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Birthing Center Rule Advisory Committee
September 13, 2021
10:00 a.m. via Zoom

RAC MEMBER ATTENDEES	
Colleen Forbes	LDM and former chair of the Board of Direct Entry Midwifery
Desiree LeFave	Bella Vie Gentle Birth
Hermine Hayes-Klein	Oregon Association of Birth Centers
Karen DeWitt	Oregon Association of Naturopathic Physicians
Kaylyn Anderson	Consumer
Laura Erickson	Alma Midwifery Services
Lynette Pettibone	American Association of Birth Centers
Margy Porter	Bella Vie Gentle Birth Center
Meredith Mance	Aurora Birth Center
Silke Ackerson	Oregon Midwifery Council
Willa Woodard	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Rebeckah Orton	Astoria Birth Center
Sharron Fuchs	Public Citizen
OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Dana Selover	PHD-Health Care Regulation & Quality Improvement
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement

Welcome and Overview

Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and reviewed housekeeping items. Participants were asked to enter their name, organization and whether they are a RAC member or member of public into the Chat.

Review of August 24th Meeting Notes

D. Selover asked RAC members if there was any feedback on the notes.

RAC member wished to clarify the following:

- Page 6, second bullet:
  - The primary purpose of the consult is to get more information on the condition and potential risk from the consulted provider and findings or recommendations may or may not be made. Language should allow for that and it was recommended that OAR 333-

077-0125 language could be changed to reflect, "…information, findings, and/or recommendations" instead of just references to "any findings or recommendations."
  - "Consulting providers" (the birthing center OOH provider) have experienced that "consulted providers" (those persons who are consulted to obtain information on a potential conditions and risks) do not want any recommendations documented in the client's chart because it may create a liability risk for the consulted provider who may not have conducted an exam. The consulting provider may also face a liability risk for not following a consulted provider's information, recommendation or finding even though there may be a client approved plan of care.
- Page 6, bullet 5, sub-bullet 2:
  - RAC member commented that the statement on page 6, bullet 5, sub-bullet 2 should not be meant to imply that all hospital-based birth providers do not know applicable administrative rules or that all hospital-based providers believe that OOH births are not safe.
- Page 7, bullet 4:
  - Low risk as defined in the Health Evidence Review Commission (HERC) guidance is only one way that Oregon regulations define low risk. The Board of Direct Entry Midwifery (DEM) regulations and the freestanding birth center regulations define low risk that enables more people to access OOH birth than low risk as defined by HERC. The Oregon Association of Birth Centers position is that any move to replace the current freestanding birth center definition of low risk with a new definition that restricts access to birth centers must be evidence-based and data driven.

D. Selover noted that comments specified in the Chat field will be recorded in the meeting notes and will not be subject to restatement or reinterpretation.

Proposed OAR 333-077-0125 – Risk Status Assessment and Consultation Requirements

D. Selover opened discussion on OAR 333-077-0125 and noted that based on discussions from the July 21 and August 24 RAC meetings and discussions with the Department of Justice (DOJ) legal counsel for the Health Care Regulation and Quality Improvement program, the program has integrated feedback to the greatest extent possible and the version sent by e-mail for this meeting today is what will move forward for purposes of filing with the Secretary of State's office for the public hearing. This version is what should be considered for future discussions and voting on the risk factor tables.

From the program's perspective, it balances the definitions and procedures from the Board of DEM rules, Medicaid requirements, and the birthing center administrative rules and statutes. To the extent that anything remains unclear, the program's intent is to draft interpretive guidance once rules are adopted.

Recap of the rule:

- Section (1) provides definition of 'provider of maternity care.'
- Section (2) and (3) addresses initial and ongoing risk assessments.
- Section (4) requires referral or transfer based on Table I or Table II criteria.
- Section (5) outlines the consulted provider requirements and communication with the client.
- Section (6) identifies documentation requirement for the client record.

- Section (7) provides that a birthing center may continue to provide prenatal care even if the client meets criteria in the risk factor tables provided that informed consent is obtained from the client.

It was noted that RAC members will have another opportunity to provide comments on this rule through the public hearing and written public comment period. The program is required to respond to all comments shared at the public hearing and submitted in writing during the official public comment period.

It was further noted that if RAC members wanted to add to the Chat "for the record" statements on this rule, or to submit additional comments by e-mail, the program will take those comments into consideration.

