they do not have.  <i>NO CHANGE TO RULE LANGUAGE</i>
65	410 IAC 39-8-1(c)(1)	410 IAC 39-8-1 Sec. 1 C1: A MFM specialist is <b>readily available at all times</b> for onsite consultation and management with <b>full</b> privileges. Current recommendation in the Guidelines for Perinatal care, pg. 18 has that for level III, MFM’s should be available at all times onsite, by telemedicine, or by telephone with <b>in-patient</b> privileges.  Is there a reason why an MFM would need to be available readily available to come in and see a patient when the hospitalists are managing in-patient’s with MFM consult.	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	RESPONSE: Thank you for your comment. The rule language will be altered to provide clarification.  <b>CHANGE TO RULE LANGUAGE:</b> The language regarding MFM was already altered for previous comments (31, 32, 33, 34, 35, 36, 37) to offer clarification. No additional change is required.
66	410 IAC 39-8-1(c)(1)	Perinatal Centers. Section 1.c.(1) MFM specialist readily available...with full privileges. (p.18) There is not a clear definition of what “full privileges” includes. Is that defined by the facility?	Parkview Health in Fort Wayne and the northeastern region, Kathleen Detweiler, BSN, RN Women’s and Children’s Navigation and Program Manager	RESPONSE: Thank you for your comment. The rule language will be altered to provide clarification.  <b>CHANGE TO RULE LANGUAGE:</b> The language regarding MFM was already altered for previous comments (31, 32, 33, 34, 35, 36, 37) to offer clarification. No additional change is required.

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67	410 IAC 39-8-2	<p><b>Qualifications for perinatal centers</b> Sec. 1 (c)(1)A maternal-fetal medicine (MFM) specialist readily available at all times for onsite consultation and management with full privileges</p> <p><b>Comment</b> We want to clarify that to become an Obstetric Level III facility/Perinatal Center that an MFM physician <b>does need to be onsite</b> with full privileges, but then it is <b>acceptable for this MFM specialist to only consult with affiliate hospitals only through phone or telemedicine?</b></p> <p><b>Support services</b> 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. (section 5)</p>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	<p>RESPONSE: The rule language will require that a Perinatal Center has an MFM readily available at all times for their individual facility. Affiliate hospitals will require MFM consultation and availability based upon the rule language specific to their desired certification. Please refer to the rule document regarding support services offered to affiliates.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
68	401 IAC 39-8-2(a)	<p><b>Perinatal collaboration</b> each perinatal center shall annually engage in a minimum of 2 efforts sponsored by the dept supporting improved outcomes Please define “efforts sponsored by the department”</p>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	<p>RESPONSE: As sponsored efforts become available the department will make Perinatal Centers aware. These are examples over the last two years of various annual opportunities including AIM bundle participation, Labor of Love Summit, Transport Conferences, Breastfeeding Conference, IPQIC Taskforces, etc.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
69	410 IAC 39-8-2(b)	<p>at least annually, Perinatal Center and affiliates shall review metrics recommended by the dept.</p> <p>a. Clarify- will state share data with PC’s or will affiliates send data to PC’s b. How will state notify PC’s what metrics to collect/cover/track? c. How will PC’s receive data from/about affiliates?</p>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System	<p>RESPONSE: At this time, requests for data will be made by ISDH and the facility will submit the information that they have available. There are currently no specific data elements that must be gathered. When the metrics are available the department will make facilities aware.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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70	410 IAC 39-6-6	<b>Data Reporting Requirements: Sec. 6.</b> (p.17) When will hospitals be notified of the specific data that we will need to report? What will be the frequency of the reporting? It is a heavy burden to collect data retrospectively. If these items change over time, can we expect to get advance notice so that reports can be designed in EMR's?	Parkview Health in Fort Wayne and the northeastern region, <i>Kathleen Detweiler, BSN, RN</i> Women's and Children's Navigation and Program Manager	RESPONSE: Requests for data will be made by ISDH and the facility will submit the information that they have available. There are no specific data elements that must be gathered.  <i>NO CHANGE TO RULE LANGUAGE</i>
71	410 IAC 39-6-6	Reporting requirements raise several questions. It is not clear what type of data elements need to be submitted, how often and to what agency the data will be sent. This is vague and needs to be clarified	Cindy Adams, PhD, RN, ANP-BC, NEA-BC St. Vincent	RESPONSE: Requests for data will be made by ISDH and the facility will submit the information that they have available. There are currently no specific data elements that must be gathered.  <i>NO CHANGE TO RULE LANGUAGE</i>
72	410 IAC 39-8-8(b)	Why are affiliations limited to 1 perinatal center? Some perinatal centers may have desired services that others do not provide.	William A. Engle, MD Neonatologist, IUSM	RESPONSE: For an affiliate to have more than one Perinatal Center would create confusion as to who is responsible to the affiliate for each requirement. If there is a facility that has services you are interested in, you may enter into agreements for consultation, transfer, etc. that are not related to the Perinatal Center memorandum of understanding. The Perinatal Center/affiliate relationship will cover aspects outlined in the rule document. Other services may be provided by facilities based on various other agreements outside of the memorandum of understanding for Perinatal Centers.  <i>NO CHANGE TO RULE LANGUAGE</i>
73	410 IAC 39-8-8	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	Patty Scherle Director of Women and Infant Services, Memorial Hospital and Health Care Center, Jasper	RESPONSE: The department will alter the rule language to offer clarification on the timeline for entering into a memorandum of understanding with a Perinatal Center.  <b><i>CHANGE TO RULE LANGUAGE:</i></b> <u>Rule 8, Section 8, a</u> CHANGE TO:

