PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement
Kate Brown, Governor

Oregon Health Authority

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Birthing Center RAC
May 30, 2019
9:00 – Noon; Room 1B

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Brooke Bina (phone) for Laura Erickson	Alma Midwifery Services
Karen DeWitt	Oregon Association of Naturopathic Physicians
Colleen Forbes	Chair, Board of Direct Entry Midwives
Jason Gingerich (phone) for Cat Livingston	OHA-Health Evidence Review Commission
Barbara Holtry for Ruby Jason	Oregon State Board of Nursing
Meredith Mance	Aurora Birth Center
Danielle Meyer	Oregon Association of Hospital & Health Systems
Samie Patnode	OHA-Health Licensing Office
Margaret Porter	Bella Vie Birth Center
Petra Prostrednick	Bella Vie Birth Center
Stefanie Rogers	Providence
Anna Stiefvater	OHA-Public Health, Maternal & Child Health
Alice Taylor	American Association of Birth Centers
Willa Ervin (phone)	Rogue Birth Center
Michele Zimmerman-Pike	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Doreen Davis	OHA-Health Licensing Office
Sharron Fuchs	Chiropractor trained in out-of-hospital births
Desiree LeFave (phone)	Bella Vie Birth Center
Tracy Lawson-Allen (phone)	Andaluz Birth Center
OHA Staff	
Anna Davis	Survey and Certification Manager, Health Facility Licensing and Certification
Lacey Martinez	Surveyor, Health Facility Licensing and Certification
Dana Selover	Section Manager, Health Care Regulation & Quality Improvement
Mellony Bernal	Administrative Rules and Legislative Policy Analyst, Health Care Regulation & Quality Improvement

Welcome / Administrative Rule Process
Dana Selover welcomed RAC members and RAC members introduced themselves. D. Selover reviewed the meeting agenda and provided an overview of rulemaking process and scope of committee:

- The Oregon's Administrative Procedures Act is the basis for agency rulemaking, and each agency has slightly difference processes. RACs are convened to address proposed changes to administrative rules based on new (or changes to) state or federal laws, implementing national guidelines, stakeholder request, etc.
- The Authority proposes administrative rule language that the committee will react to during RAC meetings.
- A RAC may meet only once or may meet over the course of year or longer depending on the nature of the rules. It is expected that this RAC will meet no more than three times, but additional meetings may be scheduled if necessary.
- RAC membership is made up of both clinical and operational expertise, and special interest associations.
- Proposed rules will be filed with the Secretary of State's Office identifying changes to the rules and possible fiscal impact. A public hearing will be scheduled and interested parties notified to obtain public comment. Both oral and written comments may be submitted.
- Staff will review and respond to public comments including making additional changes to the rules based on comments received and identify an effective date.
- The RAC is advisory only. Input will be considered, however, the OHA retains the final decision on final rule text. The RAC is open to the public, however, it is not subject to public meeting law requirements.
- Rules must align with statute. The program will consider scientific evidence and will focus on the client's quality and safe care. Effect of rules on the provider are considered but only secondary to the care of clients.
- Membership is based on representation across the state, including size and location of birthing centers. Subject matter experts have also been invited. According to OHA policy, outside entities may send only one representative to participate on the RAC. Members may send delegates if unable to attend.
- The RAC will be staffed by the program. Meeting notes will be drafted and shared with the RAC. Meetings will be audio recorded. Meeting material will be shared at least one week before the next scheduled meeting date.
- Time will be allotted on the agenda for public comment.
- Correspondence from RAC members regarding the rules is public information and will be shared with the entire RAC.
- The goal is to have final draft rules and the public hearing concluded by October 2019 and rules effective by January 1, 2020.

Agency Roles

Organizational charts were shared with the RAC to identify the different OHA programs and their roles involved in out-of-hospital (OOH) births. The HCRQI program will work to align OHA rules; however, we recognize there may be some differences.

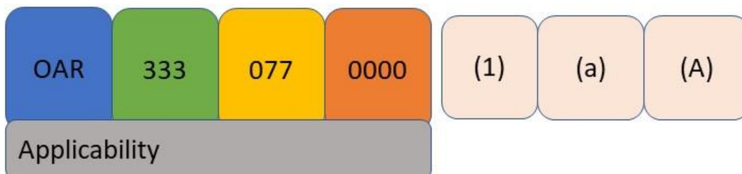
- Health Policy and Analytics, Health Evidence Review Commission (HERC): Reviews clinical evidence to guide the OHA in making benefit-related decisions for its health plans. Risk factor guidelines were developed in November 2015 and are currently under reconsideration. A meeting is scheduled for Thursday, June 6th to continue review of the draft coverage guidelines and material

will be posted on the web at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Meetings-Public.aspx. Persons may sign-up on a listserv to receive notifications about this work.

- The Center for Health Protection houses programs that conduct most of the regulatory work; Health Care Regulation and Quality Improvement regulates all non-long-term care facilities including birthing centers. The Health Licensing Office regulates provider types including midwives, through the Board of Direct Entry Midwifery.
- It was noted that per ORS 442.015, a birthing center is included in the definition of health care facility, and as such any statute that affects health care facilities will impact birthing centers.
- The current HERC guidelines were shared as well as proposed direct entry midwifery (DEM) rules which are currently out for public comment. It was noted that while the HERC guidelines are currently under review and changes are under consideration for DEM rules, the HCRQI program determined that it would proceed with revisions to the birthing center rules to establish a foundation. As other program rules and guidelines are finalized, HCRQI will monitor and make changes to its birthing centers rules as determined necessary.
- D. Selover shared that the HERC coverage guidance will be used as the basis for revised birthing center risk factor tables.

Rule Overview

D. Selover provided an overview of the proposed rulemaking document and explained elements of a rule number. Birthing center rules will have its own Division number (077) and be removed from their current location under 076. When discussing rules, only the rule number (last 4 digits) and applicable section numbers need to be identified.



Oregon Administrative Rule

Chapter # - Chapter 333 represents OHA, Public Health Division

Division # - Division 077 – Division number assigned to specific program or topic (example birthing centers)

Rule # - Rule 0000 – Rule numbers assigned for each rule category

Rule Title – a general title for the rule category based on content of the rule

(1) Section (1)

(a) Subsection (a)

(A) Paragraph (A)

Rules have been structured to align with other health care facility types and includes standard licensing language regarding the application process up front and enforcement language at the end.

RAC member noted that the initial birthing center rules were based on American Public Health Association guidelines from 1982.
Proposed Rule Changes – Standard Licensing Rule Elements
OAR 333-077-0000 – Applicability
This rule identifies the purpose and applicability of the rules. RAC members had no comments.
ACTION: None
OAR 333-077-0010 – Definitions
It was noted that as the rules are reviewed and discussed, RAC members should consider what additional definitions may need to be added, amended or removed. RAC member noted that the following definitions should be amended: • Certified Nurse Midwife should be amended to strike 'certified' and replace with 'licensed' given passage of SB 64; • Direct Entry Midwife should reflect 'licensed' direct entry midwife; • Discharge appears to be limited to release or transfer to another health care facility and it should be clear that a client or newborn could be released to home; • Naturopathic physician definition should be added that includes a reference to certification in natural childbirth.
ACTION: Amend definitions as noted above. RAC members consider additional definition changes necessary as the rules are reviewed.
OAR 333-077-0015 – Application and Fees
Rules are an overview of the application required, reference to fees adopted in ORS chapter 441 and other responsibilities of a birthing center. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-077-0020 – Application Review
Rule specifies what the OHA will consider in reviewing an application for license. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-077-0025 – Approval of License Application
Rules provide information on approval of a license application. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-076-0490 – Submission of Plans

This rule is being repealed as language has been moved to OAR 333-077-0220 under 'Physical Environment.' RAC members had no comments.
ACTION: None
OAR 333-077-0030 – Denial of License Application
This is standard facility licensing rule language. Language was moved from OAR 333-076-0570 to specify the notification requirements for denying a license which must comply with the Administrative Procedures Act under ORS chapter 183. Deleted sections (1) through (4) have been moved to enforcement and violations rules numbered OAR 333-077-0230 and 0250. RAC members had no comments.
ACTION: None
OAR 333-077-0035 – Expiration and Renewal of License
Minor modifications were made, and rule reference updated. Standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-077-0040 – Return of License
Clarifies actions necessary if a licensed birthing center chooses to close. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-076-0560 - Classification
Rule is being repealed as it does not apply to birthing centers. RAC members had no comments.
ACTION: None
OAR 333-076-0570 – Hearings
Rule is being repealed to align with other facility licensing rules. Language has been added to OAR 333-077-0030. RAC members had no comments.
ACTION: None
OAR 333-076-0590 – Adoption by Reference
Rule is being repealed to align with other facility licensing rules. Publications will be adopted by reference in the rule where the publication is mentioned. RAC members had no comments.
ACTION: None
OAR 333-077-0045 - Waivers
Standard facility licensing rule language which allows a birthing center to request a waiver of rule requirements. RAC members had no comments.
ACTION: None
OAR 333-077-0050 - Complaints

OAR 333-076-0610 is renumbered to 333-077-0050 and clarifies procedures relating to complaints issued against a birthing center. This is standard facility licensing rule language.
Discussion:

- RAC member inquired about language relating to public notice about a complaint and whether it applied to other licensed facility types. Program staff clarified that this notice is not about specific complaints but rather a general notice to inform clients who to contact if they want to make a complaint.
- RAC member inquired whether there is a process for complaints about a systems issue or a trend that is specific to the facility versus a provider. Program staff provided an overview and noted that records will be requested based on the type of complaint received and the alleged non-compliance. Records are requested for a specified time period and a sample taken where staff will look at both the specific complaint and from a systems perspective. Example – Are written policies in place, that comply with OARs? Are the policies being followed?

RAC members had no further comments.

ACTION: None

OAR 333-077-0055 – Investigations

Rule language pertains to actions the OHA will take in investigating a complaint issued against a birthing center. This is standard facility licensing rule language. Discussion:

- RAC member asked for clarification on the investigation process. The rule implies that an investigation is opened each time a complaint is issued, which is contrary to how professional licensing boards conduct an investigation. RAC member noted that some complaints may not lead to an investigation, as the complaint is evaluated to determine whether there is enough evidence to suggest a violation of any rule or law. Program staff noted that complaints are triaged to determine whether there is enough information to suggest a violation of rule or law. If after review, and any further follow-up to receive additional information, it is determined that the complaint is outside OHA's jurisdiction or there is not enough evidence to proceed, an investigation will not be conducted.
- The complaint intake form and frequently asked questions about complaints can be found at: www.healthoregon.org/facilitycomplaints
- RAC member suggested that language be added or amended to clarify that not every complaint will lead to an investigation or an investigation is conducted only when there is sufficient evidence of non-compliance.
- Program staff noted that the program will consider whether additional clarification can be added or if interpretation of the rule is sufficient.
- RAC member asked whether there is a current policy in place that guides the agency in the triage process. Program staff indicated that there are internal guidelines in place about the complaint triage process.
- RAC member concurred with previous comments and suggested that section (1) be amended to indicate that Authority staff **may** begin an investigation. Stating that an investigation is automatic will place birthing centers on the defensive.

ACTION: Program staff will review section (1) and consider possible amendments to clarify the complaint process.

OAR 333-077-0060 – Survey
Rule language pertains to actions the OHA will take in conducting initial and triennial surveys to determine compliance with birthing center licensing laws and rules. Describes actions taken by the OHA including issuing findings. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None.
OAR 333-077-0230 – Violations
Rule identifies what is considered a violation which is standard facility licensing rule language. RAC members had no comments.
ACTION: None.
OAR 333-077-0240 – Informal Enforcement
Language specifies what occurs when a facility is found to be out of compliance with rules and regulations. A statement of deficiency is issued, and facilities are offered an opportunity to dispute findings. Facilities must create a plan of correction within a specified time period for the OHA to review and approve. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None.
OAR 333-077-0250 – Formal Enforcement
Rule specifies actions necessary if the OHA determines substantial failure to comply with licensing laws. The OHA may issue a notice of proposed suspension or revocation. Civil penalties may also be issued. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None.
OAR 333-077-0260 – Civil Penalties, Generally
Rule clarifies civil penalty procedures. This is standard facility licensing rule language. RAC members had no comments.
ACTION: None
OAR 333-077-0070 – Governing Body Responsibility
This rule outlines responsibilities and expectations of the Governing body. Discussion: • RAC member expressed concern about section (3) which is specific to physicians that are admitted to practice in a birthing center and states that physicians must be organized in a medical staff to review the practices of the birthing center and propose medical staff by-laws. It was suggested that the rule language implies that physicians are serving in a supervisory capacity over all provider types which is not the birthing center model in Oregon. Physicians do not inherently have power in a birthing center and this rule could undermine how a birthing center operates. It was noted that licensed independent medical providers could be considered medical staff.

- It was suggested that the rule be rewritten to clarify that not only physicians, but all provider types admitted to practice in a birthing center, be organized into a medical staff to review professional practices of the birthing center and propose by-laws.
- Program staff will need to review statute (ORS 441.055) since physicians are not the primary provider in a birthing center. RAC member noted it's important to understand the intention of the rule which is that there should be staff that are reviewing the professional practices of the birthing center for purposes of reducing morbidity and mortality, and improving client care, and that by-laws are being adopted. These efforts can still occur but need to include different types of providers not just physicians.
- Notwithstanding the comments provided regarding physicians, a RAC member remarked that the proposed Governing Body language is in compliance with the American Association of Birth Center standards.
- RAC member commented that subsection (2)(d) should strike reference to physicians and specify 'ensure all health care personnel admitted to practice in the facility are granted privileges…'
- RAC member remarked that subsection (2)(b) should be amended to ensure that it's feasible that an owner of a facility may also serve as the administrator or chief executive officer. Given the size of many birthing centers, one person may serve in several capacities. Staff noted that the rule is currently written in a manner that does not suggest an owner could not be an administrator, and the program can ensure that interpretive guidance is established that would make this clear.

ACTION: 1) Program staff will consider statutory language and review references to physicians to determine whether changes can be made that will comply with ORS 441.055. 2) Amend section (2)(d) to strike reference to physicians.

OAR 333-077-0080 - Personnel

Personnel requirements for a birthing center are established in this rule. Discussion:

- RAC member requested that naturopathic physician be included under subsection (1)(b). Program staff noted that the definition of physician includes naturopathic physicians.
- RAC member inquired whether two staff must be present at all times even during postpartum care. It was noted that subsection (1)(b) is currently written to require that one provider and one other staff person be present at all times a client is in present in the birthing center.
    - Current birthing center rules require 'adequate number of qualified, and where required, licensed or registered personnel on duty and immediately available…'
    - It was noted that a client can quickly become unstable and there must be staff ready to respond.
    - Adding requirement for additional staffing for postpartum care will place small birthing centers at risk of closure given that there are few clients and reimbursement is minimal. Additionally, if two persons are required and there are only two staff in a small birthing center, and another client goes into labor, there won't be anyone 'fresh' to manage the other birth. Once a mother and newborn are considered stable, one person should be considered sufficient.
    - RAC member noted that one person is often managing a client until active labor or right before delivery. It was noted that subsections (1)(b) and (c) are similar, although

(c) includes a reference to student. It was suggested that the two subsections should mirror each other. Example provided of one person on site, and a policy that addresses how and when to call for additional assistance, and what type of assistance. Program staff questioned what a policy and procedure may look like in terms of determining how one staff person can take care of an emergency situation and also call for help. RAC member responded that a 'panic button' is in operation in a specified birthing center so with just one touch of button, emergency assistance is called.
   - RAC member noted that the staffing requirement appears to be more stringent than hospital requirements.
   - RAC member commented that CNAs (certified nursing assistants) operate according to a prescribed list of duties from the Oregon State Board of Nursing and require supervision. CNAs are not independent providers and facilities that may be using a CNA in this capacity should double-check with the Board to ensure the facility is operating within requirements.
   - RAC member remarked that it's important to differentiate between hospital births and low-risk births that occur at a birthing center. It's important for applicable licensed providers to be readily available 3-4 hours after a birth occurs. Many birthing centers have clients that once considered stable continue to stay at the birthing center for 24-48 hours, not necessarily for medical care rather to be in a relaxed environment, taken care of and not rushed home. It was suggested that the national model is to have one person assisting prior to active labor and during post-partum. Data on outcomes is based on this model and does not suggest there are any problems or safety concerns. All midwives and other staff are trained to manage an emergency even if only one person is present. The hospital model should not be applied to the birthing center model.
   - It was noted that the American Association of Birth Centers recently addressed staffing. The AABC has adopted a new certified birth assistant training program for personnel including unlicensed personnel. The standards committee reviewed and determined that a licensed provider determines the client is stable and appropriate for discharge home, then it is okay for an unlicensed provider to be with that client.
   - RAC member suggested that if rules were not changed, this staffing model could create shorter postpartum stays for some birthing centers to stay within budget making it unsafe for the client and newborn.
   - Program staff encouraged RAC members to submit any data or other information related to staffing models based on various phases of labor to Mellony Bernal.
- RAC member suggested that subsection (1)(a) is too ambiguous. The RAC member noted that a birthing center can have a list of licensed community providers that have agreed to assist when extra help is needed; but the rule does not appear to speak to this. It was noted that section (2) clarifies that a birthing center must maintain personnel records on "all employees, contractors and volunteers working at the facility…"
- In terms of the training specified in subsection (1)(d), the following elements were discussed:
   - RAC member suggested that all licensed providers attending a birth should be trained in neonatal resuscitation (NRP.)
   - RAC members suggested that licensed providers attending birth should be trained in both neonatal resuscitation and adult resuscitation. Questions were raised whether

reference to "certified in CPR" was adequate and whether BLS certification was better suited.

- Current rule [OAR 333-076-0670(5)], specifies all personnel providing *direct client care* must be trained in cardiopulmonary resuscitation (CPR) and there must be a record of current CPR certification. In addition, there must be present at each birth one practitioner trained in care and resuscitation of the newborn. It was noted that in one birth center, all staff, including the office receptionist, are trained in CPR but not certified in BLS.
- Additional questions were raised about CPR certification versus BLS. It was noted that infant CPR is comparable to a red cross CPR course. Certification in NRP is a program that is very distinct from basic CPR courses. The rule needs to be very clear on intent given the distinct differences.
- Licensed Direct Entry Midwife (DEM) rules require certification in neonatal resuscitation and certification in CPR for infants and adults.
- RAC member remarked that it is difficult for many licensed DEMs to obtain NRP training as in some areas of the state as hospitals are not allowing them to take the course.
- RAC member noted that at time of birth it is necessary that two people are present that are trained in both CPR and NRP. Once a client and newborn are considered stable, one person trained in CPR and NRP is sufficient for staffing purposes.
- RAC member shared that the North American Registry of Midwives (NARM) that certifies professional midwives nationwide specifies: ***NARM** only accepts certification from courses which include a hands-on skills component. Online-only courses are not accepted. Approved **CPR** courses include the American Heart Association, the Red Cross, and American Safety and Health Institute (ASHI) Basic Life Support.*
- RAC member shared that the American Academy of Pediatrics recommends that each delivery should be attended by two individuals, at least one of whom has NRP training and would recommend the rules state the same. Another RAC remember remarked that in a birthing center, it’s important that both birth attendees be trained given that in the birthing center setting, there is not a resuscitation team available.

- RAC members had no further comments on subsections (1)(e) through (i) and sections (2) and (3).

ACTION: 1) Reconsider requirement that two staff must be present at all times a client is present in the birthing center. Consider staffing requirements based on specific phases of labor (active labor versus post-partum). 2) If RAC members have information or data relating to staffing and various phases of labor, submit to M. Bernal. 3) Clarify specific life saving training requirements for staff attending births.

SUMMARY OF REMAINING RULES

D. Selover provided a quick run through of remaining rules.

- Policies and procedures
- Client care services including prenatal care, intrapartum care and postpartum care
- Admission and discharge (where risk factor tables will be discussed)
- Client transfer

- Medical records
- Surgical services
- Laboratory services
- Pharmacy and anesthetic services
- Dietary services
- Newborn care and screening
- Equipment and supplies
- Infection control
- Quality assessment and performance improvement
- Facility safety and emergency preparedness
- Physical environment

D. Selover encouraged RAC members to bring relevant association recommendations or other guidelines to the next RAC meeting (AABC, AAP, NARM, etc.) as we work through remaining proposed rules.

Risk Factor Tables

D. Selover provided a brief overview of revised risk factor tables that will be discussed at the next RAC meeting. It was noted that the existing "absolute risk factor" tables are based on phase of delivery (prenatal, intrapartum and postpartum) and exclude persons from out-of-hospital birth (with some exception for imminent birth.) These tables do not include references to consultation.

The revised risk factor tables were drafted using the HERC guidelines as the basis.

- Table 1 – Risk factors for exclusion at admission based on maternal history, previous fetal history and current pregnancy complications.
- Table 2 – Risk factors or complications for transfer to hospital during intrapartum or postpartum care based on maternal, fetal and uteroplacental considerations.
- Table 3 – Complications requiring consultation at admission during care based on maternal and fetal history and current pregnancy

D. Selover encouraged RAC members to be prepared with comments, amendments or ideas on different formatting and content for the tables at the next RAC meeting.

RAC member suggested that the three-column format across the page is easier to follow and should be adapted to all tables.

NEXT STEPS

D. Selover encouraged RAC members to bring relevant association recommendations for policies and procedures to the next RAC meeting (AABC, AAP, NARM, etc.)

M. Bernal will be sending out a doodle meeting poll to query possible dates and time for next meeting (within 4-6 weeks).

PUBLIC COMMENT

Public comments:

- Sharron Fuchs provided the following comments:
    - 0010 definitions – Consider adding all provider types with out-of-hospital births within their scope of practice to definitions (i.e. add chiropractic physicians with certification in natural child birth to the definition of physician.)

- It was suggested that chiropractors without natural child birth certification have been called to assist at birthing centers which should not be allowed. It was recommended that birthing centers, through the credentialing process, require all provider types to have relevant child birth certification.
- All provider types should keep relevant chart notes that are available.
- References to naturopathic midwife is confusing and it was suggested that the term Doctor of Naturopathy with certification in natural childbirth be used instead.
- 0055 investigations – it was suggested that any complaint should result in opening a complaint investigation even if a facility had a recent 'site investigation.' This would ensure that the complaint is looked at separately to make sure that no violations occurred based on the specific complaint.
- RAC members were encouraged to go to specific provider type boards to review notices of intent and notices of final orders. Many do relate to birthing centers and would capture many concerns about issues that arise that may be remedied with revised birthing center rules.

Meeting adjourned at 11:58 a.m.

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Birthing Center RAC
July 17, 2019
9:00 – Noon; Room 1E

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Kaylyn Anderson (phone)	Consumer
Karen DeWitt	Oregon Association of Naturopathic Physicians
Laura Erickson	Alma Midwifery Services
Colleen Forbes	Chair, Board of Direct Entry Midwives
Jennifer Gallardo	Andaluz Birthcenter
Jason Gingerich (phone) for Cat Livingston	OHA-Health Evidence Review Commission
Hermine Hayes-Klein	Oregon Association of Birth Centers
Ruby Jason	Oregon State Board of Nursing
Desiree LeFave	Bella Vie Birth Center
Rebecca Long	OHA-EMS and Trauma Systems
Meredith Mance	Aurora Birth Center
Samie Patnode	OHA-Health Licensing Office
Margaret Porter (phone)	Bella Vie Birth Center
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Willa Woodard-Ervin (phone)	Rogue Birth Center
Michele Zimmerman-Pike (phone)	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Brooke Bina (phone)	Alma Midwifery Services
Olivia Bunn	Consumer
Hannah Cornman	Consumer
Debbie Cowart	Growing Family Birth Center
Doreen Davis	OHA-Health Licensing Office
Sharron Fuchs	Chiropractor trained in out-of-hospital births
Lindsie Lincoln	Growing Family Birth Center
Lynette Pettibone	Consumer

OHA PHD Staff	
Anna Davis	Survey and Certification Manager, Health Facility Licensing and Certification
Lacey Martinez	Surveyor, Health Facility Licensing and Certification
Dana Selover	Section Manager, Health Care Regulation & Quality Improvement

Mellony Bernal	Administrative Rules and Legislative Policy Analyst, Health Care Regulation & Quality Improvement

Welcome / Overview
Dana Selover welcomed RAC members and RAC members introduced themselves. Members of the public also introduced themselves. D. Selover provided a brief overview of the agenda and restated the goal is to have rules filed by October/November for purposes of a public hearing and have rules in effect by January 2020. Meeting notes have been drafted that summarize the May meeting. Audio files of the meetings are available upon request. It was noted that the action items from the May meeting are still in progress and will be shared at a future meeting. Comments on notes: • Correction made to Sharron Fuchs title. RAC members that were unable to attend the May meeting provided the following comments with respect to possible changes to the rules. The following comments do not reflect the May meeting discussion: • Efforts should be made to make sure that definitions are non-discriminatory, such as consistency in how definitions for health professionals are framed. • Consider looking to the American Association of Birth Centers (AABC) for the definition of 'freestanding birthing center' which avoids low risk/high risk language. References to uncomplicated should be removed throughout the rules and replaced with normal physiological birth. Risk is a spectrum and many risks can be managed in a birth center as a midwife is able to stabilize some complications. A birth center therefore can facilitate a birth that may have complications, but complications were resolved.   – Staff noted that statutory requirements, including any definitions that are established in statute, must be considered. (Freestanding birth center is defined in statute (ORS 442.015) and includes reference to low risk deliveries.) Clarifying language can be considered and the program can also provide interpretive guidance for purposes of administrative rules. • It was also suggested that the rules need to ensure that the administration of surveys and investigations guards against cultural bias of out-of-hospital (OOH) births. It was suggested that many investigations against birth centers and midwives is a result of cultural bias. Additional clarification is needed to describe who will be conducting the initial assessment to determine whether a complaint is investigated and, if an investigation is warranted, who will be conducting the investigation. It was suggested that persons conducting the investigation be of the same license type of the people under investigation and have personal experience with OOH births. • RAC member representing the Oregon State Board of Nursing noted there appears to be a significant misunderstanding on how CNAs can or cannot be used based on the discussion noted in the minutes regarding supervision of CNAs. RAC member clarified that a CNA can only be supervised by and take direction from a licensee of the Oregon State Board of Nursing, i.e. LPN, RN, or CNM. CNAs cannot be supervised by or take direction from a physician, naturopath or licensed

direct entry midwife. It was further noted that if a CNA does not work under the direct supervision of a licensee of the Board of Nursing, they would be working as an unregulated care provider and any hours worked could not be counted toward license renewal. CNAs do not have a scope of practice, rather authorized duties under OAR chapter 851, division 63.

- RAC member noted that the AABC does have a certified birth assistant (CBA) training for unlicensed providers and according to the Commission on Accreditation of Birth Centers (CABC) accreditation standards, there is a system in place that does allow a CBA to stay and provide care postpartum if a client is ready for discharge rather than a midwife.

ACTION: 1) Consider changes to definitions for provider types using consistent terms; 2) consider providing clarification for the definition of 'freestanding birth center' to address use of terms relating to risk; 3) provide the RAC with additional information about OHA process for complaint investigations and surveys; and 4) ensure that rule language is written that avoids any conflict with the nurse practice act with respect to CNAs.

Proposed Rule Changes

D. Selover reminded RAC members that proposed rules were drafted based on the following:

- Alignment with other facility type licensing rules;
- Consideration of other Oregon agency and board rules including the Health Evidence Review Commission and Board of Direct Entry Midwifery;
- Consideration of other states' regulations and national accrediting boards; and
- Federal or nationally recognized guidance.

OAR 333-077-0090 – Policies and Procedures

D. Selover noted that policies and procedures mostly contain things that may also be detailed in other rules. For example, the requirement for an infection control policy, points to a rule specific to infection control which will identify specific requirements.

The following comments were provided on specific sections:

- Section (2) requires that the care and services of a client in a birthing center must be supervised by specified providers.
  - Reference to certified nurse midwife needs to be changed to licensed nurse midwife given passage of recent legislation. This section also references nurse practitioners (NP) and it was noted that NPs by their training and competency do not have the legal scope of practice to deliver babies. Licensed nurse midwives are also NPs, so it was recommended that reference to NPs be removed.
  - Question was raised about the term 'certified professional midwife' – a certified professional midwife is the national certification that licensed direct entry midwives have. It was noted that a traditional midwife may choose not to be a licensed DEM but can still be designated as a certified professional midwife. RAC agreed that reference to certified professional midwife (CPM) could be removed as supervisory provider.

- RAC member remarked that under current rules it specifies that there must be adequate numbers of qualified, and where required, licensed or registered personnel on duty. It was noted that many birthing centers use traditional midwives for post-partum care and questioned why reference to CPM should be removed. Staff noted that the section in question is for purposes of supervising the care and services of clients and not just working in a center.
- Additional question was raised by a RAC member about the definition of supervision and whether a midwife can still be considered 'supervising' if the midwife has left the building. Staff noted that the rule is not about whether a person must be on site or not, rather is about who is professionally responsible for all the client care and services in a center.

- RAC member remarked that the group should discuss intent in terms of the type of provider who should be able to manage or supervise the services of a birthing center. It was noted that based on discussion, an NP without midwifery specialty cannot manage a center; should the same be true of any physician who does not specialize in maternity care?
  - RAC member suggested that the physician definition be amended to clarify that a physician must have childbirth experience or specialize in maternity care. Staff noted that it needs to consider further including whether it is most appropriate to change the definition or whether such a requirement should be placed elsewhere.
  - RAC further discussed licensing and education requirements for both physicians and nurse practitioners which are significantly different.

- Subsections (3)(a) through (u) specifies the types of policies that a birthing center must have. Discussion:
  - Subsection (3)(h): RAC member questioned risk factor assessment during the antepartum stage if a client may be seeking prenatal care only. For example, client may not be eligible for delivery at birthing center due to risk factors, but the client wishes to have prenatal care performed by birthing center. Subsection (3)(h) specifies that a risk assessment must occur in accordance with Table I which would exclude a client from 'receiving care' at a birthing center. Another RAC member suggested changing 'receiving care' to receiving intrapartum care or performing a delivery. Staff will consider further.
  - Subsection (3)(j): RAC member questioned requirement to consult with a care provider that is credentialed in a hospital. It was suggested that this is too restrictive. Current rule requires only that a birth center have a system delineating how and when the center will seek consultation with clinical specialists. Staff noted that this requirement was added based on adoption of the HERC guidance.
    - RAC member noted that the consultation requirement under HERC has been a real problem and suggested that adoption of the HERC guidance is inappropriate for a facility or a provider type and will restrict the services of the midwife or

center. It was further noted that the Board of DEM has also been working on rule language to ensure that appropriate consultations occur. There needs to be flexibility to allow midwives to make clinical assessments about who the correct consultant may be on a case by case basis.

- RAC member noted that the Board of DEM rules leave the consultation requirement fairly flexible.
- There are many reasons for a provider to seek consultation, but the most frequent problem is when a consult is needed with someone other than a maternity care provider, such as a hematologist.
- RAC member expressed concern that requiring consultation with a provider that has hospital privileges may result in consultation being withheld due to providers that may not support OOH births or care being rendered by a midwife or a birth center. RAC member questioned what the goal of the consultation provision is. If it is to ensure that clients are transferred expeditiously and smoothly, that is already provided for in the rule relating to transfers. If the requirement is to second guess the midwife's risk assessment, then that could be considered discriminatory as these are all licensed professionals with necessary skills and training. If the goal is to ensure that a client understands a doctor's assessment of the risk factors, then that is more of an informed consent issue and recommending consultation to the client rather than requiring it. Some clients already understand the risk factors and a midwife can advise but not require a client to follow-up on a consultation.
- RAC member noted that consultation is a relationship between the midwife and whomever that person is consulting with. If the consultation leads to care being provided elsewhere, that should be considered a referral or transfer. Consultation should be considered a collegial relationship between two experts.
- Staff noted that the purpose of consultation is for the health and safety of the client and newborn. Consultations are a requirement across all spectrums.
- RAC member remarked that Table III should define the nature of the consultation.
- RAC member noted that the last draft of the revised HERC coverage guidance does differentiate between requirements for consultation and transfer of care. Detailed language has not been written yet and will be discussed at the September meeting. Concerns identified in this RAC will be taken back to HERC staff.
- RAC member commented that the level of care of the facility not the clinician might be better in rule. It was suggested that many birth centers already have staff that have hospital privileges so it's unnecessary.
- RAC member shared information about Southern Oregon and noted that a physician may not be the best person to consult. It was suggested that physicians rarely understand the scope of licensed DEMs nor the laws relating to

freestanding birthing centers. Advice received may be out of line with current laws and a lot of time is spent educating the physician. It was recommended that current rule language remain in place.

  - RAC member noted that consultation may not be for the client but the baby as well. Consultation may be sought in other geographic areas if a center is experiencing problems in a certain hospital or region. There are many physicians that support OOH births.
  - RAC member noted that it's important for other members to understand that there are many places where it is difficult to find providers that will provide a consultation for an OOH birth scenario. While consults can be obtained from other geographic areas this may result in difficulties for the client if the consult results in an in-person appointment. Rules should not be drafted that penalize midwives or birth centers when there are documented experiences of bias in areas of the state. The Oregon Perinatal Collaborative has made it a priority to work on home birth and birth center transfer improvement.
  - Staff asked that RAC members not assign any kind of intent to other providers regarding birth care. The role of the RAC is to consider the health and safety of the client and newborn.

- Subsection (3)(n): RAC member questioned what is the definition of prompt availability? A birth center must be ready for any emergency including a disaster. It was noted that there is a separate rule dedicated to emergency preparedness requirements. Promptly available is used currently in rule and it was noted that there are currently no problems with enforcement pertaining to promptly available.
- Paragraph (3)(q)(B): RAC member inquired whether administration of Vitamin K was voluntary. It was noted that the Newborn Care and Screening rule (333-077-0170) directs a birthing center to the requirements in OAR 333-021-0800. These rules provide that a parent may decline administration of vitamin K.
- Subsection (3)(u): It was noted that all health care facilities are required to comply with patient notification requirements. Since a health care facility is defined under ORS 442.015 to include birthing centers, a birthing center must also comply.

ACTION:

1) Find and replace the term "certified nurse midwife" or "nurse midwife nurse practitioner" with "licensed nurse midwife";
2) Revise section (2) by removing reference to nurse practitioner and certified professional midwife;
3) Consider language that clarifies that a birth center may provide prenatal care regardless if client is eligible to have delivery at center;
4) Consider making consultation requirement more flexible so that birthing centers can consult with any clinical specialist as determined necessary and not only with those that have hospital privileges.

