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Birthing Center Rule Advisory Committee
January 10, 2022
1:00 p.m. via Zoom

RAC MEMBER ATTENDEES	
Desiree LeFave	Bella Vie Gentle Birth Center (Administrative)
Hermine Hayes-Klein	Oregon Association of Birth Centers
Jennifer Gallardo	Andaluz Waterbirth Center
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 (Clinical)
Michelle Zimmerman-Pike	Oregon Affiliate of the American College of Nurse Midwives
Sarah Wickenhagen	Oregon State Board of Nursing
Silke Ackerson	Oregon Midwifery Council
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Christina Baldisseri	Alma Midwifery Services
Ray Gambrill	AllCare Health
Sharron Fuchs	Public
OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Dana Selover	PHD-Health Care Regulation & Quality Improvement
Diane Quiring	Health Systems Division – Medicaid Programs Unit
Lacey Martinez	PHD-Health Facility Licensing & Certification
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, member of public, or staff of Oregon Health Authority into the Chat.

November 29th Meeting Notes

RAC members were asked via e-mail to submit any comments on proposed changes to the November 29th meeting notes by e-mail.

Overview of Rulemaking Progress

Dana Selover provided a summary of progress to date:

- This RAC has been meeting since May 2019 with delays due to the COVID-19 pandemic.
- The main rule text has been reviewed by the RAC and actions have been taken based on feedback received. Some of those changes have already been brought back to the RAC for further review. Outstanding action items such as dietary services will be shared with RAC along with the final draft rule text in the future.
- The RAC has been reviewing the risk factor tables which were developed to align with the 2015 Health Evidence Review Commission (HERC) coverage guidance. The RAC has made significant progress with Table I and recommendations have been made on which risks should be retained as an absolute risk factor for exclusion and which risks should be moved to consultation under Table III. Resources such as the Board of Direct Entry Midwifery (DEM) administrative rules, revised 2020 HERC coverage guidance, American Association of Birth Centers (AABC) national standards, and the Commission for Accreditation of Birth Centers (CABC) indicators for compliance have been considered in these discussions. It was noted that Table II would be discussed for purposes of today's RAC meeting.
- There are four remaining risk factors on Table I that need to be considered which include VBACs, multiple gestation, gestational age, and non-cephalic presentation. These four risk factors will take significant meeting planning, facilitation and preparation. It was noted that the program will work with the RAC to plan this meeting(s).
- A public hearing will be scheduled after final draft rules and tables have been completed. The public hearing is an opportunity for interested persons to present oral testimony or submit written comments on the proposed rules for further consideration. The program will take into consideration the comments and testimony received and will respond to the comments and consider possible additional changes.

RAC member noted concern that the November minutes could be interpreted that the risk factors that were deferred from previous discussions would not be considered further. The overview provided helped alleviate some of these concerns but RAC member requested a more specific plan by the end of this meeting on future discussions related to these remaining risk factors. Additionally, it was requested that there be a dialogue on why such risk factor tables are necessary in this setting when similar tables do not exist in other health care settings and would restrict access to care, and what data was considered to add the additional risk factors that do not exist on current tables in effect.

D.Selover reiterated that the purpose of administrative rules for birthing centers as well as all licensed health care facility types that the program oversees is not to restrict access but to ensure quality health and safety of clients or patients.

- RAC member via chat affirmed statement that the proposed rule changes would restrict access to care.
- RAC member via chat noted that level of detail in rule "specific to freestanding Birth Centers vs. lack of detail with regards to Hospital rules" is not commensurate for provider types. It was also stated via chat that the proposed rules are "not standard in other states whose DOH also has the charter of providing safety and protecting the public."

D.Selover shared information on passage of HB 2993 (2021 Oregon Laws, chapter 463) which passed during the 2021 Oregon legislative session. This bill will require changes to the RAC

which includes identifying membership that "represent the interests of persons and communities likely to be affected by the rule." The legislature has specifically asked that state agencies consider black, indigenous and people of color (BIPOC) communities as these communities are frequently not included in discussions. The Department of Justice is working on interpretive guidance. The Authority must either modify the RAC membership or develop a way to receive input on the proposed rules from impacted communities before filing with the Secretary of State. This requirement may cause further delays as we work on understanding legal guidance and how to proceed.

- RAC member via chat asked, "am I not representing the community utilizing these services under this rule?" D. Selover responded that this individual is a community representative, but the intent of the law is much bigger. Additional information will be forthcoming on how community input will be sought.