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		<p>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!</p>		<p>“Any facility not certified by the department as a perinatal center shall affiliate with a perinatal center. The department will notify facilities when a sufficient number of 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.”</p>
74	410 IAC 39-8-8(c)	<p>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?</p>	<p>Parkview Health in Fort Wayne and the northeastern region,  <i>Kathleen Detweiler, BSN, RN</i>                      Women’s and Children’s Navigation and Program Manager</p>	<p>RESPONSE: The rule language requires perinatal centers to affiliate with at least one hospital outside of its own network, and allows for the department to assign unaffiliated hospitals as needed. The rule language will be altered to account for future situations when all facilities have entered into perinatal center / affiliate relationships, leaving none to be assigned.</p> <p><b><i>CHANGE TO RULE LANGUAGE:</i></b>  <u>Rule 8, Section 8, c</u>                      “Every perinatal center shall affiliate with at least one (1) hospital outside of its own network, unless none are available.”</p>
75	410 IAC 39-8-8	<p>We recognize and understand there will be inherent costs associated with meeting the responsibilities and resources associated with being a Level IV/ Perinatal Center as outlined. For example, each MOU between delivering entities include: providing a reliable Interfacility transport program, quality review, and inter professional education requires both human and material resources which</p>	<p>Cindy Adams, PhD, RN, ANP-BC, NEA-BC System Chief Nursing Officer St. Vincent</p>	<p>RESPONSE: Thank you for your comment. The number of affiliate relationships and geographic location of those affiliates is not dictated by the rules document beyond requiring one affiliate outside of the perinatal center’s network. The perinatal center may enter into affiliate agreements in the geographic area of their choosing. Some aspects of the perinatal center / affiliate relationship may be undertaken via telephone, telemedicine, conference</p>

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		are costly. We are eager to work with aligned facilities to improve health outcomes. However, we have concerns about the feasibility of entering such agreements with hospitals who are in geographic areas of the state that will preclude a cohesive working relationship. To that end, we believe it will be important to allow hospitals to regulate the number of MOUs that they engage upon based on their capacity to provide such services.		calls, etc. to enable strong relationships in various locations.  <i>NO CHANGE TO RULE LANGUAGE</i>
76	410 IAC 39-8-8	If the state implements the proposed rules will the verbiage of this document negatively impact the number of centers meeting the criteria for a Level III and Level IV center? If there is a drop in number of Level III and IV centers, do the centers that still remain after implementation have enough capacity to absorb the volume throughout the state for the areas no longer being served by the facilities that did not receive their anticipated LOC designation?	Deaconess The Women’s Hospital 4199 Gateway Blvd Newburgh, IN 47630	RESPONSE: Thank you for your comment. The department feels facilities certified as Level III or IV will have the capacity to support the patient population requiring this level of care. Continued collaboration between facilities and the surveyor team during the gap analysis and over the last year has lead the department to believe the number of Level III and IV facilities will certainly be sufficient. In fact, in some geographic locations, there may be more higher level facilities than necessary to accommodate volume.  <i>NO CHANGE TO RULE LANGUAGE</i>
77	410 IAC 39-8-1(b)	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.	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	RESPONSE: The department agrees that Level 3 and 4 Obstetric units with Level 3 or 4 Neonatal units should be able to be perinatal centers. We will clarify the language.  CHANGE IN 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.