OAR 333-077-0100 – Client Care Services

The intent of this rule is to identify the services available to clients and clarify client disclosure requirements and client rights.
• Section (2): RAC member questioned whether "a copy of" included an electronic copy. Staff responded yes.
• Subsection (2)(c): RAC member inquired about intent and whether every medication and every piece of equipment needed to be listed in a client disclosure. It was requested that it be removed since too many details in a client disclosure may not be read. RAC concurred.
• Subsection (2)(f): RAC member suggested that reference to professional liability insurance should be added along with malpractice coverage, i.e. "malpractice coverage or professional liability insurance."
  − Another RAC member questioned whether it was necessary to share that a provider has malpractice coverage.
  − It was noted that the client disclosure information proposed in this rule comes from the Board of DEM current rules. The Board requires that a client be informed whether a midwife does or does not have malpractice coverage.
  − RAC member shared that it is assumed in a hospital setting that all providers have malpractice coverage, but not all midwives do.
  − RAC member shared that professional liability insurance is the most current terminology used.
  − Malpractice is a term that most persons relate to. It was further noted that the term malpractice insurance is used in DEM statutes.
• Subsection (2)(i): RAC member asked that reference to 'consultants and related services and institutions' be removed as it would make the client disclosure too lengthy. The goal is to make sure that clients read the information and not make the disclosure too unwieldy. RAC concurred.
• Subsection (3)(c): RAC member asked that ethnicity, gender identification and sexual orientation be included. RAC concurred.
• Subsection (4)(c): RAC member suggested that when decisions are made about consultation requirements as discussed under 0090 (policies and procedures) that the language be mirrored in this rule.
• Section (5): RAC member suggested that (b) and (c) be removed as there is not a lot of evidence that supports doing weight checks for a woman with a healthy BMI. Additionally, RAC member was unaware of any clinic that completes hematocrit and many clinics and hospitals are doing fewer UAs.
  − Discussion ensued regarding language. The intent is not to require all these tests at every exam rather that the tests be performed at some point.
  − RAC suggested that the language be revised to reference "if indicated." Another RAC member disagreed and suggested that evidence suggests that testing is not necessary. If language is added, it needs to be very general.

- Section (7): It was noted that language specifies "an assessment" which alludes to there being only one and there may be more. It was suggested that the term "an" be removed. RAC concurred.
    - RAC member inquired whether additional language such as comfort measures and physical assistance be included under subsection (7)(a). It was suggested that this not be a minimum requirement rather allow birthing centers the flexibility to identify additional services. The term "consists of" is not all inclusive.
    - Several RAC members suggested removing reference to skin-to-skin contact and breastfeeding attempts under subsection (7)(c). RAC concurred.
- RAC members were encouraged to share possible language with Mellony by E-mail for sections (5) through (7).

ACTION: 1) Revise sections (2) and (3) as indicated above; 2) Mirror consultation language that is adopted in policies and procedures under subsection (4)(c); and 3) RAC members requested to provide feedback on possible text for sections (5) through (7).

Public Comment

Two members of the public shared concerns regarding exclusion of women from birthing centers who would be categorized as vaginal births after cesarean (VBAC). These members of the public shared their personal experiences with VBAC. It was suggested that current data does not support the exclusion. It was also suggested that women may choose to have an unassisted birth at home if restrictions are not reconsidered.

Sharron Fuchs reiterated previous suggested changes that were shared at the May 30th RAC meeting and additional suggestions.

- 0010 – Definition of physician should include chiropractic physicians.
- 0090(3)(a) – Types of procedures that are prohibited in a birth center should be specified (i.e. vacuum extractions or forceps).
- 0090(3)(b) – All providers must have privileges (no walk-ons).
- 0100 – Both services provided and not provided should be listed.
- 0100(2)(f) – Statute for DEMs specifies malpractice coverage, so it should be kept in rule. It was further noted that some places have insisted that clients sign a mandatory arbitration agreement which is improper and inappropriate.

Debbie Cowart, Owner of Growing Family Birth Center in Lebanon, shared concerns about the HERC guidelines being adopted in the proposed rules and also suggested that women may choose to have an unassisted birth at home if the guidelines are adopted for birthing centers.

Next Steps

The next RAC meeting will begin at 333-077-0110 admission discharge. There are number of rules remaining that may take additional time including the physical environment requirements and the proposed tables.

Jason Gingerich shared that the HERC Evidence-based subcommittee will be discussing the risk factor guidance at its September 12th meeting and will be posting the document for public comment shortly after. It was noted that best way to comment on the guidance is during the

public comment period to allow staff to research and prepare a response. Public comment will be reviewed at the December 5th meeting and the full committee will make final decisions in January or March 2020. D. Selover noted that the Birthing Center RAC may need to reconvene after the HERC guidance is finalized.
ACTION: Mellony Bernal will be sending out a meeting doodle poll to work on scheduling the next RAC meeting.

PUBLIC HEALTH DIVISION
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Birthing Center RAC
September 4, 2019
9:00 – Noon; Room 177

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Kaylyn Anderson (phone)	Consumer
Susie Corcoran	Aurora Birth Center
Karen DeWitt	Oregon Association of Naturopathic Physicians
Laura Erickson	Alma Midwifery Services
Colleen Forbes	Chair, Board of Direct Entry Midwives
Jennifer Gallardo	Andaluz Birth Center
Hermine Hayes-Klein	Oregon Association of Birth Centers
Desiree LeFave (phone)	Bella Vie Birth Center
Cat Livingston	OHA-Health Evidence Review Commission
Danielle Meyer	Oregon Association of Hospitals and Health Systems
Samie Patnode	OHA-Health Licensing Office
Anna Stiefvater	OHA-Public Health, Maternal & Child Health
Alice Taylor (phone)	American Association of Birth Centers
Willa Woodard-Ervin (phone)	Rogue Birth Center
Michele Zimmerman-Pike	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Brooke Bina (phone)	Alma Midwifery Services
Doreen Davis	OHA-Health Licensing Office
Judy Davis	Public
Greg Eilers	Women's Healthcare Associates, Midwifery Birth Center
Sharron Fuchs	Chiropractor trained in out-of-hospital births
Athena Riley (phone)	Public
OHA PHD HCRQI Staff	
Anna Davis	Survey and Certification Manager, Health Facility Licensing and Certification
Lacey Martinez	Surveyor, Health Facility Licensing and Certification
Dana Selover	Section Manager, Health Care Regulation & Quality Improvement
Mellony Bernal	Administrative Rules and Legislative Policy Analyst, Health Care Regulation & Quality Improvement

Welcome / Overview
M. Bernal opened meeting and RAC members and public introduced themselves.

D. Selover reviewed agenda and provided brief overview of rule number reference. It was noted that the rules have been drafted in a manner to align with other health care facility types where applicable. Furthermore, rules must align with statutory provisions including any definitions defined in statute. After RAC discussions have been completed, if it becomes apparent that statutory changes are necessary, the program will consider possible legislative amendments and further steps necessary.

Draft rules refer to other administrative rules adopted by other public health programs which this program does not have control of in terms of changes. The program can forward recommendations to the applicable program but cannot change anything outside its oversight.

D. Selover noted that in addition to public health, two other offices under OHA are working simultaneously on out-of-hospital birth rules - the Health Evidence Review Commission and the Board of Direct Entry Midwives (DEM). Public health will try and align with OHA agency partners where possible and noted that each program has different language relating to risk factors and transfer criteria. To the extent possible, public health does not want to have criteria that is conflicting.

Survey staff and managers are present to share information on process and outreach.

D. Selover asked if there were any questions prior to getting started on rule review. One RAC member asked if future meetings could be scheduled well in advance for ease of calendaring. M. Bernal responded yes.

July 17th Birthing Center RAC meeting notes

Staff noted that the program is continuing to work on action items from the previous meetings. All action items will be discussed at a future meeting. RAC members had no further comments or questions.

ACTION: None

OAR 333-077-0110 – Admission and Discharge

Staff clarified that the program is continuing to work from the same rule set originally sent out in May. Both clean and tracked changes versions are available. It was noted that while the track changes version appears to indicate a lot of new text, many of the current rules were just moved to a different location and are not actually new text. It was also noted that the risk factor tables will be reviewed at a future meeting.

Many of the elements in this rule have been moved from current rule number 333-076-0670.

Sections (1) and (2): RAC member inquired whether either of these sections refer to the consultation requirements. Staff responded no.

Section (3) requires a risk assessment within 14 days and updated throughout pregnancy. It was noted that the current language does not specify how many or time frame for the updates and

staff noted that it would be up to the provider's clinical judgement for ongoing assessments.
Discussion:

- RAC member asked what is meant by the "initial request for care," e.g. initial in-person visit, phone-call, etc.? It was noted that some clients come in for an initial, free consult which is not the initial prenatal visit. It was suggested to use the terminology 'initial prenatal visit' in rule. It was noted that the DEM rules reference 'prenatal care visit.'
- RAC member suggested it needs to be clear that it is a clinical visit versus a consult visit and another RAC member suggested using the term 'from initiation of care.'
- RAC member suggested there may be some potential conflict with billing if using the term 'prenatal visit.' RAC discussed possible other terms and concluded that 'initial prenatal care visit' is appropriate regardless of billing. It was suggested that the intention is clear and providers all know when the initial prenatal visit occurs.
- RAC concurred with "initial prenatal care visit."

Section (4) regarding consultation requirements specifies that the birthing center shall refer a client to an appropriate health provider or facility if it is determined, after consultation, that an out-of-hospital (OOH) birth is no longer appropriate. Discussion:

- RAC member expressed concern about language given the wide range of consultation categories. Rules should not be written that would require a client and midwife to be bound to transfer care based on the opinion of a consulting provider. A consultation includes making sure the client and midwife have the information needed to make an informed decision.
- Staff suggested that the language should not be so narrowly interpreted and questioned whether the DEM rules have language regarding required transfer of care after consultation. RAC member responded that clients may choose to make an informed decision regardless of risk after consultation with the consultant and provider, that the shared decision-making process must be documented and informed consent obtained and documented.
- RAC member suggested that the language is duplicative considering that a midwife and client can determine for any number of reasons that an OOH birth is no longer appropriate. The rules already establish risk factor tables that govern when a birthing center must transfer a client. The language suggests that there are additional issues besides risk factor tables that could lead to transfer which creates ambiguity.
- RAC member agreed that the language may be misunderstood and further clarity may be needed. Currently, clients may choose to continue care and work with their midwife on a different plan regardless of any recommendation made from a consultant. The rule implies that the care should cease.
- Another RAC member reiterated that it is a client's choice. Clients can take information and make their own decision on continued care. It was noted that a vast majority of clients would choose to transfer but not all.

- Another RAC member indicated that she did not read the language as requiring the birthing center to be bound by a consultant's advice, rather, once it's determined between the client and birthing center that due to the risk factor consulted for was no longer appropriate for an OOH birth, the client would need to be referred and transferred.
- RAC member suggested considering language like the DEM, such as 'If after consultation conducted in accordance with OAR, midwife and client determine an OOH birth is no longer appropriate, the birthing center shall refer the client to an appropriate health care provider or facility. If a decision is made not to transfer, the birthing center must obtain client's signature acknowledging that she has received and understands the information and has made an informed choice."
- RAC member suggested that the term "no longer appropriate" doesn't appear to correspond with a client's right to make an alternative decision to stay out of the hospital.
- Staff will review the DEM rules and the comments received and will redraft this section taking into consideration a conversation between the birthing center and the client, documentation and notification requirements, on-going consultation and monitoring, etc.

Section (5) describes that a birthing center generally discharges a client within 24 hours and specifies that if care extends beyond that time, or if a client or newborn is not in satisfactory condition, or meets risk factor exclusions, arrangements must be made to transfer the mother and newborn. Discussion:

- RAC member noted that clients may be kept beyond 24 hours given time of day;
- RAC member remarked that rules requiring pulse oximetry screening state the screen must happen after 24 hours and prior to discharge and newborn screening is supposed to occur after 24 hours as well. Lastly, when a client chooses to stay longer than 24 hours, services continue including monitoring vital signs, perineal care, helping establish breastfeeding, emotional and physical support, and newborn observation. The requirement should be removed from rule.
- Question was posed whether to clarify that care can extend beyond 24 hours, but not based on client need, rather client choice.
- It was noted that there is an existing conflict in the sentence.
- RAC concurred that the 24-hour requirement be removed.

Section (6) identifies requirements for a discharge plan. Discussion:

- Question was posed about subsection (6)(b) relating to referrals to newborn screenings. RAC member suggested changing to reflect that newborn screenings must be completed by the birthing center or a referral needs to occur. A question was posed whether a birthing center completes the two-week follow-up screening. It was noted that it's variable, some birthing centers do while others do not.
- RAC member suggested changing (6)(b) to: 'Referral for newborn screenings, as needed.'

- For subsection (6)(c), RAC member suggested that there is nothing that would necessitate a referral for "continuity of care." Most clients will self-refer for OB/GYN care or pediatric care and the language is therefore not necessary.
- It was noted that the term "referral" has a specific meaning that may not apply in this rule. The term "provision" was suggested as a possible change.
- Staff asked birthing center representatives what is currently put in a discharge plan. Responses included:
  - One-line statement that indicates to follow-up with a pediatrician or pediatric provider within eight weeks
  - Warning signs for mom and baby
- There should be an expectation that the baby is seen at 2 weeks and 8 weeks for a follow-up whether by a pediatric provider or the birthing center, and that should be stated in the discharge plan. In addition, reference to newborn hearing screening and any other follow-up care should also be included. RAC member responded that 8 weeks should not be specified in rule since the visit may occur between 6 to 8 weeks.
- RAC member suggested changing to "plans for newborn screening and ongoing care." This allows for flexibility while giving families a framework on next steps.
- RAC member noted that all the elements discussed are provided to clients PRIOR to delivery.
- It was noted that subsection (6)(a) is redundant and should be removed. The screenings <u>are</u> the follow-up visits.

RAC member noted to staff that while considering changes to be made in this rule, consider adding language that addresses a client's right to refuse transfer. Providers cannot legally abandon care of a client, so they are put in a difficult situation when a consulting provider recommends a transfer and the client refuses. Provisions should be made to allow care if a client makes that choice.

ACTION: 1) Amend section (3) removing "request for care" and replace with "prenatal care visit;" 2) Redraft section (4); 3) Remove reference to care extending beyond 24 hours from section (5); 4) Redraft section (6) eliminating subsection (6)(a) and rewriting (b) and (c).

OAR 333-077-0120

The rule provides that a birthing center shall have a policy on essential lifesaving measures and requirements for client transfer. Staff noted that given discussion above, reference to "when care extends beyond 24 hours" will be removed. RAC members had no further comments.

ACTION: Remove reference to care extending beyond 24 hours.

OAR 333-077-0130 – Medical Records

Staff noted that medical record rules are standard across all facility types with some exceptions. It was noted that the rule is largely the same with only minor modifications. Discussion:

- For subsection (1)(g), RAC member suggested removing the term 'continuous' and replace with ongoing. Continuous has a specific definition (e.g. without a pause or interruption) which does not apply to assessments.
  - Staff suggested the term 'ongoing' is ambiguous.
  - RAC member noted that 'ongoing' aligns with other language in DEM rules.
  - RAC member suggested removing the term altogether since it is in the medical record section. Any assessment, regardless of frequency, would need to be documented.
  - RAC member agreed with ambiguity in term 'ongoing' and suggested the term 'appropriate.' RAC member suggested that how a provider monitors is defined by the practice standards and would therefore presumably be "appropriate." Staff indicated similar concerns in terms of ambiguity.
  - The term 'intermittent' was suggested by another RAC member and aligns with American Association of Birth Centers (AABC) standards.
  - Staff will review the discussion and propose changes.
- RAC member inquired about purpose of subsection (1)(n). Staff noted that because a birthing center is defined as a health care facility in statute, a birthing center is subject to all statutory requirements pertaining to a health care facility. ORS 441.098 requires a health practitioner that refers a patient for a diagnostic test or health care treatment or service to a facility that the practitioner has a financial interest, to disclose such financial interest both orally and in writing at the time of referral. OAR chapter 333, division 072 outlines the requirements. Failure to comply with the requirements are investigated by the provider licensing boards.
- Staff asked RAC members regarding reporting necessary for the Center for Health Statistics (CHS) and the information required under (1)(p). Do the elements in this rule make sense or overlap with the CHS reporting?
  - It was noted that the rule requirement is very minimal compared to other data documented.
  - Staff asked whether the CHS data can be stored as part of the medical record. RAC member indicated no. It must be stored separately and is destroyed after one year.
  - DEM rules are not as detailed.
  - RAC member inquired about documentation of complications of pregnancy or delivery that may be relevant information for a pediatric provider. Another member suggested that subsection (1)(L) – the discharge summary – would provide that relevant information.
- RAC member inquired whether it was necessary to document the consistency and color of stools noted in subparagraph (2)(p)(E)(ii). Additional RAC members suggested that the information was excessive.
  - Consider aligning with paragraph (E)(iii) – stool and urinary output.
  - Change (E)(ii) to number of stools or stool output.

- It was noted that the record does not need to reflect frequency of stool output only that that there has been output within the first 24 hours.
- RAC member indicated that more information is necessary than just stool within 24 hours.

- RAC member inquired about the term 'authenticated' and timing of authentication in section (3). The rules require the record be handed over at time of transfer. It is possible that the record has not been completely authenticated at the time of transfer, especially if it's an emergent transfer. Additional language was requested to ensure that the record can be authenticated after transfer if necessary.
  - Staff will look at federal guidance and language used in other facility types.
  - Concern was expressed by RAC member that for small businesses with small staff the focus needs to be on the patient versus express completion of a record.
  - AABC standards should also be considered.
- RAC member suggested that the medical record is the property of the patient and not the facility. Staff noted that this language is across all facility types and the intent is that the facility is responsible for the record and ensuring prompt access to the record in accordance with federal privacy laws. Follow-up – There are no federal or Oregon statutes that specifically identify medical record ownership. The OHA has been given statutory authority to promulgate rules for health care facilities and these rules have identified that the property of the medical record is the facility. In accordance with federal and state regulations, a client has the right to obtain copies of medical records.
- Section (12) is existing language and standard across facility types.
  - RAC member asked how a facility is supposed to identify a 'qualified clinical record practitioner.'
  - RAC member noted that this is especially concerning in rural Oregon.
  - RAC member inquired whether there is some expectation that annual reviews occur given current rule language.
  - Staff noted that this is current rule and will review and respond.

ACTION: 1) Reconsider the term 'continuous' in subsection (1)(g). Review use of terms in other rules and consider aligning. 2) Revise subparagraph (1)(p)(E)(ii) to stool output. 3) Consider adding language in section (3) that identifies a time frame for authentication. 4) For purposes of section (12), identify history on qualified clinical record practitioners and determine how a facility might identify a qualified person and what the general expectations are.

OAR 333-077-0140 – Surgical Services

This rule specifies that surgical services are limited to procedures pertaining directly to pregnancy, labor and childbirth and procedures must be consistent with the practitioner's scope of practice. The rule further clarifies that tubal ligation or abortions shall not be performed. Discussion:

- RAC member inquired why tubal ligation and abortions would be restricted if the procedures are within a practitioner's scope of practice. Staff noted that this is current rule under OAR 333-76-0650, Service Restrictions.
- RAC member suggested that there are birthing centers across the nation that perform both abortions and birth related services. RAC member asked whether Oregon wants to continue to keep this option restricted and asked other RAC members whether there are birthing centers in Oregon that would want to provide that service.
  - RAC member responded that if the definition is not in statute, the OHA should consider removing the restriction. It is possible that some birthing centers in the future may want to provide such a service.
- Staff noted that the statutory definition of birthing center under ORS 442.015, is a facility licensed for the primary purpose of performing low risk deliveries.
- RAC member suggested that other states that have a full-service birthing center would also have a clinic that was not technically part of the birthing center where those services were offered. Staff noted concerns about co-location; if two facility types are using the same room for a different purpose, it's problematic. Issues around sharing space for different services is not exclusive to birthing centers; it also impacts ambulatory surgery centers, home health, etc.
- RAC member argued that while the definition indicates 'primary purpose,' it does not mean 'exclusive' and makes it possible for a birthing center to provide the service whose primary purpose is delivery of a live baby of a wanted pregnancy.
- Another RAC member agreed with removing the restriction if it's within a practitioner's scope. RAC member remarked that such a service is likely beyond the scope in many centers, but if a center wanted to have a physician, this could be a service offered especially given the current safety regulations in place and access to equipment.
- Staff will consider further.

ACTION: Staff will explore history on the current restriction and consider further.

OAR 333-077-0145 – Laboratory Services

Rule provides that a birthing center must provide or make available, laboratory services using a licensed clinical laboratory. RAC members had no feedback on this rule.

Action: None

OAR 333-077-0150 – Pharmacy and Anesthetic Services

Rule outlines requirements for both prescription and non-prescription medications. Discussion:

- RAC member noted that in section (3), the rule states that expired medications shall be disposed of by incineration. Birthing centers do not have the means to incinerate medications on-site. Plans are in place to hand medications over to other facilities that can incinerate. It was further noted that the rule does include the statement "or other equally effective method."

- RAC member inquired about use of expired drugs for purposes of student training. These medications go into a different part of the facility and separate from medications for clinical use.
  - Staff noted that the rule does allow the storage of expired medication in a separate location and must be clearly identified.
  - RAC member indicated that in one center the 'med log' identifies where the medication is stored and whether it's used for educational purposes or destroyed.

Action: None

OAR 333-077-0160 – Dietary Services

Rule requires a birthing center to make food available to clients. All food services must meet the requirements of OHA Food Sanitation rules or if a center makes arrangements with an external vendor, a written contract must be in place. Discussion:

- RAC member noted that currently food is offered to clients and may delivered by a food service such as Grubhub, Uber Eats, etc. but there is no written contract.
- Staff noted that there needs to be some standards and oversight in place, when a client is under the care of a health care facility.
- RAC member noted that a client can order their own food from whomever they choose.
- RAC member noted that the dietary service rule is an example where aligning with other facility types does not fit given the scale of operation. RAC member questioned what are the barriers for compliance? Would the requirement result in Centers closing due the fiscal impact?
- Commercial kitchens would not be possible in many Centers.
- RAC member asked about the adult foster home model and whether it would be possible for birthing centers.

Action: Staff will investigate further including other dietary service rule models.

OAR 333-077-0170 – Newborn Care and Screening

This rule outlines requirements for several screenings that are currently in rule and have been moved. Discussion:

- RAC member clarified for others that the right to informed refusal has not been removed. It is in the rule that is referred to in each section.
- RAC member remarked that paragraph (4)(d) relating to pulse oximetry screening specifies that the screening must be performed 'no sooner than 24 hours' and shared that the birthing center usually discharges prior to 24 hours and thus the screening occurs sooner. It was suggested that 'no sooner than 24 hours' be removed.
  - Staff noted that the rule also specifies 'or as close to discharge as possible.'
  - RAC member expressed concern for removal given physiological changes in newborn. Current language is important and should remain in place.

- RAC member noted that if a client is discharged sooner, the client may return to the Center for another screening or through a home visit.
- RAC member questioned whether additional language was necessary to specify that a repeat screening is necessary if the first pulse ox is captured significantly before 24 hours. RAC member responded that sometimes this is not possible given location of parents.

- RAC member expressed concern about the different types of informed consent necessary if a parent declines screening [(4)(h) and (5)(b).] The pulse ox rule only requires that a parent's declination be recorded in the newborn's medical record, while the chlamydial or gonococcal eye ointment must sign a witnessed affidavit. RAC member suggested that this would require a notary.
  - Staff will review the relevant rules and consider further informed consent requirements.
  - RAC member indicated that OAR chapter 333, division 019 does not appear to align with current practice and needs to be revised. Staff will follow-up with appropriate program staff.
- RAC member questioned how a birthing center is informed about a pulse ox screening performed by the hospital when a client and/or newborn was transferred.
  - Staff noted that similar (if not identical) rules are in place for hospitals. Staff will review further.

Action: 1) Staff will review the types of informed consent requirements necessary to decline the types of screening and determine if any form of alignment may occur. 2) Staff will review Division 19 rules and follow-up with applicable program staff. 3) Staff will review the hospital pulse ox rules and determine whether there are any documentation or notification requirements back to the birthing center for patients who transferred from a birthing center.

Next Steps

Remaining rules for review include:

- Equipment and supplies (0180)
- Infection control (0190)
- Quality Assurance and Performance Improvement (0200)
- Emergency Preparedness (0210)

Staff requested that RAC members review in advance and be prepared with comments and possible suggested changes.

Staff further noted that two additional large items to go through include the Physical Environment rule (0220) and risk factor tables. The physical environment rule adopts national standards from the Facilities Guidelines Institute (FGI). An additional document will be shared that will help walk members through the FGI requirements and Facility, Planning & Safety staff will be present to discuss.

Lastly, the action items and proposed changes will also need to be considered as well as whether any other definitions need to be added, changed or removed. Staff suggested that the next meeting wrap up 0180, 0190, 0200, 0210 and risk factor tables. Another meeting will be scheduled to finish up the physical environment rule and review the action items. - RAC member suggested that at least three meetings will be necessary and that the risk factor tables will likely require one full meeting. - RAC member suggested that the physical environment standards will also take a lot of time. Staff indicated that three meetings will be scheduled and hope to conclude sooner.
ACTION: Staff will send out link for doodle poll.

Meeting adjourned at 11: 52 a.m.

PUBLIC HEALTH DIVISION
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Birthing Center RAC
October 16, 2019
9:00 – Noon; Room 177

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Kaylyn Anderson (phone)	Consumer
Karen DeWitt	Oregon Association of Naturopathic Physicians
Jennifer Gallardo	Andaluz Birthing center
Hermine Hayes-Klein	Oregon Association of Birthing centers
Desiree LeFave	Bella Vie Birthing center
Cat Livingston	OHA-Health Evidence Review Commission
Meredith Mance (phone)	Aurora Birthing center
Danielle Meyer	Oregon Association of Hospitals and Health Systems
Margaret Porter	Bella Vie Birthing center
Anna Stiefvater	OHA-Public Health, Maternal & Child Health
Alice Taylor	American Association of Birthing centers
Michele Zimmerman-Pike	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Brooke Bina (phone)	Alma Midwifery Services
Debbie Cowart (phone)	Growing Family Birthing center
Jody Davis	Public
Lindsey Lincoln (phone)	Growing Family Birthing center

OHA PHD HCRQI Staff	
Barbara Atkins	Plans Reviewer; Facilities, Planning & Safety
Mellony Bernal	Administrative Rules and Legislative Policy Analyst; Health Care Regulation & Quality Improvement
Anna Davis	Survey and Certification Manager; Health Facility Licensing & Certification
Rebecca Long	Paramedic/Health Educator; EMS and Trauma Systems
Lacey Martinez (phone)	Surveyor; Health Facility Licensing & Certification
Dana Selover	Section Manager; Health Care Regulation & Quality Improvement
Patrick Young	Plans Reviewer; Facilities, Planning & Safety

Welcome / Overview
M. Bernal opened meeting and RAC members and public introduced themselves. D. Selover reviewed agenda. It was noted that depending on how far the RAC can get through the remainder of the rules, a conversation would occur at the end of the meeting to discuss future meeting topics including the risk factor tables. It was further noted that both the OHA-Health Evidence Review Commission and the OHA-Board of Direct Entry Midwifery are currently considering risk factors as well.

September 5, 2019 Birthing Center RAC meeting notes

D. Selover asked if there were any comments on the September meeting notes.

- RAC member noted that the wrong website was attributed to the Commission for the Accreditation of Birthing centers (CABC). The CABC web address is: www.birthcenteraccreditation.org. The website for the American Association of Birthing centers (AABC) is www.birthcenters.org. **Follow-up:** the incorrect web address attributed to the meeting notes is actually found in the 2018, FGI Guidelines for the Design and Construction of Outpatient Facilities. Staff have contacted the Facility Guidelines Institute to make them aware of this issue so the FGI can consider posting an erratum.
- RAC member inquired about the process for addressing action items and any further amendments to rules. RAC member also asked for more concrete notice when risk factor tables will be reviewed.
  - It was noted that this RAC is an advisory committee only and suggested revisions must align with policy, statutes and other administrative rules. Staff are reviewing action items, researching information shared and considering whether suggested changes may conflict with other rules or regulations; considering other states' rules and regulations; reviewing the AABC and CABC standards; etc.
  - A document will be shared at a future RAC meeting which will identify all the action items from the RAC meetings, whether the agency has proposed new language or chose to keep existing language, and a justification for the decision made. RAC members will be given an opportunity to provide additional comments on the agency's proposed changes from the action items. The agency will consider final RAC comments and will propose a final draft of the rules that will be submitted to the Secretary of State's office along with a Notice of Proposed Rulemaking Hearing. The final proposed rules and rulemaking hearing notice will be shared with the RAC, licensed birthing centers and other interested parties.
  - It was noted that the agenda for each meeting will reflect what the meeting's discussion topics will be. It is anticipated that the risk factor tables will be discussed at the November 22nd meeting. It was further noted that public comment on the risk factor tables will not be taken at the RAC meeting. Public comment will be taken instead at the public hearing, the date of which is to be determined.

ACTION: Revise notes accordingly.

OAR 333-077-0180 – Equipment and Supplies
This rule summarizes the list of equipment required in a birthing center and that a birthing center must have a system to monitor equipment and supplies for purposes of regular maintenance and ensuring adequate supplies are available. Infection control measures must also be applied. Discussion: • RAC member expressed concern about reference to fetal monitoring equipment and equipment to maintain 'optimum body temperature' of a newborn. It was noted that birthing centers are handling normal physiologic birth and most fetal monitoring is done through intermittent auscultation with a doppler rather than an external electronic fetal monitoring (EFM) system. An EFM should not be required at a birthing center. Birthing centers generally maintain body temperature through skin-to-skin contact with the mother with a blanket. Concern was expressed that 'equipment' may be interpreted as an infant warmer system which a birthing center should not be required to have. Question was posed whether the language was vague enough not to require more hospital-grade systems or whether additional clarification was needed. − Staff noted that that section (1) of the rule refers to "appropriate" equipment and as such fetal monitoring equipment is that equipment which is appropriate for a birthing center based on low risk clientele. − RAC member noted that under AABC standards, continuous fetal heart rate monitoring is not permitted in a birthing center. Intermittent auscultation with a doppler is used. It was further noted that during labor if continuous fetal heart rate monitoring is indicated, then a birthing center needs to transfer to a hospital. **Follow-up:** Based on follow-up correspondence from RAC member, it was suggested that intermittent auscultation of the fetal heart rate for low risk women during labor also aligns with opinions/positions of the American College of Obstetricians and Gynecologists (ACOG) and the Association of Women's Health, Obstetric and Neonatal Nurses. − RAC member expressed concern in subsection (1)(d) referencing the term 'equipment' for maintaining body temperature. Staff asked other RAC members to share the types of equipment used to maintain temperature. Examples shared included radiant heater, heating pads, heated blankets, space blanket. − RAC member suggested that the language used is acceptable. − Another RAC member suggested that blankets, heating pads, etc. may not be understood as equipment. • RAC member asked what is meant by the term 'governing body' in subsection (1)(k). It was noted that the rule is referencing the governing body of the birthing center.
ACTION: Consider adding the term 'supplies' after equipment in subsection (1)(d).

OAR 333-077-0190 – Infection Control
This rule specifies that a birthing center must establish and maintain an infection control program which must be managed by a qualified individual and overseen by a committee responsible for controlling and preventing infections in the birthing center. Several written policies are required and compliance with OR-OSHA bloodborne pathogen standards and Public Health Division communicable disease rules. The birthing center must also clean, disinfect or sterilize equipment or supplies in accordance with the latest CDC standards. Discussion: • Staff noted that the CDC guidelines referenced continue to keep the 2008 reference in the title; however, there have been revisions since then. Counsel present during the meeting noted that the revision date must be included, and the rule will be updated accordingly. RAC members had no comment.
ACTION: Amend the reference to the CDC guidelines for disinfection to include the relevant revision date.
OAR 333-077-0200 – Quality Assessment and Performance Improvement (QAPI)
The QAPI rule (pronounced Kwah-pee) specifies that a birthing center must have a program in place that actively measures, analyzes and tracks issues and implements strategies to improve client health outcomes and client safety. Systems need to be set up to identify issues that a birthing center doesn't want to happen, how those issues are going to get noticed, how those issues are going to get studied to determine how they happen, how the birthing center is going to fix it, and how is it going to be monitored in future. Discussion: • RAC member asked whether there are any standardized indicators and performance measures that are used across all birthing centers? • RAC member asked whether the Authority would specify the content of a QAPI program during a survey or whether the Authority would just confirm that a program exists, that outcomes and indicators were identified, and quarterly meetings conducted. Staff shared that there is no intent to identify specific indicators or outcomes. • RAC member noted that the AABC has identified quality improvement standards and the CABC has developed quality improvement indicators for accreditation. These standards can be found on printed pages 16-18 of the document, "Standards for Birthing centers" located on the web at: https://www.birthcenters.org/page/Standards. The CABC indicators can be found on pages 171-196 of the document, "Indicators of Compliance with Standards for Birthing centers, Edition 2.1" found on the web at: https://www.birthcenteraccreditation.org/go/get-cabc-indicators/. • RAC member suggested that if the intent is to align with the accreditation indicators then the rule should reflect that a birthing center needs to develop a process that complies with the CABC. • Staff noted that these standards and indicators could be adopted by reference, or some minimum standards and indicators can be identified and placed in rule, or a complete list of standards and indicators can be spelled out.

- RAC member suggested that given the number of bodies that have specified QAPI requirements (AABC, CABC, Board of DEM, other professional provider boards and organizations, licensing standards, etc.) it becomes very complicated and is concerning to tie standards to one organization or body. Flexibility is needed.
- RAC member remarked that the language as written is appropriate.
- It was noted that licensed direct entry midwives are required to record aggregate data in MANA Stats which includes information on adverse outcomes.
- RAC member remarked that quarterly meetings for small birthing centers that have very few births may be excessive. Staff noted that the Authority believes that quarterly meetings are an absolute minimum including for birthing centers that have relatively few births. Too much time can elapse before appropriate steps are addressed to ensure client safety and improved client health outcomes.
- RAC member agreed that quarterly meetings are appropriate and that the current proposed language without the specificity of indicators is appropriate. The onus is on the individual birthing center to identify appropriate indicators based on its accreditation status, provider type, and the licensing rule.

Based on the discussion, the Authority does not intend to make any changes to the proposed rule.

ACTION: None

OAR 333-077-0210 – Facility Safety and Emergency Preparedness

Staff provided an overview of emergency preparedness (EP) across the state. EP includes dealing with wildfires, earthquakes, ice storms, wind storms, snow storms, flooding, disease epidemics, etc. Expectations for licensed health care facilities at all levels has changed at both the state and national level. The Centers for Medicare and Medicaid Services (CMS) adopted a new rule in November 2016 and health care facilities were given one year to come into compliance. Federal rules are tailored to every type of health care facility including facilities that care for persons in their homes. Section (2) of this rule was drafted based on these national standards. Section (1) is standard facility rule language relating to facility and environmental safety.

An EP program consists of the following:

- Risk assessment and planning
    - Plan is based on performing a risk assessment using an "all-hazards" approach, focusing on capacity and capability
    - An "all-hazards" approach is specific to the location of the provider and considers types of hazards in the area (e.g. power failures due to wild fire; located near an oil refinery; etc.)
    - Updated annually
- Policies and procedures
    - Developed and implemented based on the plan and risk assessment

- Address a range of issues including sheltering in place, food for clients and staff, evacuation plans, tracking patients and staff
    - Updated annually
- Communication plan
    - Comply with county and state laws
    - Coordinate patient care across health care providers and health care facilities
    - Update annually
- Training and testing
    - Develop and maintain initial and ongoing training and testing of staff including training on policies
    - Demonstrating knowledge of emergency procedures at least annually
    - Conduct drills and exercises to test the plan at least twice a year. Coordinating with other facilities in the area is useful.