Additionally, it was noted that passage of this bill will require that the statement of need and fiscal impact identify how adoption of these rules will affect racial equity in this state.

- RAC member asked whether the Authority would pause meetings to expand the RAC to include more representatives of the committee? D.Selover responded that pausing may be one solution. RAC member further stated that racial equity with respect to maternal health care is important because of racial mortality disparities. A process for identifying persons should be considered or members of this RAC should be asked to reach out to members of the community working on issues of equity and issues of BIPOC concern about inclusion on the RAC.
- RAC member expressed excitement about this mandate to ensure community representation including from persons of color. It was stated that the community most impacted by these rules is not the general population of birthing people, rather people who choose a birth center birth and the best way to reach those people is through midwives in birth centers. Families who choose a birth center birth will have very different input then the general population of birthing families. It was further noted that a number of organizations are currently working on these issues such as Forward Together, a BIPOC led organization, working on birthing issues.

Risk Factor Table II – Risk Factors for Complications for Transfer to Hospital during Intrapartum or Postpartum Care

D. Selover reminded RAC members that the proposed risk factor tables were developed considering the 2015 HERC coverage guidance and noted that since the Authority started this RAC process, both the HERC coverage guidance and DEM rules have been revised. It was noted that Table II as drafted may not be as practical as initially proposed and D. Selover requested feedback on transfer risk factors. The Authority has cross walked each of the risk factors to identify what revised 2020 HERC coverage guidance states as well as the DEM rules. Additionally, it was noted that the Authority also looked at recent information released from Washington state. D. Selover asked for general feedback on the layout and format of the table.

- RAC member noted that any midwife is always considering whether someone needs to be transferred and it is unclear what the benefit would be for a table to include risk factors "for consideration." D. Selover responded that having a list of things where there is an expectation that the client will be transferred is not only good for the practitioner in a

birthing center but for the clients as well, so if serious issues arise, there is an agreement in place that the client will be transferred to another setting.

- RAC member indicated that the table structure is fine.
- RAC member expressed that as written the "consideration for transfer" columns are confusing based on the title of the table but was generally supportive of having "consideration" language.
- RAC member commented that format is easy to read and would be easy to read for patient as well.
- RAC member stated via chat that the color of the columns should be consistent with the action needed. For example, a mandatory transfer should be in red. RAC member further commented via chat whether unvaccinated COVID was considered as a risk factor in the development of these tables.
  - RAC member responded that the relative risk for stillbirth is a small increase for a low-risk population. The evidence is early and evolving and it was recommended that it not be included on the tables.
  - RAC member indicated that including an unvaccinated COVID-19 risk factor could result in fewer low risk women being served and concurred that it is too early to include without further evidence.
- RAC member shared that there are several risk factors that could be considered non-emergent if symptoms resolve.
- RAC member stated that the table is useful, however should be revised to include only those risk factors that would clearly result in a transfer. Risk factors "to consider for" would be very confusing for both providers and families.

D. Selover asked RAC members based on discussion whether the table should be amended to include only those risk factors that are an indication for transfer and amend language to provide more guidance such as 'unresolved' or 'ongoing' such as that used by the Midwife Association of Washington State (MAWS).

- RAC member questioned comments made regarding MAWS issuing guidance. They do have clinical indications for transfer, but these are not established in law. It was noted that Washington and several other states may issue guidance, but it is not established in law. RAC member via chat supported this comment about the distinction between rules and professional standards. D.Selover noted that providers and facilities use any number of guidance material to develop policies and procedures.
- RAC member indicated support of how the table is currently written using "maternal considerations for transfer" as it serves as a reminder of those factors that should be considered for transfer but allows the practitioner to make the decision, especially if the risk is resolved.
- RAC commented that if there is not a definite action, it should not be in rule as it creates liability for the practitioner and confusion for the Authority for purposes of an investigation. The Authority cannot investigate whether something has been considered. The rule needs to be able to clearly identify the appropriate action. A table that states "consideration for transfer" has high risk of liability. The table should be much smaller and clearly identify only those risk factors that are an indication for transfer and clearly enforceable.
- RAC member stated agreement orally and via chat that they agree with the above comments. RAC member commented that there are too many possible risk factors to

include and would be a never-ending list with multiple rows for consideration and will likely create loopholes. Providers should be able to use their clinical judgements as they are already considering these issues. It will also create a lot longer charting process and additional scripts will need to be created. Laws should be cut and dry – these are the reasons for transfer, these are the reasons for consult and everything else falls under the scope of the provider's license.