Risk Factor Table I – Risk Factors for <u>EXCLUSION AT ADMISSION</u>

Staff placed the consensus model decision making poll choices into the Chat. RAC members will choose one of these options for purposes of voting on risk factors:

> "1" - I can say an enthusiastic yes to the recommendation (or action).
> "2" - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
> "3"- I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths & weaknesses and need more discussion or more work done.
> "4" - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
> "5" - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

D. Selover summarized that these risk factors are currently proposed as "absolute risk factors" which would exclude a person from having an OOH birth in a birthing center.

CURRENT PREGNANCY COMPLICATIONS
<u>Group B Strep (Unknown carrier state)</u>
<u>Group B Strep (If mother is positive, lack of informed consent on prophylaxis)</u>

- RAC member noted that there are clients who choose not to test for Group B Strep who could remain low risk.
- RAC member noted that pregnant people just like all other patients should be able to have informed choice and be able to decline testing or screening. Furthermore, it is not a risk factor that should exclude someone from care. HERC only excludes if there is a lack of informed consent on prophylaxis if mother is GBS positive <u>and</u> declines prophylaxis.
- Additional RAC members concurred with comments above orally and via Chat.
  - RAC member commented that based on other criteria and rules, this is an overstep. From a safety perspective, it is unclear how either of these criteria impact safety.
  - Example provided from RAC member of having child in hospital and being able to decline testing based on informed choice. Choice falls to patient, not the provider nor insurance. Requiring testing impacts the rights of pregnant persons.

- It's not the unknown carrier state that puts someone at risk, rather if there are other signs or symptoms.

D. Selover asked for feedback specific to a pregnant person who is known positive and doesn't agree to antibiotic prophylaxis. Discussion:

- RAC member stated that decision making about the possibility of antibiotic prophylaxis needs to be noted but if the client declines treatment with antibiotics that is still their right and is not helpful as a birth center exclusion.
- RAC member stated that if the rules already allow a client to provide informed consent and continue to receive care, this would be redundant.
- RAC member echoed that it's redundant and a client is choosing to test, or not to test, based on informed consent to begin with.
- Via Chat, RAC members stated:
  - "Unknown carrier state WITH prolonged ROM, preterm labor, maternal fever, etc. could be listed as consult criteria, not an absolute risk factor."
  - "If given informed consent a birthing person should still have the right to decline prophylaxis and it falls to the midwife's clinical knowledge to assess in an ongoing fashion any cumulative risk factors that would indicate a need for transfer or for prophylaxis."
- RAC member noted that while it is understood that there are a lot of sources that were looked to for the conclusions drawn on the HERC tables, it was asked whether there is any evidence that birth centers in Oregon have not been able to safely care for people in the absence of Group B Strep being listed. Staff noted that only looking at Oregon data does not prove that the risk is not relevant. RAC member stated, "we can't look to other American maternal health systems because we have such vast differences in the way that maternal health systems are constructed from state to state in this nation. Regulations and the level of integration that impact birth centers in other states don't allow us to draw evidence from safety outcomes because there are so many other variables…"
- Via Chat, RAC member concurred with above comment and noted that there is information and data about GBS outcomes in Oregon and current practices have not been a source of poor outcomes.

Additional discussion ensued regarding what is meant by "lack of informed consent on prophylaxis." A few RAC members interpreted the statement to mean that the birth center provider did not provide informed choice. It was noted that this risk factor is based on the HERC guidance which specifies: "Lack of informed consent on prophylaxis if mother is GBS positive and declines prophylaxis." It does not mean that the birth center did not provide relevant information and informed choice. It was suggested that should this risk factor move forward either as an absolute risk factor or move to consultation, additional clarification is needed.

<u>POLL: Retain Group B Strep (unknown carrier) as an absolute risk factor? Results:</u>

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.

- 0 - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 100% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Retain Group B strep (lack of informed consent on prophylaxis/mother is positive and declines antibiotic prophylaxis) as an absolute risk factor? Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 18% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 82% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Additional discussion ensued regarding the meaning of "lack of informed consent" and removing the risk factor entirely from the table if a pregnant person knowingly chooses to decline antibiotic prophylaxis after being fully informed of the potential risks. Several RAC members concurred via Chat. It was further stated that part of the problem with the HERC guidance and other regulations is that language is frequently interpreted differently by the patient, the provider and the state.

POLL: Move Group B strep (lack of informed consent on prophylaxis/mother is positive and declines antibiotic prophylaxis) to consultation. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 30% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 70% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Hypertension (Pre-existing and chronic)
Hypertension (Pregnancy induced with blood pressure ≥ 140/90 on two consecutives readings taken at least 30 minutes apart)

Discussion:

- RAC member indicated that the American College of Obstetricians and Gynecologists (ACOG) recommends offering induction for pregnant people as early as 37 weeks if there are two elevated blood pressures on two consecutive readings but that this issue can also be managed. It was stated that hypertension may not be pre-eclampsia but is a signal of potential risk.