Discussion:

- RAC member reflected that one of the slides included a reference to medical emergencies and asked if the EP plan was relevant to newborns that need to be transferred. Staff responded no.
- Staff member noted that one important area of the communication plan that comes up is the need to have non-electronic systems for medical records to use for transfer in an emergency. Most electronic medical record vendors offer alternatives in this scenario.
- RAC member asked about subsection (1)(d) of rule relating to rodents, flies and insects and asked what the expectation from OHA was in terms of taking reasonable steps to prevent flies, insects, etc.
    - Staff responded that the intent is to prevent infestations of rodents and insects that could pose a danger to clients. A few incidental flies or mosquitos is not going to result in a request for a reduction plan; however, a location that has standing pools of waters where mosquitos are breeding and there is a West Nile outbreak, there may be an expectation to address.
    - Additional information can be brought to the RAC from the Public Health Veterinarian if needed regarding the potential for diseases.
    - Question was raised in terms of a location where 50% of the building is used for client care; whereas the other 50% of the building is used for another purpose – what is the obligation to prevent rodents and insects from the entire structure or just the 50% where client care occurs? Staff responded that it would look at whether the entry impacts the birthing center and its patients (i.e. rodents can carry diseases that are airborne; whereas diseases from insects require the insect moving from point A to point B.)
    - Staff noted that for purposes of the built environment inspection as prerequisite to licensure, if windows and doors can remain open, screens need to be on them; sinks on exterior walls, where the drain pipe is leaving the wall needs to be fully

sealed; if there is a basement, there shouldn't be cracks in the foundation where you can see daylight. The "envelope" of what contains the birthing center is subject to the inspection, not adjacent spaces that are not associated with the birthing center.

- RAC member noted that the rule reflects "measures taken" and many birthing centers have quarterly inspections with exterminators who may also work to ensure that holes are sealed, etc.

ACTION: None

OAR 333-077-0220 – Physical Environment

D. Selover provided a brief overview of the physical environment rule which was initially adopted in 1985 with subsequent revisions in 1990, 2006 and 2008. It was noted that many stakeholders over the last several years have asked the Authority to consider adoption of the FGI guidelines for health care facilities. The Authority convened a workgroup and after a year of review and deliberation, the FGI guidelines have been adopted for all health care facilities except birthing centers.

B. Atkins provided more details through a slide presentation of the work of the Facility, Planning and Safety program. A high-level summary of the slides is noted below, and the presentation will be shared and is available upon request.

- The FPS program reviews any alteration, addition or new construction of both long-term care facilities and non-long-term care facilities.
- Built environment requirements go above and beyond Oregon Building Codes to address the needs of health care facilities.
- OAR 333-675-0000(2) outlines the criteria for health care facility projects that are subject to FPS plan review. The FGI specifies exceptions to review requirements.
- Facilities can request a waiver of specific standards.
- FGI standards were promulgated after the federal Department of Health and Human Services (DHHS) removed general building standards from federal regulation and asked the American Institute of Architects to maintain and revise the standards moving forward. Since the federally mandated standards were removed from federal regulations, Oregon developed their own rules based upon the standards that had previously been published.
- Many states have adopted the FGI guidelines.
- It was recognized that there is a difference between a home birth, a birthing center and a hospital. The intention of the rule is to fall in the middle between a clinical and non-clinical environment and not be too extreme.
- A generalized cross walk of the current standard compared to the FGI standards was shared.

Discussion:

- RAC member suggested that the standard, that consideration be given to emergency transport time, is not evidence-based. Rural birthing centers exist because there is no

maternity care in many areas of the state including in some of the rural hospitals. These centers are designed to meet the needs of the rural community. Staff noted that "consideration" is not enforceable.

- RAC member remarked that the further a woman needs to travel for prenatal care leads to poorer outcomes.
- RAC member noted that parking spaces and public transportation may be undue barriers.
- RAC member expressed concern regarding the minimum hallway width for birthing centers located in houses. Staff noted that for purposes of the American with Disabilities Act, 36" would be the absolute minimum. FGI is 44."
- It was reiterated that the proposed changes affect only new construction/new licensure and renovations and additions.
- RAC member suggested that the RAC needs to discuss whether FGI should be adopted at all versus identifying any proposed changes to the FGI.
- RAC member asserted that many of the states that have adopted the FGI guidelines have birthing centers located in a hospital versus a freestanding facility. It was further noted that most of the Oregon licensed birthing centers attend less than 75 births a year. The OHP facility fee for birthing centers is $1200. It was suggested that the CABC has robust facility guidelines that should be considered.
- RAC member shared that the AABC has provided information on 5 states that have adopted FGI guidelines (Kentucky, Michigan, Vermont, Tennessee and Oklahoma) and Washington DC. Based on calls made by the RAC member, it was suggested that:
    - In KY, MI, and VT there are no freestanding licensed birthing centers; only hospital birthing centers.
    - In Washington, DC there are no freestanding licensed birthing centers. There is one birthing center that is designated as an FQHC (Federally Qualified Health Center.)
    - In TN, there is one licensed freestanding birthing center with many staff.
    - In OK, licensing is optional, and none are licensed. The RAC member suggested that the FGI standards make it fiscally impossible for them to become licensed.

  RAC member indicated additional contacts were made with other states and suggested that adoption of FGI would make it fiscally impossible for freestanding birthing centers to be licensed in Oregon and would create a barrier for women receiving services. RAC member asked why FGI standards are needed for birthing centers and agreed with other comment that the CABC standards should be considered.
- Staff noted that it has also sent an inquiry to all 50 states' licensing agencies to get feedback on those states' licensing requirements including physical environment standards.
- RAC member expressed concern about the term "vacuum" which has a different meaning in the birthing center environment. Staff noted that in this context the "oxygen and vacuum available" is meant to imply that suctioning of airway is available.

- RAC member asked whether ice cube trays would be considered self-dispensing; staff responded no.
- RAC member expressed concern regarding the requirement that a handwashing station is required in the birthing room. Example shared of a birthing cottage where the client can birth anywhere in the cottage where a handwash station may not be in the room where the client eventually delivers.
- RAC members expressed concern about the medication room requirements including:
  - Requiring medication be stored in a separate room prevents quick accessibility;
  - Work counters being away from traffic is problematic (example shared where medications are stored on table in hallway for quick access);
  - There are very few medications administered in a birthing center;
  - Separate room requirements will prevent the use of homes for birthing centers;
  - It was suggested that the facility space itself does not change the outcomes. It was further asked whether safety gaps have been identified in the existing OARs that make adoption of the FGI or any other amendments to rule necessary.

  Staff noted that the idea behind the medication room standards is to alleviate any distractions when counting out meds. It was further noted that the medication room can be an area.

Staff noted that based on discussion, additional consideration will be given to:

- Identifying standards that promote health and safety while preserving the ability of less high-tech facilities to provide care safely and in areas where hospitals may not be available or don't offer maternity care services; and
- Reviewing the current rules and CABC standards and comparing to FGI.

RAC member remarked that the Oregon Midwifery Council would not support the adoption of the current proposed rule that adopts the FGI standard. It was suggested that the guidelines did not involve midwife or birthing center expertise. It is easier to support the adoption of standards such as the CABC since it is known who was involved in setting the standards and that the standards are currently in use. An example was shared about the FGI lighting requirements and room size that suggest the needs of the different facility types are very diverse and should not be applied across all facility types.

RAC member noted that for purposes of patient and baby safety, the state should be encouraging birthing centers to remain open. The Strong-Start initiative sponsored by CMS and HRSA showed that Strong Start participants in birthing centers had better outcomes at lower costs compared to other Medicaid participants with similar characteristics https://innovation.cms.gov/initiatives/strong-start/). As such, more birthing centers should be opened and based on comments about other states, the FGI standards could prevent this from happening. The CABC standards should be considered instead of FGI.

RAC member suggested that the FGI standards are not relevant such as clearance requirements around a bed; a birth can happen anywhere in the facility. Standards are unnecessary and while

they may not impact currently licensed centers, they are significant barriers to opening new birthing centers.

RAC member noted that the FGI standards result in increased costs whereas one of the advantages of a birthing center is they are more cost effective.

RAC member remarked that both ACOG and the American Academy of Pediatrics recognize accredited birthing centers as level one maternity facilities and encourage the existence of birthing centers. The CABC indicators should be considered as they reflect the evidenced based AABC standards. It was suggested that 'alongside midwifery units' (AMUs) are expected in the future. These are midwifery lead birthing centers in, adjacent to, or very close to a hospital. AMUs would be accredited by the CABC and would operate like a freestanding birthing center. For example, if continuous fetal monitoring is indicated, the mother would need to move to the adjacent maternity unit to continue care.

RAC member asked about accessing the FGI guidelines. Staff noted that the guidelines are available to be viewed in the HCRQI office.

ACTION: Staff will review and analyze the CABC standards and compare to the FGI standards for further consideration and draft new language.

Next Steps

Future meetings are scheduled for Friday, November 22 at 9:00 a.m. and Friday, December 20th at 9:00 a.m. **Follow-up: The December 20th meeting has been canceled.** Persons who are not able to attend are welcome to submit comments in writing which would be shared at the RAC meeting for discussion. Remaining issues for discussion include:

- Risk factor tables;
- Edits to physical environment standards;
- Review of agency's response to action items identified in the RAC meetings.

At the meeting where action items and responses are reviewed, RAC members will be given an opportunity to provide additional feedback which staff will take into consideration prior to filing final proposed rules with the Secretary of State's office for a public hearing.

Risk factor tables are scheduled for discussion on November 22nd. If time allows and revisions are ready for discussion, edits to the physical environment will also be discussed.

It was noted that the Board of DEM is discussing proposed rule revisions on October 24th.

It was further noted that based on the feedback received during the risk factor discussion, and discussions with OHA leadership, it is possible that the Authority may delay filing final proposed rules until after the Board of DEM and the Health Evidence Review Commission has completed their work. Additional RAC meetings would be scheduled as deemed appropriate.

If rules are completed by end of the year and filed in January, a public hearing would not occur until March or April (after the legislative session has concluded.)

RAC member expressed concern that future meeting dates are close to holidays and asked that they be rescheduled. Staff noted this would be very challenging given other work being completed.

RAC member agreed that until the HERC has concluded its work on risk factors for coverage, that it would be difficult to complete the risk factor tables for birthing centers. It was noted that the earliest the HERC would reach a decision is March 2020.

RAC member disagreed with waiting for completion of the HERC guidance. HERC is coverage guidance only and is not meant to dictate scope of practice or regulation for facilities.

Staff encouraged RAC members to provide input prior to the November meeting regarding the proposed risk factor tables.

ACTION: 1) RAC members to submit suggested feedback on risk factor tables prior to the November 22nd meeting. 2) Staff will reconsider holding December meeting and reschedule for January if necessary.

Meeting adjourned at 11:53 a.m.

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Birthing Center RAC
November 22, 2019
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Anna Davis	Survey and Certification Manager; Health Facility Licensing & Certification
Rebecca Long	Paramedic/Health Educator; EMS and Trauma Systems
Dana Selover	Section Manager

Welcome
M. Bernal opened meeting and RAC members and public introduced themselves.

October 16, 2019 - Birthing Center RAC meeting notes
D. Selover asked if there were any comments on the October meeting notes. RAC members had no comments. D. Selover reminded RAC members that action items are being tracked and responses to action items will be shared at a future meeting.

NOTE – Clarifying statements for these November minutes were submitted by a RAC member at the January 24, 2020 BC RAC meeting. These comments are attached at the end of this document for reference.

Overview

D. Selover provided an overview of the purpose of today's meeting which is to review the risk factor tables. D. Selover reminded RAC members where references to the risk factor tables were made in rule and asked the RAC to think about what the risk factor tables mean for birthing centers and not individual providers. A birthing center may be staffed by several different providers, so while there are other risk factor discussions taking place for purposes of direct entry midwives and Medicaid payment, the risk factors for purposes of this RAC need to be considered as it relates to the facility and how those factors may apply to other types of providers, including the type of equipment that can be used in these facilities, extra staff available, etc.

Risk factor tables are referenced in the following rule locations:

1) Policies and procedures (0090) which requires birthing centers to have policies for purposes of assessing risk status; referral and transfer and consultation;
2) Client care services (0100) for purposes of requiring consultation if certain risk factors are present;
3) Admission and discharge (0110) for purposes of excluding clients from admission or requiring discharge if a client meets specified risk factors; and
4) Client transfer (0120) for risk factors that warrant a transfer.

It was noted that the current risk factor tables are specific to risks that are present at time of or prior to admission, and that occur during intrapartum and postpartum care.

Staff remarked that the purpose of these tables is to ensure safety and reduce risks in an out-of-hospital (OOH) setting and clearly identify factors that are not considered low risk given the definition of freestanding birthing center in ORS 442.015.

RAC member expressed concern that the revised tables were structured to align with the Health Evidence Review Commission (HERC) and suggested there is no safety data to support such a drastic change. Since implementing the HERC criteria for Medicaid patients, RAC member suggested there was a 75% drop in OOH births for clients covered by OHP. If similar risk factors are adopted for all women, most women will be excluded from receiving services in a birthing center. RAC member indicated that the HERC criteria may be reasonable for Medicaid to decide

coverage, but based on discussions with midwives and patients, it has not been successful overall. RAC member added that women feel they have been discriminated against, there is an increase in expenses, and reduction in access, etc. with no change in actual outcomes.

D. Selover noted that these rules may need to wait until after the HERC and Board of Direct Entry Midwives have completed their work and consider how the guidance changes. Given the HERC's process and review structure, it was determined that the Public Health Division would model those risk factors for initial rule discussions.

C. Livingston noted that when HERC started its process, it was based on other countries and systems that have very high quality out-of-birth practices with excellent outcomes (e.g. United Kingdom and Netherlands). A key priority of the state is to keep women safe and have better outcomes. Additional follow-up will be needed to investigate the data that suggests a 75% reduction in access.

RAC member asked whether there is a problem that even needs to be solved or are the revisions being made just to update for alignment? It was noted that making sure OOH birth is safe for women is the highest priority and to ensure that OOH births offered to women on Medicaid is offered in the safest, possible way. The risk criteria proposed reflect that intent.

RAC member remarked that it is great that the Public Health Division is updating the risk factor tables for the birthing centers but has serious concerns about the process:

- The HERC does not set the scope of practice for any provider type and the HERC guidelines are not considered the scope of practice for any provider type.
- The HERC guidelines do not dictate what hospitals or other facility types can provide.
- The HERC guidelines are only coverage guidance for persons who are covered by Medicaid and other boards and insurers can use them to inform their process.
- The efforts to apply the HERC guidelines to Public Health Division rules, the Board of Direct Entry Midwifery scope of practice and other processes, is irregular and is not the way the HERC is used for other provider or facility types and is strongly objected to.
- The HERC is a great process to look at vetted research about specific categories.
- It is not appropriate to consider the DEM rules unless the RAC also considers the Board of Naturopathic Physicians rules and Certified Nurse Midwife rules given the provider types that function in licensed birthing centers. These providers are expected to follow the standards of their professions.
- If looking at standards, it would be more appropriate to use the American Association of Birthing centers standards which are equally applicable to all three provider types and specifically to this setting.

RAC member responded to comment that HERC guidance was developed using models from other countries that have very high-quality OOH birth practices with excellent outcomes with additional concerns.

RAC member suggested that the Netherlands have always had a system where healthy women give birth at home with midwives and that a hospital is a back-up and they have always had better outcomes than the United States. Further, what makes an OOH birth safe in another country is integration.

RAC member added that the list of Obstetric Indications (LOI) is used in the Netherland. The LOI designates the most appropriate care provider for women with defined medical or obstetric conditions and is updated on a regular basis. It is always implemented based on the woman's informed consent and refusal. It is never used to prescribe what a woman must do, but rather as a source of information which is how the risk factors should be used here.

D. Selover remarked that the OHA and RAC are not arguing about the rights of individuals, but rather having a conversation about how to apply the statutory definition of a freestanding birthing center licensed primarily for the purpose of performing low risk deliveries.

RAC member shared concern that the HERC tables are for Oregon Health Plan insurance coverage which is not the same as evidence-based and best practice for a provider. To equate that they are the same is a disservice. It was suggested that the evidence used for the tables is not up-to-date and doesn't reflect more current evidence on topics. If safety is the intent, then current evidence needs to be used.

C. Livingston remarked that the HERC is actively reviewing up-to-date evidence. The HERC review process and all evidence used is open and posted for everyone to consider. Public meetings and public comment are actively sought during the HERC process.

It was noted that the PHD may need to delay in filing rules to consider the additional evidence gathered.

RAC member shared that there is more to the story than just the evidence reviewed such as additional factors. Women understand the risks involved and should not have their choice taken away and taking this away may lead to increased deaths.

RAC member suggested that the HERC does not look at coverage for interventions that happen in the hospital that are not evidenced based that lead women to choose a community birth or delivery at a birthing center. If a hospital bans vaginal birth after cesarean (VBACs) then women have a choice to go to a hospital for another C-section or go to a birthing center or have a home birth. If a birthing center can't attend a woman having a VBAC then the choice may be an unassisted VBAC delivery at home. Many interventions that happen in the hospital are not evidenced based and that is what motivates a woman's choice to seek an OOH birth.

RAC member suggested that there is a maternity care crisis in Oregon and these discussions are very important for women's health. RAC member asked whether the HERC looked at the Strong Start data – an initiative funded by the Centers for Medicare and Medicaid Services aimed to reduce preterm births and improve outcomes.

C. Livingston responded that at the time of the initial drafting of guidance, the Strong Start study had not completed its findings. It is now being reviewed and will be considered in the review cycle that is currently being conducted. The study does not meet the inclusion criteria because it is not comparative, however, it is being considered for possible inclusion.

RAC member remarked that while OHA's intention to align with the HERC is understood, over the past five years, the data suggests that there are fewer low-risk women giving birth in birthing centers, when there is very strong data that more low risk women need to be encouraged to have this option.

RAC commented that women are choosing to have unattended deliveries because of the current guidance in place. A policy cannot be created that will push women to have unattended births when there is not strong data that indicates poorer outcomes.

RAC member stated that most research relevant to OOH birth outcomes does not meet the HERC study criteria (MANA Stats studies, Strong Start study, etc.) Most studies around birth outcomes are observational and are not considered by the HERC but should be considered in this process.

RAC member suggested that there are excellent birth outcomes in OOH births in Oregon. From 2015, 2016, 2017 and preliminary data for 2018 data, the perinatal mortality data for midwife attended planned OOH births in Oregon is less than 1 per 1,000; and is comparable to countries such as the Netherlands and the United Kingdom.

RAC member remarked that the Oregon data based on the Snowden study did show an increase in morbidity and mortality for infants with an OOH birth. Reducing maternal morbidity and mortality is very important but reducing the same for the infant is also important.

RAC member responded that the Snowden study data is from 2012 and 2013 which did show an increased risk of perinatal mortality for babies born in Oregon in an OOH setting.

RAC member commented that in response to that study, a quality improvement program was developed to address issues. Current data shows that perinatal mortality at OOH births is now lower than for planned hospital births. Midwifery care and midwifery responses to concerns is what has made a difference.

RAC member noted that the Oregon State Board of Nursing (OSBN) is seeing more and more Certified Nurse Midwifes graduate from out-of-state (OOS) programs that do not supervise or oversee students; have unlimited seating so there is no faculty to student ratio; students must find their own preceptor; and students can deliver babies unsupervised by the preceptor.
Discussion:

- The OSBN is concerned about the number of cases, public complaints and access to qualified providers.
- The OSBN does not have authority over the OOS education programs.

- There is concern about the variation in quality of care. Clinicians are not of equal caliber and thus risk factor tables may be necessary to clarify standards;
- The rights of the infant must also be considered.

RAC member shared that there are national organizations that have birthing center standards that are evidenced-based which should be enough. Additional standards should not be necessary. RAC member noted a study that indicated that a VBAC is safe for women with one cesarean, there were 0 per 1000 postpartum deaths at birthing centers.

RAC member responded to concerns shared about rights to infants. Discussion and comments from RAC members:

- If there is evidence that any OOH neonatal loss is related to a risk factor that is missing from a previous table, then that is evidence that should be considered;
- Authors of Snowden study indicated that there should be a focus on integration in order to eliminate disparities;
- Midwives do not have the power to change or improve integration (which means receiving transfer). Midwives do not have the power to get physicians to cooperate with them during prenatal care;
- If the state really wants to improve perinatal outcomes, it should require integration;
- Everyone is looking out for the baby and everyone is concerned about outcomes. When looking at decision making, the mother is the most concerned and vested in the outcome of a birth. Women are making choices based on best intentions and knowledge.

D. Selover noted that a mother's choice is based on the best information available to her. It's not about doubting the woman in making the decision, it's about the information that the woman receives and how that may or may not be influenced. It's important that when informed consent occurs, that it is standardized and fully comprehensive. A woman should have all the information she needs. Discussion and comments from RAC members:

- Standardized information for specific risk factors would be supported.
- Concern was raised about the manipulation of information (in both directions) in determining whether the information provided was adequate to make an informed choice.
- In order to make a risk analysis, a woman must have both the short-term perinatal risk as well as any long-term risk to themselves which is often systematically undervalued (e.g. cesarean surgery).
- Many women have already done a lot of research on risks and are thus making a more informed decision.

RAC member remarked that from a consumer standpoint of the safety of the mother and child, the woman is trusting that the provider has the best interest of the mother and child in mind and that the provider has the most current evidence-based data.

In response to concerns about OOS, Certified Nurse Midwife education programs, a RAC member shared that the Commission on Midwifery Education must accredit all midwifery education

programs which sets forth the standards that programs must meet in order to offer those programs. Some OOS programs may be more stringent than in-state and requiring students to get their own preceptor may help with assertiveness and finding a good fit which may influence the care given in the future. Further comments from RAC members:

- Question was asked whether this problem was in birthing centers only or systemic. Response was it's systemic and has nothing to do with the facility type.
- License means the individual has met a minimum set of standards and the public trusts them to be safe.
- Not all advanced practice nurses understand their scope.
- There are many great OOS programs; the OSBN is just raising awareness of concerns received.
- Patients receiving information and patients being informed are completely different and some providers may not understand.
- The OSBN is seeing more and more scope creep with less and less knowledge about what the scope of practice really is.

RAC member noted that the amount of informed choice in a birthing center is profoundly different than what is offered in other health facilities.

D. Selover shared that the RAC needs to consider the following and asked what order to discuss these issues:

1) Risk factor table content and ease of use;
2) How tables compare to the past and other guidance;
3) How to apply consultation versus exclusion and transfer. There is not enough clarity on the process. The DEM has really good information in their rules.

RAC members voted to review the risk factor tables. D. Selover noted that this RAC does not have the structure to look at data in a nuanced way to determine whether the data is good or bad. This is why the program is referring to the HERC.

C. Livingston noted that the HERC has reviewed all comparative literature and guidelines including the AABC, UK, Netherlands, etc.

RAC member noted that the intent is not to introduce new studies about specific things that fall under the HERC. The HERC has done great work in accumulating relevant studies. The main issue is that the HERC does not consider as high-quality evidence, the vast majority of research that specifically relates to birthing center births, home births or OOH births generally in the U.S. Funding for research in the U.S. for midwifery and OOH births is marginalized, and comparative studies between OOH births and in-hospital births have not been funded. It was further noted that, it's not because the research that is happening is not useful. It is very useful to look at studies that look at tens of thousands of OOH births. These additional studies are relevant for purposes of birthing center rules. The state cannot hold to a comparative study standard when there is no willingness to look at what is actually happening in planned OOH births.

C. Livingston noted that the HERC included evidence from other countries which is very supportive of OOH births. Comparative data is needed to understand outcomes otherwise there are issues of bias. Both US data and out-of-country data was considered.

RAC member inquired whether there was agreement that information such as MANA stat data specific to Oregon births and outcomes is relevant? Comments from RAC members included:

- Oregon Midwifery Council looks at both Oregon and national MANA stat data which should be considered, along with Center for Health Statistics data.
- Need to look at maximum safety balanced with informed choice.
- Need to figure out how to consider the data.

Risk Factor Table 1 – Exclusions at Admission

D. Selover opened discussion on the risk factor tables noting that the RAC will review the lists and identify factors that RAC members agree should remain on the list, or those factors where additional data or additional conversation is needed.

Table 1 - Exclusions at admission is meant to identify women that come to the birthing center at various phases of pregnancy and present with a risk factor that will exclude them from receiving care.

MATERNAL HISTORY	RAC RECOMMENDATION
Cesarean section or other hysterotomy	**DEFER DISCUSSION**
Eclampsia/Pre-eclampsia requiring preterm birth/HELLP Syndrome	**DEFER DISCUSSION**
• RAC member remarked that Eclampsia and Pre-eclampsia are more common in the first pregnancy and it shouldn't be assumed that it will happen again. • RAC member suggested that anything being added (that is not currently in place with existing rules) decreases access to birthing centers and should not be considered unless Oregon data suggests otherwise. • RAC member noted that these indicators were not previously in rule because a birthing center could take a client who had a previous pregnancy where they had pre-eclampsia or eclampsia and monitor them for possible future exclusion. o NOTE - CURRENT OAR TABLE 1 – ADMISSION – states: "ABSOLUTE RISK FACTORS – If present at the time of admission to the birthing center, the following conditions would necessitate transfer of the client to a higher level of care: - Eclampsia; preeclampsia with lab abnormalities.	

• RAC member remarked that any decisions made should not limit rural birthing centers who might be providing prenatal care even if a client plans to have a hospital birth. Example was provided of a birthing center taking care of clients, for example, with twin gestations. Clients were planning to deliver in the hospital but had access issues with getting prenatal care. Nothing should prevent any birthing center from providing prenatal care. • Staff noted that based on current rules and risk factor tables, it's not just exclusion from birth care in a birthing center, it would include pregnancy care. Pregnancy care could be offered in a separate, distinct space from the center. It was noted that based on previous RAC discussions, one of the action items was to allow a birthing center to provide prenatal care even in instances where a client may have certain risk factors. This action item is under consideration. • RAC member remarked that it's completely appropriate for a midwife working in a birthing center to provide care for someone with a history of eclampsia, HELLP syndrome, or preeclampsia requiring preterm birth. Risk factors have warning signs that would allow a provider to refer or transfer as necessary. • RAC member remarked that women can make an informed choice, if they're given data and proper information. Additionally, a patient can be appropriately transferred to the hospital in time and potentially still have a better outcome given advantages to care in the midwifery setting. • It was noted that this is a HERC exclusion for OOH birth services and is a risk factor that is universally excluded for OOH birth. • RAC member suggested that eclampsia, preeclampsia and HELLP syndrome are manageable risks as opposed to absolute risk factors as a maternal history element not as a current pregnancy complication. • RAC member suggested that these factors might make more sense as requiring a consultation with a physician for purposes of prenatal care. In rural areas, pregnant women are frequently cared for in communities that are planning to birth at OHSU which is a multi-hour trip. These clients intend to go see a physician and are in consultation with a physician during their prenatal care. • RAC member remarked that each pregnancy be thought of separately unless it's something like an RH factor that lasts forever. The conditions under consideration are not lifelong chronic conditions. They're acute conditions that come up with a pregnancy. Women should be watched more closely, additional labs considered including more frequent testing, and require consultation with an obstetrician, but they shouldn't be excluded from care. • RAC member shared that women could receive co-care where they're established with a doctor, and in communication with the doctor during prenatal care because it is just not possible for her to get the care and	

attention she needs from a physician, as often as may be needed for whatever reason. • RAC member indicated that an integrated care system is a great approach where the midwife is collaborating with maternal/fetal medicine specialist and obstetricians that are willing to provide collaborative care. It's very common for women who have historical factors or current pregnancy complications, to drive several hours to see an OB or specialist, and alternate care visits with a midwife at a birthing center. Birthing centers should not be excluded from providing care under those circumstances. • RAC member suggested that a high-risk birth is one for which a risk has actually manifested. Otherwise, there is an attenuated risk of becoming at risk and the risk of a future risk is being used to try and deny access. Midwives have shared that that they have the training and skills to identify the risks that have the potential to manifest. If the fear is that providers lack the skills or training or ability to make those risk analyses, the place to deal with that is through the provider's licensing board. Rules should not be written that assume practitioners do not know how to do their job under their license. • D. Selover remarked that the program is looking at the rules from a perspective of ensuring safety not denying access. RAC member responded that not allowing a woman to birth in a birthing center, when the woman has been informed and continues to choose an OOH birth, is patient abandonment and not about safety. • RAC member clarified that the revised DEM rules allow only supportive care if a pregnant woman meets exclusion criteria or indication for transfer. Supportive care includes nutritional counseling, emotional support, and social development. This may occur while the woman is receiving clinical care from a physician. If the condition resolves then the midwife can resume full responsibility of care. A collaborative care model would be ideal and is what makes OOH birth safe in other countries. • RAC member suggested that a history of HELLP syndrome needs to be an exclusion factor.	
4th degree laceration without satisfactory functional recovery	**RETAIN**
• RAC member remarked that this factor should remain as an exclusion • RAC members agreed.	
Retained placenta requiring surgical removal	**REVISE and RETAIN**
• RAC member remarked that this factor should remain as an exclusion • RAC member suggested that this statement is not descriptive enough and should be revised to reference accreta. • It was noted that women with a history of placental accreta are at increased risk for the same condition in subsequent pregnancies. RAC member reiterated a woman's right to choose to continue to receive care	

and questioned where the cut-off line is for acceptable risk (e.g. percent risk of occurrence). RAC member suggested this should not be an absolute exclusion if a woman chooses to continue to receive care.	
Uterine rupture	**RETAIN**
• RAC member suggested this factor remain as an exclusion • RAC members agreed.	

PREVIOUS FETAL HISTORY	**RAC RECOMMENDATION**
Neonatal encephalopathy	**DEFER DISCUSSION**
• RAC member suggested that the terminology is not accurate enough and should be changed to HIE (hypoxic-ischemic encephalopathy). • RAC member expressed concern that neonatal encephalopathy is result of various events that are not necessarily recurrent.	
Stillbirth or neonatal death (unexplained) or previous death related to intrapartum difficulty	**REVISE and RETAIN**
• RAC member noted that many religious patients choose not to interfere with a pregnancy while the fetus is still inside and also choose not to have an autopsy. Pushing these clients to a hospital discriminates against their freedom of religion. • RAC member noted that religious clients frequently do not get an anatomy screen ultrasound, wouldn't have an autopsy, and a birthing center would not have evidence that something was 'unexplained by anomaly.' • RAC member indicated support of retaining 'stillbirth related to previous intrapartum difficulty.' • RAC member remarked that a lot of women choose OOH birth if they have a previous loss in a hospital. Retaining 'stillbirth related to previous intrapartum difficulty' may lead to outcry from consumers. • RAC member echoed that there are a lot of clients that inherently distrust hospitals and retaining stillbirth may result in many women having unassisted births. • Majority of RAC members voted to keep 'stillbirth related to intrapartum difficulty' as an exclusion factor.	
Placental abruption with adverse outcome	**RETAIN**
• RAC members agreed to retain as an exclusion factor.	

Risk factor discussion ended given time. HCRQI staff will consider the best method to facilitate future discussion including voting mechanism.

ACTION: HCRQI staff will consider a different process for use in future meetings for discussing and voting on risk factors in Tables I through III.
Follow-up on FGI Discussion
Based on feedback received from RAC members, staff reconsidered the physical environment requirements for birthing centers. A crosswalk was created comparing current Oregon Structural Specialty Code (OSSC), American National Standards Institute (ANSI), and National Fire Protection Association (NFPA) requirements alongside the Commission for Accreditation of Birth Centers (CABC) indicators of compliance and the Facility Guidelines Institute recommendations. A copy of the revised proposal was shared with the RAC and RAC members were asked to review the revised proposal and send concrete feedback to Mellony Bernal and Barbara Atkins. RAC members were also asked to specifically consider references that refer to "adequate space" or "adequate storage" which is unenforceable. RAC members were asked to submit suggested criteria for those references.
ACTION: Comments from RAC members on the proposed revised physical environment standards are **due by January 10th, 2020.** (Reference email sent on December 3, 2019).
Next Steps
Next meeting is scheduled for January 24, 2020 at 9:00 a.m.
ACTION: Staff will send out an e-mail with additional meeting poll links.

Meeting adjourned at 12:00 p.m.

Memorandum

To: Mellony Bernal, Oregon Health Authority
From: Hermine Hayes-Klein, JD on behalf of Oregon Association of Birth Centers
Re: January 24, 2020 RAC Meeting for Birth Center Rules: Corrections to Minutes from November 22, 2019 RAC Meeting
Date: January 27, 2020

At the beginning of the January 24, 2020 OHA RAC Meeting for Oregon Birth Center Rules, I offered the following clarifications regarding the November 22, 2019 meeting minutes. Despite these clarifications, the minutes have been consistently thorough and excellent, and that they had generally captured robust exchanges with accuracy.

1. P.2: "Since implementing the HERC criteria for Medicaid patients, RAC member suggested there was a 75% drop in OOH births for clients covered by OHP."
   a. Clarification: The context of this paragraph suggests that the 75% drop in OHP clients able to access OOH birth is due to OHA's refusal to cover women with risk factors included in HERC. The point that I heard being made at that meeting (by some of the OOH providers, I believe) was that the dramatic decline in access to OOH midwifery services, since implementation of HERC, is due as much to discrimination and bias in OHA's OOH prior authorization process, as to the way OHA is using HERC to deny coverage for OOH births that are within the birth center and the providers' legal scope of practice. See, e.g., the Report from the Out of Hospital Birth Prior Authorization Review Workshop, 9/2018.

2. P.3: "RAC member suggested that the Netherlands have always had a system where healthy women give birth at home with midwives, and that a hospital is backup and they have always had better outcomes than the U.S. Further, what makes an OOH birth safe in another country is integration."
   a. Clarification: I made this point in response to Cat Livingston's remark that many of the risk factors in the HERC Guidelines were included in the guidelines for transfer in nations with the best outcomes for OOH birth, and she cited the Netherlands and the UK. At that point, I didn't suggest, but accurately stated that the Netherlands' healthcare system has always considered childbirth to be a normal physiological event with the potential to become a medical event, rather than a medical event by definition, and have treated it as appropriate for women to give birth at home with midwives, and to save doctors and hospitals for the event that medical treatment is actually needed. I stated that Dutch perinatal and maternal outcomes over the last century have been better than ours, and disprove the American cultural belief that the safest place for normal birth is at the hospital under the care of physicians. Studies out of the Netherlands, the UK and Canada indicate that, when OOH birth is integrated, it has the same short-term perinatal outcomes as planned hospital birth, but much healthier long-term outcomes for mother and baby. The thing that makes OOH birth safe in nations like the Netherlands, UK and Canada is integration and continuity of care, not guidelines imposed as rules restricting access to midwifery care. The authors of the Oregon

Snowden study expressed this point publicly, stating that the conclusions from their study should not be to blame midwives or to restrict access to OOH birth, but to improve integration and continuity of care.

   b. My main point was that it is important to understand that all of the nations with safe OOH maternity services treat their guidelines for transfer from midwifery to medical care as intersectional with the woman's right of informed choice, and the provider's bioethical duty of non-abandonment. Women are provided with midwifery care if they refuse medical care, and ensured secure access to medical services in the event they come to need or choose them. Secure integration and access to care should be the focus of OHA's effort to optimize safety for OOH birth.