- Additional comments made by RAC members via chat:
  - Some risk factors do not seem to have anything to do with safety of birth centers, for example, laceration repair. It is the education, training and experience of the clinician, not the location.
  - More comfortable with consideration.
  - Consideration for transfer allows the practitioner to decide based on whether the condition is resolving quickly or does the individual need to be transferred.
  - Guidance makes more sense than rules when other providers don't have similar level of details in what they can do.
  - Rule writing should not be an educational textbook and should not include details that would not be considered an emergency.
  - Agree with consideration for transfer or two separate lists, if needed at all.
  - Rules should be clear not considerations. Remove the things that are minor which midwives know how to consider.
  - Agreement with RAC member comments that the table should clearly identify only those risk factors that are an indication for transfer and clearly enforceable.
  - Not an educational tool. It is a safety mechanism.
- D. Selover asked only RAC members to vote via chat whether there is any support for keeping the table (Table II) using the term consideration. Indicate support by typing yes (Y) or No (N).
  - 9 out of 12 members present voted No.
  - RAC member via chat stated, "Indications for Transfer" would be better; there is no need for 'absolute.'
  - RAC member indicated via chat that LDM (Licensed Direct Entry Midwifery) rules do not apply to all birth center clinicians.

Intra or Postpartum Maternal Considerations for Transfer

Bladder or rectal dysfunction

The following amendments were recommended via chat:

- Inability to void
- Unresolved bladder or rectal dysfunction
- Ongoing or unresolved bladder or rectal dysfunction
- Unresolved inability to void

Several RAC members via chat indicated to remove altogether. D. Selover asked for rationale why it should be removed even if amended.

- RAC indicated that that it would result in a lengthy list. It's common sense. If catheterization or other treatment does not work, of course the provider will transport.
- RAC member agreed with comment above via chat.

- RAC member stated it's too broad of a category to include on such a list and most of the time it is resolved or is a non-urgent consultation. The level of urgency would not be related to this table.

The following poll was administered:

POLL: Retain bladder or rectal dysfunction as written or amended as an indication for transfer. 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.
- 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.

Enlarging Hematoma

- RAC member stated they would not include as an indication to transfer as there is a lot of variability. Each provider is well versed in what they are comfortable managing; some hematomas would result in a transfer whereas other would not. D.Selover asked whether any more descriptive detail could be added to identify those that would require transfer. RAC member indicated that if for some reason this risk was being managed poorly, then consideration could be given to a size or cut off after review of literature.
- RAC member stated that enlarging hematoma is identified in the LDM rules as an indication for transfer, however, agreed it is too vague. An enlarging hematoma can be the size of quarter or size of grapefruit. Table should be reserved for risk factors that have very clear evidence and reasons to state that it should be an indication for transfer. D. Selover asked how it is defined in the DEM rules and RAC member responded it is not and stated that it is one of the items in the DEM rules that is too vague. Additional comments via chat included:
  - Enlarging hematoma is vague and details for safety are related to hemorrhage.
  - Serious hematoma is covered by signs of unresolved shock or maternal pain.
  - Falls under hemorrhage.
- D. Selover noted that staff will follow-up with the DEM Board to identify how this is applied.

The following poll was administered:

POLL: Retain enlarging hematoma as an indication for transfer. 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.
- 9% - 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.
- 91% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>Hemorrhage – Hypovolemia, shock, transfusion required</u>