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78	410 IAC 39-4-3(c)(1)(B)	<p>The Proposed Rule at 410 IAC 39-4-3(c)(1)(B) provides:</p> <p><i>Sec. 3. (c) Each Obstetric Level III facility shall ensure the following staffing requirements are met (Obstetric Level II plus the following):</i></p> <p><i>(1) Physician services, as follows:</i></p> <p><i>(A) An obstetrician-gynecologist (OB-GYN) physically present at all times.</i></p> <p><i>(B) MFM specialist readily available at all times. (Emphasis added)</i></p> <p>Per the 2015 American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine, Obstetric Care Consensus on Levels of Maternal Care on page 5 under the Definitions, Capabilities, and Types of Health Care Providers for Level III, it states “MFM with inpatient privileges available at all times, either onsite, by phone or by telemedicine. Consequently, we would recommend the phrase “readily available at all times” be changed to “available at all times” with regards to the MFM specialist.</p>	Marissa G. Kiefer, MHA Vice President Riley Children’s Health	SAME AS COMMENT #31.
<b>COMMENTS BELOW THIS LINE WERE FOUND IN THE TRANSCRIPT OF THE PUBLIC HEARING BUT DID NOT APPEAR TO BE ADDRESSED ABOVE.</b>				
79	410 IAC 39-5-3(b)(1)(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 infant within a time interval that incorporates neonatal risks and benefits with the provision of emergency care.	Marissa G. Kiefer, MHA Vice President Riley Children’s Health	RESPONSE: Thank you for your comment. This will be clarified as described in Comment 61.

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		We would suggest for the purposes of this subsection that “readily available” will be “readily available at all times” be modified to “available at all times,”		
80	410 IAC 39-8-8	MOU Relationships – When facilities may use other transfer arrangement such as border facilities beyond their MOU agreements. Cost associated with having those affiliates and not receiving their transports.	Rothenberg – St. Vincent	RESPONSE: The memorandum of understanding between Perinatal Center and affiliate is entirely separate from a transfer agreement between any two facilities. Hospitals may choose to transfer patients to any facility outside of their Perinatal Center.  <i>NO CHANGE TO RULE LANGUAGE</i>
81	410 IAC 39-4-1(c)(2)(I)  <b>Repeats</b> 410 IAC 39-5-1(c)(2)(E)  410 IAC 39-6-3	Cost associated with meeting staffing AWHONN guidelines.	Rothenberg – St. Vincent	RESPONSE: The <i>Guidelines for Perinatal Care, Eight Edition</i> support the AWHONN staffing guidelines.  <i>NO CHANGE TO RULE LANGUAGE</i>
82	410 IAC 39-4-3(c)(1)(B) 7	Rule for MFM coverage Level III does not currently mirror the 8 <sup>th</sup> edition of the American College of Obstetrics and Gynecologists Perinatal Levels of Care Guidelines definition on page 17.	Union Hospital, Terre Haute– Jennifer Harrah, nursing care manager of newborn intensive care	RESPONSE: Thank you for your comment. The department will alter the rule language to coincide with requirements found in <i>Guidelines for Perinatal Care, Eighth Edition</i> . The language will change in accordance with Comment 31.
83	General Comment	These requirements increase costs without a clear understanding of the direct impact that it will have to benefit infant mortality.	Paula Autry, CEO, Lutheran Hospital, Fort Wayne, IN	RESPONSE: Thank you for your comment. The rule document is based on the <i>Guidelines for Perinatal Care, Eighth Edition</i> in order to ensure each delivering facility follow evidence-based best practice recommendations for