3. P.4: "D. Selover remarked that the OHA and the RAC are not arguing about the rights of individuals, but rather having a conversation about how to apply the statutory definition of a freestanding birthing center licensed primarily for the purpose of performing low risk deliveries."
   a. Clarification: My response to Dana's point here didn't make it into the minutes, but I think it's important:
      i. This committee is meeting to write the regulations that will affect which women can or cannot give birth at a birth center, given the medical risk factor Tables that Oregon uses to define access to birth center care. Under Oregon birth center rules, licensed birth centers cannot provide services to women with the risk factors listed on the Tables. The existing Tables were presumably drafted with the idea that they would keep women and babies "safe." The drafters of these proposed rules presumably have data indicating that there is a safety gap that justifies adding many more risk factors to the Tables, and therefore excluding many more women from birth center care. This committee meeting is the time for OHA to present the evidence indicating that adding the new risk factors on the draft tables would actually serve the goal of "safety."
      i. However, while the purpose of the regulations is obviously to optimize public health and safety for the women who give birth in Oregon and their babies, it should go without saying that these regulations, which are laws, must be written in a way that anticipates, respects, and upholds the legal rights of the people affected by those rules. The Oregon Health Authority, and its agents and representatives, are the State. It is one thing for hospitals to routinely ignore and violate the legal rights of pregnant women, as they do by withholding healthcare support for vaginal birth, and offering only support for surgical delivery, to women with risk factors that they don't like or find inconvenient, like prior cesarean section. But the State of Oregon doesn't have that luxury. The State of Oregon has the obligation to respect and uphold its citizens' rights. That includes their rights to medical decision-making generally, and pregnant women's rights to make medical decisions on behalf of both themselves and their unborn babies, in particular.

    ii. This committee has a choice, whether to write regulations that respect and uphold the reproductive, constitutional, and human rights of women in Oregon to make informed medical decisions, even if they make decisions that we personally would not make. Or this committee can erode those rights by drafting regulations that ignore women's rights to make the safest decision for themselves and their babies, and abandon care if they make certain decisions, with the result of diminished safety. Portland, Oregon should be a place where women's rights are not only remembered and recognized as relevant to the laws that affect them, but are protected and secure.

4. P.6: "Everyone is looking out for the baby and everyone is concerned about outcomes. When looking at decision-making, the mother is the most concerned and vested in the outcome of a birth. Women are making choices based on best intentions and knowledge."
    a. My point here didn't make it into the minutes:
        i. Everyone involved in a birth is making decisions on the basis of best intentions and knowledge, patient and providers. And no matter who is making the decision, sometimes babies do not survive childbirth. No matter how everybody involved may feel about the risks of a tragic outcome, no matter how scared anybody may be for the baby, there is no legal question about who has the right to make decisions for the baby, during pregnancy and childbirth. That person is the mother, the pregnant woman, because when she makes decisions for the baby, she is also making decisions about her own body. There is no law, in Oregon or federally, that has removed pregnant women from the class of people who get to make autonomous medical decisions. Therefore, any discussion of the rights and needs of the baby need to make clear for the minutes that legally, the rights of the infant are protected by respecting its mother, and her right to make decisions on both of their behalves. The rights, and needs, of the baby are not protected by bullying and coercing pregnant or birthing women into medical interventions that they don't want, in the names of "the rights of their unborn baby."

5. P.7: "RAC Member noted that the amount of informed choice in a birthing center is profoundly different than what is offered in other health facilities."
    a. By "profoundly different," the RAC member (not myself) was explaining that the informed consent/ choice process is far more thorough, detailed, meaningful, and frequent in birth centers than in other health facilities, because informed consent and patient autonomy are foundational to the midwifery model of care.

Thank You!

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement
Kate Brown, Governor

Oregon Health Authority

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Birthing Center RAC
January 24, 2020
9:00 – Noon; Room 1-E

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Kaylyn Anderson (phone)	Consumer
Karen DeWitt	Oregon Association of Naturopathic Physicians
Laura Erickson	Alma Midwifery Services
Colleen Forbes	Former Chair, Board of Direct Entry Midwives
Jason Gingerich (phone) for Cat Livingston	Health Evidence Review Commission
Hermine Hayes-Klein	Oregon Association of Birthing centers
Desiree LeFave	Bella Vie Birthing center
Meredith Mance	Aurora Birthing center
Samie Patnode (phone)	Board of DEM
Margaret Porter	Bella Vie Birthing center
Alice Taylor (phone)	American Association of Birthing centers
Willa Woodard Ervin (phone)	Rogue Birth Center
Michele Zimmerman-Pike	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Brooke Bina (phone)	Alma Midwifery Services
Kelley Burnett (phone)	Medical Director, All Care Health
Coleen Connolly (phone)	Medical Director, Trillium Community Health Plan
Debbie Cowart	Growing Family Birthing center
Jody Davis	Public
Dr. Gamble (phone)	Associate Medical Director, All Care Health
Lindsey Lincoln (phone)	Growing Family Birthing center
Kailia Wray (phone)	Midwife

OHA PHD HCRQI Staff	
Mellony Bernal	Admin. Rules and Leg. Policy Analyst; Health Care Reg. & Quality Improvement
Anna Davis	Survey and Certification Manager; Health Facility Licensing & Certification
Rebecca Long	Paramedic/Health Educator; EMS and Trauma Systems
Dana Selover	Section Manager; Health Care Regulation & Quality Improvement

Welcome / Overview
M. Bernal welcomed RAC members and participants introduced themselves.

November 22, 2019 Birthing Center RAC meeting notes

D. Selover asked whether members of the RAC had any comments on the November meeting notes? RAC member submitted clarification to comments made and that were summarized in the minutes. This document is attached and will be appended to the November meeting notes as well. The November meeting notes have been edited to include the following statement:

- Clarifying statements for these November minutes were submitted by a RAC member at the January 24, 2020 BC RAC meeting. These comments are attached for reference.

ACTION: November notes will be edited to include the statement noted above and the comments made at this meeting will be attached to both the November meeting notes and these January notes.

Overview – Dana Selover

Dana Selover provided an overview of where the RAC is in the process of these rules.

- The rule language has been reviewed by the RAC including several housekeeping changes made for alignment with other licensed facility types. The RAC is now focused on the risk factor tables.
- The program is tracking action items from each of the previous RAC meetings and is working on edits based on those action items. At least one future meeting will be designated to review these action items, the programs response to the action item, and any edits made to the rules.
- The DEM rules have been completed and were made effective January 1, 2020.
- The Health Evidence Review Commission's (HERC), Evidence Based Guidelines Subcommittee (EbGS) last met on December 5, 2019 at which time final proposed edits to the Coverage Guidance for Planned Out-of-Hospital Birth were made. The revised proposed guidance was posted for public comment from December 10, 2019 and closed on January 9, 2020. The EbGS will be reviewing those comments at its meeting on February 6, 2020 and will decide on whether to approve, amend or ask staff to make further changes for consideration. If approved to move to the HERC, the proposed new coverage guidance would be considered at its March 12, 2020 meeting.

RAC member remarked that in addition to the birthing center rules, the direct entry midwifery rules and the HERC guidelines, there are additional rule sets that need to be considered including the Board of Naturopathic Examiners and State Board of Nursing rules for Certified Nurse Midwives. Staff acknowledged separate provider rules but noted that the HERC, the Board of DEM and this office are all part of OHA, all three of which have been working on amendments to rules or guidance. RAC member reiterated that regardless purview, the other Boards and the scope of practice rules under each, will be impacted by the Birthing Center rules.

D. Selover noted the following:

- Rules adopted by the Board of DEM include the scope of practice standards for licensed direct entry midwives. These rules include patient interaction, consultation requirements, as well as some risk factor exclusions.
- The HERC guidance is specifically for the Medicaid population for purposes of payment and is driven by the values of safety, benefits versus potential harm, and optimal outcomes.
- As a rule's advisory committee (RAC), recommendations made, and proposed rule language is channeled through legal counsel to ensure that the rules meet the statutory requirements. It is understood that prenatal care and consultation occurs in a birthing center; however, as defined in statute a freestanding birthing center is a facility for the primary purpose of performing low risk deliveries. As such, the program's focus in terms of rules is safety.
    - Rules were initially adopted in 1985 and risk factor tables were adopted in 2006 in order to define what is a low risk birth. The Board of DEM and the HERC have been established since then and have also established low risk birth criteria and as such the program needs to take into consideration this work.
    - The program must also consider the survey teams that must go out and verify compliance using survey tools, functional checklists, record review and interview questions to determine compliance including adequate and appropriate application of the risk factor tables.
    - Despite the scope of practice standards adopted by provider licensing boards, the program has proposed language based on the HERC guidelines because those guidelines are based on low harm, low risk. If changes are needed, a method to justify disagreeing is necessary (data, evidence, national practice guidelines, etc.)
    - Decisions made by the program will not be made in the same manner that the HERC or the Board of DEM does. This program does not have the same framework for evidence-based review as the HERC. As such, in considering changes, the program is seeking information from the RAC for justification for change, including evidence through national guidelines or research articles.

RAC member thanked another RAC member who brought up the different provider type rules and understands that birthing center rules should not be in direct conflict with different provider type rules. However, examples of situations exist where a birthing center benefits from being able to take a patient who was not going to get her OOH birth paid for because with extra consultation, additional assessments, etc. can be safe to deliver OOH. Additional rules should not be added that don't affect safety especially if other measures can be put in place (assessments, consultations, etc.) to make things safe for a well-informed consenting woman.

RAC member remarked that all accredited birthing centers have multiple lists of criteria in place to meet the definition of only low risk birth established by the Commission on Accreditation of Birth Centers.

RAC member commented that based on information provided, it's the term "low risk deliveries" that appears to be the focus and treating risk as an 'on/off switch' to determine which bucket will women fit. RAC member further stated that presumably existing risk factor tables were determined to have met the statutory definition and now the proposal is to redefine rules to make HERC guidance the definition. While laws written must meet the statutory definition of freestanding birthing center, they must not contradict other statutes including that Oregon citizens have a right of informed consent and refusal. RAC member further asserted in response to comment that RAC members provide evidence-based material or guidelines to dispute certain risk factors, that if the Authority is adding risk factors that were not previously identified, then the burden is on OHA to present the data that supports the change. Follow-up from RAC representative: Oregon's statutory right to decision-making is ORS 127.507.

RAC member thanked other RAC members for comments and noted that the different criteria for different providers can be challenging. AABC standards for risk criteria are very brief. Complications that may affect outcomes are how they address risk factors which implies that there should be an integrated system with collaboration, consultation and referral. This RAC is in a unique position to bridge the gap between the HERC guidelines, DEM rules and other standards. RAC member read the following statement from the AABC standards:

> "The birth center respects and facilitates a pregnant person's right to make informed choices about their health care and their baby's health care based on their values and their beliefs."

RAC member further stated that the AABC believes that decisions should be made by licensed providers and the licensed birth center facility, in collaboration with the team – the team being an integrated system. It is a woman's constitutional right to refuse care which supersedes state's rights.

RAC member echoed other RAC member comments that the RAC should remember there are other provider scopes of practice to consider. Each provider type should be trusted to manage the care of a client based on those provider scope of practice laws. Scope of practice should not be managed in a facility setting. Additionally, if rules are going to be more restrictive, clear evidence needs to be provided that shows there is a decrease in safety that moves the criteria from low risk. While birth centers exist for low risk women, from information reported at the last meeting there is no clear line on what is low risk and what is not. VBACs are an example where there are risks both in the birthing center and a hospital setting based on data.

RAC member remarked that when looking at evidence, the RAC must also consider that just because evidence may suggest that there is an increased recurrence of a specific condition, it doesn't mean they are at an increased risk because they select OOH care. What should be looked at is what is the difference in birth site outcomes.

RAC member stated that since the inception of the HERC guidelines, many women on Medicaid have not been able to be served. If the HERC guidelines are adopted, an increased number of women with risk factors may seek to give birth at home by themselves and this should be considered as discussions continue. Women know there are increased risks and sometimes the

risks are very small; these women believe that giving birth in a hospital is a bigger risk. The RAC needs to consider women's rights and make sure that women are not excluded.

Staff remarked that in terms of making decisions about the risk factors, the program is driven by the statutory definition of a freestanding birthing center. If persons are dissatisfied with the definition and any unintended consequences from adopting rules, then they should be actively seeking a statutory change and working to include things such as accreditation language or acknowledging that risk should be defined based on provider scope of practice laws. Staff further noted that it seeks guidance from the Oregon Department of Justice in determining interpretation and compliance with Oregon statute.

RAC member responded that the intent is not to change the statute, but rather to acknowledge that risk is variable and there is no defining line that says yes or no, or on and off.

Staff noted that the reason the HERC guidelines were proposed as the foundation for these rules is not to restrict access as has been suggested in previous meetings. Whether that is an indirect result of that is acknowledged but it is not the program's intent to restrict - it is to follow statute, get expert input during the RAC process, and, to the extent possible, align across the OHA what makes the best sense and guidance received by legal counsel. Considerations are the statute, the multiple provider types, the process, the policy, the documentation for decision making, the risks, and managing the consultation. Managing consultations and how that will look will need to be discussed in the future. The decision maker is not the person who was consulted with but rather part of shared decision making process.

HERC staff shared the draft recommendation relating to consultation.

> 'Consultations may be with 1) a provider (MD/DO or CNM) who has active admitting privileges to manage pregnancy in a hospital and/or 2) appropriate specialty consultation (e.g., maternal-fetal medicine, hepatologist, hematologist, psychiatrist). For infectious conditions such as uncomplicated urinary tract infections or sexually transmitted infections, no consultation is necessary if patient receives appropriate treatment.'

OOH birth guidelines do not differentiate between provider types. Broad coverage criteria apply regardless of provider type. The same criteria apply to an MD or DO attending an OOH birth.

RAC member responded that while HERC applies to all provider types, however, the state saying Medicaid can have Care Oregon that does not allow some provider types to deliver outside of the hospital is effectively applying it differently to different provider types.

RAC member remarked that her birth center does operate differently because they have physicians that are licensed to provide care when there is a history of 3rd and 4th degree tears, etc. They have providers that have privileges with the hospital so it's redundant to consult with themselves. Persons who have not met criteria have been able to be served but with extra consultation. Some risk factors are mitigated through further studies such as extra ultrasounds.

Staff thanked RAC members for their comments. Staff provided an overview of a polling system that will be used using a consensus model decision making tool. The program is trying to gauge where priorities are in terms of risk factors. The poll will consist of the following choices:

- "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.

RAC members were asked whether anyone was opposed to revisiting those risk factors discussed at the last meeting. RAC concurred.

Staff provided an overview on how the voting poll devices worked.

Risk Factor Table 1 – Risk Factors for EXCLUSION AT ADMISSION

Maternal History –

Cesarean section ~~or other hysterotomy~~

- November 24th meeting, RAC had requested to defer discussion.
- RAC member requested that these criteria be separated as she would vote differently on each criterion. RAC concurred.
- Poll Results:
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 0% - I find the recommendation acceptable and have no serious objections.
  - 0% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 8% - I do not fully agree with the recommendation and need to register concern.
  - 92% - I do not agree with the recommendation and will actively block its movement.
- Defer for further facilitated discussion.

Other hysterotomy

- Poll Results:
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 45% - I find the recommendation acceptable and have no serious objections.
  - 9% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 27% - I do not fully agree with the recommendation and need to register concern.
  - 18% - I do not agree with the recommendation and will actively block its movement.

RAC member asked how the poll will drive further discussion on the criteria. Staff suggested that if the majority of RAC members agree, then minor discussion may be needed. If there is no agreement or the poll is across the board then more discussion will be necessary. If the majority indicates no agreement with recommendations, the program will consider additional facilitated discussions.

- Discussion:

- RAC member remarked that hysterotomy is a very broad topic and should be included in the list for consultation.
- Additional RAC member concurred.
- Staff asked if this was based on the heterogeneous nature of what can fit under the criteria and should be considered on a case by case basis? RAC concurred.
- Staff asked if there was any national guidance or accreditation that would support. RAC member responded that 1) in agreement with having hysterotomy as a consultation criterion and 2) that the AABC will lean towards consultation on many of the risk factors.
- Staff asked if there are any scope of practice guidance for this topic or if it's part of general practice? RAC member responded that it falls under more general guidance acknowledging that there could be a potential for complications so additional consultation would be sought, surgery notes referenced, size of incision, etc.
- RAC member remarked that under the DEM rules extensive transfundal surgery or para uterine rupture is listed as transfer criteria which defines a more significant uterine surgery. Previous myomectomy is in the consultation criteria.
- Staff asked RAC to consider whether "other hysterotomy" should be moved to consultation criteria or whether additional verbiage is necessary to clarify more extensive procedures such as transfundal surgery. Given the wide variety of providers, RAC member suggested keeping the criteria more general and moving to consultation, and suggested stating "hysterotomy other than cesarean."
- Staff asked if there was any support for adding more specific language for extensive procedures for exclusion. RAC indicated no.
- RAC member concurred with leaving language more general because of the different provider types and stated she does not see any value to adding more specificity.
- RAC member stated that the AABC would agree with more general language.

Eclampsia (eclamptic seizure)

- RAC member wanted to make clear based on November discussion, that this is not referring to a maternal history of preeclampsia rather maternal history of eclamptic seizures. RAC concurred.
- RAC member asked if there was any data on the likelihood of eclamptic seizures occurring again. It was noted that a client with a previous history would get a baseline assessment and would be watched carefully for symptoms. RAC member further asked if a "risk of a risk" is something that should be eliminated? Staff responded that consideration needs to be given not only to the probability that it will happen again, but the possible negative outcomes if it were to occur. It was noted that the HERC requires a transfer for eclampsia, preeclampsia requiring pre-term birth, HELLP syndrome and preexisting or chronic hypertension. RAC member noted that if data suggests that there is a 20% likelihood that a woman with preeclampsia may get it again, that means that 80% of women are excluded

from an OOH birth. It was further noted that many times the fastest way for a woman to get care is through a midwife.

- RAC member noted that if a pregnant woman has a history of eclampsia and she wants midwifery care then an OOH birth consultation or a referral for consultation with a maternal fetal medicine (MFM) specialist is very appropriate. The specialist would also consider what are the chances of this happening again. The MFM or OB consult would also be collaborating with the midwife and would outline things that would already be looked for. RAC member reiterated that many factors will fit under consultation including eclampsia. Based on the consultation the woman could make an informed choice on how to proceed with care.
- RAC member remarked that when looking at factors for excluding care even things that are considered serious, what makes a difference is how quickly things can happen. For example, a history of previous uterine rupture should be on the exclusion list, whereas, for things like HELLP Syndrome, eclampsia, preeclampsia requiring pre-term birth, there are warning signs and while serious, there is time to get the client to the appropriate provider and to the appropriate facility for delivery.
- Staff noted that based on the discussion the recommendation would be for consultation and appropriate monitoring.
- RAC member acknowledged point made by staff in terms of looking at risk factors based on the function of the severity of risk. The analysis of whether a risk requires transfer needs to be a combination of severity of risk multiplied by alacrity of onset; the quickness with which something may happen. If it happens quickly and catastrophically such that there is no time to access appropriate medical care, then that suggests the woman would be safer starting in a medical setting. A severe risk with a very slow onset would not be a reason to exclude because there is time for consultation and transfer. When looking at factors and how a birth center works, a lot of what makes things safer or dangerous in an OOH setting comes down to whether a birthing center can stabilize the risk and transfer if it starts to manifest or does the time necessary to transfer to the hospital increase the risk of death.
- RAC member remarked that with a prior history of eclampsia, onset of preeclampsia, or eclampsia can develop very rapidly, within a matter of hours, and should not be taken off the table without having data on recurrence rates for a history of eclamptic seizure as well as HELLP syndrome.
- RAC member remarked that they appreciate the comment and a person with a history of eclamptic seizure is very serious. On the other hand, while it can happen quickly, with education a birth center could address it.
- RAC member questioned whether the table referred to exclusion for admission including exclusion for prenatal care. Staff remarked that the program is still considering previous discussion regarding allowing a birthing center to continue to provide prenatal care for clients that would be ineligible for an OOH birth.

- RAC member suggested that the title of Table 1 should be changed based on intent. The term "admission" is often thought of in terms of admission at labor not admission to a birthing center. It was suggested that it be retitled "Risk Factors for Exclusion Prenatally."
- Poll Results (keeping maternal history of eclamptic seizure as an exclusion factor at admission for prenatal care):
  - 9% - I can say an enthusiastic yes to the recommendation (or action).
  - 9% - I find the recommendation acceptable and have no serious objections.
  - 9% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 73% - I do not fully agree with the recommendation and need to register concern.
  - 0% - I do not agree with the recommendation and will actively block its movement.
- Poll Results (moving maternal history of eclamptic seizure to consultation at admission for prenatal care):
  - 83% - I can say an enthusiastic yes to the recommendation (or action).
  - 0% - I find the recommendation acceptable and have no serious objections.
  - 17% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 0% - I do not fully agree with the recommendation and need to register concern.
  - 0%- I do not agree with the recommendation and will actively block its movement.

HELLP Syndrome

- November 24th meeting, RAC had requested to change to consultation and to defer discussion.
- RAC member remarked that the recurrence rate of HELLP syndrome is 2-6% with warning signs and recommended it be moved to consultation criteria as there is time to appropriately manage the client.
- RAC member stated that it makes sense that when there is a history of complications or risk of complications that midwives consult with appropriate specialists. It would make sense to consult with someone who has studied a particular risk factor extensively.
- Poll Results: keeping maternal history of HELLP syndrome as an exclusion factor at admission for prenatal care
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 8% - I find the recommendation acceptable and have no serious objections.
  - 8% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 50% - I do not fully agree with the recommendation and need to register concern.
  - 33% - I do not agree with the recommendation and will actively block its movement.
- Poll Results: moving maternal history of HELLP syndrome to consultation at admission for prenatal care
  - 73% - I can say an enthusiastic yes to the recommendation (or action).
  - 27% - I find the recommendation acceptable and have no serious objections.
  - 0% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 0% - I do not fully agree with the recommendation and need to register concern.

- 0% - I do not agree with the recommendation and will actively block its movement.

Pre-eclampsia requiring preterm birth

- Poll Results (keeping maternal history of pre-eclampsia requiring preterm birth as an exclusion factor at admission for prenatal care):
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 0% - I find the recommendation acceptable and have no serious objections.
  - 0% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 17% - I do not fully agree with the recommendation and need to register concern.
  - 83% - I do not agree with the recommendation and will actively block its movement.
- Poll Results (moving maternal history of pre-eclampsia requiring preterm birth to consultation at admission for prenatal care)
  - 42% - I can say an enthusiastic yes to the recommendation (or action).
  - 50% - I find the recommendation acceptable and have no serious objections.
  - 8% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 0% - I do not fully agree with the recommendation and need to register concern.
  - 0% - I do not agree with the recommendation and will actively block its movement.
- RAC member noted that in terms of improvements that can be made, a birthing center will not be able to perform a preterm birth. It should not be mandatory for a consultation when there is maternal history of preeclampsia so that MFM providers are not overburdened with consultations that are not necessary.
- RAC member concurred with no consultation is necessary. Mothers who have had preeclampsia with preterm birth are going to recognize signs and not want to go down the same path. Burdening an MFM with a consult on a mom who is going be to careful, along with the midwife watching for signs and symptoms, is unnecessary.
- RAC member indicated that Oregon really needs to move to a model of integrated maternity care that works so well in other countries. The more that people collaborate, the more of an integrated system that will be developed. It was acknowledged that geography may play a role in support of this model.
- RAC member noted that even if the rules did not require a consult, it does not mean that a woman and/or her provider will not choose to obtain one. Many women may choose to have a co-care model where other women may not choose that model.
- RAC member concurred with comments that it is an undue burden on MFM providers.
- It was noted that this is an exclusion for licensed direct entry midwives but not nurse midwives.
- RAC member remarked that this is an appropriate consult because it is not simply a consult for preterm birth or for preeclampsia. It is a consult for preeclampsia that requires a preterm birth which is a measure of severity and it would be useful to have a full risk evaluation.

- RAC member suggested clarifying a certain gestation period for this risk factor. Staff indicated that if RAC members wanted to suggest such a change to do so.
- Discussion ensued regarding gestation periods and categories of risk.

Fourth-degree laceration without satisfactory functional recovery

- RAC member noted that women meeting this criterion could benefit from midwives. Example shared of a client whose first birth was in a hospital, sustained a 4th degree laceration, developed a fistula, had two surgeries to repair, moved and came to the birth center for care. The client received midwifery care for the pregnancy but then delivered at the hospital. Exclusion from prenatal care is not supported by the draft language.
- RAC member suggested changing to a consultation requirement as "satisfactory functional recovery" is a broad term and depends on when it is measured as it changes over time.
- RAC member stated that it should be a woman's decision with informed consent based on information from providers.
- RAC member noted the criteria is a history of unsatisfactory recovery and these women are under the care of a provider. While there is a risk of recurrence, it is not necessarily an emergency depending on the support and resources in a birthing center.
- RAC member agreed with comments made and would refer a client as necessary. Adding more clarification may make it more effective.
- RAC member remarked that when the pathology or the risk factor listed in the table was caused by unnecessary intervention in previous hospital birth, that is when birthing centers and OOH midwives are confronted with clients who feel strongly about not returning to that model of care. RAC member further stated that it is important to read the studies that show that 4th degree lacerations occur most commonly in the presence of episiotomy and that episiotomy is an ultimate unnecessary routine intervention in a hospital setting. Information was shared from an article and the RAC member noted that the midwifery model of care is getting a baby over an intact perineum and midwives are experts in working with the perineum. Women who select midwifery care have really done their homework in wanting to have a baby with an intact perineum. Follow-up – Study referred to: *Relationship of episiotomy to perineal trauma and morbidity, sexual dysfunction, and pelvic floor relaxation,"* M. Klein et al, American Journal of Obstetrics & Gynecology (1994).
- Staff noted that under HERC guidance 4th degree laceration without satisfactory functional recovery is an absolute exclusion. 3rd degree in prior pregnancy and 4th degree with satisfactory functional recovery is a consult. Staff further noted that it would be helpful to see studies that would support changing to a consultation.
- RAC member noted that this factor is specific to without satisfactory functional recovery and some people may be recommended for a cesarean delivery because of the potential damage to an already nonfunctional pelvic floor. Its best evaluated in a consult to consider the research and individual client risks.

- Poll Results (keeping maternal history of 4th degree laceration w/o satisfactory functional recovery as an exclusion factor at admission for prenatal care):
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 17% - I find the recommendation acceptable and have no serious objections.
  - 0% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 42% - I do not fully agree with the recommendation and need to register concern.
  - 42% - I do not agree with the recommendation and will actively block its movement.
- Poll Results (moving 4th degree laceration w/o satisfactory functional recovery to consultation at admission for prenatal care):
  - 83% - I can say an enthusiastic yes to the recommendation (or action).
  - 8% - I find the recommendation acceptable and have no serious objections.
  - 0% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 8% - I do not fully agree with the recommendation and need to register concern.
  - 0% - I do not agree with the recommendation and will actively block its movement.

Uterine rupture

- Poll Results: (Keeping maternal history of uterine rupture as an exclusion factor at admission for prenatal care):
  - 73% - I can say an enthusiastic yes to the recommendation (or action).
  - 18% - I find the recommendation acceptable and have no serious objections.
  - 9% - I can live with the recommendation, but I'm not overly enthusiastic.
  - 0% - I do not fully agree with the recommendation and need to register concern.
  - 0%- I do not agree with the recommendation and will actively block its movement.
- It was noted by RAC member that women should be able to consult and receive prenatal care if this risk factor is present but should not be able to deliver OOH. The issue of providing prenatal care but delivering in hospital will be considered further.
- RAC member asked if the Oregon Health Authority has jurisdiction over prenatal care. Staff noted that if prenatal care is offered in a clinic separate from the birthing center, OHA does not have jurisdiction. If the prenatal care is provided in the birthing center, then the facility license means OHA has some jurisdiction.

Retained placenta requiring surgical removal

Deferred to next meeting given lack of time.

Next Steps

Staff noted that the next meeting is scheduled for March 2nd. The program will continue to use the polling system and work through the remainder of the tables. RAC members were encouraged to come prepared with relevant data, literature, guidance, etc. to the next meeting.

Meeting adjourned at Noon.

Memorandum

To: Mellony Bernal, Oregon Health Authority
From: Hermine Hayes-Klein, JD on behalf of Oregon Association of Birth Centers
Re: January 24, 2020 RAC Meeting for Birth Center Rules: Corrections to Minutes from November 22, 2019 RAC Meeting
Date: January 27, 2020

At the beginning of the January 24, 2020 OHA RAC Meeting for Oregon Birth Center Rules, I offered the following clarifications regarding the November 22, 2019 meeting minutes. Despite these clarifications, the minutes have been consistently thorough and excellent, and that they had generally captured robust exchanges with accuracy.

1. P.2: "Since implementing the HERC criteria for Medicaid patients, RAC member suggested there was a 75% drop in OOH births for clients covered by OHP."
    a. Clarification: The context of this paragraph suggests that the 75% drop in OHP clients able to access OOH birth is due to OHA's refusal to cover women with risk factors included in HERC. The point that I heard being made at that meeting (by some of the OOH providers, I believe) was that the dramatic decline in access to OOH midwifery services, since implementation of HERC, is due as much to discrimination and bias in OHA's OOH prior authorization process, as to the way OHA is using HERC to deny coverage for OOH births that are within the birth center and the providers' legal scope of practice. See, e.g., the Report from the Out of Hospital Birth Prior Authorization Review Workshop, 9/2018.

2. P.3: "RAC member suggested that the Netherlands have always had a system where healthy women give birth at home with midwives, and that a hospital is backup and they have always had better outcomes than the U.S. Further, what makes an OOH birth safe in another country is integration."
    a. Clarification: I made this point in response to Cat Livingston's remark that many of the risk factors in the HERC Guidelines were included in the guidelines for transfer in nations with the best outcomes for OOH birth, and she cited the Netherlands and the UK. At that point, I didn't suggest, but accurately stated that the Netherlands' healthcare system has always considered childbirth to be a normal physiological event with the potential to become a medical event, rather than a medical event by definition, and have treated it as appropriate for women to give birth at home with midwives, and to save doctors and hospitals for the event that medical treatment is actually needed. I stated that Dutch perinatal and maternal outcomes over the last century have been better than ours, and disprove the American cultural belief that the safest place for normal birth is at the hospital under the care of physicians. Studies out of the Netherlands, the UK and Canada indicate that, when OOH birth is integrated, it has the same short-term perinatal outcomes as planned hospital birth, but much healthier long-term outcomes for mother and baby. The thing that makes OOH birth safe in nations like the Netherlands, UK and Canada is integration and continuity of care, not guidelines imposed as rules restricting access to midwifery care. The authors of the Oregon

Snowden study expressed this point publicly, stating that the conclusions from their study should not be to blame midwives or to restrict access to OOH birth, but to improve integration and continuity of care.

b. My main point was that it is important to understand that all of the nations with safe OOH maternity services treat their guidelines for transfer from midwifery to medical care as intersectional with the woman's right of informed choice, and the provider's bioethical duty of non-abandonment. Women are provided with midwifery care if they refuse medical care, and ensured secure access to medical services in the event they come to need or choose them. Secure integration and access to care should be the focus of OHA's effort to optimize safety for OOH birth.

3. P.4: "D. Selover remarked that the OHA and the RAC are not arguing about the rights of individuals, but rather having a conversation about how to apply the statutory definition of a freestanding birthing center licensed primarily for the purpose of performing low risk deliveries."
    a. Clarification: My response to Dana's point here didn't make it into the minutes, but I think it's important:
        i. This committee is meeting to write the regulations that will affect which women can or cannot give birth at a birth center, given the medical risk factor Tables that Oregon uses to define access to birth center care. Under Oregon birth center rules, licensed birth centers cannot provide services to women with the risk factors listed on the Tables. The existing Tables were presumably drafted with the idea that they would keep women and babies "safe." The drafters of these proposed rules presumably have data indicating that there is a safety gap that justifies adding many more risk factors to the Tables, and therefore excluding many more women from birth center care. This committee meeting is the time for OHA to present the evidence indicating that adding the new risk factors on the draft tables would actually serve the goal of "safety."
        i. However, while the purpose of the regulations is obviously to optimize public health and safety for the women who give birth in Oregon and their babies, it should go without saying that these regulations, which are laws, must be written in a way that anticipates, respects, and upholds the legal rights of the people affected by those rules. The Oregon Health Authority, and its agents and representatives, are the State. It is one thing for hospitals to routinely ignore and violate the legal rights of pregnant women, as they do by withholding healthcare support for vaginal birth, and offering only support for surgical delivery, to women with risk factors that they don't like or find inconvenient, like prior cesarean section. But the State of Oregon doesn't have that luxury. The State of Oregon has the obligation to respect and uphold its citizens' rights. That includes their rights to medical decision-making generally, and pregnant women's rights to make medical decisions on behalf of both themselves and their unborn babies, in particular.

ii. This committee has a choice, whether to write regulations that respect and uphold the reproductive, constitutional, and human rights of women in Oregon to make informed medical decisions, even if they make decisions that we personally would not make. Or this committee can erode those rights by drafting regulations that ignore women's rights to make the safest decision for themselves and their babies, and abandon care if they make certain decisions, with the result of diminished safety. Portland, Oregon should be a place where women's rights are not only remembered and recognized as relevant to the laws that affect them, but are protected and secure.

4. P.6: "Everyone is looking out for the baby and everyone is concerned about outcomes. When looking at decision-making, the mother is the most concerned and vested in the outcome of a birth. Women are making choices based on best intentions and knowledge."
   a. My point here didn't make it into the minutes:
      i. Everyone involved in a birth is making decisions on the basis of best intentions and knowledge, patient and providers. And no matter who is making the decision, sometimes babies do not survive childbirth. No matter how everybody involved may feel about the risks of a tragic outcome, no matter how scared anybody may be for the baby, there is no legal question about who has the right to make decisions for the baby, during pregnancy and childbirth. That person is the mother, the pregnant woman, because when she makes decisions for the baby, she is also making decisions about her own body. There is no law, in Oregon or federally, that has removed pregnant women from the class of people who get to make autonomous medical decisions. Therefore, any discussion of the rights and needs of the baby need to make clear for the minutes that legally, the rights of the infant are protected by respecting its mother, and her right to make decisions on both of their behalves. The rights, and needs, of the baby are not protected by bullying and coercing pregnant or birthing women into medical interventions that they don't want, in the names of "the rights of their unborn baby."

5. P.7: "RAC Member noted that the amount of informed choice in a birthing center is profoundly different than what is offered in other health facilities."
   a. By "profoundly different," the RAC member (not myself) was explaining that the informed consent/ choice process is far more thorough, detailed, meaningful, and frequent in birth centers than in other health facilities, because informed consent and patient autonomy are foundational to the midwifery model of care.

Thank You!

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement
Kate Brown, Governor

Oregon Health Authority

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Birthing Center Rule Advisory Committee
March 2, 2020
9:00 a.m. – Room 1-B

RAC MEMBER ATTENDEES	
Silke Akerson	Oregon Midwifery Council
Kaylyn Anderson (phone)	Consumer
Laura Erickson	Alma Midwifery Services
Jennifer Gallardo	Andaluz Birth Center
Hermine Hayes-Klein	Oregon Association of Birth Centers
Desiree LeFave	Bella Vie Birth Center
Meredith Mance (phone)	Aurora Birth Center
Samie Patnode (phone)	Board of DEM
Margaret Porter (phone)	Bella Vie Birth Center
Alice Taylor	American Association of Birth Centers
Willa Woodard Ervin (phone)	Rogue Birth Center
Michelle Zimmerman-Pike	American College of Nurse Midwives
OTHER INTERESTED PARTY ATTENDEES	
Debbie Cowart	Growing Family Birth Center
Sharron Fuchs	Public
OHA Staff	
Mellony Bernal	Admin. Rules and Leg. Policy Analyst; Health Care Reg. & Quality Improvement
Anna Davis	Survey and Certification Manager; Health Facility Licensing & Certification
Rebecca Long	Paramedic/Health Educator; EMS and Trauma Systems
Dana Selover	Section Manager; Health Care Regulation & Quality Improvement

Welcome
Mellony Bernal opened meeting, reviewed housekeeping items and members introduced themselves.