- D. Selover commented that the language used in DEM rules reads as 'significant hemorrhage unresponsive to treatment with or without sustained vital sign instability or shock. The DEM rules also refer to signs or symptoms of shock.
- RAC member via chat suggested changing language to Hemorrhage, ongoing **and** unresponsive to treatment **and** signs or symptoms of shock. Inclusion of 'AND' is important. Several RAC members concurred with this suggestion via chat.
- RAC member via chat stated that signs of shock include rapid pulse and some people have this in general. Signs of shock may also include nausea.
- RAC member indicated support for the LDM language with the exception of signs or symptoms of shock. Initial signs of shock may be treatable. Recommended that language should be changed to 'signs or symptoms of shock that do not resolve with treatment.' D. Selover asked how that is addressed in midwifery practice when the LDM rules require transfer. RAC member responded that they do everything needed to address the patient's needs, call 9-1-1, and then often the client will stabilize, and transport is not needed.
- RAC member indicated that significant hemorrhage unresponsive to treatment with signs or symptoms of shock allows providers to immediately treat the hemorrhage (anti-hemorrhagic medication, IV fluids, possible catheter). Transfer would occur if there is not a response to that treatment.
- RAC member suggested changing to 'signs or symptoms of shock despite IV therapy and anti-hemorrhagic medication.'
- RAC member noted that their understanding of the LDM rules is even though the rules are written as indicated, the way that it is considered in an investigation is based on whether the LDM treated the condition and if it didn't resolve, did they transfer. Midwife subject matter experts are involved in every investigation conducted by the DEM Board. Since a midwife is not involved in OHA-Public Health investigations of a birth center, the rule needs to be very clear.
- RAC member suggested a different experience in investigations and agreed that the wording is very important.
- D.Selover noted that she will share recommendation with the DEM Board, and they will need to speak for themselves on this topic.
- RAC member noted via chat that the proposed amendment noted above removes the reference to 'transfusion needed.' It was noted that a hemorrhage may stop and the person relatively stable, but the blood loss was so substantial that transfer for transfusion is still indicated.

D. Selover proposed the following vote via chat:

- On Table II amend the hemorrhage risk factor to require a transfer for "Ongoing hemorrhage and unresponsive to treatment and signs or symptoms of shock or requires a transfusion."

- 9 out of 12 members voted Yes.

Infection requiring hospital treatment – Endometritis, wound

- RAC members via chat indicated the following:
  - Simplify to 'any infection requiring hospital treatment'
  - Remove the two extra words 'endometritis & wound'

POLL: Retain as a transfer requirement and amend to: Infection requiring hospital treatment.
Results:

- 70% - I can say an enthusiastic yes to the recommendation (or action).
- 30% - 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.

ACTION: 1) Revise Table II to indicate "Indications for Transfer" and include only those risk factors that would require a transfer; 2) Amend table as discussed; and 3) Follow-up with DEM Board for information on how 'enlarging hematoma' is applied in DEM rules and share information with respect to signs or symptoms of shock.

Planning for Future Meetings

In order to keep the momentum going on the work occurring, a decision was made to convene the RAC during legislative session in February for two hours. D. Selover recommended that we continue with Table II for next RAC meeting. As time and work allows, meetings will be lengthened back to 3 hours. Table II discussion will begin with 'laceration requiring hospital repair' and will continue in order from there.

D. Selover asked for input from the RAC regarding how to structure discussions on the four risk factors from Table I that had been deferred.

- VBAC will be an important long discussion.
  - Representation from DEM needed to reflect on discussion from their rules.
  - Up-to-date material and data are needed.
  - RAC members via chat suggested the following:
    - Material needed from the CABC.
    - VBAC discussion needs its own two-hour meeting.
    - Inviting Jen Kamel, "VBAC expert"
    - Ask RAC members to submit all related materials ahead of meeting and invite a representative from the International Cesarean Awareness Network (ICAN) as well as Melissa Cheyney to share evidence about VBAC in the community setting.
  - RAC members were asked to share contact information for the individuals recommended to participate with M.Bernal.

- RAC member asked that the Authority share which specific items will be discussed at least two weeks prior to the meeting date and allow for public comment. D. Selover noted that for purposes of the RAC discussion, the meeting should be limited to subject matter experts invited to participate. Public comment will occur after the final draft rules are posted for public hearing and persons will be allowed to testify orally.
- RAC member asked where the state stands on the issue of VBACs and D.Selover responded that it's been a couple of years since both the HERC and the DEM board have had their conversations so further discussions about the evidence and how providers are practicing is warranted, as well as hearing from individuals who have received those services.

- D. Selover asked with the remaining risk factors of VBAC, gestational age, multiple gestation and non-cephalic presentation whether the RAC had any preference in the order those remaining risk factors would be discussed.
- Email will be sent to RAC members asking for related material and possible persons to invite based on their expertise on the topic.
- RAC member stated that rules are being made for a facility but how much would these rules control the scope of practice of providers who work within that place? Practitioners whose scope does not include VBAC would not facilitate a VBAC, but what if there is a provider who works at a birth center who does have certain procedures within their scope. D.Selover noted that setting does matter and there may some limitations of procedures that can be done in a birthing center setting independent from the scope of practice. Some procedures may require access to more equipment and lifesaving measures that would not be present in a birthing center.

Wrap Up
Next two meetings are scheduled for February 15th at 1:00 p.m. and March 8th at 1:00 p.m.

RAC adjourned at: 3:00 p.m.