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				<p>the safe care of women and infants in Indiana. The document does not dictate the level of care any individual facility must apply for. Each facility may select the level of care they wish to certify as, based upon the costs they are able and willing to incur. The department supports the best practices outlined in the <i>Guidelines for Perinatal Care, Eighth Edition</i> as one effort among many in reducing our state’s infant mortality.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
84	General Comment	<p>We are invest – a physician investor owned hospital. It’s important for us to listen to our physicians and to hear their concerns, and what we’re hearing from them is also that there are changes to the standards that are needed to make it more effective, to make sure that we’re compliant and improve the care to our citizens.</p>	<p>Paula Autry, CEO, Lutheran Hospital, Fort Wayne, IN</p>	<p>RESPONSE: Thank you for your comment. The rule document is based on the <i>Guidelines for Perinatal Care, Eighth Edition</i> in order to ensure each delivering facility follow evidence-based best practice recommendations for the safe care of women and infants in Indiana. The guidelines were developed through a collaborative effort among national physician professional organizations including the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP).</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
85	<p>General Comment</p> <p>410 IAC 39-4-3(b)(1)(B)</p>	<p>Page 21-25, General comments of commitment to meet requirements,                      Voiced Concern: “one size does not fit all. The unintended consequence of legislation that does not adequately address these concerns could be dire and lead to diminished access for most Hoosiers by virtue of lack of availability of higher-level centers and overcrowding of those centers that remain.”                      Comment: “The Women’s Hospital is excited to participate in the perinatal level of care process. We’ve undoubtedly benefited from the challenge to review and improve our policies, protocols, and processes. Our institution has rededicated itself to</p>	<p>Brennan Fitzpatrick, Medical Director for Perinatal Medicine and Ultrasound at the Women’s Hospital in Newburgh, Indiana.</p>	<p>SEE RESPONSE TO COMMENT 29</p> <p>“Available at all times” is defined in the rule document as: <i>available twenty-four (24) hours a day, seven (7) days a week for consultation and assistance.</i></p>

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		<p>providing education and support to our regional partners to improve perinatal outcomes, and employ the vision of the Perinatal Standards Committee.”</p> <p>Specific Comment 1) Same as - Comment 29 (Description of Critical Care Specialists – who does this include physicians, type of providers such as mid-level providers?)</p> <p>Specific Comment 2) “readily available” is defined, but “available” is not.</p>		
86	General Comment	<p>“Yeah, we rise in support as well to this legislation. This is eight years in the making that the State of Indiana and the State Department of Health have been working on levels of care. You know, we will submit written comments to you that, you know, take into account many of the comments that the hospitals here today have stated, along with several other organizations that weren’t able to be here today.</p> <p>I think, you know, there’s opportunity. You know, a lot of it talks about some of the inflexibility of the rules. Any time to take guidelines and place them into the kind of strict constructs of the Administrative Code, there’s difficulty in providing updates and clarifications.</p> <p>And so, you know, I think that it’s an opportunity for the State Department of Health to give itself authority to provide kind of explanations and changes with the rules, allow for flexibility within the rules with some of the changes that have been suggested. So, we would encourage the Department to – wherever possible, to add this flexibility, to give itself the authority to provide</p>	Andy Van Zee, IHA – Indiana Hospital Association	<p>RESONSE: Thank you for your comment. The department believes we have been flexible where appropriate and have responded to the commenters more specific written comments previously noted in the document.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		interpretive guidance with respect to implementation of this rule.”		
87	410 IAC 39-7-1	<p><b>410 IAC 39-7-1 Inter-hospital Transfer Requirements</b>                      Sec 1. (b) references Indiana Perinatal Transport Standards issued by the Indiana Perinatal Quality Improvement Collaborative (IPQIC) dated October, 2018.                      Comment: Specialty teams need to be adequately trained for the patient population the team is caring for. Properly trained Respiratory Therapists should be allowed to be part of the maternal team as the secondary provider; the Maternal RN being the expert in that population and the team leader overseeing the RT (or paramedic). For neonatal transport teams, NNP or Neonatal RN should be allowed to be the primary staff. We request that the guidelines be updated to allow the Medical Director to have control in who he/she deems is appropriate to send on the transport.</p>	IHA	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
88	General Comment	<p>Please consider this a Letter of Support for Union Hospital's comments on the proposed LSA #18-416 Perinatal Hospital and Birthing Center Levels of Care rule. As Director of Neonatology at Union Hospital, I can attest to the quality of care provided to patients in the Central Southwestern region. Union Hospital can better meet the needs of the community by operating as an Obstetric Level III facility. Were it not, twenty-four babies in 2018, would have systematically been transferred at least an hour away from home leading to families spending weeks or months commuting back and forth. This total does not account for the dozens of women who remained pregnant past 32 weeks based on the care given by our team of</p>	Daniel Bruzzini, MD, MBA, CPE, Director of Neonatology, Union Hospital	<p>RESPONSE: Thank you for the support. ISDH cannot comment on the certification of specific facilities.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		<p>obstetricians and neonatologists, in consultation with maternal and fetal medicine physicians in Indianapolis.</p> <p>Remaining an Obstetric Level III facility is imperative in our region as we are the only access point for the surrounding rural and underserved communities where resources are severely limited or lacking</p>		
89	General Comment	<p>A former patient submitted a comment in support of Union Hospital’s comments on the rule. She shared her personal story of care at the facility and stated the importance of having a Level III OB and NICU in Terre Haute.</p>	Danielle Isbell, Former Patient, Union Hospital	<p>RESPONSE: Thank you for your comment. ISDH has responded to Union Hospitals comments and cannot comment on the specific designation of a facility.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
90	General Comment	<p>Please accept my support, as President and CEO of Union Health, for the proposed LSA #18-416 Perinatal Hospital and Birthing Center Levels of Care rule.</p> <p>Our experience in partnering with the State Department of Health (ISDH) as an Obstetric Level III and a Neonatal Level III facility as well as wrapping services around our at-risk patients through perinatal navigation has been paramount as we strive to meet the needs of our most vulnerable patients and their families, particularly those living in our neighboring rural and underserved communities.</p> <p>We look forward to continuing our partnership with ISDH, Indiana Hospital Association, and Indiana Perinatal Quality Improvement Collaborative (IPQIC) to ensure we not only maintain but grow our current level of services as it</p>	Steve Holman, President & CEO, Union Health	<p>RESPONSE: Thank you for your comment. ISDH has responded to Union Hospitals comments and cannot comment on the specific designation of a facility.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