- RAC member questioned via Chat where the 30-minute interval comes from as her understanding is that diagnosis is at least 4 hours apart. RAC member responded via Chat that the Board of DEM administrative rules state: "Hypertension at or above 140 systolic or at or above 90 diastolic on two (2) separate occasions that are more than four (4) hours apart, or hypertension at or above 160 systolic or at or above 110 diastolic on one (1) occasion." **Follow-up for clarification – this is listed under OAR 332-025-0021(10)(j) under Indication to transfer – antepartum.**
- RAC member stated that the Board of DEM language is more accurate as to what OOH providers would do and would be more protective for the client. Consecutive blood pressures are not clinically valuable.
- RAC member stated that hypertension alone can cause risk, it's not just its association with pre-eclamptic toxemia (PET). Clients whose blood pressures are close to that range are monitored and possible PET labs drawn. Often times a client sent to the hospital with those blood pressures are sent home whereas under midwife care, blood pressures are frequently checked with frequent follow-ups.
- RAC members via Chat stated:
  - PIH (pregnancy induced hypertension) is a stand-alone risk.
  - I would feel more comfortable with the criteria used by the British Columbia College of Midwives which has "gestational hypertension without evidence of pre-eclampsia" as an indication for consultation whereas preeclampsia is an indication for transfer
- RAC member stated that pre-eclampsia and eclampsia are separate risk criteria. Clients may have marginal hypertension but drawing labs may identify whether the client actually does have pre-eclampsia. The Board of DEM language was well researched and meets the needs of OOH providers.
- RAC member concurred with changing to four hours apart. It was noted that pre-existing hypertension or chronic hypertension may be well controlled and thus should be a consultation criteria.
- RAC member via Chat suggested moving both risk factors to consultation.

D. Selover noted that polling to retain each risk factor as written will occur and then after the poll, will discuss whether to consider the Board of DEM language and moving it to consultation.

<u>POLL: Retain pre-existing and chronic hypertension as an absolute risk factor. Results</u>:

- 9% - I can say an enthusiastic yes to the recommendation (or action).
- 9% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 55% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 9% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 18% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Retain pregnancy induced ≥140/90 on two consecutive readings taken at least 30 minutes apart. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 27% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 27% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 45% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

D. Selover asked RAC members to comment via Chat how many would support the DEM language as an alternative.

- RAC members supported adoption of the Board of DEM language.
- One RAC member stated that they preferred the DEM language, but do understand a request to change to consult to allow for CNM and NP providers with a larger scope.
- RAC member indicated, "the other part of Hypertension recommendation for BP to be taken 30 minutes later, if the BP is in the danger zone- you should not even wait 30 min to retake BP VS transport." It was further stated that better language is needed.
- RAC member supported DEM language if the word 'gestational' (from British Columbia College reference) is added.
- RAC member expressed concern that the current LDM language is too restrictive in some cases and doesn't think that a person who has two readings of 142/80 on two different occasions necessarily needs transfer, for example. RAC member responded that moving the language to consultation may mitigate restrictive language.
- RAC member concurred with comment above and indicated that baseline BP should be considered as BP does increase slightly at the end of pregnancy.

D. Selover asked RAC members to comment via Chat how many would support moving these risk factors to consultation and what the language might look like.

- Several RAC members indicated support of adopting the language and moving to consultation criteria.
- One RAC commented that if the DEM language is adopted to add, "without additional evidence of pre-eclampsia."
- RAC member suggested adding language about immediate transfer for dangerously high BP.

Induction of Labor

Discussion:

- RAC member clarified that pharmacological induction of labor (Misoprostol, Cytotec, and Pitocin) is not within scope of practice for OOH birth and does not include breast pump, castor oil, or other natural substances.