January 24, 2020 Birthing Center RAC meeting notes
Dana Selover asked RAC members whether there were any comments or proposed changes to the January meeting minutes. RAC member pointed out a spelling error in an individual's name. Minutes will be updated to reflect correct spelling as follows: Kailia Wray. No further comments were made.

Overview

D. Selover reviewed agenda and provided an overview of where the RAC is in the process of the rules including the voting process on the risk factors from the last meeting.

- RAC member inquired when the RAC would further discuss prior cesarean section risk factor. D. Selover remarked that more preparation for that discussion is needed as the agency needs time to consider the articles that have been forwarded to the program.
- D. Selover noted that the RAC will continue to discuss the risk factors in the order they appear on the table and use the straw poll consensus options used from the last meeting.
- RAC member remarked that in terms of the polling, she will always promote an integrated system of care and shared decision making. While some risk factors are appropriate to exclude birth from a birthing center, they may not be appropriate to exclude from receiving care from a birthing center prior to birth. RAC member stated that evidence supports that care in a birthing center has better outcomes, lower pre-term birth rates, fewer c-sections, etc. even with a planned hospital delivery.
- Another RAC member shared that birthing centers fill an important gap in rural Oregon where there are limited prenatal care options. It was asserted that pregnant women in rural Oregon would be significantly safer and better served receiving prenatal care in their local community even if planning for a hospital delivery.
- D. Selover noted that allowing birthing centers to provide prenatal care even when certain risk factors are present is an action item that is still under consideration.

Risk Factor Table 1 – Risk Factors for EXCLUSION AT ADMISSION

Discussion and Polling

Maternal History

Retained placenta requiring surgical removal (exclusion at admission)

Discussion:

- RAC member suggested that more clarity is needed around the term "requiring surgical removal." There may be a wide range of issues with a retained placenta, not all of which include placenta previa or accreta.
- D. Selover noted that there are a wide range of issues on all risk factors and that a birthing center's policy and procedures, conversations with clients, assessing a client's history, and documentation are all important to consider when deciding whether a birth is appropriate or not at a birthing center. Consideration needs to be given to both how a birthing center will implement and how the Authority will regulate.
- RAC member reiterated that more definitions or clarity is needed because there is a difference between a denotative and connotative definition of surgery. Someone going into the O.R. does not necessarily mean the placenta had to be surgically removed.
- RAC member shared that "requiring surgical removal" is fairly clear and that charting could show 'manual' removal versus 'surgical' removal.
- D. Selover asked RAC members to consider interpretive guidance as a way to address some of the issues being raised as opposed to actual rule text.

- RAC member suggested amending to state retained placenta requiring surgical removal with instruments.
- RAC member stated that these kinds of issues are why most risk factors need to be moved to consultation. There are too many variables to keep as an absolute risk factor. Midwives and providers need to be trusted to consult on individual situations.
- Poll Results:
  - 0% - I can say an enthusiastic yes to the recommendation (or action).
  - 18% - 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.
  - 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.
  - 55% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Prior to voting on moving factor to consultation, D. Selover shared the following:

- There is both the expectation that there is clarity around what low risk is and what it is not;
- There are some factors that are not appropriate without surgical back-up. There is no surgical back-up nor intensive care at a birthing center;
- Consider low risk, high harm; low frequency, high harm. Some things may be rare but if it does happen, there is no time to react nor to get the client transferred in time. There needs to be a balance. Example given of a patient going to a trauma hospital versus a non-trauma hospital. The trauma hospital is prepared with appropriate staffing, services, and equipment.

Discussion:

- RAC member noted the importance of having access to the hospital records to determine possible surgical removal or other.
- RAC member remarked that the way this risk factor is written presents a problem. It was stated that most members would agree that placental accreta or percreta are appropriate exclusions. The term "surgical removal" can include much more which may not be appropriate exclusions. RAC member suggested that it would be more appropriate to define the risk factor to include the term(s) placental accreta, increta or percreta.
- RAC members and staff discussed voting poll options and D. Selover noted that this is an advisory committee, and members are giving advice on how the rules could be changed for the better. It was further noted that concerns can be addressed through added definitions, additional information, interpretive guidance, etc. Further discussion ensued regarding clarifying voting options.
- RAC member remarked that they would be embarrassed to consult with a provider about potential risks when identifying in a record something like a placenta falling out or using an instrument such as forceps. Providers have very little time for consultation as it stands now. It was suggested that the risk factor should be history of accreta for absolute exclusion. The provider should be trusted to understand a previous 'op' report and be

able to determine possible risk. If there is something in the report that would require a consultation, then a consultation should occur.

- RAC members concurred with previous suggestion that the absolute risk factor should be previous history of placenta accreta, increta or percreta. The following vote was taken:
  - **Previous history of placenta accreta, increta or percreta** (exclusion at admission)
    - 73% - I can say an enthusiastic yes to the recommendation (or action).
    - 18% - 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.
    - 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.
    - 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

PREVIOUS FETAL HISTORY

Neonatal encephalopathy (exclusion at admission)

Discussion:

- D. Selover noted that the tables currently under review were based on the 2015 HERC guidance. Since that time, HERC has proposed moving neonatal encephalopathy to the consultation criteria.
- RAC member noted that the HERC recently took steps to reconsider current guidance and the birthing center rules should not be more restrictive than the HERC. RAC member concurred that this factor should be moved to consultation.
- RAC member remarked that neonatal encephalopathy may result from a variety of different sources and would thus may exclude many women.
- RAC member suggested that this factor should be removed altogether including from consultation. It was suggested that the consultation list will be so long that it will result in increased costs. It was further stated that it will not improve outcomes since there is no problem given current laws.
- RAC member stated that with respect to consultation, it's not about asking a physician for permission. Regardless of risk factors, a woman has the choice to make her own medical decisions based on receiving relevant information about the safest options available. RAC member further stated that the HERC guidelines are for purposes of payment only and not about who can give birth at a birthing center. RAC member asked whether there was any data suggesting bad outcomes in Oregon and if so, it is the state's obligation to share that data. D. Selover responded, as indicated in previous meetings, the HERC guidelines were used as basis for alignment and is the agency responsible for looking at health evidence across the board - not evidence limited to Oregon. Just because something hasn't occurred in Oregon doesn't mean that the risk is not relevant.

- RAC member suggested that more detail around this topic was necessary since encephalopathy is a broad term (could be microcephaly in previous pregnancy, hydrocephalus, hypoxic ischemic encephalopathy, etc.)
- RAC concurred with comments about both informed choice and that evidence should not be Oregon based only, or even nationally. HERC does and has looked at international studies. The fact that consultation is an option is very important and relevant to families who have been faced with previous adverse outcomes. Consultation leads to shared decision making based on as much evidence that can be obtained.
- RAC member cited evidence to support not including this factor as a full exclusion. Both the British Medical Journal and the American College of Obstetricians and Gynecologists state that this can occur with various etiologies. Recent research has focused on optimal resuscitation practices for babies with cardiorespiratory depression, such as delayed cord clamping after establishment of ventilation and resuscitation in room air. These are all standards of care within midwifery practice and birthing center practice.

  Source(s):
  https://fn.bmj.com/content/102/4/F346?utm_campaign=adcfn&utm_source=trendmd&utm_medium=cpc&utm_content=consumer&utm_term=1-A

  https://www.uptodate.com/contents/etiology-and-pathogenesis-of-neonatal-encephalopathy?search=neonatal%20encephalopathy&topicRef=6216&source=see_link

- Based on discussion, D. Selover recommended voting on Neonatal Encephalopathy as consultation requirement not an exclusion.
  - **Previous fetal history – neonatal encephalopathy as a consultation requirement not an exclusion at admission**
    - 27% - 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.
    - 18% - 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.
    - 27% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Placental abruption with adverse outcomes (exclusion at admission)

Discussion (exclusion):

- RAC member shared that placental abruptions could be associated with secondary factors, such as a woman with a high Amniotic Fluid Index (AFI) due to fetus with an anomaly. During the next pregnancy, ultrasounds and tests are normal so the individual should no longer be at risk for placental abruption.

- RAC member indicated that an additional secondary factor could be domestic violence or other injury.
- RAC member indicated that placental abruption could be due to hypertension that occurred in first pregnancy but may not be exhibited in subsequent pregnancies.

Discussion (consultation):

- RAC member indicated that she consults on many things and adding additional factors will overwhelm her practice and hesitates to continue to add everything to consultation. Additionally, RAC member stated it's hard to consider when consultation has not been defined.
- RAC member suggested that this factor is not necessary since women who have had a placental abruption have likely received additional information at the time of the abruption from their provider about how likely this would occur again.

D. Selover suggested voting on the following:

- **Retain placental abruption with adverse outcomes on ANY table?**
  - 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.
  - 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.
  - 91% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Stillbirth or neonatal death (unexplained) or previous death related to intrapartum difficulty (exclusion at admission)

Discussion:

- D. Selover noted that the HERC has revised its guidance that is out for comment and which now specifies "Prior stillbirth/neonatal death."
- RAC member indicated that this factor should be removed completely as each pregnancy is different. The parents will know more about history and records can be obtained to identify what happened in previous delivery.
- RAC member concurred with previous statement as it can be related to so many different possibilities. RAC member indicated that several different studies look at recurrent rates of stillbirth. She further stated that while it is known there can be an increase in reoccurrence of stillbirth, it's not reoccurrence that is the issue, rather it's whether the birth site changes the rate of reoccurrence and what affect it has on actual outcomes. She further stated that evidence does not support that a change in birth site or treating these pregnancies as high risk will improve outcomes. There are two different studies that show there's little evidence that the approach prevents any stillbirth in the next pregnancy and still increases morbidity from unnecessary interventions. Including this risk factor will create additional issues by not allowing access to care for these families.

RAC member further noted that there is agreement among multiple bodies of study that hands on care with a provider who listens to needs, takes and spends time with individual in appointment and provides strong emotional support does help these families. This is a strong principle of the midwifery model of care. Having this factor as an exclusion will decrease safety options for families.

Source(s):
https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.14424%4010.1111/%28ISSN%291471-0528.JANUARY2016OBESITYANDWOMENSHEALTH

https://www.bmj.com/content/350/bmj.h3080.full.pdf+html

- RAC member indicated that this factor is appropriate for consultation as it's currently worded. If the text were to change to just "prior stillbirth/neonatal death," then it should be removed entirely.

D. Selover suggested voting on aligning with the revised HERC guidance as follows:

- **Amend text as "Prior stillbirth/neonatal death" and move risk factor to consultation.**
  - 27% - 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.
  - 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.
  - 45% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- **Removing "prior stillbirth/neonatal death" altogether.**
  - 55% - I can say an enthusiastic yes to the recommendation (or action).
  - 18% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
  - 18% - 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.
  - 9% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

CURRENT PREGNANCY COMPLICATIONS

Anemia – hemoglobin < 8.5 g/dL (exclusion at admission)

Discussion:

- RAC member asked at what point in pregnancy is this factor referring to. D. Selover responded at birth (admission for labor.)
- Vote - **Anemia – hemoglobin < 8.5 g/dL (at admission for labor)** [exclusion at admission – absolute risk factor]
    - 82% - I can say an enthusiastic yes to the recommendation (or action).
    - 18% - 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.

Bleeding Disorder – Thrombosis, thromboembolism, thrombocytopenia (platelets <100,000), other (exclusion at admission)

Discussion:

- Current rule specifies "Thrombosis, active/current" with no reference to platelet counts

- Proposed revised HERC guidance has revised and separated to specify the following:
    - Suspected or diagnosed thrombosis or thromboembolism and
    - Thrombocytopenia (platelets <100,000)

  D. Selover asked if these factors should be kept together as 'bleeding disorder' or separated?
- RAC member suggested removing the reference to platelets <100,000 stating that many women may have idiopathic thrombocytopenia that can safely be cared for out-of-hospital [<75,000 but not less than 50,000 may be better choice.] Other bleeding disorders should be considered under consultation as there is a very wide range of categories some of which can be dangerous or others that can be easily managed outside of the hospital setting.
- RAC member suggested removing platelet count altogether as is currently established in rule. Providers should know what a normal or abnormal platelet count is.
- RAC member suggested moving risk factor to consultation and in this case the consult should be with a hematologist.
- RAC member expressed concern about use of the term "stable" noting it is neither useful nor accurate as some stable conditions may be a problem.

D. Selover recommended voting as follows:

- **Suspected or diagnosed thrombosis and thromboembolism** (exclusion at admission)

- 45% - I can say an enthusiastic yes to the recommendation (or action).
- 27% - 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.
- 9% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- **Thrombocytopenia <100,000** (exclusion at admission)
    - 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.
    - 36% - 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.
    - 55% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- **Thrombocytopenia <75,000** (exclusion at admission)
    - 83% - I can say an enthusiastic yes to the recommendation (or action).
    - 8% - 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.
    - 8% - 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.

D. Selover recommended not including nor voting on "other bleeding disorder." RAC members concurred.

Diabetes (exclusion at admission)

Discussion:

- D. Selover noted that the risk factor on the proposed table reads as follows: Diabetes – Gestational – uncontrolled or controlled with medication; and then listed as a separate bullet - Type I or Type II.

- RAC member remarked that under current rules birthing centers can take care of persons with Type 2 diabetes if the person does not need medication to control it.
- RAC member suggested that someone who is taking metformin should be able to be taken care of out-of-hospital. It was suggested that the risk factor be edited to allow persons with Type 2 diabetes or gestational diabetes treated and controlled with oral medications could have an OOH birth.
  - It was noted by a RAC member that pursuant to the Board of Licensed Direct Entry Midwifery, Type 2 diabetes or gestational diabetes treated with insulin or oral medications is an indication for transfer.
  - RAC member commented that while a pregnant woman could proceed with normal fetus growth and extra assessments, such as ultrasounds, can ensure normal growth, it's the possible risk of hypoglycemia after birth that may be best monitored in a hospital setting.
  - RAC member suggested that absolute exclusion of care may not be appropriate as many women receive continued support, nutritional guidance, etc. from birthing centers; however, delivery at a hospital may be what a woman opts for given increased risk for hypoglycemia based on education and shared decision making.

D. Selover recommended voting as follows:

- **Retain as written – Diabetes * Gestational – uncontrolled or controlled with medication; * Type I or Type II** (exclusion at admission)
  - 18% - 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.
  - 18% - 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.
  - 36% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.
- **Amend – Diabetes * Gestational (uncontrolled or controlled with other than oral medication); * Type I; or * Type II (uncontrolled or controlled with other than oral medication) and move to consultation**
  - 64% - 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.
  - 18% - 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.
  - 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Drug or Alcohol Use with High Risk Factor for Adverse Effects to Fetal or Maternal Health (exclusion at admission)

Discussion:

- D. Selover noted that the initial revision proposed by HERC included a reference that persons receiving medication-assisted treatment for opioid use disorder would be a consultation requirement. This has been removed from the latest HERC proposal that is currently out for comment.
- RAC members had no further comment.
- Vote as written:
  - 73% - I can say an enthusiastic yes to the recommendation (or action).
  - 18% - 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.
  - 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Eclampsia or Pre-eclampsia (exclusion at admission)

Discussion:

- None
- Voting as written:
  - 100% - 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.
  - 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Fetal (risk factors) (exclusion at admission)

Discussion:

- D. Selover noted that there are several factors listed and asked if the risk factors should be discussed separately. RAC concurred.

Abnormal fetal heart rate, doppler, surveillance studies (exclusion at admission)

Discussion:

- D. Selover noted that the HERC proposed revision had initially included the following under 'fetal monitoring and movement' which would require transfer:
    - Abnormal fetal heart rate, Doppler, or surveillance studies
    - Repetitive or persistent abnormal fetal heart rate pattern during labor
    - Inability to adequately follow an intermittent auscultation protocol
- RAC member stated that it's important to consider pregnancy and labor separately. Additionally, it was stated that more specificity, or definitions are needed based on how it is currently written. A time frame, or reference to persistency is necessary as there are some disqualifiers that are very temporary and could be resolved without intervention.
- RAC member concurred adding more specificity about time frame.
- RAC member provided examples of fetal heart rate issues where intervention wouldn't have been necessary and suggested the risk factor be moved to consult. Other RAC members concurred with consult.
- RAC member commented that 'abnormal surveillance studies' should remain in the exclusion category.
- RAC member suggested having these factors be listed under consult. Other RAC members concurred.
- RAC member asked that it be clear that when a person with a risk factor requires transfer and the issue resolves, the person can come back for midwifery care.
- RAC members suggested adding the term 'unresolved' or 'not resolved at onset of labor.' Some RAC members disagreed with adding 'at onset of labor.'
- RAC member expressed concern that 'abnormal fetal surveillance' may be too broad and too restrictive especially when a consultation would be beneficial.
- Another RAC member responded that the term 'unresolved' is concerning. Birthing centers should not wait until something is resolved in certain cases before it's evaluated. Consider "persistence" for heart rate. Surveillance studies that are marginal should not be considered abnormal.
- RAC members discussed types of testing and how some may be interpreted. RAC member indicated that consultation would take care of many concerns discussed.

D. Selover asked that RAC members do the following:

1) Submit to M. Bernal possible language changes in this category for future voting including if moving to consultation what the language would look like;

2) Be prepared at next meeting with concrete language changes;

3) Submit information that would support changes to risk factors.

NEXT STEPS

RAC to submit possible changes and make recommendations for language on each item.

Next meeting is scheduled for April 17 at 9:00 a.m. RAC member requested that the meeting be changed because some birthing centers will not be available to attend. M. Bernal will submit new meeting poll.

Meeting adjourned at 12:00 p.m.

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement

Kate Brown, Governor

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Birthing Center RAC
August 3, 2020
9:00 a.m. (Go-To-Webinar)

RAC MEMBER ATTENDEES	
Alice Taylor	American Association of Birth Centers
Desire LeFave	Bella Vie Gentle Birth Center
Hermine Hayes-Klein	Oregon Association of Birth Centers
Jennifer Gallardo	Andaluz Waterbirth Center
Julia Bailey (for Silke Ackerson)	Oregon Midwifery Council
Karen DeWitt	Oregon Association of Naturopathic Physicians
Kaylyn Anderson	Consumer
Margy Porter	Bella Vie Gentle Birth Center
Meredith Mance	Aurora Birth Center
Michele Zimmerman-Pike	American College of Nurse Midwives
Samie Patnode	Board of Direct Entry Midwives
Susie Corcoran	Aurora Birth Center
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Sharron Fuchs	Public

OHA Staff	
Anna Davis	PHD, Health Facilities Licensing and Certification
Barbara Atkins	PHD, Facility Planning and Safety
Dana Selover	PHD, Health Care Regulation & Quality Improvement
Lacey Martinez	PHD, Health Facilities Licensing and Certification
Matt Gilman	PHD, Facility Planning and Safety
Mellony Bernal	PHD, Health Care Regulation & Quality Improvement
Rebecca Long	PHD, EMS and Trauma Systems

Welcome and Overview

Mellony Bernal opened the RAC meeting which, due to the current COVID pandemic, is being conducted remotely by Go-To-Webinar. All future meetings will be conducted remotely until such time as it is deemed safe to begin holding in-person meetings.

Instructions for remote participation were given.

Roll call of RAC members was initiated and RAC members introduced themselves.

Review of March 3rd Meeting Notes

M. Bernal asked RAC members whether anyone had any comments or proposed changes to the March meeting notes. RAC member requested that the RAC member organizations be updated to reflect 'birth center' not birthing center. RAC member, Michelle Zimmerman-Pike, noted that she did participate in the March meeting and should be reflected as a participant.

Action – Minutes will be revised to reflect the changes noted.

Agenda Review and Update

- D. Selover noted that in addition to continuing the risk factor discussion and polling, staff will begin to review work completed on action items from previous RAC meetings.
- RAC members were reminded about the options for the straw poll consensus for the risk factor discussion. A copy of the risk factor table and the elements to be discussed were shared on the webinar.
- The OHA will continue to work through tables as currently drafted and will consider, with the RAC's input, which format might be best for adoption in final rules.
- The Board of Direct Entry Midwifery currently has rules out for comment – deadline to comment is 08/28/2020 by 12:00 PM – see: https://www.oregon.gov/oha/PH/HLO/Pages/Board-Direct-Entry-Midwifery-Laws-Rules.aspx
- The Health Evidence Review Commission will be reviewing the draft Out-of-Hospital Birth Guidance at its 08/13/2020 meeting. Information about the meeting and material can be found at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Meetings-Public.aspx

Risk Factor Table I – Risk Factors for EXCLUSION AT ADMISSION Discussion and Polling

For purposes of polling relating to the risk factors, the three questions that will be considered are:

1) Should the risk factor remain as an exclusion?
2) Should the risk factor be moved to consultation?
3) Should the risk factor be removed altogether?

Current Pregnancy Complications

<u>Fetal: Blood group incompatibility with atypical antibodies, or Rh factor sensitization</u>

Discussion:

- RAC member recommended moving to consultation as there are antibodies that have no effect on pregnancy.
- RAC member concurred with recommendation. As written, it is too broad of a category to be an absolute risk factor.
- RAC member concurred with previous statements. Even if there are antibodies that could affect the pregnancy, they could be titering so low that it is inconsequential.
- RAC member concurred that the risk factor should be moved to consult.
- RAC member concurred that consultation is appropriate.

Poll Question: Move blood group incompatibility with atypical antibodies, or Rh factor sensitization to consultation?

- Results:
  - 75% - I can say an enthusiastic yes to the recommendation (or action).
  - 25% - 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.

Fetal: Gestational age – preterm (< 37 weeks + 0 days) or postdates (> 41 weeks + 6 days)

Discussion:

- RAC member asked whether this would allow a woman to be in labor at the birth center at 42 weeks. As written, staff indicated no. It was further noted that a woman who is in active labor prior to 42 weeks + 0 days could remain at the birth center if transfer is not safe or birth is imminent.
- RAC member indicated that the AABC rules allow a woman in labor to not 'risk out.'
- RAC member noted that the most recent HERC guidance clarifies that exclusion is ≥ 42 weeks 0 days unless the woman is already in active labor at 41 weeks 6 days. It was suggested that the risk factor be clarified further.
- RAC member agreed with clarification. It was further noted that clients may have normal fetal surveillance studies and may decline a transfer of care and questioned whether this would be considered abandonment of care. It was suggested to consider adding consultation in this scenario. Staff noted that birth centers have similar limitations now, and asked what makes this requirement different in terms of communicating than when other transfers also apply? RAC member indicated there is no evidence to support that there is an immediate risk to mom and baby that would require a transfer.
- Staff agreed that clarifying language for a woman in active labor prior to 42 weeks 0 days is appropriate.
- RAC member suggested referencing on-set of labor and indicated that CABC accredited birth centers have different rules. Women are being consistently monitored, have stress tests, etc. there isn't any additional risk by having them stay an extra day.
- RAC member inquired why there was a change from 36 weeks to 37 weeks? Staff noted change was based on alignment with the 2015 HERC guidance.
- RAC member indicated that it's important to remember that every provider has a more expanded scope than what may be allowed by HERC and limits the scope of providers who at a bare minimum can deliver between 36 weeks 0 days to 42 weeks 0 days. It is not in the best interest of clients to restrict providers further just because the birth may be happening in a birth center. It was further noted that there are times that a client may need to be transferred for a post-date induction and the hospital determines it is safe to delay for a few days. The birth center is then placed in a peculiar position if the client goes into labor prior to the scheduled induction date. As written, RAC member commented that the criteria do not serve safety and many factors are not being considered. It just changes the physical environment from a birth center to a client's home and does not serve the safety of the client.

- Staff noted that even though providers have different scopes, a birthing center setting is different than a hospital setting as the professional scope for an individual is different than a scope in a different type of setting. The Public Health Division is not limiting the scope of practitioners. It must apply the statutory requirement that a birthing center is primarily for low risk births.
- RAC member replied that a CPM is working in a low risk setting as well pursuant to statute. The discussion needs to include what the scope of practice is for each of the provider types and what is considered safe by community standards in out-of-hospital (OOH) births.
- RAC member concurred with comments of previous RAC member.
- RAC member concurred with previous two comments. It was noted that the HERC guidelines have restricted birth center scope where it has not restricted home birth scope. Birth center client scope of care should not continue to be restricted by taking away the additional weeks.
- Staff from the Health Licensing Office noted that during the public comment period for the DEM rules, there was a lot of discussion about the difference between 42 weeks and 43 weeks.
- RAC member stated that the HERC guidelines are not guidelines or regulations for scope of practice for any provider in any setting, rather are internal guidelines used by the Oregon Health Authority to determine Medicaid coverage for out-of-hospital births. Consideration needs to be given to the DEM regulations that are written specifically for childbirth in the OOH setting, based on evidence and in settings that are less equipped than a birth center to handle complexities. A client should be trusted to have a conversation with her provider and decide on setting.
- Staff responded that the state is not interfering with access to OOH birth but must follow the statutory provision of primarily low risk births in a birthing center and consider the safety of the client when amending and adopting rules.
- RAC member stated that baby outcomes from labors that begin naturally have different statistical outcomes at 36 weeks than inducing at 36 weeks.
- RAC member indicated that based on evidence reviewed for OOH births, taking into consideration regular fetal surveillance studies, spontaneous onset of labor between 36-37 weeks, and between 42-43 weeks does not show an increased risk. RAC member volunteered to pull together the evidence to share with the RAC.
- Staff noted that given the information shared and potential evidence for specific gestational ages, it was recommended that the polling for this risk factor be delayed.
- RAC member expressed appreciation for the comments made and supported recommendation to delay the poll for this risk factor. RAC member noted the AABC standard for gestational age is 36 weeks to 42 weeks.
- Staff from the Health Licensing Office offered to share literature that was presented to the Board of Direct Entry Midwifery for rulemaking in 2016 and 2019 and will forward to staff.

Poll Question: *Polling for this risk factor has been delayed in order to review literature described by RAC members.*

Fetal: Intrauterine growth restriction (fetal weight < 5th percentile using ethnically appropriate growth tables, or concerning reduced growth velocity on ultrasound)

Discussion:

- RAC member inquired what weight is being reflected with this risk factor. Another RAC member responded that the weight would depend on the actual gestational age so that is why an actual weight is not reflected.

- Concern was registered by RAC member that basing information only on an ultrasound does not take into consideration the person's ethnicity and as such the verbiage should reflect 'and' not 'or.'
- Staff noted that in administrative rule, "or", means the same thing as 'and/or.' Whereas when using the term 'and,' both conditions must be met. The agency is unable to use 'and/or' in rule.
- RAC member stated that the rules need to be understandable to practitioners and stating 'and/or' would be preferable. Staff responded that even if the term 'and/or' could be used, it is interpreted to mean that only one of the two qualifiers needs to be met. If both conditions need to be met, then the agency would use the term 'and.'
- RAC member concurred with changing the term to 'and.' It was noted that based on a person's ethnicity, some babies in a low percentile are normal and healthy. If the goal is to require both conditions, then and/or would not be appropriate based on how it would be interpreted.
- RAC member concurred that both conditions should be met, not just one or the other. Additionally, it was suggested that the risk factor be moved to consultation. There a lot of tiny families that have tiny babies that are completely healthy and to risk them out would affect access to care. It was suggested that ethnically appropriate growth tables do not adequately account for small stature families.
- RAC member concurred with suggestion that this risk factor be moved to consultation.

<u>Poll Question: Keep intrauterine growth restriction as an absolute risk factor with the requirement that both ethnically appropriate growth tables and velocity on ultrasound be considered?</u>

- 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.
  - 18% - 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.
  - 36% - 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.

<u>Poll Question: Move intrauterine growth restriction to consultation with the requirement that both ethnically appropriate growth tables and velocity on ultrasound be considered?</u>

- Results:
  - 100% - 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.
  - 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Fetal: Molar pregnancy

Discussion:

- RAC members did not have any comments.

Poll Question: Keep molar pregnancy as an absolute risk factor.

- Results:
  - 92% - I can say an enthusiastic yes to the recommendation (or action).
  - 8% - 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.

Fetal: Multiple gestation

Discussion:

- RAC member stated that her birth center can't perform multiple gestations because of the CABC requirement; however, other birth centers can and licensed midwives at home can. It was noted that allowing multiple gestations at a birth center may be a closer transport to a hospital then when a client is planning birth with multiples at home.
- RAC concurred with previous comment. Multiple gestation births are occurring all around by providers licensed to do so except at birth centers. The twin birth restriction does not make sense given the birth center is already set up and prepared to handle.
- RAC member suggested moving to a consultation since it is within the scope of practice of providers that work in a birth center. Clients' under a provider's care should be given the option of utilizing the entire scope of that provider's license. Birth centers are closer to hospitals and as such the client's safety would be enhanced for those clients that live further out.
- Staff from Health Licensing Office noted that multiple gestation was very controversial during the DEM rulemaking, and the types of twins were separated out as follows:
  - Required to transfer - monochorionic, monoamniotic twins.
  - Required for consultation – dichorionic, diamniotic twins; monochorionic, diamniotic twins.
- RAC member remarked that prior to the multiple birth restriction, there were no adverse outcomes in her birth center relating to twin births and concurred with moving to consultation;
- RAC member stated that AABC criteria includes singleton pregnancy and dicephalic presentation; however, the AABC does not support choice restrictions or restriction on informed decision making. Concurred with recommendation to move to consultation as there may be extenuating circumstances. Birth centers are generally much closer to hospitals and women will choose a home birth if they cannot birth at a birth center.
- RAC member remarked where is the line drawn or where is twin birth in the spectrum of risk? Compared to singleton births, twin births are at higher risk, but the question becomes how do you weigh the potentially slightly increased risk for having a twin birth in a birth center versus a woman's right to choose the circumstances of her birth.

- RAC member expressed concern with requiring a consult with a doctor that has no experience with birthing twins. It was recommended to separate out the types of twins, aligning with the DEM rules, and identifying what risk factors may apply to each of those. Staff responded that the idea is to consult with someone who has experience in delivering twins. It was noted that the expectation for consultation has been broadened and will be discussed during review of the action items.
- RAC member stated that it is important for a birth center to continue to provide prenatal care even if a hospital birth is planned due to multiples.

Poll Question: *Polling for this risk factor has been delayed in order to review literature and consider DEM rules described by RAC members.*

Fetal: Non-cephalic fetal presentation

Discussion:

- Staff remarked that more data and information may be needed to further discuss and suggested that RAC members share what data or other information is needed to discuss.
- RAC member suggested that the verbiage needs to be changed to indicate that a surprise breech where birth is imminent can be performed at a birth center. Staff noted that for any of the risk factors, if birth is imminent and risk for transferring is higher, then the birth center should follow-through with the birth.
- RAC member stated it would be helpful to have data relevant to the risk factors for both planned cesarean and physiological birth for women with risk factors. It would be helpful to have data on the number of Oregon hospitals that offer physiological birth for both breech and twins, and the provider types that maintain the skills to safely deliver twins and breech babies vaginally. The Oregon Association of Birth Centers could gather some of this data.
- RAC member indicated that she will send an article to M. Bernal on the risks, values and decision making surrounding pregnancy, published in the OB/GYN Journal, that provides good support for the point that it's not the providers' obligation to eliminate risk but to help patients weigh risks, benefits and potential harm informed by scientific evidence and guided by patient-centered ethics.

Poll Question: *Polling for this risk factor has been delayed in order to review literature and consider DEM rules described by RAC members.*

Risk factor discussion concluded.

Action Items from Previous RAC Meetings

A table was shared summarizing the action item requests from previous meetings and the Authority's responses to those actions and proposed rule edits. RAC members were asked to consider the change and provide only new comments or new information.

M. Bernal reviewed the following actions:

OAR 333-077-0010 – Definitions

Certified Nurse Midwife definition was not changed as requested given discussion with Oregon State Board of Nursing and legislation that passed in 2019. The definition was changed to reflect the following:

- *Certified nurse midwife means a registered nurse who is licensed under ORS chapter 678 as a nurse practitioner specializing in nurse midwifery.*

Direct Entry Midwife was amended as requested at the May 2019 meeting:

- *Licensed direct entry midwife means a person licensed under ORS 687.405 to 687.495.*

Physician was amended as requested at the May 2019 meeting. In addition, since chiropractic physicians are included as a provider type on the Oregon Health Plan, Out-of-Hospital Birth Guide, chiropractic physician was included in the definition.

- *Physician means:*
  A person licensed as a doctor of medicine or osteopathy under ORS chapter 677;
  A person licensed as a naturopathic physician under OARS chapter 685, and who has obtained a certificate of special competency in natural childbirth in accordance with OAR 850-035-0230; and
  A person licensed as a chiropractic physician under ORS chapter 684 and who has obtained a certificate of special competency in natural childbirth in accordance with ORA 811-015-0030.

RAC member suggested that the definition of DEM be amended to reference a certified professional midwife (CPM) instead of 'person.' It was noted that not all CPMs are licensed DEMs. Definitions align with statutory language.

Discharge was amended for clarity as requested at the May 2019 meeting.

- *Discharge means:*
  The release or transfer of a client or newborn who was a client of a birthing center to home;
  The transfer of a client or newborn to another health care facility; or
  A client or newborn who has died.

Freestanding Birthing Center was not changed as requested. The definition will continue to align with statute that specifies that a birthing center is licensed for the primary purpose of performing low risk deliveries.

OAR 333-077-0050 – Complaints
OAR 333-077-0055 – Investigations

RAC members had requested in May and July 2019 to add additional clarification in the complaint and investigation rule to identify the complaint triage process. The Authority will not make any changes to these rules. Complaint reviews and investigations are a matter of standard operating procedures for specific allegations of non-compliance. The Authority has jurisdiction to investigate matters relating to non-compliance with the birthing center administrative rules and relevant statutes. Sharing information pertaining to complaints and investigations is better suited in FAQs that can be obtained from the website or in conversations with staff versus formal language in rule. All matters relating to complaints against specific provider types are referred to the appropriate health professional licensing board.

It was further noted that these rules align with other facility types.

OAR 333-077-0070 – Governing Body Responsibility

Section (2) of this rule was revised as requested at the May 2019 meeting. While the original language was based on requirements in statute for all health care facilities, it is understood that physicians are not common providers in birthing centers and as such corrections are necessary. Practitioner terms were updated to align with the Commission for the Accreditation of Birth Centers (CABC) and include 'clinical provider' and 'clinical staff.' CABC definitions for these terms were provided for reference and staff asked RAC members to consider whether the definitions are appropriate in order to add to the definitions section (OAR 333-077-0010).

- *(2) The governing body shall:*
  (a) Establish in writing: …
  (D) Required training for all employees and clinical providers with privileges that includes, but is not limited to…
  (c) Ensure that all clinical staff for whom state licenses are required are currently licensed, certified or registered;
  (d) Ensure that all clinical providers health care personnel admitted to practice in the facility are granted privileges consistent with their individual training, experience and other qualifications;
  (e) Ensure that procedures for granting, restricting and terminating privileges of all clinical providers exist, and that such procedures are reviewed on a regular basis; …
- *(3) All clinical providers admitted to practice in the birthing center shall effectively review the professional practices of the birthing center for purposes of reducing morbidity and mortality and for improving client care.*

RAC member inquired what the process would look like if a birth center was full but had additional midwives available to assist but at a neighboring birth center. Staff noted that birth centers should have written agreements in place in this scenario and that the midwife would have to be credentialed at the birth center where birth would take place. RAC member suggested that this rarely occurs, and it would not be feasible to have all midwives credentialed at all possible birth centers. Staff noted that the requirement is in statute and thus must be adhered to. It was further noted that a midwife would be operating under the license of the other birth center and must follow the policies and procedures of that birth center, not the policies and procedures of the center where the midwife is primarily located.