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		<p>is instrumental to ensuring we reduce our region's infant mortality rate.</p>		
91	410 IAC 39-5-3(c)(1)(B)	<p><b>b)</b> <i>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):</i></p> <p><b>(1)</b> <i>Each Neonatal Level III facility shall have the following facility capabilities:</i></p> <p><b>(A)</b> <i>Provide sustained neonatal life support.</i></p> <p><b>(B)</b> <i>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.</i></p> <p><b>(C)</b> <i>Pediatric surgical specialists (including anesthesiologists with pediatric experience) <u>readily available at all times</u> 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. (Emphasis added.)</i></p> <p>As written, every Level III NICU must have pediatric surgeons and anesthesiologists with pediatric expertise available to be physically present on site to perform neonatal surgical procedures. According to the Guidelines for Perinatal Care (8th edition), these providers should be “at the site OR at a closely related institution by prearranged consultative agreement” (Table 1-4, pages 29-30). Further, on page 32 of the</p>	Marissa G. Kiefer, MHSA Vice President Riley Children’s Health	See response to Comment #61

Comment #	Rule	Comment	Submitted	Discussion
		<p>Guidelines, it states: “Prearranged consultative agreements can be performed using, for example, telemedicine technology, or telephone consultation, or both from a distant location.”</p> <p>There are insufficient numbers of pediatric surgeons or anesthesiologists with pediatric experience to require facilities to have these providers physically present at every Level III NICU in the state of Indiana. More likely, adult providers would be utilized to fulfill this requirement leading to poorer outcomes for this vulnerable, high-risk population. Consequently, we would suggest for purposes of this subsection that “readily available at all times” be modified to “available at all times” to reflect Guidelines for Perinatal Care.</p>		
92	410 IAC 39-4-3(c)(1)(A)	<p><u>410 IAC 39-4-3</u> under Obstetric Level III facility requirements,(c-1-a) “ an obstetrician-gynecologist (OB-GYN) physically present at all times.</p> <p>This will significantly increase costs for organizations to support Level III requirements. Many physician practices are in close proximity to a delivering hospital but physicians are not present on site. In order to meet the standard could this verbiage suggest that they would be “readily available” so as to not influence significant cost for organizations where physician coverage is close but not physically on the site of the delivering hospital.</p>	Angela M. Bratina, MSN, RN, FNP-BC, NE-BC Franciscan Health Indianapolis Administrative Director, Center for Women & Children	<p>RESPONSE: Thank you for your comment. The rule document is based on the <i>Guidelines for Perinatal Care, Eighth Edition</i> in order to ensure each delivering facility follow evidence-based best practice recommendations for the safe care of women and infants in Indiana. The guidelines were developed through a collaborative effort among national physician professional organizations including the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP).</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
93	410 IAC 39-5-3	<p><u>410 IAC 39-5-3</u> under Neonatal Level III facility requirements, section g(b-1-c) “Pediatric surgical specialist....”</p>	Angela M. Bratina, MSN, RN, FNP-BC, NE-BC Franciscan Health Indianapolis	See Comment #61