- RAC member noted that another induction of labor method that is used that is not pharmacological but mechanical is the foley bulb. This is used nationally and should be considered as an option for Oregon birth centers. It was requested to change the risk factor to state "Induction of Labor – Pharmacological."
- RAC member noted that the foley bulb induction of labor is within the community midwife scope of practice and should not be an indication to transfer.
- RAC member indicated that it needs to be clear that pharmacological does not include any herbal remedies.
- Additional RAC members via Chat requested to include reference to pharmacological.
- RAC member via Chat asked what the CABC guidelines were. RAC member responded via Chat that the CABC does not specifically address induction. "P&P's for use of any medications prescribed, dispensed or administered in the birth center are consistent with current national guidelines and based on the best available evidence is the relevant statement." **Follow-up: CABC - Indicators of Compliance with Standards for Birth Centers, Edition 2.2, Effective 4/1/2020:**
  - **1C.1.j. Clients requiring intrapartum interventions not appropriate in a birth center should be transferred to the appropriate level of care in a timely manner. These include but are not limited to: Pharmacologic agents for cervical ripening, induction and augmentation of labor; fetal monitoring beyond intermittent auscultation; regional spinal or epidural anesthesia; operative vaginal birth; cesarean birth.**
  - **The indicator further states that this does not prohibit the use of nonpharmacological or mechanical methods of *induction of cervical* ripening such as Foley bulbs, breast pumps or herbal or homeopathic preparations. The birth center is required to have a policy and procedure in place if any of these nonpharmacological or mechanical methods are used.**
- RAC member stated via Chat that the definition of "pharmacology" is relating to the branch of medicine concerned with the uses, effects and modes of action of drugs.
- RAC member stated via Chat that she disagreed with any references to herbs, castor oil, or Foley bulbs in the wording as it could prove to be restrictive.
- RAC member stated that "drugs" is key in the definition and herbology doesn't fall under that and doesn't think it's in best interest to try to include it, as it would make it more restrictive.
- RAC member stated via Chat that it is not within the scope of the RAC to list potential herbal induction methods – need to just vote on pharmacologic induction is not allowed (Pitocin, etc.)
- RAC member via Chat indicated that herbs or castor oil should not be referred to specifically. Staff asked for clarity around the types of herbs used to ensure there is no misunderstanding. A brief discussion ensued regarding the need to identify the criteria for client transfer and restricting the language to Pharmacological Induction of Labor should be sufficient.

POLL: Retain induction of labor (pharmacological) as an absolute risk factor. Results:

- 90% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.

- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 10% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Based on results of poll, a decision was made not to take a separate vote on moving the criteria to consultation.

Genital Herpes (Active infection at time of labor)

Discussion:

- RAC suggested changing the language to "primary outbreak for genital herpes at time of labor." Acyclovir is used for outbreaks, and lesions that are drying can be covered.
- RAC members concurred via Chat.

POLL: Retain genital herpes (*primary outbreak at time of labor*) as an absolute risk factor.
Results:

- 80% - I can say an enthusiastic yes to the recommendation (or action).
- 20% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 0% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Hepatis B (Unknown status)
Hepatis B (Positive status)

Discussion:

- RAC member noted that most clients in her practice are willing to test for Hepatitis or HIV for the first pregnancy but not subsequent pregnancies given costs and religious beliefs. It was suggested that both Hepatitis B and HIV remove reference to unknown status.
- RAC member noted that there are protocols available to help protect the provider and the infant in terms of use of PPE making Hep. B manageable.
- RAC member indicated via Chat "PTR-HBV generally do well during labor with reactivation of the virus and disease is uncommon." RAC member further commented that for clients from SE Asia that are carriers, protocols are instituted along with a Hepatitis vaccination for the infant afterwards.
- RAC member questioned via Chat whether OOH providers can administer HBIg to babies born to Hepatitis B positive people. RAC member responded via Chat that she believed CNMs, and NPs can administer.
- RAC member suggested via Chat removing 'unknown status' and moving to consultation table.

- Another RAC member suggested via Chat to remove unknown status for STI testing and move positives to consultation. Another RAC member via Chat concurred.

POLL: Retain Hepatitis B (unknown status) as an absolute risk factor. Results:

- 10% - I can say an enthusiastic yes to the recommendation (or action).
- 0% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 0% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 20% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 70% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Retain Hepatitis B (positive status) as an absolute risk factor. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 20% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 10% - I can live with the recommendation, but I'm not overly enthusiastic. I have questions about the strengths and weaknesses and need more discussion or more work done.
- 50% - I do not fully agree with the recommendation and need to register concern. However, I will not block the recommendation. More discussion is necessary for full support.
- 20% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Wrap Up

Polling was concluded given the time frame.

Staff asked RAC members to consider the remaining risk factors on Table I and to be prepared to discuss. Remaining items include: HIV, Rubella, Syphilis, Varicella, Mental illness requiring inpatient care, Placental, Prelabor rupture of membranes, & Refractory hyperemesis gravidarum.

Next meeting is scheduled for October 18th at 2:00 p.m.

RAC adjourned at: 11:58 p.m.