

Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

Comment #	Rule #	Public comment	Submitted by	Response/ rule change
1	<p><u>Rule 8</u> <u>Perinatal Centers Sec. 1.</u> <u>(a) (3)</u></p>	<p>The current draft rule states “Perinatal centers will work with affiliate hospitals by providing the following.....transport of mother and newborn”.</p> <p>I recommend this be changed to “facilitate the transport of mother and newborn when requested” to clarify the perinatal center does not have to do the transporting themselves but could instead utilize their transfer center to engage the support of another transport team and that affiliates are not required to send all transports to the perinatal center.</p>	<p>Martha Allen, MSN, RN Regional Perinatal Center Director 7240 Shadeland Station Way  Indianapolis, IN 46256 Phone 317-621-7420  Cell 317-771-3656  Martha.Allen@eCommunity.com www.facebook.com/eCommunity   www.twitter.com/chnw</p>	<p><b>RESPONSE:</b> Thank you for your comment. The rule language will be altered to reflect this change.</p> <p><b>CHANGE TO RULE LANGUAGE:</b> Rule 8, (1) (a) (3) The purpose of perinatal centers is to coordinate perinatal care throughout the state by affiliating with delivering facilities. Perinatal centers will work with affiliate hospitals by providing the following: (1) Training. (2) Quality assurance review. (3) <i>Facilitation of</i> transport of mother and newborn. (4) Other support services as necessary.</p>
2	<p><u>410 IAC 39-8-5 Support services Sec. 5. (3)</u></p>	<p>The current draft rule states “Delivering facilities serving as perinatal centers shall provide the following support to affiliate hospitals at all times....MFM outpatient services.”</p> <p>I recommend this point be removed since it does not match (1) “MFM specialist consultation by phone or telemedicine” and does not align with (5) “Neonatal consultation by phone or telemedicine”, both under the same section. Leaving this point in may lead affiliates to expect MFM outpatient services be provided in person at their hospital which would at times be an unnecessary and</p>	<p>Martha Allen, MSN, RN Regional Perinatal Center Director 7240 Shadeland Station Way  Indianapolis, IN 46256 Phone 317-621-7420  Cell 317-771-3656  Martha.Allen@eCommunity.com www.facebook.com/eCommunity   www.twitter.com/chnw</p>	<p><b>RESPONSE:</b> ISDH agrees that this requirement could be misunderstood as requiring MFM outpatient services at affiliate hospitals. ISDH will remove that language to clarify that outpatient services at affiliate hospitals is not required. Because the language is removal, no change is noted below.</p> <p><b>CHANGE TO RULE LANGUAGE:</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.</p>

Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

		inefficient utilization of this very limited resource.		<p>(2) Maternal-fetal transport including a reliable and comprehensive communication system to initiate transport.</p> <p>(3) Communication with the discharging obstetrician-gynecologist (OB-GYN) or MFM specialist, and the referring OB-GYN or family medicine physician regarding the outcome of pregnancy, recommendations for postdelivery care or continued interpregnancy care, and management of the next pregnancy including, when appropriate, birth spacing.</p> <p>(4) Neonatal consultation by phone or telemedicine.</p> <p>(5) Neonatal transport, including a reliable and comprehensive communication system to initiate transport.</p> <p>(6) Developmental follow-up program for high-risk newborns.</p>
3	410 IAC 39-3-1 Birth center requirements	I am submitting a concern regarding a discrepancy between birthing centers and Level I obstetrical care. The standards do not allow TOLAC or VBACs at Level I hospitals. The Commission for the Accreditation of Birth Centers indicates the answer to the question if TOLAC and VBACs are allowed at the birthing centers to be:	<p>Patti Brahe, BSN, MHA Senior Vice President Women and Children’s Services</p> <p>Parkview Regional Medical Center 11109 Parkview Plaza Drive Entrance 3, Suite 205</p>	<p><b>RESPONSE:</b> The Indiana Code defines a birthing center as “a freestanding entity that has the sole purpose of delivering a normal or uncomplicated pregnancy.” ISDH does not consider a TOLAC to be a normal or uncomplicated pregnancy, so TOLACs would not be allowed in a birthing center.</p> <p><b>NO CHANGE TO RULE LANGUAGE</b></p>

Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

		<p>Yes, CABC accredited freestanding birth centers and Alongside Maternity Centers may choose to offer Trial of Labor After Cesarean (TOLAC). (Note: Vaginal Birth After Cesarean (VBAC) is one result of TOLAC.)</p> <p>My concern is the allowance of a potentially high risk procedure at a lower level of care. I appreciate your attention to my concern.</p>	<p>Fort Wayne, IN 46845</p> <p>Office: (260) 266-7971</p> <p>Cell: (260) 417-3923</p>	
4	410-IAC 39-4-1	<p>We would like to submit the following concerns and requests for your consideration. The Guidelines for Perinatal Care Eighth edition has been instrumental in providing best practice standards for our hospitals provider coverage, nursing standards and expectations for care for the maternal, newborn and newly delivered dyad. We ask ISDH and governing bodies consider adding the recommended consult lists located in the back of the book, located in Appendix B on pages 597-598 and then Appendix C on pages 599-600.</p> <p>For example, in 410-IAC 39-4-1, a Level I facility, “provides care of the uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum, intrapartum or postpartum period....” The document goes on to say that the Level I should establish, with its higher level of care (perinatal center) what risks and necessitating consult, referral and transfer should look like. With the inclusion of a defined, recommended OB-GYN and MFM</p>	<p>Kristyn Beaver, BSN, RNC-OB Beacon Health System Perinatal Outreach Coordinator</p>	<p><b>RESPONSE:</b> The consultative direction given in Appendix B &amp; C are recommendations and may be used within nursing and medical leadership to guide policies on consultation for achieving risk appropriate care. Providers should, at the minimum, seek consultation as recommended - but continued medical treatment and transfer are left up to provider decisions and scopes of care as defined within each institution. We do not believe it is necessary to incorporate this into the rule.</p> <p><b>NO CHANGE TO RULE LANGUAGE</b></p>

Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

		<p>consultation/referral list from ISDH this would help guide practitioners at all levels. With health care provided by a wide range of physicians and practitioners in a wide variety of settings, this would be a critical first step in identifying early on when expert consultations should take place. In adding such appendices, this would help to remove some of the politics that exists in the current health care environment. The goal is to reduce our maternal mortality and morbidity, keep the families together whenever possible and helping our babies to be delivered in an appropriate leveled facility. The added piece of maternal mortality, seeking higher and expert consultations, only makes sense to spell it out in such a document as you've/we've created in Title 410.</p>		
5	410-IAC 39-8-1:	<p>Comment #2: 410-IAC 39-8-1: Definitions: Can ISDH please clarify or define: Full privileges as stated in the RULE 8; Sec. 1 1 (c)(1) perinatal center MFM coverage? In our facility, this means privileges without restrictions. Is this what the ISDH is implying or does it mean MFM's have delivering privileges as well?</p>	<p>Kristyn Beaver, BSN, RNC-OB Beacon Health System Perinatal Outreach Coordinator</p>	<p><b>RESPONSE:</b> The decision to award and define privileges lies within each individual facility, as the services and providers in each hospital may vary greatly. ISDH will accept any hospital definition of full privileges.</p> <p><b>NO CHANGE TO RULE LANGUAGE</b></p>
6		<p>Regarding Transports: At the last public comments, we were not allowed comment to the transport regulations and was told that the rules regarding transports was closed. Our understanding was that we could indeed comment on these transport rules as they are still part of the Title 410 Perinatal guidelines.</p>	<p>Kristyn Beaver, BSN, RNC-OB Beacon Health System Perinatal Outreach Coordinator</p>	<p><b>RESPONSE:</b> To clarify previous comments on this issue, the ISDH has chosen to fully incorporate by reference the transport guidelines issued by the Indiana Perinatal Quality Improvement Collaborative (IPQIC) because ISDH agrees with them and believe they address what is needed for this rule. ISDH cannot change a document fully incorporated by reference because it was</p>

		<p>We'd like to pose the following questions again regarding team composition. It has come to light that there will be major lack in maternal transport capability in certain areas of the state. We ask again that ISDH consider allowing more flexibility in letting the medical control/Transport Medical Directors have a say in who is to be part of the teams, maternal or neonatal, rather than strictly limiting them to the current composition. Maternal teams, as stated in the rules shall consist of a Maternal Fetal RNC as primary, secondary must be a paramedic and a third could be an RT. Neonatal Team composition consists of the NICU RNC as primary, secondary personnel, RT and third NNP or advanced practice nurse specialized in NICU. CAMTS only states that for specialty teams, team members be trained in the patient population they are caring for. In our Level III facility, NNP's, for instance, do hands on care in the NICU unit and would be perfectly capable to be the primary provider on a neonatal transport with an RT. Allowing NNP's (or advanced practitioners trained in NICU) to be the primary persons in the compartment, an RT being a second, would allow some flexibility without compromising care. We ask that you consider the following NICU team composition to reflect:</p> <ol style="list-style-type: none"> <li>1.RNC or NNP or advanced practice provider trained in NICU as primary</li> <li>2.RT</li> </ol>		<p>created by a separate entity and does not believe any changes are needed.</p> <p><b>NO CHANGE TO RULE LANGUAGE</b></p>
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Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