RAC member further inquired about other staffing scenarios. Staff indicated that discussions about specific scenarios should be discussed outside of the RAC meeting and could be included in an FAQ document.

OAR 333-077-0080 – Personnel

The Authority was asked at the May and July 2019 to reconsider staffing requirements and ensure that language does not conflict with the nurse practices act. Section (1) of the rule was changed to:

- *A birthing center shall, at a minimum:*
  (a) Maintain a sufficient number of clinical staff on duty and on call to provide effective client care and all other related services, and to ensure that no client in active labor shall remain unattended;
  (b) Have one clinical staff person trained in the use of emergency equipment and certified in neonatal resuscitation endorsed by the American Academy of Pediatrics, on duty at all times a client is present;
  (c) Have one clinical provider present at each birth. A second clinical staff person trained in the use of emergency equipment and certified in neonatal resuscitation, endorsed by the American Academy of Pediatrics skills shall be present during each birth;

(d) Ensure all clinical staff providing direct client care hold a current American Heart Association Basic Life Support (BLS) Provider or equivalent CPR course completion document (the course must include a practical skills evaluation);
(e) Ensure that employees, contractors and volunteers receive appropriate orientation including orientation to written policies and procedures;
(f) Have a job description for each position that delineates the qualifications, duties, authority and responsibilities inherent in each position;
(g) Conduct an annual work performance evaluation for each employee; and
(h) Create an annual continuing education plan for its employees.

OAR 333-077-0090 – Policies and Procedures

At the July 2019 meeting, it was requested that the term 'Certified Nurse Midwife' be changed throughout the rule to 'licensed nurse midwife.' As discussed above under 0010 – Definitions, the term will remain the same.

Section (2) was revised as suggested at the July 2019 meeting by removing the reference to nurse practitioner and certified professional midwife. Section (2) of the rule was changed to:

> *(2) The client care and services of each birthing center shall be under the supervision of a manager who shall be a licensed direct entry midwife, certified nurse midwife, or physician.*

RAC member suggested that a Certified Professional Midwife be added back. While they may no longer be a licensed DEM and attending births, they would still have the experience necessary to oversee and run a birthing center.

Staff from Board of DEM noted that for purposes of this rule, the issue is around supervising client care and client services not the operation of the center. It was questioned whether an unlicensed provider can supervise client care or services in a birth center.

RAC member suggested that a traditional midwife who is not a licensed midwife cannot attend a birth in an Oregon birthing center.

> **ACTION – Based on feedback provided, staff will look further at statutes and existing rule and report back.**

Under section (3), staff noted that an additional amendment was made based on requirements in ORS 433.017 that require physicians, naturopaths and nurse practitioners that attend a pregnant woman to take or cause to be taken a sample of blood for tests related to infectious conditions.

- *(3) A birthing center shall develop and implement written policies and procedures that include, but are not limited to, the following…*
  (n) Performance of appropriate laboratory services including tests required pursuant to ORS 433.107 and the rules adopted thereunder.

Relating to blood draws, RAC member inquired whether the language clarifies that a "CPM" can draw blood. Additionally, it was questioned whether this would require a COVID test and whether a woman could decline a COVID test.

Staff from Board of DEM noted that nothing in the language would appear to preclude a licensed DEM from drawing blood. PHD staff noted that OAR 333-019-0036 specifies that routine tests shall include syphilis, hepatitis B and HIV and does not specify COVID. PHD staff will inquire with Acute and

Communicable Disease program to determine whether future changes to include COVID are being considered.

The action items to consider language that clarifies that a birth center may provide prenatal care regardless of whether the client is eligible to deliver at a birthing center and to consider making consultation more flexible so that a birthing center can consult with other clinicals specialists will be discussed under new rule OAR 333-077-0125 - 'Assessment of Risk Status and Consultation Requirements.'

> **ACTION – Staff will seek input from legal counsel regarding the statutory provisions relating to provider types and blood draws. Staff will also inquire with the Acute and Communicable Disease Program whether they are considering adding COVID testing to OAR 333-019-0036.**

OAR 333-077-0100 – Client Care Services

Section (2) was revised as suggested at the July 2019 meeting. Section (2) of this rule was changed to:

- *(2) Each client shall sign, and receive a copy of, a client disclosure form which includes, but is not limited to, the following information:*
  (a) Services provided to client and newborn;
  (b) Risks, benefits and eligibility requirements;
  (c) Responsibilities of the client and family members or legal representatives;
  (d) Fees for services including financial arrangements;
  (e) Malpractice coverage or professional liability coverage;
  (f) Risk assessment, consultation and transfer requirements;
  (g) Emergency care and transport plan in the event of complications to the client or newborn; and
  (h) Identity and qualifications of clinical staff.

Subsection (3)(b) was revised as suggested at the July 2019 meeting. Section (3) of this rule was changed to:

- *(3) The statement of client rights shall include, but is not limited to, the following:*
  (b) Clients shall be offered services without discrimination as to race, ethnicity, color, religion, gender identification, sexual orientation, national origin or source of payment;

Subsection (4)(b) and (c) were revised to reference new rule OAR 333-077-0125 as follows:

- *(4) A birthing center shall: ...*
  (b) Assess the client's risk status throughout pregnancy, labor and delivery in accordance with OAR 333-077-0125 to determine if out-of-hospital birth is appropriate.
  (c) Consult with a provider of maternity care who is credentialed to admit and manage responsibilities in a hospital, or other specialty provider, in accordance with OAR 333-077-0125…

RAC member inquired whether the committee will be able to see a full version of the rules in a tracked changes format. Staff responded yes.

Section (5) was revised as suggested at the July 2019 meeting by removing references to specific tests. Section (5) has been amended as follows:

- *(5) A birthing center that provides* ***prenatal care*** *shall perform regular, periodic prenatal exams and assessments of client and fetus risk status. A prenatal exam shall include at a minimum:*
  (a) Physical exam;
  (b) Urinalysis and other laboratory screenings as determined necessary by the clinical provider;
  (c) Discussions about the client's health and newborn's health including good nutrition and how to reduce pregnancy complications and newborn's risk for complications;
  (d) Fetal health assessment; and
  (e) In third trimester, discussions about preparing for childbirth and classes available;

RAC member inquired whether the reference to "physical exam" might conflict with telehealth services that are currently being performed due to COVID-19. Staff noted that the program is currently reviewing all facility types and where accommodations can be made in terms of regulatory expectations.

ACTION – Staff will consider further whether additional language is needed to allow for telehealth options given the current pandemic.

Section (6) was revised based on comments emailed by a RAC member after the July 2019 meeting. Section (6) is amended as follows:

- *(6)* ***Intrapartum care*** *provided by a birthing center shall include, but is not limited to:*
  (a) Periodic assessment of the client's physical health and emotional and psychological needs including but not limited to:
  (A) Monitoring of vital signs;
  (B) Urinalysis if indicated;
  (C) Pain assessment; and
  (D) Frequency of contractions.
  (b) Periodic assessment of the fetus's health including but not limited to:
  (A) Monitoring fetal heart rate and fetal movement; and
  (B) Abdomen palpation to determine fetal lie and presentation;
  (c) Comfort measures including but not limited to:
  (A) Physical assistance;
  (B) Emotional support; and
  (C) Pain relief methods; and
  (d) Companionship during labor and childbirth with a client's companion of choice.

Section (7) was revised as suggested at the July 2019 meeting. Section (7) is amended as follows as follows:

- *(7)* ***Postpartum care*** *shall consist of periodic assessment of the client's health and newborn's health.*
  (a) The client health assessment includes but is not limited to:
  (A) Physical exam;
  (B) Laboratory screening tests, if applicable;
  (C) Education in child care including breastfeeding, immunization, and referral to sources of pediatric care;
  (D) Provision of or referral to family planning services; and
  (E) Referral to newborn screenings as required in OAR 333-077-0170 if screenings are not provided by the birthing center.

(b) The newborn health assessment includes but is not limited to:
(A) Physical exam;
(B) Laboratory screening tests, if applicable; and
(C) Screenings for newborns in accordance with OAR 333-077-0170.

NEXT STEPS
M. Bernal asked RAC members to watch for e-mail with meeting poll request. For the immediate future, all meetings will be conducted remotely only.

PUBLIC HEALTH DIVISION
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Birthing Center Rule Advisory Committee
July 21, 2021
9:00 a.m. via Zoom

RAC MEMBER ATTENDEES	
Colleen Forbes	Former chair, Board of Direct Entry Midwifery
Danielle Meyer	Oregon Association of Hospitals and Health Systems
Desiree LeFave	Bella Vie Gentle Birth
Hermine Hayes-Klein	Oregon Association of Birth Centers
Jennifer Gallardo	Andaluz Waterbirth Center
Karen DeWitt	Oregon Association of Naturopathic Physicians
Kaylyn Anderson	Consumer
Kelsey Fischer (for Silke Ackerson)	Oregon Midwifery Council
Laura Erickson	Alma Midwifery Services
Lynette Pettibone	American Association of Birth Centers
Margy Porter	Bella Vie Gentle Birth Center
Michelle Zimmerman-Pike	American College of Nurse Midwives
Ruby Jason	Oregon State Board of Nursing
Stefanie Rogers	Providence Health Systems
Willa Woodard	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Kori Pienovi	Women's Healthcare Associates' Midwifery Birth Center
Sharron Fuchs	Public Citizen

OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Dana Selover	PHD-Health Care Regulation & Quality Improvement
Lacey Martinez	PHD-Health Facility Licensing & Certification
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Samie Patnode	PHD-Health Licensing Office

Welcome and Overview

Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and reviewed housekeeping items. RAC members, OHA staff and members of the public introduced themselves.

Dana Selover thanked RAC members for their patience as OHA staff continue to respond to the COVID-19 pandemic, wildfires, and the 2021 legislative session. A quick refresher on what the RAC has done was shared:

- The core rule text was reviewed. Staff tracked action items and have developed responses which the RAC began to review at the August 3, 2020. After the risk factor tables are completed, staff will bring back to complete the review.
- The RAC has been reviewing absolute risk factors in Table I. It was noted that the proposed Tables I through III were developed based on the Health Evidence Review Commission's (HERC) Planned Out-of-Hospital Birth Coverage Guidance, dated 11/12/2015. It was further noted that the Board of Direct Entry Midwifery (DEM) and the HERC have since updated rules and guidance. Staff are conducting polls on whether the risk factor should remain as an exclusion or move to a consultation requirement. D. Selover noted that there are some risk factors that will need to be further discussed and which will occur late.
- The RAC reviewed the physical environment rule which was initially based on the Facility Guidelines Institute standards for freestanding birthing centers. Based on comments received from the RAC, the rule was amended and redistributed to RAC members for consideration. Additional follow-up on the proposed changes will occur later.

It was noted that to make it through all the tables, D. Selover suggested meeting more frequently but for shorter periods of time. The goal is to have final rules in place by end of June 2022.

Review of August 3, 2020 Meeting Notes

The August 3, 2020 notes were shared. D. Selover noted that half the meeting was devoted to working through the initial responses to action items and the other half to discussing risk factors and conducting straw poll. Depending on how quickly meetings get scheduled in the future, meeting minutes may be delayed. It was noted that state offices are opening in September but it not clear when in-person meetings will occur. RAC members located further away will likely want to continue to participate remotely and staff need to consider how a hybrid meeting model will work.

Risk Factor Table I – Risk Factors for EXCLUSION AT ADMISSION

CURRENT PREGNANCY COMPLICATIONS

<u>Oligohydramnios/Polyhydramnios</u>

Dana asked RAC members for feedback. Discussion:

- RAC member suggested that each of the factors be discussed separately and not grouped together as they are very different. D. Selover asked RAC members whether they had comments on whether to keep as an exclusion. RAC member stated she would defer to others but noted that she has seen many neonates born after concerns of oligohydramnios or polyhydramnios that are normal. She suggested it be listed under consultation requirement. It was further noted that there are different degrees of these conditions that may be a clear indication for a hospital delivery.
- RAC member agreed with separating the conditions for discussion. RAC member further stated that if the water breaks prior to a biophysical profile it could be low even if there were no previous concerns.
- Discussion ensued amongst RAC members about whether additional text is necessary to clarify that it does not apply if someone's water breaks and therefore fluid is low, and onset of labor could occur just after that.

- D. Selover remarked that it is assumed that water measurement occurs before water breaks. RAC member responded 'in theory' but some pregnant persons do not have a biophysical profile (BPP) until 41 weeks, water breaks, and then BPP would show as low.
- RAC member stated that a potential issue is it may discourage providers from conducting a BPP after membrane was ruptured. Additional clarity is needed as someone may have borderline 'oligo' due to dehydration which may resolve within 24-48 hours. Moving the risk factor to consultation is an option, but more definition is needed.
- RAC member agreed with separating the conditions and agreed that normal births may occur based on degrees. Also agreed that 'oligo' exclude rupture of membranes and move to consult.
- HLO staff via the chat noted that 'poly' is under antepartum consult.
- RAC member stated via chat to define levels for 'oligo' and 'poly.' D. Selover noted that the downside of putting more definitions around clinical terms in rule, means that it is more difficult to make changes if clinicians or science suggest something different, and especially if it is something that will be moved to consultation. Two RAC members remarked via chat concurring that no numbers should be specified.
- RAC member stated via chat that both 'poly' and 'oligo' are requirements for consult on current LDM rules.
- RAC member stated via chat that the state of Washington requires consult.
- RAC member noted via chat that HERC has the conditions listed as a transfer.
- Several RAC members stated via chat that the conditions do not need to be separated if moving to consultation.
  - Two other RAC members agreed via chat but with the clarification that it excludes rupture of membranes.
  - Another RAC member stated via chat that rupture of membranes does not need to be stated since this would be taken into consideration during the consult.
  - D. Selover asked whether rupture of membranes isn't already considered under the clinical definition in 'olio?' The consult takes everything into consideration.
  - RAC member remarked that rupture of membrane can occur on the same day that someone has a BPP and as such would have 'oligo.' This should not require a consult because 'oligo' was due to the rupture and the pregnancy person would likely go into labor same day. Requiring a consult in this scenario would be inappropriate. D. Selover questioned again whether this isn't already common practice and taken into consideration where a provider is more concerned about 'oligo' in last trimester versus around time of birth.
  - RAC member stated that additional clarification is needed to protect the provider due to increased scrutiny.
  - RAC member suggested via chat that they would agree with consult if language is updated to consult for 'oligo' except in cases with documented rupture of membrane.

<u>POLL: Retain Oligohydramnios/Polyhydramnios (excluding rupture of membrane) as an absolute risk factor? Results:</u>

- 8% - 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.
- 31% - 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.
- 62% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Move Oligohydramnios/Polyhydramnios (excluding rupture of membrane) to consultation requirement? Results:

- 54% - I can say an enthusiastic yes to the recommendation (or action).
- 38% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 8% - 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.

RAC member asked before proceeding with additional polling to discuss how consultation is being defined in the draft rules which may affect the vote of birthing center members. It was suggested that historically the rules defined consultation in a way that ultimately leaves the decision making with informed consent to the providers and their clients. It was asked whether the rules specify that the consult must be with a provider with hospital privileges and are the birthing centers obliged to follow the in-hospital providers recommendation?

Staff displayed the following draft language both on screen and in the chat, which was developed in response to comments provided by RAC members in previous meetings:

333-077-0125

Risk Status Assessment and Consultation Requirements

(1) A birthing center shall assess a client's risk status throughout pregnancy, labor and delivery to determine if an out-of-hospital birth is appropriate based on the risk factor criteria specified in Tables I and II, or any consultation conducted based on the criteria specified in Table III.

(2) A risk assessment shall be performed within 14 calendar days of the initial prenatal care visit and updated throughout the pregnancy, labor, and delivery.

(3) Appropriate referral or transfer to a higher level of care shall occur if the client, fetus, or newborn meet any of the risk factor criteria identified in Tables I or II.

(4) A birthing center shall consult with a provider of maternity care who is credentialed to admit and manage responsibilities in a hospital, or other specialty provider, if a client or fetus meet any of the consultation criteria specified in Table III.

(a) A birthing center shall include the client during the consultation, if possible. If the client is unable to participate during the consultation, the birthing center shall notify the client about all recommendations made by the consultant.

(b) The birthing center shall document the consultation, recommendations made, and discussions with the client.

(c) If a consultation determines that an out-of-hospital birth is no longer acceptable due to the client meeting risk factor criteria specified in Tables I or II, the birthing center shall refer or transfer the client to an appropriate health care provider or facility.

(5) Notwithstanding sections (3) and (4) of this rule, if a risk assessment or consultation determines that an out-of-hospital birth is no longer acceptable, a birthing center may continue to provide prenatal care to a client, if the birthing center obtains the client's informed consent including at a minimum:

(a) The client is informed of all potential risks and provides consent to continue to receive prenatal care;

(b) The client acknowledges that birth will be planned at a hospital;

(c) Documentation of subsections (5)(a) and (b) of this rule is noted in the client's medical record.

Staff also displayed and posted in the chat the Board of DEM's current OAR language relating to consultation:

OAR 332-025-0021

(14) "Indication for Consult" means a condition or clinical situation that places a birthing person or newborn at increased obstetric or neonatal risk but does not automatically exclude a birthing person or newborn from a community birth or midwifery care.

(15) When a birthing person or newborn present with one (1) or more indications for consult the LDM must:

(a) Arrange for transfer of care; or

(b) Comply with all the following:

(A) Consult with an Oregon licensed health care provider, as defined in OAR 332-025-0021(20) and (21) of this rule, who is experienced and knowledgeable about the indication for consult unless a different Oregon licensed health care provider is otherwise stated specifically within this rule;

(B) Communicate to the birthing person the recommendations given by the consulting Oregon licensed health care provider if the birthing person was not present at the consultation;

(C) Obtain informed consent in accordance with OAR 332-025-0120;

(D) Make a plan with the birthing person about the indication; and

(E) Document the recommendations, consultation, discussion, informed consent, and plan.

…

(21) For the purpose of this rule "consultation" means a dialogue for the purpose of obtaining information or advice, with an Oregon licensed health care provider who has direct experience handling complications of the risk(s) present, as well as the ability to confirm the indication for consult, which may include, but is not limited to confirmation of a diagnosis and recommendation(s) regarding management of medical, obstetric, or fetal problems or conditions. Consultation may be by phone, in person, or in writing.

(22) For the purpose of this rule “Oregon licensed health care provider” means a physician or physician assistant licensed under ORS 677, a nurse practitioner who is licensed as a nurse midwife under ORS 678 or nurse practitioner licensed under ORS 678, a naturopath licensed under ORS 685, or a licensed direct entry midwife licensed under ORS 687.

Discussion:

- D. Selover noted that moving the discussion from risk factor polling to defining consultation is going to slow down process, and while staff are happy to consider additional input, staff will not be able to finalize language on the spot.
- Based on language displayed, RAC member asked what if the client and provider do not agree with the consultant's recommendation because of bias. It was further questioned whether insurance would cover.
- RAC member stated that section (4) is a problem because it requires consultation with a provider of maternity care who is credentialed to admit and manage responsibilities in a hospital and hospital based providers have little knowledge or experience with out-of-hospital or birthing center births and the things necessary to make it safe. It was also stated that some of the risk factors that would require consultation would be best done with a hospital based provider because of the nature of the risk factor but for some other risk factors it is more sensible for a birthing center or out-of-hospital provider to consult with another out-of-hospital provider that has experience with that risk factor. Turning to a hospital-based provider with no relevant knowledge or experience is not a useful exercise. Staff responded that there is additional language that would allow other specialty providers for purposes of consultation not just providers with hospital privileges. RAC member stated it would be helpful to further define who other specialty providers would include.
- RAC member stated that the language in subsection (4)(c) is vague and the passive voice should be removed. How and who is making determination needs to be clarified. If the ultimate determination is made by the out-of-hospital provider in collaboration with the client, and the client's right of informed consent, then the Oregon Association of Birth Centers (OABC) would accept that. Any language that could be interpreted that the hospital-based provider makes the decision would not be acceptable.
- RAC member had further concerns with section (5) where based on informed consent a birthing center can provide prenatal care, the OABC position would be that ultimately as long as the client remains within scope for the birthing centers, the client can make an informed choice on how they want to proceed. It was asked that that the language be amended to remove reference to "prenatal" and specify provide care to the client.
- RAC members via chat expressed concern about continuing to vote on risk factors when it is not clear what consultation is or disagree with current draft language.
- RAC members via chat stated that the Board of DEM consultation language is defined well, and most birthing centers agree with the DEM language.
- RAC member stated via chat that it is necessary to document the consultation, the recommendations and not following the recommendations to document why the recommendations are not being considered/followed.
- D. Selover noted that out-of-hospital providers are still subject to their licensing board rules and must follow such rules regardless if practicing in a birthing center or in a client's home.
- HLO staff shared that if a consult is necessary, the midwife must consult with a defined provider (physician or physician assistant licensed under ORS 677, a nurse practitioner who

is licensed as a nurse midwife under ORS 678 or nurse practitioner licensed under ORS 678, a naturopath licensed under ORS 685, or a licensed direct entry midwife licensed under ORS 687), obtain a recommendation which is communicated to the birthing person if not present for the consultation. The midwife can move forward with the plan with informed consent from the client.

- D. Selover asked RAC members to vote via chat how many would like to not move forward with the risk factor discussion and discuss consultation instead. Majority of RAC members via chat chose consultation for further discussion.
- D. Selover recessed the meeting until 10:30 a.m. to allow staff time to consider consultation language.

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

The meeting was reconvened at 10:35 a.m.

Staff re-displayed the proposed rule on risk assessment and consultation (OAR 333-077-0125) and in the chat posted the Board of DEM OAR definition for 'consultation' and 'Oregon licensed health care provider.'

OAR 332-025-0021
(21) For the purpose of this rule “consultation” means a dialogue for the purpose of obtaining information or advice, with an Oregon licensed health care provider who has direct experience handling complications of the risk(s) present, as well as the ability to confirm the indication for consult, which may include, but is not limited to confirmation of a diagnosis and recommendation(s) regarding management of medical, obstetric, or fetal problems or conditions. Consultation may be by phone, in person, or in writing.
(22) For the purpose of this rule “Oregon licensed health care provider” means a physician or physician assistant licensed under ORS 677, a nurse practitioner who is licensed as a nurse midwife under ORS 678 or nurse practitioner licensed under ORS 678, a naturopath licensed under ORS 685, or a licensed direct entry midwife licensed under ORS 687.

333-077-0125
Risk Status Assessment and Consultation Requirements
(1) A birthing center shall assess a client's risk status throughout pregnancy, labor and delivery to determine if an out-of-hospital birth is appropriate based on the risk factor criteria specified in Tables I and II, or any consultation conducted based on the criteria specified in Table III.
(2) A risk assessment shall be performed within 14 calendar days of the initial prenatal care visit and updated throughout the pregnancy, labor, and delivery.
(3) Appropriate referral or transfer to a higher level of care shall occur if the client, fetus, or newborn meet any of the risk factor criteria identified in Tables I or II.
(4) A birthing center shall consult with a provider of maternity care who is credentialed to admit and manage responsibilities in a hospital, or other specialty provider, if a client or fetus meet any of the consultation criteria specified in Table III.
(a) A birthing center shall include the client during the consultation, if possible. If the client is unable to participate during the consultation, the birthing center shall notify the client about all recommendations made by the consultant.
(b) The birthing center shall document the consultation, recommendations made, and discussions with the client.
(c) If a consultation determines that an out-of-hospital birth is no longer acceptable due to the client meeting risk factor criteria specified in Tables I or II, the birthing center shall refer or transfer the client to an appropriate health care provider or facility.
(5) Notwithstanding sections (3) and (4) of this rule, if a risk assessment or consultation determines that an out-of-hospital birth is no longer acceptable, a birthing center may continue to provide prenatal care to a client, if the birthing center obtains the client's informed consent including at a minimum:
(a) The client is informed of all potential risks and provides consent to continue to receive prenatal care;

(b) The client acknowledges that birth will be planned at a hospital;
(c) Documentation of subsections (5)(a) and (b) of this rule is noted in the client's medical record.

D. Selover noted that the issues before the RAC are to discuss the following:
1) Who can provide consultation;
2) Who and how is ultimate determination made based on consultation.

Discussion:

- RAC member commented that if the birthing center rules align with the definitions of the Board of DEM for consultation as displayed in the chat, birthing centers would be supportive. D. Selover noted that for current discussion purposes only, staff will consider approving the definition of Oregon licensed health care provider adopted by the Board of DEM for purposes of who can provide consultation for purposes of exclusion. The consulting provider may not be associated with the birthing center seeking the consult. In terms of the definition of consultation, the program needs additional time to consider the language and the potential consequences of adopting. For example, an LDM may not be able to confirm a medical diagnosis like other providers depending on the risk factors.
- D. Selover asked neonatologist for feedback on the proposal. RAC member supported the proposed provider definition with the caveat that it cannot be someone from within the birthing center due to potential bias. It was noted that all providers need to continue to work on patient centered relationships and work towards how to best serve the patient and meeting the patients needs regardless of the setting.
- RAC member via chat asked whether the external requirement would include MDs and CNMs who are affiliated with the birthing center? D. Selover indicated that the program will need to consider this.
- RAC member stated there are two primary concerns with the proposed draft language: 1) only consulting with providers who have hospital privileges (which would be addressed by using the DEM provider definition); and 2) the outcome of the consultation (which should be resolved before moving forward.) It was stated that if the decision is that the birthing center must follow the consulting provider's recommendation, then the birthing centers would not support. D. Selover reiterated that that the program has an obligation in statute to adopt rules for birthing centers for clients with low risk birth and as such, the program needs additional time to consider how to address circumstances where there is a difference of opinion on whether the birth is still considered low risk based on the consultation. RAC member responded that the issue is when does a client come out of the low risk box. The absolute risk factors specified in the tables are those factors that would require a client be transferred; however, the consultation table is for clients that don't meet the absolute criteria but have clinical issues that need to be considered further. RAC member further stated that the regulations should be written so that an out-of-hospital provider's 'opinion' does not supersede the birthing center provider's experience and give power to the consulting provider to decide low risk which gives the consulting provider the power to contradict the rules and make a determination of who gets to access out-of-hospital birth with a competitor. Clarifying consultation is therefore necessary for continuing risk factor discussions. D. Selover noted that while there may be a differing opinion it does not mean that a consulting provider does not understand risk and birth regardless of the setting.

- RAC member stated that there are very few providers in rural Oregon that can perform consultations and all of which are entirely biased. Many hospital-based rural providers do not believe any out-of-hospital birth is safe. RAC member urged program to carefully consider unintended consequence of allowing a biased provider to make the final decision.
- RAC member echoed thoughts of previous RAC members that it would be inappropriate for the consultant to be the deciding factor on whether an out-of-hospital birth is appropriate. RAC member further stated that while a consultant may be an expert on a specific condition or risk factor, they are not an expert on out-of-hospital birth and not an expert on midwife scope of practice and the tools and equipment a midwife has access to. She further stated that the midwife is the out-of-hospital birth expert. Example provided of a consultant who recommended in hospital birth even though no specific risks or consequence were given that might impact the baby that couldn't have been managed by the midwife. The consultant stated that she recommended all births, even low risk, to be done in a hospital in case something happens. The autonomy of the providers is taken away as well as that of the client. RAC member further stated that subsection (5)(a) should be edited as there is no possible way to list every possible risk. Consider replacing with the client is reasonably informed of likely severe or common risks.
- RAC member stated via chat that some birthing centers in Oregon are near very biased hospital providers and who have acted very unprofessional.
- RAC member stated via chat that the comment that “high risk” birth only happens in hospitals implies that only hospital providers would know how to assess that risk and misses the point. A uterine scar is a risk that both in-hospital and out-of-hospital providers understand and manage under Oregon law. Some providers would consider the existence of a uterine scar “high risk,” others would not. What is important to OABC is ensuring that the hospital providers are not given the power to define who is “high risk” in a way that contradicts scope of practice for OOH midwives and birth centers.
- RAC member stated that she wanted to make sure that the language would exclude the use of hospital-based certified nurse midwives or physicians that their birthing center consults with (e.g. obstetricians, fetal maternal medicine doctors) across the Portland metro area. Provider types each have their own professional scope of practice and rules. D. Selover remarked that the exclusion language may need to be considered further.
- RAC member suggested in section (5)(a) to use the term 'material risks' as noted in ORS 677.097.
- RAC member stated via chat that sometimes midwives call to consult with hospital providers who feel a level of confidence with a risk factor that is not appropriate for out-of-hospital birth. Midwives have to be able to be trusted to determine what is appropriate.
- RAC member stated via chat that a consult is for more information, but the patient and midwife as long as practicing within their scope should make the final decision.

D. Selover asked the RAC based on the discussion so far whether the RAC wants to continue with risk factor tables or continue with consultation discussion. A majority of the RAC members voted to continue with the consultation discussion.

The following comments on the proposed rule were discussed:

- Section (1) – A birthing center shall assess a client's risk status throughout pregnancy, labor and delivery to determine if an out-of-hospital birth is appropriate based on the risk factor criteria specified in Tables I and II, or any consultation conducted based on the criteria specified in Table III.
  - No comments provided.
- Section (2) - A risk assessment shall be performed within 14 calendar days of the initial prenatal care visit and updated throughout the pregnancy, labor, and delivery.
  - RAC member stated that to make a decision about risk, often times records must be obtained which may take additional time. The time frame should be more ambiguous but state that it must be done during early part of care.
  - Staff noted that a risk assessment is an on-going process and for purposes of this rule a clear timeline is needed for the initial determination. As additional information is obtained it would be expected that records are updated and documented.
  - RAC member stated via chat that 21 days is more appropriate as it could take 14 days to acquire previous records. Other RAC members via chat concurred with 21 days.
  - RAC member indicated that the rule states the "birthing center" shall assess and should be modified to indicate who is actually doing the assessment. D. Selover noted that this is likely addressed by other rule language including policies and procedures and defining clinical staff and clinical provider.
- Section (3) - Appropriate referral or transfer to a higher level of care shall occur if the client, fetus, or newborn meet any of the risk factor criteria identified in Tables I or II.
  - RAC member clarified that Table 1 is risk factors for exclusion at admission and Table 2 is risk factors or complications for transfer to hospital during intrapartum or postpartum care. The RAC member indicated that additional clarification is needed to ensure the correct interpretation of "exclusion at admission" - is exclusion at time of labor?
  - RAC member via chat stated that she reads the language of (3) to interface with the tables, which only require providers to refer or transfer after the risk factor is identified, which might only happen on admission.
  - HLO staff noted that the Board of DEM rules, OAR 332-025-0021 (1) through (6) discuss ongoing risk, timing and resolved indications.
  - RAC member commented that a lot confusion is around whether "at admission" means at time of care or at time of labor and additional clarification should be considered.
  - D. Selover noted that the program may issue interpretive guidance for clarification purposes.
- Section (4) - A birthing center shall consult with a provider of maternity care who is credentialed to admit and manage responsibilities in a hospital, or other specialty provider, if a client or fetus meet any of the consultation criteria specified in Table III.
  (a) A birthing center shall include the client during the consultation, if possible. If the client is unable to participate during the consultation, the birthing center shall notify the client of all recommendations made by the consultant.
  (b) The birthing center shall document the consultation, recommendations made, and discussions with the client. (document participants in the consultation, information shared

with the consulting provider, recommendations made, and discussions with the client) (decisions made by the client).
(c) If a consultation determines that an out-of-hospital birth is no longer appropriate due to the client meeting risk factor criteria specified in Tables I or II (consider removing reference to tables I and II), the birthing center shall refer or transfer the client to an appropriate health care provider or facility.

- D. Selover noted that as discussed previously the program will consider adopting the Board of DEM definition for a provider who can consult.
- RAC member via chat recommended that section (4) be amended to align with Board of DEM rules.
- RAC member via chat stated that the language should be consistent with Oregon State Board of Nursing for nurse practitioners.
- RAC member remarked that for purposes of subsection (4)(c) the Board of DEM rules are better. A client must be allowed to make an informed choice on whether to proceed with an out-of-hospital birth despite consultation recommendations.
- RAC member stated that the current language in subsection (4)(c) needs to be revised to note the client's choice.
- RAC member via chat recommended revising subsection (4)(b) indicating document the consultation, recommendations made, discussions with and decisions made by the client.
- Staff recommended via chat suggested edits for subsection (4)(b) including, 'to document participants in the consultations, information shared with the consulting provider, recommendations made, and discussions with the client.' Staff asked whether any RAC members had any concerns about with existing Board of DEM rule language in section (15) of OAR 332-025-0021.
- RAC member via chat indicated that paragraphs (D) and (E) in subsection (15)(b) of the Board of DEM rules is loved.
- RAC member remarked that a risk factor in Tables I or II are considered a high-risk birth and as such is an indication to transfer. In table III, the risk factors are a grey area and if after a consultant the client is still low risk within the midwife's scope of practice, a plan can still be made to birth in the birthing center and would solve the problem with people working in more rural areas where a doctor may be biased. D. Selover noted that there is one situation where language is needed for absolute risk factors (e.g. molar pregnancy) and the other situation where there is a grey zone. The Board of DEM language works for the consultation but not necessarily for the absolute exclusion. RAC members disagreed via chat and suggested that section (15) Board of DEM language works.
- D. Selover noted that if a consultation results in a finding of a risk factor in Table I or II, the client must be transferred. If the consultation, based on risk factors in Table III, results in a recommendation that is not in Table I or Table II, information about risks must be shared with the client and to the people providing care, then subsection (15)(b) language would apply. Language would need to be clarified.
- RAC member suggested that additional language referring to tables I or II in subsection (4)(c) is redundant given language in section 3. It was reiterated that RAC members want to address what is the purpose of the consultation and who is the decision maker. She further supported the Board of DEM language. D. Selover

responded with an example of a new finding that was not previously known but may have been caught by a consultant. RAC responded that it still doesn't seem relevant regardless of source as it would still require a transfer.
  - RAC member stated via chat that it "Allows for informed consent of patient if in that gray area. With all the info from consulting provider and their midwife."
  - RAC member stated via chat that she would like clarification on whether the passive voice will be removed since the passive voice removes the person who is acting from the sentence and is exactly what is needed to determine who is making the decision.
- (5) Notwithstanding sections (3) and (4) of this rule, if a risk assessment or consultation determines that an out-of-hospital birth is no longer appropriate, a birthing center may continue to provide prenatal care to a client, if the birthing center obtains the client's informed consent including at a minimum:
  (a) The client is informed of all potential risks and provides consent to continue to receive prenatal care;
  (b) The client acknowledges that birth will be planned at a hospital;
  (c) Documentation of subsections (5)(a) and (b) of this rule is noted in the client's medical record.
  - RAC suggested via chat to revise section (5) to specify 'common and/or significant risks.'
  - Staff suggested considering "known potential risks and likelihood of occurrence."
  - RAC member stated via chat that "likelihood of occurrence" can be tricky; percentages are public health figures and may not map to a specific client.
  - RAC member suggested via chat that subjection (5)(b) be amended to 'the client acknowledges that the birth has been recommended to occur at the hospital' since some clients may look for a different provider and/or birth site.
  - RAC member via chat agreed with reference to 'material risk.'

D. Selover stated that the core of the rule is that a consultation is needed, the findings of the consultation, and that the client is informed and involved in the conversation.

Staff noted the time of 12:02 p.m. and D. Selover indicated that the program will work on this rule language further. Staff will send another meeting poll to identify a couple of meeting dates.