Comment #	Rule	Comment	Submitted	Discussion
		Can this read similar to the (b-1-b) with ophthalmology to clarify that a level III must be able to consult and get rid of “available at all times” as that confuses the subject. Level III facilities will not have neonatal surgery and it would be up to the level IV to ensure “readily available at all times.”	Administrative Director, Center for Women & Children	
<b>COMMENTS ON TRANSPORT GUIDELINES, Rule 7</b>				
94	410 IAC 39-7-1	<p><b>410 IAC 39-7-1 Inter-hospital Transfer Requirements</b></p> <p>Sec 1. (b) references Indiana Perinatal Transport Standards issued by the Indiana Perinatal Quality Improvement Collaborative (IPQIC) dated October, 2018.</p> <p>Comment: Specialty teams need to be adequately trained for the patient population the team is caring for. Properly trained Respiratory Therapists should be allowed to be part of the maternal team as the secondary provider; the Maternal RN being the expert in that population and the team leader overseeing the RT (or paramedic). For neonatal transport teams, NNP or Neonatal RN should be allowed to be the primary staff. We request that the guidelines be updated to allow the Medical Director to have control in who he/she deems is appropriate to send on the transport.</p>	IHA	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
95	Rule 7, 4.4	<p>- Maternal team composition:</p> <p>*According to CAMTS; specialty teams need to be adequately trained for the patient population the team is caring for. We are asking why an RT could not be part of the maternal team as the secondary provider; the Maternal RN being the expert in that population and is team leader overseeing the RT (or paramedic). We ask that</p>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System Office-574-647-1658	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

Comment #	Rule	Comment	Submitted	Discussion
		allowing the Medical control to have control in who he/she deems is appropriate to send on the transport.	Fax- 574-647-7323 574-892-5131	
96	Rule 7, 4.5	<p>Neonatal Team composition:                      Minimum staff:                      A. Neonatal nurse                      B. And one of the following                      a. NNP;                      b. RT; or                      c. Paramedic</p> <p>Our question: Why can't an NNP be a primary team member with an R.T.? Is there a reason an RN has to be with the NNP if the NNP doesn't feel it's necessary? NNP's at a level III do know how to operate the isolettes and pumps. Again, we are asking that Medical control have control of who is on the neonatal team; based on the patient's needs. Thank you for your consideration in the questions.</p>	Kristyn Beaver, BSN, RNC-OB Perinatal Center Coordinator Beacon Health System Office-574-647-1658 Fax- 574-647-7323 574-892-5131	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
97		<p><b>Comment</b> Specialty teams need to be adequately trained for the patient population the team is caring for. Properly trained Respiratory Therapists should be allowed to be part of the maternal team as the secondary provider; the Maternal RN being the expert in that population and the team leader overseeing the RT (or paramedic). For neonatal transport teams, NNP or Neonatal RN should be allowed to be the primary staff. We request that the guidelines be updated to allow the Medical Director to have control in who he/she deems is appropriate to send on the transport.</p>	IHA	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>
98		<p>In the new 2018 Indiana Perinatal Transport Guidelines, The Women's Hospital would like to mention the following items that we believe have been mistakenly left out:                      Standards</p>	Deaconess The Women's Hospital 4199 Gateway Blvd Newburgh, IN 47630	<p>RESPONSE: The transport guidelines have been incorporated as they exist at this time. The department is unable to alter these guidelines.</p> <p><i>NO CHANGE TO RULE LANGUAGE</i></p>

Comment #	Rule	Comment	Submitted	Discussion
		6.3 left off Human Factors 6.4 left off Infection control 8.3 left off Human Factors 8.4 left off Infection control		