		<p>We ask that you consider the following Maternal team composition to reflect:</p> <ol style="list-style-type: none"> <li>1.RNC maternal fetal nurse</li> <li>2.Parametic, or</li> <li>3.RT as secondary personnel</li> <li>4.Or both.</li> </ol> <p>Allowing RT's to be a second in the compartment for a maternal team would also allow some flexibility, again, without compromising care. These RT's and paramedics would be trained in the patient populations they would be transporting. All team composition decisions would be made by the medical control and would be taken on a case by case basis.</p> <p>Thank you again for your consideration of our concerns and suggestions.</p>		
7	<p>410 IAC 39-4-1 Obstetric Level I facility requirements Section (c) Staffing Requirements (1) Physician Services &amp; (3) Anesthesia Services</p>	<p>I would like to see clarification on anesthesia availability/dedicated OB anesthesia services based on the number of deliveries a hospital has per year. We are a Level I OB and neonate facility. However, we currently have approximately 1300 deliveries per year. Is there a recommendation for dedicated OB anesthesia services based on number of deliveries versus level of care?</p>	<p>Teneesa Stuckey MSN, NEA-BC, RNC-OB Director of Obstetrics 574-364-2914 200 High Park Ave, Goshen, IN 46526</p>	<p><b>RESPONSE:</b> The <i>Guidelines for Perinatal Care, Eighth Edition</i> does not utilize delivery volume to guide recommendations. Each individual facility should consider their own volumes, and complete a risk assessment to guide decisions on the provision of care.</p> <p><b>NO CHANGE TO RULE LANGUAGE</b></p>
8	<p>410 IAC 39-3-1 Birth Center requirements Section 1 (2) (A)</p>	<p>Angela Lyttle: Good Morning. I'm Angela Lyttle, A-N-G-E-L-A, Lyttle, L-Y-T-T-L-E. I am a certified nurse-midwife and I am the managing owner and clinical director of Sacred Roots Midwifery &amp; Birth Center here in Indianapolis. I'm here to speak in regard to 410 IAC 39-3-1, Birth Center Requirements, which states that each birth</p>	<p>Angela Lyttle CNM Sacred Roots Midwifery &amp; Birth Center, Indianapolis, Indiana</p>	<p><b>RESPONSE:</b> The intention of the rule requiring an established agreement between a birthing center and receiving facility was not meant to necessarily imply a <i>formal written</i> agreement. Each birthing center should be able to articulate a plan for access to acute care services at a receiving hospital.</p>

		<p>center shall establish the following policies and procedures established agreement with the receiving hospital.</p> <p>This language asks the small business, the birth center, to obtain an agreement from a hospital competitor in order to operate without any impetus for the hospital to comply. This is not in alignment with the national standard for birth centers that has been set by the Commission for the Accreditation of Birth Centers, or CABC. CABC indicators clearly state that a written agreement is not required between the birth center and receiving facility. As ISDH has recognized in the rules that unaffiliated hospitals may need to be assigned to perinatal centers, birth centers require similar language and protection for assignment to a receiving hospital should this become necessary for licensure. This is of particular in rural hospital or rural communities where there may only be one receiving hospital. The levels of care legislation and rule seeks to improve access to care and decrease barriers specifically to address Indiana’s abysmal maternal, fetal and infant mortality rates, these rules affect real people and real communities. States that are doing the best have strong midwifery presence and seamless collaboration between providers and communities.</p> <p>With this rule midwives in rural communities who wish to open birth centers will potentially be blocked from creating safe licensed care spaces that consistently show strong outcome for low-risk healthy women with healthy low-</p>		<p><b>NO CHANGE TO RULE LANGUAGE</b></p>
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Second Public Hearing Comments 5/17/19 - Perinatal Levels of Care Rules

		<p>risk pregnancies. This required agreement without reciprocal protection is a barrier to care for these rural families in rural communities.</p> <p>One other point that I wasn't planning to make but just reading the economic impact statement, it does speak to there are grants available from the American Association of Birth Centers Foundation to support accreditation expenses. I just want to make note that those grants are available only to nonprofit birth centers. Thank you.</p>		