PUBLIC HEALTH DIVISION
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Birthing Center Rule Advisory Committee
August 24, 2021
9:00 a.m. via Zoom

RAC MEMBER ATTENDEES	
Desiree LeFave	Bella Vie Gentle Birth
Hermine Hayes-Klein	Oregon Association of Birth Centers
Karen DeWitt	Oregon Association of Naturopathic Physicians
Kaylyn Anderson	Consumer
Lynette Pettibone	American Association of Birth Centers
Margy Porter	Bella Vie Gentle Birth Center
Michelle Zimmerman-Pike	American College of Nurse Midwives
Silke Ackerson	Oregon Midwifery Council
Willa Woodard	Rogue Birth Center

OTHER INTERESTED PARTY ATTENDEES	
Kori Pienovie	Womens Healthcare Associates, Midwifery Birth Center
Rebeckah Orton	Astoria Birth Center
Stephanie Bates	Public Citizen
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
Samie Patnode	PHD-Health Licensing Office

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 July 21 Meeting Notes

D. Selover asked RAC members if there was any feedback on the notes. Clarification was provided to RAC member who questioned element of the meeting notes that specified "for current discussion purposes only." It was noted that several additional steps occur prior to final proposed rulemaking with the Secretary of State including review by the Department of Justice. As a reminder, the Birthing Center RAC is advisory only. The Oregon Health Authority will consider the RAC's input, however, the Authority retains the final decision on final rule text.

Proposed OAR 333-077-0125 – Risk Status Assessment and Consultation Requirements
D. Selover opened discussion on the proposed changes to OAR 333-077-0125 based on discussions from the July 21 RAC meeting. As requested, the rule was revised to incorporate the definition of Oregon licensed health provider based on the Board of Direct Entry Midwifery administrative rules. It was noted that sections (1) and (5) would be discussed together. (1) As used in this rule, "provider of maternity care" means a physician or physician assistant licensed under ORS 677, a nurse practitioner who is licensed as a nurse midwife under ORS 678 or nurse practitioner licensed under ORS 678, a naturopath licensed under ORS 685, or a licensed direct entry midwife licensed under ORS 687. (5) A clinical provider at the birthing center shall consult with a provider of maternity care if the client or fetus meet any of the consultation criteria specified in Table III. The consulting provider of maternity care must be: (a) Credentialed to admit and manage responsibilities in a hospital; or (b) A specialty provider (for example, maternal-fetal medicine, hepatologist, psychiatrist); and (c) Experienced and knowledgeable about the indication(s) for consult. As the rule is currently proposed, the 'provider of maternity care' is the person that a clinical provider at the Birthing Center would consult with if the client or fetus meet the consultation criteria specified in the proposed Table III. The Authority asked the RAC members to describe how 'providers of maternity care' without specialized credentials may offer specialty consultation? Discussion on sections (1) and (5): • RAC member stated that while the minutes correctly described the birth centers position on consultation language, the proposed language in section (5) does not. Question was posed why the Authority did not adopt DEM language directly. The Authority responded that the Board of DEM language was used as a foundation. These rules are for birthing centers (facility) not individual providers. • Concern was noted that it is unclear where consultation with another out-of-hospital (OOH) provider, such as a licensed DEM, is allowed in the rule based on the examples provided under "specialty provider." It was suggested that the Board of DEM definition for consultation be incorporated – "consultation means a dialogue for the purpose of obtaining information or advice, with an Oregon licensed health care provider who has direct experience handling complications of the risk(s) present, as well as the ability to confirm the indication for consult, which may include, but is not limited to confirmation of a diagnosis and recommendation(s) regarding management of medical, obstetric, or fetal problems or conditions." • RAC member concurred that for purposes of consultation it is important to include language that ensures a provider has direct experience handling complications of the risk(s) present given the number of different risks and remarked that section (5) is unwieldy, and specificity may be problematic. • Staff noted that the Authority will consider adding a licensed DEM to the examples or possibly list as a separate provider. It was noted that it's important to make sure that both OOH providers and hospital-based providers are included. RAC members commented via chat that DEM's should be listed as a specialty provider. It was further noted via chat, that

there are risk factors that may require a specific type of consultant for purposes of licensed DEMs (example Direct Coomb's positive requires a consultation with a pediatric care provider.)

- Concern was expressed about use of the term "provider of maternity care" when a consultant may be a pediatrician or pediatric subspecialist
- RAC member noted that the scope of practice of the provider must also be considered for purposes of consultation.
- It was noted that for purposes of a survey and determining compliance with the requirement that an individual had direct experience with specific risks, the Authority would expect the facility to ensure that the education and training of the provider would be documented in the birthing center records, and that the education and training are specific to the condition/diagnosis/risk being assessed. Staff provided additional information on enforcement and applying rules.
- Question was posed regarding how do you hold a birthing center responsible for the consultation requirement versus an individual? Staff noted that licensed facilities must make sure that policies and procedures are adopted and implemented to ensure that providers/staff are doing what is required in rule. Allegations specific to a provider's scope or license are referred to the appropriate licensing board.

Section (2) was opened for discussion:

> (2) A clinical provider at the birthing center shall assess a client's risk status throughout pregnancy, labor, and delivery to determine if an out-of-hospital birth is appropriate based on the risk factor criteria specified in Tables I and II, or any consultation conducted based on the criteria specified in Table III.

Discussion:

- RAC members had no comment.

Section (3) was opened for discussion. Staff recommended that the term "performed" be changed to "completed" based on the nature of the date language. In addition, feedback was requested from RAC members on whether the 21 days should be changed if a person does not begin receiving care until a later stage of pregnancy.

> (3) An initial risk assessment shall be performed within 21 calendar days of the initial prenatal care visit and updated throughout the pregnancy, labor, and delivery.

Discussion:

- RAC member noted that it is frequently difficult to obtain records from other providers in a timely manner which is why 21 days was requested by RAC. Clients who transfer to a birthing center late in a pregnancy are asked to bring records with them.
- No additional comments or suggestions were made by RAC members.

Section (4) was opened for discussion.

> (4) Appropriate referral or transfer to a higher level of care shall occur if the client, fetus, or newborn meet any of the risk factor criteria identified in Tables I or II based on the

performance of the initial risk assessment, periodic risk assessments or a consultation conducted in accordance with section (5) of this rule.

Discussion:

- RAC member via chat asked whether a certified nurse midwife could repair 3rd degree lacerations? If a CNM can repair, it would not be considered a consult or transfer because it is within their scope of practice. It was further stated that a facility would need to ensure that they are equipped to complete a procedure that is within the provider's scope.
- Staff noted that consideration must be given to not only the scope of practice but the facility setting and whether the necessary equipment is available, and the physical environment meets appropriate standards.
- RAC member stressed the importance of understanding the different levels of providers that work for birthing centers and the importance of having rules that do not impede provider scope. A CNM can perform 3rd degree laceration repair in a hospital or birth center.

Section (6) was opened for discussion.

(6) The consulting provider of maternity care may not be an employee or credentialed provider of the birthing center.

Discussion:

- RAC member expressed concern that there will be unintended consequences. Example provided of the medical director being employed by the birthing center and a physician call group that is theoretically employed by the same entity.
- Staff noted that there may be some risk factors that could be problematic for consulting only in-house. Staff acknowledged that credentialed providers may need to be considered further and asked RAC members whether anyone had recommended language to address issue of credentialed providers that might be appropriate.
- It was suggested that a credentialed provider with hospital privileges may be a way to address. RAC member commented that several birth centers employ nurse midwives that have hospital privileges and if something is restricted in the birth center but is within the providers' scope of practice in the hospital, it doesn't make sense that they would consult with someone outside the practice. It's more important that they are consulting with the appropriate level of provider not whether they are an employ of the birth center. It was suggested whether section (6) is even necessary.
- Staff noted concern about at what point does the consultation and decision about transferring to a higher level become a problem. The consultation is mostly for a decision to transfer to a higher level of care for the birth and possibly some prenatal care. Staff will consider further.
- Staff from the Health Licensing Office will share Board of DEM rule language for consideration.

Sections (7) and (8) were opened for discussion.

(7) A birthing center shall include the client during the consultation, if possible. If the client is unable to participate during the consultation, the birthing center shall notify the client about all findings and recommendations from the consultant.

(8) The clinical provider at the birthing center shall document the following information within seven calendar days of the consultation:
(a) Who participated in the consultation;
(b) Information shared with the consulting provider;
(c) Findings and recommendations from the consulting provider;
(d) Discussions with the client during or after the consultation about the findings and recommendations;
(e) Decisions made by the client for continued care; and
(f) Plan of care.

Discussion:

- RAC member expressed concern about the term "findings and recommendations from the consultant" in subsections (8)(c) and (d). It was stated that the purpose for the consultation is to gather information and there may not be any finding. A finding also implies that an examination is performed of a patient and some consultations may not occur with a client. It was stated that documentation of "findings or recommendations" creates a liability risk for both the provider making a recommendation and the provider receiving the information. It was further stated that recommendations are an opinion and therefore the benefit is questionable whereas the risks could be significant to the facility.
- Staff noted that for purposes of OARs, the Authority must consider what is in the best interest for the client. The point of a consultation is to ensure that the client has as much information as possible to make an informed decision so it would seem odd that a consultation would occur without the client.
- Staff noted that for purposes of a survey, the agency is not second guessing the outcome of the decision made, rather that there was meaningful input from the person consulted. A client may want to make different decision based on the information provided from the consultant. The information shared and the input from the consultant needs to be documented so that the surveyor can confirm that the consultation occurred. Further, surveys use the term “findings” not in a clinical sense, but in terms of documenting what was observed on survey.
- Staff from the Health Licensing Office noted that the Board of DEM also discussed the importance of documentation, the importance of the information provided by the consulting provider, and the decision made. The following Board of DEM rule language was shared:

  332-025-0021 (15) When a birthing person or newborn present with one (1) or more indications for consult the LDM must:
  (a) Arrange for transfer of care; or
  (b) Comply with all the following:
  (A) Consult with an Oregon licensed health care provider, as defined in OAR 332-025-0021(20) and (21) of this rule, who is experienced and knowledgeable about the indication for consult unless a different Oregon licensed health care provider is otherwise stated specifically within this rule;
  (B) Communicate to the birthing person the recommendations given by the consulting Oregon licensed health care provider if the birthing person was not present at the consultation;
  (C) Obtain informed consent in accordance with OAR 332-025-0120;
  (D) Make a plan with the birthing person about the indication; and
  (E) Document the recommendations, consultation, discussion, informed consent and plan.

332-025-0110 (2)(h) Records mean written or electronic documentation, including but not limited to documentation of all consultations pursuant to OAR 332-025-0021 (14) through (22) and recommendations regarding indications for consultation from an Oregon licensed health care provider as defined under OAR 332-025-0021(21), or any other provider specifically identified in OAR 332-025-0021;

- RAC member expressed that the Oregon Midwifery Council would be uncomfortable with removing documentation of recommendations. It was acknowledged that it's possible that no recommendations are made and that could be reflected in the documentation. There are a number of complaints and peer reviews where the recommendation from the consulting provider was not communicated with the client and the client in retrospect felt they didn't have the information needed to make an informed decision about a risk factor.
- RAC member expressed that meaningful information is desired and suggested using the term 'or' versus 'and' and replace 'findings and recommendations' with 'information.' It was stated that some OB consultant employers do not allow the birthing center to write that the OB made a recommendation. It was stated that the current language would be problematic.
- RAC member stated that some consultation occurs over the phone and without having met the client, the consultant cannot make an "official" recommendation. Changing to 'information' or replacing the term 'and' with 'or' may be helpful.
- Staff noted that depending on the risk factor there may be some consultations that require additional follow-up or more rigor that doesn't involve just a phone conversation.
- For the record comments via chat included:
  - Consulting providers do not know the birthing center rules; and
  - Consulting providers do not believe that any OOH birth is safe.

Section (9) was opened for discussion.

(9) Notwithstanding section (4) of this rule, if a risk assessment or consultation determines that an OOH birth is no longer indicated, a birthing center may continue to provide prenatal care to a client if:
(a) The client is reasonably informed of known material risks and provides consent to continue to receive prenatal care;
(b) The client acknowledges that the birth will not take place at the birthing center and that a hospital birth has been recommended;
(c) Documentation of subsections (8)(a) through (f) of this rule is documented in the client's medical record.

Discussion:

- RAC member stated that the Oregon Association of Birth Centers has a problem with any rule language that could be interpreted as "giving power to the non-birth center provider with whom the birth center is seeking the consultation to make a determination that an OOH birth is no longer appropriate if the client remains within scope." It was requested that the rules be clear that the consultant does not get to determine whether an OOH birth is no longer indicated. The client and the birth center provider through a shared decision-making process using the information shared should decide what is the safest course of care. It was further stated that language about continuing to receive prenatal care after 'risking-out' should be moved to the general sections of the rule.
- Staff noted that a risk assessment may reveal a finding that is found in the risk factor tables and therefore the birth would not be able to occur at a birthing center. Staff will consider

placement of the rule language in consultation with Department of Justice and consideration of statutory language about low risk.

- RAC member stated that the RAC is revisiting the regulations that identify who is low risk by setting the "scope of services" for birth centers through the risk factor tables. OAR 332-025 set the scope of services for Licensed DEM's.
- RAC member stated that all OOH birth providers in Oregon attend low risk births which is within their scope. RAC member further stated there are two outcomes for a consultation under DEM rules: 1) arrange to transfer care; or 2) seek informed consent to continue care after communicating recommendations and making a plan of care. It was recommended that this be allowed under the birthing center consultation rule. It was reiterated and information paraphrased from the chat that many consultants may say that there is no increased risk to the client, but they do not recommend an OOH birth.
  - RAC member via chat stated that a hospital-based provider may say there is not an increased risk for a patient when OOH birth provider will identify that there is.
- For the record comments via chat:
  - Licensed DEM statute scope of practice – ORS 687.405 As used in ORS 687.405 to 687.495, “direct entry midwifery” means providing the following services for compensation: (1) Supervision of the conduct of labor and childbirth; (2) Providing advice to a parent as to the progress of childbirth; (3) Rendering prenatal, intrapartum and postpartum care; and (4) Making newborn assessments.
  - The LDM scope of practice in statute is not tied to or related to "low risk."
  - Possible solution is while the OOH birth providers are required to consult with in-hospital providers, that in-hospital providers should be required to document and submit their recommendations and rationales as well.
- RAC member stated that "low risk" is related to the birth center statute and each of the OOH provider types (ND, CNM, and LDM) have their own statues and rules which are each distinct and have their own scope of practice. Low risk defined in the HERC guidance is only one way to relate to risk. The OOH provider scope of practice in relation to risk is a lot broader.
- Staff indicated that information will be taken under consideration and additional changes to the rule will be considered.

RAC adjourned at: 11:48 a.m.

PUBLIC HEALTH DIVISION
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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 EXCLUSION AT ADMISSION

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
Group B Strep (Unknown carrier state)
Group B Strep (If mother is positive, lack of informed consent on prophylaxis)

- 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 and 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.

800 NE Oregon Street, Suite 465
Portland, OR 97232
Voice: (971) 673-0540
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Birthing Center Rule Advisory Committee
October 18, 2021
2:00 p.m. via Zoom

RAC MEMBER ATTENDEES	
Colleen Forbes	LDM and former chair of the Board of Direct Entry Midwifery
Danielle Meyer	Oregon Association of Hospitals and Health Systems
Desiree LeFave	Bella Vie Gentle Birth
Hermine Hayes-Klein	Oregon Association of Birth Centers
Karen DeWitt	Oregon Association of Naturopathic Physicians
Kaylyn Anderson	Consumer
Meredith Mance	Aurora Birth Center
Silke Ackerson	Oregon Midwifery Council
Stefanie Rogers	Providence St. Vincent, Neonatologist
Michele Zimmerman-Pike	American College of Nurse Midwives
Willa Woodard	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Gabriela Esquivel	Community Health Worker, Samaritan Health Plans,
Holly Jo Hodges	Medical Director, Intercommunity Health Network CCO
Kati Dunigan	Community Health Worker, Samaritan Health Plans
Sean Connolly	Jackson Care Connect CCO
Sharron Fuchs	Public Citizen

OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Barbara Atkins	PHD-Facility Planning & Safety
Lacey Martinez	PHD-Health Facility Licensing & Certification
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Rebecca Long	PHD-Emergency Medical Services and Trauma Systems
Samie Patnode	Health Licensing Office, Board of Direct Entry Midwifery

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 September 13th Meeting Notes
No comments.

Risk Factor Table I – Risk Factors for EXCLUSION AT ADMISSION

CURRENT PREGNANCY COMPLICATIONS
HIV (Unknown)
HIV (Positive)

- RAC member stated that it's extremely important that a person should be able to choose not to screen for HIV and this choice should not exclude someone from birth center care. It was further stated that a person should be able to choose to decline any screening for an infectious disease.
- RAC member expressed concern about a person declining HIV testing if not low risk. There are clear benefits to initiating early treatment for the newborn in decreasing transmission and it was noted that liquid antiretrovirals are challenging to obtain.
- RAC member indicated the need to respect a client's decision to not screen due to religion or culture which makes them low risk. Providers have a discussion with the client regarding the benefits of screening and the client should be able to decline and continue care at a birth center.
- RAC member via chat noted that they are generally opposed to removing the choice to birth at a birth center for the sole reason of declining testing.
- Staff asked what the protocol differences are for both the hospital setting and birth center setting for someone who has an unknown HIV status.
    - RAC member responded that in the hospital setting a rapid HIV screening can be conducted and if concerned about risk factors (such as injected substance use history), the hospital can initiate therapy with AZT, which is recommended within 6 hours of birth if there is concern for transmission. The earlier that therapy is started the lower the risk of transmission. It was noted that it is not common in the hospital setting to have someone decline testing as it is part of the OB panel. It was suggested that language be added relevant to risk status.
    - RAC member indicated that as long as the client is low risk, there shouldn't be any difference in treatment for people who refuse testing.
    - RAC member stated via chat that it is their understanding that rapid HIV is more likely to have a false positive result.

POLL: Retain HIV (unknown status) as an absolute risk factor? Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 13% - 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.

- 25% - 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.
- 38% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Staff asked for those who voted to actively block, what other recommendation would you have?

- RAC member via chat indicated "unknown and low risk for HIV." Staff asked how low risk would be defined and whether it should be defined the same way for everyone.
    - RAC member responded that the list could be long.
    - Another RAC member noted via chat that delivery providers should be trusted to understand risk and shouldn't need to be defined.
    - RAC member stated concerns regarding restricting access to care for persons who are low risk. Uncertain what the added value is to test for low-risk scenarios. Trying to solve a problem that is not present in Oregon.
    - Several RAC members concurred with these comments.
- Another RAC member stated via chat "To be fully evidence based, I would like to see statistics on what the actual HIV positive status of prenatal testing here in OR is."
- RAC member stated via chat a suggestion that a written and signed informed declination form be included in the chart and then trust that a discussion of risk occurred and the client made an informed choice.
- RAC member suggested that HIV (unknown) should be removed altogether.

POLL: Retain HIV (known positive status) as an absolute risk factor? Results:

- 33% - I can say an enthusiastic yes to the recommendation (or action).
- 22% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren’t necessary.
- 33% - 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.
- 11% - 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.

Rubella (anytime during pregnancy)

Staff noted that this risk factor is anytime during pregnancy. The prevalence is very low in the United States and would most likely come from foreign travel.

POLL: Retain Rubella (anytime during pregnancy) as an absolute risk factor? Results:

- 20% - I can say an enthusiastic yes to the recommendation (or action).
- 80% - 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.

Syphilis (Unknown)
Syphilis (Positive)

- RAC member noted that most of the comments and issues discussed around HIV apply to syphilis. It was noted that a vast majority of clients are okay with the syphilis screening but there are some clients due to religious beliefs that refuse testing. This should not preclude a client from birth at a birth center. Known positives should be retained as an absolute risk factor.
- RAC member suggested including reference to low risk as suggested for HIV.
- RAC member commented via chat that positive status poses less risk after 24 weeks.
- RAC member remarked that they are assuming "positive" means "Positive untreated." If a person is still testing positive but is being treated the individual would be a candidate for an out-of-hospital birth. A person may have a positive RPR for years after treatment. It was suggested to change the wording to Positive – untreated.
- RAC member comments via chat that the Board of Direct Entry Midwifery (DEM) rules have this risk factor as a consult criteria for the reasons noted directly above and suggested voting on moving to consult. Staff asked for clarification on whether the suggestion is to move positive syphilis to consult and then a determination is made based on treated or untreated. RAC member agreed and stated that if anyone screens positive and it goes to consult with an appropriate provider then the determination can be made whether the client is appropriate for an out-of-hospital birth, if treated or not. It's more nuanced than no risk or high risk.
- Several RAC members concurred via chat to poll on moving to consultation.

POLL: Retain Syphilis (unknown status) as an absolute risk factor? Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 23% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 11% - 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.
- 33% - 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.
- 33% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Move Syphilis (positive status) to consultation? Results:

- 67% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - 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.

POLL: Make Syphilis (positive status - untreated) an absolute risk factor? Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 86% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 14% - 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.

Varicella (current active infection at time of labor)

- RAC member asked for information about the risk to baby relating to this infection. RAC member responded that risk is different at different gestational ages. It was previously recommended to give VZIG which is not really available. IVIG is now recommended for the newborn if mom is active. This is very rare but there is a neonatal intervention and could be best managed with consultation with a specialist given risk of transmission to newborn.

POLL: Retain Varicella (active infection at time of labor) as an absolute risk factor? Results:

- 56% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - 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.
- 11% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

POLL: Move Varicella (active infection at time of labor) to consultation? Results:

- 33% - I can say an enthusiastic yes to the recommendation (or action).
- 11% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 11% - 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.
- 33% - 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.

- 11% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- RAC member expressed concern and indicated that clarification should be provided that the risk factor is relating to primary infection and not shingles. Shingles (at time of labor) should not be a contraindication. Staff inquired whether the recommendation is to have that listed as a consult requirement. RAC member indicated that would reasonable but may not be necessary in every case.
- RAC members via chat concurred with comment above.

POLL: Add Shingles (at time of labor) as a consultation requirement. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 14% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 72% - 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.
- 14% - 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.

Mental Illness Requiring Inpatient Care

Staff noted that the risk factor is broadly written and doesn't have any indication of time frame. It was noted that the revised Health Evidence Review Commission (HERC) guidance has amended the risk factor reference. **Follow-up: HERC lists the following factors for consultation: 1) Maternal mental illness requiring psychological or psychiatric intervention; and 2) Patient currently taking psychotropic medications.**

- RAC member noted that based on the table, the risk factor is listed under current pregnancy complications and not under remote history. It was further stated that usually people who are in inpatient care are very complex, and unstable or may be on multiple medications to remain stable. A birth center would likely not have access to security or 24/7 access to a social worker or other mental health care provider. A client needing multiple resources for mental illness may be beyond the scope of a birth center.
- RAC member via chat stated, "Birth centers can safely care for clients with various mental health issues, including those who have received inpatient care during pregnancy. We request moving this to consult."
- Several RAC members concurred with statement above via chat.
- RAC member stated that mental health is so complex that place of birth should happen in consultation with the mental health care provider and team. There will be certain situations where birth at a hospital makes most sense, and other situations where a birth center would less problematic. With severe mental health issues, the midwifery team should be in contact with the mental health team, and those two teams along with the client make a plan together.
- RAC member stated via chat that "…the consult should be for a slightly broader category than the current language, 'requiring inpatient care.' Staff asked what the trigger should be. RAC member responded that requiring inpatient care is an extreme criteria. There are

situations where there may be a danger of harm to self or baby where the person doesn't require or is not able to get inpatient care and providers would hate not being able to have a consultation based on the deficiencies of the mental health care system.

- Staff asked to clarify that for purposes of a consult, it would be with the client's treatment team not just a random provider who does not know the client. RAC member concurred.
- RAC member stated they would concur with moving to consult.
- RAC member commented that yes, the client's mental health provider should be consulted with especially if the client is now stable. For someone in an unstable situation to lose midwifery care may be particularly difficult. It was further noted that birthing centers are in a position to provide home-based care and follow-up in a different way than a larger setting. While not mental health professionals, they can follow-up and contact the client's mental health provider and be a bridge. Women who first exhibit signs of postpartum depression have no idea they have depression and midwives would be beneficial.
- Staff asked RAC members what should occur for history of inpatient mental illness; should it be a consult or something else? RAC member responded that optimal care would be the midwife providing care and consulting with the mental health providers. If the illness is active during pregnancy, then consultation is mandatory. If the client is stable and has a good plan, then a consult should not be mandatory. Timing should not be addressed other than the current pregnancy. Staff asked, what about significant history in prior pregnancy. RAC member responded no, it would not change approach. Active symptoms right now are different than history. The client and provider should determine what is the best treatment plan.
- RAC members concurred with comment above via chat.

POLL: Move mental illness (active during pregnancy) to consultation with mental health professional required? Results:

- 25% - I can say an enthusiastic yes to the recommendation (or action).
- 36% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 13% - 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.
- 13% - 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.
- 13% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Concerns were noted by RAC members about what was being voted on and whether it included mental illness requiring inpatient care. Poll was revised as follows:

POLL: Move mental illness requiring inpatient care in the current pregnancy to consultation with mental health professional. Results:

- 63% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.

- 13% - 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.

Discussion concluded and next meeting will continue with placental conditions, prelabor rupture of membranes and hyperemesis.

Review of Physical Environment – OAR 333-077-0220

Barb Atkins, Plans Examiner for Facility Planning and Safety, provided an overview of the Physical Environment rule which was initially drafted using the Facility Guidelines Institute requirements. Concerns were registered by the RAC at the October 16, 2019 RAC meeting and it was suggested that the program consider the Commission for the Accreditation of Birth Centers (CABC), indicators of compliance with standards for birth centers. A cross walk of other adopted Oregon code requirements compared to the CABC standards was created and a new proposed rule suggested. The cross walk and new proposed rule were shared at the November 22, 2019 RAC meeting and RAC members were asked to provide comments via E-mail by January 10, 2020.

The new document that includes comments shared by RAC members on the new proposal was sent electronically on October 18, 2021 and the RAC proceeded to review the document.

Discussion:

- Page 1, row 1: Question was raised by RAC member regarding the classification of ambulatory care. Staff responded that under the 2019 Oregon Building Code, a birth center would be classified as an outpatient clinic, essentially meaning that the birthing person is capable of self-preservation at any time – if the person needed to, they could evacuate on their own without assistance (e.g., fire, fire alarm, etc.) compared to a hospital where a patient may be under anesthesia. NFPA classification of Ambulatory Care Facility was briefly discussed noting the differences (may not be capable of self-preservation due to anesthesia or procedures).
    - Staff clarified that the proposed rule is if someone is building a new birth center or if a significant remodel were occurring on an existing birth center. Existing birth centers have been approved under a previous code and do not need to comply with this new standard unless a significant renovation is planned (50% or more of space is going to be remodeled). It was noted that if someone wants to convert a house into a birthing center, a house is considered a residential occupancy, however, when using the house to run a business then federal compliance comes into play (e.g., accessibility, wheelchairs, discrimination laws, etc. and becomes a business occupancy.)
- Page 1, row 3: Question was raised by RAC member regarding minimum clearance for hallways, stairs, doors, etc. A birth center does not need further specifications than a clinic would. It was noted that a birth center is more like an outpatient clinic versus an ambulatory

surgical center. Staff noted the requirement for the 36" wide hallway is no more stringent than any outpatient clinic under review.

- Page 2, row 1: Staff noted comment previously provided by RAC member regarding elevators. It was noted that the program is not requiring elevators, rather providing a "heads-up" on what Oregon Building Codes require. Multi-story facilities wishing to serve laboring persons on the 2nd or 3rd floor, Oregon Building codes may require an elevator not the Oregon Health Authority. It was asked whether giving this 'heads-up' is necessary and the birthing center would need to rely on its design team to be aware of local building codes.
- Page 2, row 8: RAC member asked what is reasoning for requiring GFCI protection in outlets within 6 feet of other water source. If GFCI is on one circuit, why would multiple GFCIs be necessary? Staff noted that in a kitchen, if the first electrical circuit is GFCI protected, then each additional outlet is also protected. RAC member asked what is the benefit given the cost? Staff noted that they will research Oregon electrical code and will consider changing the rule language to reflect that the first outlet in a chain of outlets must be GFCI.
- Page 3, row 1: RAC member noted concern about the prohibition of extension cords when the state requires back-up support in case of power outage. When using generators for back-up support, extension cords are used. Also, a computer that is not a laptop will often have a surge protector which would also be an extension cord. Staff noted that 'relocatable power taps' (surge protectors) are allowed as long as they are off the floor and mounted to a wall at least 4" off the floor with non-permanent mounting (such as Velcro). Extension cords create tripping hazards to a laboring person and the prohibition is a safety precaution. Emergency preparedness trumps rules and as such use of a generator and extension cord is understandable. Staff indicated that clarification will be considered for rule.
- Page 3, row 2: Staff asked RAC for input on retaining term 'adequate lighting.' It was previously recommended that 'adequate lighting' be changed to "a minimum of ½ foot candle." Staff noted that this may create a hardship for a birthing center if a footcandle measurement is required as the center would need to submit photometric plans. Leaving the language vague may be best.
  - RAC member noted that the recommendation for foot candle came from residential lighting and was fine with 'adequate lighting.'
- Page 3, row 4: Staff shared previous comment from RAC member regarding infant identity. Staff indicated that per the CABC standards, provisions for infant security are required and may include but not limited to: "windows in birthing area have locks, birthing area access is regulated, infants are not separated from parents' area, there is no designated nursery area separate from the mother's care area, *there is a method for assuring infant identity such as Identification bracelets, foot printing, or other method*."
  - RAC member asked if any birth center does foot printing. The baby is not going to leave a client unless being transferred to hospital.
  - RAC member via chat indicated that hospitals no longer do foot printing for identification.
  - RAC asked whether any birth center is doing anything to identify newborn and requested that the identity proposal be removed from the rule.
  - RAC member echoed comment above and noted that in a birth center mom and baby are never separated. It is not common practice to do bracelets and is not necessary. It was noted that visitor logs are used when someone enters or leaves the facility and may be something to consider.

- RAC member stated that a safety plan should be implemented by a birth center and could include things like doors that are locked.
- Page 4, rows 2 and 3: Staff noted use of term "adequate space" and inquired whether more specificity should be considered. RAC member had previously stated concerns about the initial proposal specifying 7 feet in any plan dimension. Staff noted that the 7-foot reference is an Oregon Building Code requirement.
- Page 6, row 2: Staff noted previous concern registered by RAC member regarding requirement for a handwash station in each birth room. It was noted that CABC standards state, "Sufficient, convenient sink locations for all staff, clients and families, *including in birth rooms."* Staff noted that hand washing should occur in rooms where patient care is provided without touching a door.
    - RAC member asked what is considered the birthing room. Staff responded that the birth room is the room with a bed or a tub without having to access any door. The proposed rule would mean the handwash station must be located inside the room and viewable by the birthing person in the bed. RAC member responded that this would pose a problem and noted procedures such as handwashing before entering a room, use of gloves, doors to restrooms remaining ajar, cleaning procedures, etc. RAC member asked what is the benefit when no other clients will be in the area?
    - RAC member via chat agreed that this would be hard for birth centers moving forward.
    - RAC member noted that in a private birth suite, both clients and staff would have access to sink to wash hands without having to open or close a door. The door stays open all the time even when the birthing person is on the toilet so staff can monitor. Having a separate handwash station would be very challenging. It was further noted that foaming hand sanitizer is also available and would allow for hand sanitation.
    - RAC member suggested adding to rule having a hand sanitation station in the room if there is a door left open so that the providers can wash hands if needed and would be adequate. This would make it less of an obstacle for small birth centers or rural birth centers.
    - Staff indicated that they would consider the following: 1) In renovation projects when it is unattainable to provide a hand wash station in the patient room, it shall be provided in the toilet room or 2) not require a hand wash station in the birthing room but instead require an alcohol-based hand rub dispenser. Staff asked RAC to consider making it a requirement for new construction. RAC member responded that required for new construction would be reasonable; but would be challenging for persons renovating an old home. Staff noted the following language for consideration: In new construction a hand wash station shall be provided in the birthing room. In renovations and remodels of existing built environments, a hand sanitation dispenser with alcohol-based hand rub shall be provided at a minimum. RAC members concurred. One RAC member suggested that the language be for new construction, 'a hand wash sink or hand sanitation dispenser.'

ACTION: Staff will consider the following: 1) Removing reference to Oregon building code requirements for an elevator; 2) Research information on Oregon electrical code and removing reference to GFCI requirements in *all* electrical outlets within 6 ft of water source; 3) Clarifying use of extension cords in an emergency while using generator; 4)

Removing requirement for infant identification; and 5) revising requirement for hand wash station for remodel or renovation.

Wrap Up
RAC members agreed to continue discussion on physical environment at the November meeting. Next meeting is scheduled for November 29th at 10:00 a.m.

RAC adjourned at: 4:07 p.m.

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement
Kate Brown, Governor

Oregon Health Authority

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Birthing Center Rule Advisory Committee
November 29, 2021
10:00 a.m. via Zoom

RAC MEMBER ATTENDEES	
Colleen Forbes	LDM and former chair of the Board of Direct Entry Midwifery
Hermine Hayes-Klein	Oregon Association of Birth Centers
Jennifer Gallardo	Andaluz Waterbirth Center
Karen DeWitt	Oregon Association of Naturopathic Physicians
Laura Erickson	Alma Midwifery Services
Lynette Pettibone	American Association of Birth Centers
Margy Porter	Bella Vie Gentle Birth Center (Clinical)
Silke Ackerson	Oregon Midwifery Council
Susan Heinz (for Desiree LeFave)	Bella Vie Gentle Birth Center (Administrative)
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Bill Bouska	Samaritan Health Services
Christina (Baldisseri) Clay	CareOregon; LDM
Janette Gyesky	Bend Birth Center
Maegan Pelatt	CareOregon
Ray Gambrill	AllCare Health; MD
Safina Koreishi	CareOregon
Stefan Shearer	CareOregon

OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Barbara Atkins	PHD-Facility Planning & Safety
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
Rebecca Long	PHD-Emergency Medical Services and Trauma Systems
Samie Patnode	Health Licensing Office, Board of Direct Entry Midwifery

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.

Review of October 18th Meeting Notes
Dana Selover asked RAC members to submit any comments or feedback on the meeting notes via E-mail.

Review of Physical Environment – OAR 333-077-0220

Barb Atkins, Architectural Plans Examiner for Facility Planning and Safety, introduced herself. RAC members were reminded that initially the Authority proposed adopting the Facility Guidelines Institute building standards, but based on concerns registered by RAC members, the Authority proposed amended rules to align with the Commission for the Accreditation of Birth Centers (CABC). These amendments had been previously shared with RAC members and a few comments were received via E-mail. This is an opportunity to receive final feedback on suggested changes.

Discussion:

- Page 6, row 1 – RAC member inquired whether proposed rule language requires that every bathroom and birth room be wheelchair accessible when previously only one bathroom and one birth room needed to be wheelchair accessible. Staff replied that it is expected that each private birth room have a bathroom that is accessible to persons with disabilities <u>unless the birthing room is located on a floor not accessible to persons with disabilities.</u> It was noted that the CABC requires that at least one bathroom be wheelchair accessible; however, Oregon Building Codes requires that all single occupancy toilet rooms or bathrooms be handicap accessible. It was further noted that to convert a house into a birth center, it must be converted from a residential occupancy to a business occupancy, and therefore must comply with the federal Americans with Disability Act and state building codes.
  - RAC member stated concerns that every birth room must be big enough for wheelchair access which could result in fewer birth rooms to accommodate the extra space. Birth centers with multiple rooms on the main floor could be adversely impacted.
  - RAC member noted that based on risk criteria, an accredited birth center may not have disabled people in its care, especially physically disabled needing wheelchair access. Clients must be ambulatory to give birth at a birth center. Accessibility is more about a partner who may be physically disabled which is why the CABC recommends one.
  - Further information is needed on whether a physical disability is a risk criteria that would require a client be transferred.
  - RAC member inquired about whether the standard applies to new construction or remodels only. Staff reminded RAC members that existing, licensed birth centers will not be required to comply with the new physical environment rules. Existing centers are licensed and surveyed based on the rules in effect at the time of initial licensure. Remodels that completely redesign a birth room or remodels that affect more than 50% of existing space would be subject to revised rules. Birth centers subject to initial licensure or major renovation will also be impacted by these rules. A birth center may apply for a waiver of physical environment standards.
  - Several comments were posted via chat by RAC members including:

- Concern about the need to convert every floor-level birth room to having accessible with the bathroom. Previously only needed 1 accessible room. Proposed changes would greatly affect facility.
    - Concern noted that "we don't want to pull up the ladder on new birth centers opening." Opening a birth center under current laws is not easy and rules should not make it even harder for access.
    - Confirmation that it is very uncommon for a patient that is not ambulatory to meet birth center criteria otherwise.
    - Oregon Midwifery Council support of comments stated by birth center owners.
    - Concern noted with proposed accessibility language and having a single room that is accessible should be sufficient.
- Page 7, row 1 – with regard to appropriate flooring, staff clarified that the intent is not to "ruin the character of the building" rather asking for modest accommodations, for example not having carpet or slippery tiles in a toilet room.
- Page 7, row 2 – RAC member had previously shared concerns about ability to have a self-dispensing ice machine. Staff clarified that a refrigerator with an ice machine that you place a cup to is considered self-dispensing and would be acceptable. Freezer trays of ice where anyone can handle would not be acceptable.
  - RAC member provided example of an ice maker with a scoop and staff indicated that for this rule, this would not be adequate. RAC member asked other centers for examples of type of ice dispensers used.
  - Via chat, the following comments were provided:
    - Refrigerator with ice dispenser
    - Purchase on Amazon $150
    - Small pellet ice machine but it still has a scoop
  - Staff noted that the purpose of this rule is to ensure proper use and infection control.
- Page 7, row 3 – Staff noted that an exam room is not required; however, if a birth center provides an exam room, the room must have adequate space to accommodate clients, family members, and staff. Furthermore, for renovation projects of existing licensed space if a handwash station cannot be accommodated in an exam room, an alcohol-based hand rub dispenser will be required aligning with the previous discussion about birth rooms. It will be expected that for new construction, seeking new licensure, or major renovation (affecting more than 50% of the center) of existing licensed spaces, a handwash station be added. A birth center may request a waiver from this requirement.
- Page 8, row 1 – With regard to laundry service, a RAC member had previously commented that use of the term "adequately sized" and "adequate storage" is appropriate.
  - RAC member commented via chat support of use of term 'adequate.'
- Page 9, row 2 – With regard to clean and dirty laundry, the current proposed language refers to requiring 'adequate storage' to meet the needs of the birth center and that areas must be designated as clean or dirty. RAC member previously commented that 'adequate storage' could be interpreted very differently. Another RAC member previously commented that the term may be difficult to define, however, it is expected that each center has different needs. Staff asked RAC to consider language that specified for every birth room bed, a birth center shall provide 10 sq.ft. or cubic ft so that a minimum requirement is set. Discussion:
  - RAC member comment that it depends on what the number is. Smaller birth centers may be impacted based on how much floor space they have. Staff indicated that if a number is set it would likely be around 10 sq.ft. A 10 sq.ft closet is 5 ft wide and 2 ft deep. The purpose is to ensure that a birth center has enough storage space so not everything is left on a dresser or countertop, etc.

- RAC member asked if an armoire would be considered storage. Staff responded yes if it is noted as storage.
  - RAC member commented via chat support of use of term 'adequate.'
  - RAC member asked if the storage space needed to be attached or in the birth room? Staff responded that the rule does not require such and it can be anywhere in the birthing facility.
  - RAC member via chat noted that setting a specific number is not necessary and potentially cumbersome.
  - RAC member asked via chat "is that much red tape necessary?"
- Page 9, row 3 – for purposes of holding soiled material that is secure from public access, staff noted that the term 'adequately sized' for storage space is noted here as well, and if a number is chosen for laundry (as discussed above), the same number would be noted here as well. It was further noted that it would be 10 sq.ft total (clean and dirty cumulative) not for each.
  - RAC member remarked that 10 sq.ft. for each birth bed for soiled material is more concerning than general storage. Soiled material is in the laundry room. Staff responded and reiterated that it would be a combined 10 sq.ft. for both clean and soiled combined. For example, 8 sq.ft may be for clean and supplies and 2 sq.ft. for soiled. (2 sq.ft. is about the size of a linen hamper.)
  - RAC member noted via chat that they have multiple different areas (cabinets, dressers, etc.) for storage, not just one, so it would be difficult to measure. Keeping language vague would be more appropriate.
- Page 9, row 3 – continued – Staff noted that a handwash station with soap and single use paper or cloth towels must be provided within 20 ft of soiled material in order to wash hands after handling soiled material.
- Page 10, row 3 – This rule specifies that there is a means for sterilizing equipment in accordance with infection control rule 333-077-0190. The infection control rule text was placed in the chat.
  - RAC member indicated that some birth centers have autoclaves while others use a pressure cooker which should be acceptable. It was further stated that there are sterilization packs that turn a different color to ensure proper sterilization.
  - Two RAC members via chat indicated that a pressure cooker is adequate in a birth center.
  - RAC member indicated via chat that the Commission for the Accreditation of Birth Centers has stringent rules for autoclave including spore testing, record of cleaning, etc.
  - Another RAC member responded via chat that a pressure cooker "may" be adequate for sterilization depending on the PSI and its ability to maintain adequate pressure for the requisite amount of time.
  - It was noted that for purposes of the built environment, the plans examiner would not survey to see if the equipment was operating according to rule. Health Care Surveyor staff noted that it is possible that a pressure cooker could be used for sterilization; however, the pressure cooker must have manufacturer instructions that will explain temperatures and times necessary for sterilization. Manufacturer instructions must also explain routine maintenance and cleaning. The facility would need to develop policies to maintain the pressure cooker for sterilization use.
- Page 10, row 4 - Specific to fire prevention and requires that medical gases such as oxygen and nitrous oxide must meet specific storage requirements must be met. D. Selover asked staff how much of this rule is above and beyond existing requirements for any business occupancy. Staff responded that the NFPA 99 is the nationally recognized code for all health

care facilities. An office such as a doctor's office that does not require state licensure would defer to local fire inspector. It was further noted that these requirements are also from the Office of the State Fire Marshall and not the Authority. It was further noted that the local fire inspector may ask for more which is outside of the Authority's purview.

- Page 11, row 1 - Requires that a toilet facility for staff may not be the same toilet room in the birth room. A minimum of 1 toilet room for the public is required. RAC member had previously indicated that there would be no way to meet this standard as the only toilet available to the public would be within a birth suite. Staff noted that in this case the birth center could apply for a waiver. Staff reminded RAC members that these proposed rules only apply to new construction, initial licensure, or major renovations.
- Page 11, row 2 - Relating to play area is based on CABC standards and is not a designated room but rather a space for children to play.
- Page 11, row 4 – Requires a telephone be made available to families to access emergency assistance and that signage be posted. RAC members had previously stated that given the age of cell phones, this rule is not necessary. Staff noted that all health care facilities that the Authority regulates requires *access* to a telephone. There is still a generation of people who may not have a cell phone or persons may forget or not have a charger for a cell phone.
- Page 12, row 2 – Staff work area shall be provided to discuss confidential information. Staff noted the rule does not require the space be on the same floor, only that space be available so staff can work privately and discuss protected patient health information that is secure from public.
  - RAC member noted that there is access to areas where information can be privately discussed.
  - RAC member asked whether extra clarification can be written into the rule so in the future it is note interpreted differently. Additional clarification may be to clarify that the space needs to be outside the birth room.
  - Staff noted that with other rules – room means walls with a door versus area means a designated space.
  - Question was raised about secure from public access. Staff will clarify that medical records must be secure from public access.
  - It was noted that the Authority uses written interpretive guidance to provide further clarification on rules.

Staff encouraged RAC members to send any additional comments to M. Bernal via E-mail.

ACTION: Consider identifying minimum space requirements for clean, soiled, and storage spaces. Clarify that medical records must be secure from public access.

Risk Factor Table I – Risk Factors for EXCLUSION AT ADMISSION

CURRENT PREGNANCY COMPLICATIONS

D. Selover opened discussion suggesting that the following risk factors be discussed as a group:

Placental abruption/abnormal bleeding
Low lying with 2 cm or less cervical os at term; previa; vasa previa
Recurrent antepartum hemorrhage
Uteroplacental insufficiency

RAC member indicated that abnormal bleeding should be removed from placental conditions listed and considered in a different category altogether. It is very vague and can mean many different things.

- RAC member indicated support of abruption as an absolute risk criterion.
- RAC members were asked by staff to indicate whether 'abnormal bleeding' should be retained next to placental abruption. No RAC members commented that it should remain.
- RAC member suggested via chat that "abnormal bleeding along with recurrent antepartum hemorrhage" should be moved to consult criteria, not an absolute risk factor. Another RAC member commented that the definition of hemorrhage (1,000 cc's or enough bleeding that there is a physiologic response) could be why it's listed as an absolute risk factor. It's not just some blood loss but an actual hemorrhage.
- RAC member indicated that the definition of recurrent antepartum hemorrhage in the Journal of Prenatal Medicine is 'bleeding from the genital tract in the second half of pregnancy' and is not defined in the same way as a postpartum hemorrhage (1,000 cc's or more of bleeding.) It was noted that half the time antepartum bleeding may be the result of a serious underlying cause but is not always the case, thus moving to consultation would be appropriate.
- RAC member indicated via chat that antepartum hemorrhage is different than "spotting."
- RAC member stated via chat that it is assumed to be a hemorrhage.
- RAC member stated agreement that based on the definition discussed, to move to consult.

RAC member suggested changing language relating to low lying placenta based on information shared by Dr. Duncan Nielson. Rather than stating "at term," (which is vague) the language should be changed to "Low lying with 2 cm or less of cervical os *at last ultrasound prior to start of labor.*"

- RAC member concurred agreeing that there is a grey area for the definition of 'at term.' The clearer rule language can be the better.

The following polls were completed:

<u>POLL: Retain placental abruption as an absolute risk factor. Results:</u>

- 89% - I can say an enthusiastic yes to the recommendation (or action).
- 11% - 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.

<u>POLL: Retain low lying placenta with 2 cm or less of cervical os (removing reference to 'at term') – at last ultrasound prior to start of labor. Results:</u>

- 78% - I can say an enthusiastic yes to the recommendation (or action).
- 22% - 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.

POLL: Retain uteroplacental insufficiency as an absolute risk factor. 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.

For purposes of polling, staff asked the RAC whether anyone had ideas on how to define 'abnormal bleeding' or 'recurrent antepartum hemorrhage' or other suggestions.

- RAC member noted that the language would need to reflect that a "Recurrent antepartum hemorrhage" overlies with another risk factor.
- RAC member noted that the most common causes for recurrent antepartum hemorrhage are already listed elsewhere on the risk factor tables, i.e., abruption and previa. For all others, it should go to consult criteria. For example, recurrent antepartum hemorrhage in the absence of placenta abruption or placenta previa would be a consult.
- Staff asked about quantifying abnormal bleeding and what would the language look like.
- RAC member via chat suggested "Abnormal antepartum hemorrhage that does not resolve"
- RAC member concurred with suggested language above but noted a down-side of putting a quantity like 500 cc's might lead some people to believe that a workup isn't necessary until that quantity is reached. Providers should want to identify the source of bleeding regardless of the quantity. It was also noted that this should be consult criteria.
- RAC member indicated via chat that clients with abnormal antepartum hemorrhage are sent for an ultrasound and it has to resolve, and everything normalize, or the client is risked out.
- RAC members via chat concurred with comments above.
- RAC member stated via chat that the Board of Direct Entry Midwifery rules indicate consult for second or third trimester bleeding. RAC questioned whether it was bleeding or abnormal bleeding – **Follow-up: OAR 332-025-0021(17)(g) specifies: Indication for consult – Antepartum: Second or third trimester bleeding.**
- RAC member suggested "Unresolved antepartum hemorrhage of unknown cause." RAC via chat agreed with this wording.

POLL: Retain unresolved antepartum hemorrhage of unknown cause as an absolute risk factor

Results:

- 25% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 13% - 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.
- 25% - 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.
- 13% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Discussion:

- RAC member stated that the poll was confusing and thus did not vote. More discussion was requested and asked RAC members why 'unknown' is important to include. RAC member responded there are a few 'known' causes of antepartum hemorrhage and suggested that part of the confusion is per literature antepartum hemorrhage really means any antepartum bleeding. There are known causes of antepartum bleeding that do not resolve and would not risk a person out (e.g., cervical polyp that causes bleeding during intercourse.)
- RAC member suggested via chat, "I think moving to the LDM language for consult would be a simple solution."
- RAC member via chat stated that consultation would be perfect because there are many reasons for bleeding some of which are benign.

POLL: Move recurrent antepartum hemorrhage to consultation

Results:

- 78% - I can say an enthusiastic yes to the recommendation (or action).
- 22% - 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.

Prelabor Rupture of Membranes > 24 hours

RAC member stated that this is a consult criterion in the Health Evidence Review Commission (HERC) guidelines. There is no reason why this should be an indication to transfer. The risk around prelabor rupture of membranes (PROM) is complex and deserves informed choice between client and midwife.

- RAC concurred and restated this is a complex issue which a midwife will discuss the risks with their client and chart. There is clear data on the safety of expectant management with PROM up to 72 and even 96 hours. Would support removing from the absolute risk factor table.
- RAC member concurred with comments and suggested removing reference to hours or possibly include 'with signs of infection.' RAC member further suggested that the risk factor be removed altogether and should not be either an absolute risk factor or consultation requirement as this condition is something that is dealt with all of the time.
- Additional suggestions noted by RAC members via chat included:
    - PROM with signs of infection or beyond 72 hours
    - Consult should be at 48-72 hours
    - Consult at 48 hour or transfer with signs of infection
    - No absolute and no consultation – don't want client to go anywhere where additional microbes could cause infection.
    - Prolonged PROM
- RAC member disagreed with suggestion that PROM include reference to infection. Infection is already an indication for transfer. It was further stated that PROM should not be in any risk factor table, but if it was listed it should be under consultation.
- Several RAC members commented via chat agreement with above statement.

POLL: Move prelabor rupture of membranes > 24 hours to consult.

Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - 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.
- 13% - 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.
- 63% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Refractory hyperemesis gravidarum

RAC member stated that its important that the definition of 'refractory' be understood. Hyperemesis gravidarum should not be a 'risk out' however 'refractory hyperemesis' (when treatment is not effective; significant weight loss) should be a risk factor. It needs to be clear that hyperemesis alone does not risk someone out, but refractory would.

- RAC indicated via chat that hyperemesis gravidarum (HG) is defined as extreme vomiting during pregnancy associated with electrolyte imbalance, five-percent weight loss, or ketosis. It is estimated that this condition occurs in 0.3 to 10 percent of pregnant women, with a 0.8 percent hospital admission rate.
- RAC member indicated that persons with HG are managed at birth centers (IVs). Women with extreme vomiting can be cared for. The rule needs to be clearer.

- Staff noted that referring to 'refractory' means the persons is not responding to treatment and decompensating. RAC member concurred and noted that the literature clearly defines it as not a typical HG which can be severe, but refractory means it is unresponsive to treatment and could lead to eclampsia and other risk factors.
- RAC member via chat indicated that clients are typically already co-caring by the time of labor/birth and not able to even walk and not birthing out-of-hospital. HG is managed with IVs in labor and very different issue. HG should not be included.
- RAC member suggested changing to "Refractory hyperemesis gravidarum unresponsive to treatment." RAC member stated it would be redundant to have both refractory and unresponsive to treatment since refractory is defined as unresponsive to treatment.

POLL: Retain *REFRACTORY* hyperemesis gravidarum as an absolute risk factor

Results:

- 56% - I can say an enthusiastic yes to the recommendation (or action).
- 44% - 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.

Wrap Up

There will not be a December meeting. Next meeting is scheduled for January 10th at 1:00 p.m. Tables II and III are future agenda items.

- RAC member via chat inquired about plan for discussing risk factors that were previously deferred, e.g., VBAC. Staff responded that there are a few risks that will need to be discussed and brought back. RAC member noted that there are few risk factors in Table I that were not discussed at all and a meeting to discuss only these risk factors should be considered.
- Staff noted that a meeting poll will be sent out for a March meeting since February is legislative session. **Follow-up: After the RAC meeting, a decision was made to try and convene a February meeting if possible and meeting polls for February and March were sent to the RAC.**

RAC adjourned at: 11:55 a.m.

PUBLIC HEALTH DIVISION
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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.

Hemorrhage – Hypovolemia, shock, transfusion required

- 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.

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement

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Birthing Center Rule Advisory Committee
February 15, 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
Stefanie Rogers	Providence
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Christina Clay	Care Oregon/Alma Midwifery
Debbie Cowart	Growing Family Birth Center
Ray Gambrill	AllCare Health
Sharron Fuchs	Public
Stefanie Bates	Public
Tracy Lawson Allen	Midwife; Administrator OABC; Public
Wendy Smith	Legacy Emanual; Board of DEM

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
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement

Welcome and Overview
Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and other interested parties 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.

January 10, 2022 Meeting Notes

RAC members were asked via e-mail to submit any comments on proposed changes to the January 10 meeting notes by e-mail.

Overview of Agenda

Dana Selover reviewed agenda. The goal is to get through Table II and discuss framing future conversations to wrap up Table I. Additionally, it was noted that there remain a few outstanding action items from the OAR rule text that need to be reviewed (e.g., dietary services.)

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

D. Selover noted that based on feedback from the January RAC meeting, Table II was revised removing references to "consideration." It was further clarified that changes to the risk criteria based on the January discussion were not changed yet, only the title to the table. Therefore, for voting purposes, Table II consists of risk factors that would require transfer to a hospital.

Laceration requiring hospital repair:
- Cervical or 3rd or 4th degree trauma
- Extensive vaginal

RAC member indicated that these risk criteria are an important example where different provider types working in a birthing center have different scopes of practice. While this may be an appropriate criterion for a Licensed Direct Entry midwife (LDM), a Certified Nurse Midwife (CNM) or Naturopathic Physician (ND) may have the experience and scope to perform laceration repairs. Additionally, the equipment needed to do these repairs could be available in a birthing center. Retaining these criteria in the standards should reflect information about the provider and scope.

- RAC members commented on the availability of providers to come to a home or birthing center to repair a 3rd degree laceration.
- RAC member noted that "extensive vaginal repair" is too broad, for example there may be an extensive, 2nd degree repair that would be within provider scope.
- Several RAC members via chat concurred with comments above.
- D. Selover summarized that this is more an issue of scope of practice and capability versus equipment requirement. It was noted there are likely lighting and sterilization requirements and OHA staff would need to look further into equipment requirements. Examples of equipment from RAC member included lighting, firm surface and possibly retractors.

D. Selover noted that since there is nothing in the tables that refer to scope of practice what language should be considered for this risk criteria? The following suggestions were noted via Chat:

- Laceration requiring repair that exceeds scope and experience of provider
- Laceration repair at your level of knowledge, skills and ability
- Laceration requiring repair that exceeds available provider skill level

D. Selover thanked RAC members for feedback and noted that the program will need to seek advice from legal counsel on the proposed suggested language.

No poll was administered.

Retained Placenta > 60 minutes
The current proposed language is based on 2015 HERC. RAC member asked other members whether anyone had any issues with the current Birthing Center table requirement. The following differences were identified between HERC, current PHD OAR, and current DEM OAR.

2020 HERC	OAR 333-076 Current Table III	DEM OAR 332-025-0021 (11)(v)
Placental conditions - Retained placenta > 60 minutes	Retained placenta or incomplete placenta, with bleeding; suspected placenta accreta; retained placenta >3 hours	Retained placenta

D. Selover asked RAC to consider the risks and benefits for each of the different criteria noted above.

- RAC member noted that 60 minutes versus 3 hours may be based on the mother's condition and what may be occurring (e.g., breastfeeding, laceration repair, etc.) A mother may have a retained placenta and still be stable after 60 minutes, thus the value of requiring a transfer right at 60 minutes is unclear. RAC member indicated support of retaining the 3-hour maximum or a time period between 60 minutes to 3 hours if data is available to support.
- RAC member provided some background from the LDM discussion:
  - Provider judgement
  - Accepted definition is 60 minutes however, for purposes of an investigation, the chart would need to clearly document the justification of why a different decision was made
  - Flexibility and provider responsibility for assessment
- RAC members concurred with comments above via Chat.
- D. Selover noted that an investigation in a birthing center setting is different than at professional license level. Actions taken when placenta is retained for greater than 60 minutes, i.e. calling 9-1-1, transport time to hospital, etc. may add additional time.
- RAC member stated via Chat that they concurred with comments from RAC member and provided an example of woman who is not bleeding, is nursing baby, whose vitals remain normal, and then after 45 minutes provider starts to deliver placenta and it is finally expelled after 65 or 70 minutes.
- D. Selover inquired whether the literature, or by experience, indicates a time that a transfer must be taken (no later than?); CABC? Other?
  - RAC member noted that 60 minutes is the evidence, but it does not mean the placenta needs to be out exactly at 60 minutes, rather the provider needs to take action if it is not out at that point.

- Staff indicated that not having a time frame will make it difficult for an investigation. At what point does some action need to take place?
- RAC member suggested that the language be updated to reflect that the placenta does not need to be out at 60 minutes rather a provider action is taking place to get the placenta out.
- RAC member suggested via Chat that the 3-hour time frame is reasonable as a place to draw a hard line.
- RAC member suggested via Chat including language about active management after an hour. Providers all know that transfer is needed for a hemorrhage that is not under control.

- Staff noted for purposes of voting consider that a provider takes action at 60 minutes and the placenta may be expelled after 70 minutes, how may the RAC vote?

POLL: Retain "Retained placenta" as a mandatory transfer criteria. Results:

- 11% - I can say an enthusiastic yes to the recommendation (or action).
- 22% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 33% - 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.
- 11% - 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.
- 33% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Temperature ≥ 38.0º C (100.4º F)

Staff noted that DEM rules are different with respect to temperature as follows:

OAR 332-025-0021(11)(f) – Indication to Transfer Intrapartum

- Two temperatures at 100.4 degrees Fahrenheit or 38 degrees Celsius or greater within one hour; or
- One temperature at 102.2 degrees Fahrenheit or 39 degrees Celsius or greater.

D. Selover noted that 2020 HERC requirements specify: Maternal temperature ≥ 38.0 degrees Celsius in labor/postpartum

RAC member stated that the LDM rule is preferred because there are situations where someone could temporarily have an increased temperature due to other passing issues such as being in the tub too long. D. Selover asked whether that was based on guidance or other literature. RAC member did not recall but indicated part of it is clinical experience. D. Selover further noted that a 'fleeting temperature' is different than actually having an ongoing temperature.

RAC member comments via Chat included:

- Risk factor should include "unresponsive to treatment or unrelated to known causes like cytotec."

- "Pitocin will temporarily elevate maternal temp, so it's common to wait for the dose to wear off and recheck temperature. I meant miso[prostol]."
- "A single elevated temperature of 38 or greater does not meet the definition of a fever.
- "Can we change it to say fever not temperature?"

RAC member indicated that modeling language after the Board of DEM rules would work, one hour is a reasonable amount a time for medications to wear off and get a more accurate reading including considering other factors such as being in a tub.

Additional comments from RAC member via Chat:

- "I have experienced a client with a cytotec fever that lasted 3 hours."
- "Current birth center laws are good. They give you that leeway needed for waterbirth. 101."

RAC member suggested referencing 'unresolved' or 'persistent' but concurred with LDM language.

RAC member indicated that temperature is trying to address infection and as discussed other things may cause an elevated temperature. In any setting, it is not necessarily treated until it reaches the definition of a fever. An isolated temperature at a hospital is not necessarily going to be treated any differently. RAC member indicated the LDM language makes a lot of sense.

D. Selover called for vote as drafted:

<u>POLL: Retain "Temperature ≥ 38º C (100.4º F) as a mandatory transfer criteria. Results:</u>

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 11% - 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.
- 22% - 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.
- 67% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>Chorioamnionitis or other serious infections including but not limited to:</u>
<u>- Cytomegalovirus (CMV)</u>
<u>- HIV</u>
<u>- Rubella</u>
<u>- Toxoplasmosis</u>

Staff noted that HIV – Known and unknown status was discussed under Table I.
D. Selover noted that HERC guidance under infectious conditions has Chorioamnionitis listed separately as well as Toxoplasmosis.

- RAC member via Chat indicated that chorio should be separately from other infections.

- RAC member concurred with Chat comment and noted that Chorioamnionitis really should be separate from the rest of the listed risk factors and stated no objection to chorioamnionitis. CMV, Rubella and Toxoplasmosis make sense but are prenatal not intra or post-partum and belong in one section. HIV is a totally different topic and also prenatal. A person with well controlled HIV could be a birth center candidate with good PPE.
- D. Selover noted that if the infection is listed in Table I it may not be necessary to list in Table II.
- RAC member agreed that conditions should stay in prenatal except chorio and chorio should be changed to persistent and unresolved signs because sometimes signs of chorio may resolve. Via Chat, this RAC member indicated "Other infections should be dealt with prenatally and need a consult." Further stated, "Suggested language: Persistent unresolved signs of Chorioamnionitis."
- RAC member stated both for discussion and via Chat that CMV, Rubella and Toxoplasmosis would generally not be found intrapartum even in a hospital setting. If someone comes in without labs, they might run a prenatal panel which would have HIV and Rubella but the overwhelming majority of times that is a prenatal issue and is probably not needed on this table.
- RAC members concurred via Chat.

D. Selover called for vote for each risk factor as currently written. For purposes of Chorioamnionitis, it is assumed that this condition has been diagnosed and that language such as persistent or unresolved is not necessary.

POLL: Retain "Chorioamnionitis" as a mandatory transfer criteria. Results:
- 44% - I can say an enthusiastic yes to the recommendation (or action).
- 22% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 22% - 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.
- 11% - 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.

POLL: Retain "Rubella" as a mandatory transfer criteria. Results:
- 33% - I can say an enthusiastic yes to the recommendation (or action).
- 11% - 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.
- 33% - 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.
- 22% - 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 "Known HIV positive status" as a mandatory transfer criteria. Results:

- 11% - I can say an enthusiastic yes to the recommendation (or action).
- 11% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 11% - 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.
- 33% - 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.
- 33% - 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 "Toxoplasmosis " as a mandatory transfer criteria. Results:

- 13% - I can say an enthusiastic yes to the recommendation (or action).
- 13% - 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.
- 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.
- 25% - 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 "CMV" as a mandatory transfer criteria. Results:

- 11% - 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.
- 11% - 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.
- 67% - 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.
- 11% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

A RAC member via Chat indicated that the infections voted upon need to be in a prenatal consultation category and RAC members via chat concurred.

Failure to progress/failure of head to engage in active labor

RAC member recommended removing the reference to failure of the head to engage as with multiples it is more common for the head not to engage than to engage. Recommended adoption of the LDM rule with failure to progress because they are more specific. "Failure to progress" may be defined in many ways.

- LDM rule states, 'lack of adequate progress in second stage with cephalic presentation, which means no descent after a maximum of three hours of active pushing in cases with complete dilation and ruptured membranes.'

RAC member indicated that this risk factor is more appropriate for specific provider practice standards or rules. Something this vague (failure to progress/failure of head to engage) should not be in a facility type rule. This is subjective and provider judgement and would be difficult to define.

RAC member concurred with previous comments. It can be normal for a multiple to not have head engage and the failure to progress could be a reason to transfer but would be hard to do a chart review and say at what point someone was classified as "failure to progress." There are more standard definitions in second stage not in first stage and even 'active labor' has changed over time. It may be reasonable to remove entirely.

D. Selover noted that any change to this should be based not only on comments about practice but relevant literature. Taking it out would be in conflict with both HERC and LDM rules.

- RAC member stated that the issue is there is no agreed upon definition of 'failure to progress' and it is an area of active debate in the literature, among professional organizations and is constantly changing. It's important to note that in the LDM rule it only relates to second stage. Birth center rules should have a clear delineation of things that should not occur at a birth center. RAC member noted that even LDM rule has been an issue in terms of investigations. Taking it out of Birthing Center rules does not change the requirement that an LDM must follow LDM rules.
- D. Selover responded that this is an example of where it is being approached from a medical-legal perspective versus risk factor perspective and really good justification to change is needed.
- RAC members via Chat commented:
  - We have enough other rules where we would transfer someone if lack of progress was causing issues.
  - Failure to progress according to whom or which graph?
  - The definition would be so broad
- RAC member indicated that the only way to make clear would be to define active labor and add 'along with non-reassuring heart rate tones' which is already covered and as such would be redundant. She further agreed that it should be removed altogether or possibly align with LDM rules. RAC member commented that in most cases with bad outcomes related to prolonged labor, there are probably other factors going on like chorioamnionitis, un-reassuring heart rate tones, or other clearly defined factors.
- RAC members via Chat commented:
  - Agree that failure to progress is very vague. We have specific policies and procedures related to prolonged early, active, and second stage labor. Mostly related to maternal and fetal stability and maternal consent to continue with labor at the birthing center.
  - If risk factor remains it should be failure to progress in second stage only.
  - Failure to progress is unacceptably vague. This should mirror the LDM rule for consistency and because it defines "lack of adequate progress."

D. Selover called for vote:

POLL: Retain "Failure to progress" as a mandatory transfer criteria. 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.
- 11% - 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.
- 89% - 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 "Failure of head to engage in active labor" as a mandatory transfer criteria. 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.

RAC member noted that as members vote on different sections, a lot of discussion and inability to reach agreement is because there are different provider scope types that need to be addressed. Rules would be less complicated by just including language that acknowledges 'within provider's defined scope and experience.' It was further noted that there are too many different layers that must be complied with - Birth Center licensing, LDM licensing and OHP licensing. It feels like the BC licensing rules restrict not only LDMs, but CNMs and other people working in birth centers. D. Selover acknowledged and reminded RAC that Birthing Centers are limited in statute to low risk births and provider types are not subject to that same restriction. D. Selover noted that the birthing community could work with the Oregon legislature to change that limitation. The HERC requirements, the provider requirements and the Birthing Center requirements all must abide by their respective statutory authorities.

Prolapsed umbilical cord

RAC member commented via Chat, "transport"

D. Selover called for vote:

POLL: Retain "Prolapsed umbilical cord" as mandatory transfer criteria. Results:

- 100% - 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.

Repetitive or persistent fetal heart rate patterns

RAC member stated that this language is not clear enough and may be in another section which addresses non-reassuring fetal heart rate tones. There are some arrythmias that 'act up' during labor and become more persistent but would not necessitate a transfer. It was suggested that an absolute transfer criteria should reflect "non-reassuring or fetal compromise" and have arrythmias or persistent fetal rate be a consult criteria.

D. Selover noted this is intrapartum condition.

RAC member shared on behalf of another birthing center owner that could not attend the RAC to consider adding reference to unresponsive to treatment.

RAC member via Chat shared that PACs are an example of a persistent abN fetal heart rhythm that does not necessarily require transfer.

D. Selover called for vote:

POLL: Retain "Repetitive or persistent abnormal fetal heart rate pattern" as a mandatory transfer criteria. Results:

- 75% - I can say an enthusiastic yes to the recommendation (or action).
- 13% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 13% - 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.

Uterine rupture, inversion or prolapse

RAC member remarked that "prolapse" should be removed entirely or moved to a different section as there are different variants of prolapse, some of which may require physical therapy in the post-partum period. A prolapse could be moved to consult. A uterine rupture or inversion would be a mandatory transfer.

RAC member concurred with comment above and indicated that since rupture and inversion are so different, they should be listed by themselves.

RAC member concurred with separating out.

RAC member remarks via Chat:

- Prolapse under consult or take out
- Prolapse should be under consult not transfer
- Uterus prolapse procidenta is a transfer

D. Selover called for vote:

POLL: Retain "Uterine rupture" as a mandatory transfer criteria. Results:

- 100% - 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.
- 0% - 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 "Uterine inversion" as a mandatory transfer criteria. Results:

- 78% - 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.
- 22% - 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.

POLL: Retain "Uterine prolapse" as a mandatory transfer criteria. Results:

- 11% - 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.
- 33% - 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.
- 56% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Thick meconium staining of amniotic fluid

RAC member noted that data is clear that meconium in absence of fetal distress and other things can be well-managed in the out-of-hospital setting and it should be removed as NRP does not recommend suctioning of the perineum anymore. Meconium by itself should not necessitate a transfer.

RAC members via Chat indicated agreement with comment above.

D. Selover called for vote:

POLL: Retain "Thick meconium staining of amniotic fluid" as a mandatory transfer criteria.
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.

Planning for Future Meetings

Given time frame left. D. Selover suggested that the March meeting be changed to complete Table II and bring back some of the remaining rule language, such as dietary services.

- RAC member agreed with plan to get through rest of risk factors in Table II and circle back to the Table I deferred risk factors. RAC member asked whether additional time would be granted to submit additional material for the topics to be discussed. RAC member further suggested that in order for the meetings to be meaningful and robust, it would be important for people who believe these risk factors should be included in the new tables to be present to be able to articulate concerns that are driving their inclusion. It was further asked that OHA include persons who can speak to the inclusion of these risk factors on the Table to articulate concerns and allow persons to respond to those concerns as well as have experts on the data present who can speak to what the safest rule is going to be.
- D. Selover indicated this would be discussed further at the March meeting and yes, the deadline to submit material will be extended and information will be shared by e-mail.

Wrap Up

RAC member shared concern that there was confusion on the vote for retained placenta. RAC member asked what was voted on. D. Selover responded that knowing that the evidence states 60 minutes, the vote was to keep. **Follow-up: Discussion and vote for retained placenta greater than 60 minutes is noted on pages 3 and 4.**

It was noted that staff will work on preparing a document that identifies RAC member vote outcomes.

RAC member asked to re-vote on this risk factor. It will be considered for the next meeting.

Next meeting is scheduled for March 8 at 1:00 p.m.

RAC adjourned at: 2:50 p.m.

PUBLIC HEALTH DIVISION
Office of Health Care Regulation and Quality Improvement

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Birthing Center Rule Advisory Committee
March 8, 2022
1:00 p.m. via Zoom

RAC MEMBER ATTENDEES	
Danielle Meyer	Oregon Association of Hospital and Health Systems
Desiree LeFave	Bella Vie Gentle Birth Center (Administrative)
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 (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
Stefanie Rogers	Providence Hospital
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Christina Clay	Care Oregon/Alma Midwifery
Kori Pienovi	Women's Healthcare Associates' Midwifery Birth Center
Melissa Kaiser	Women's Healthcare Associates' Midwifery Birth Center
Molly Okerman	Women's Healthcare Associates' Midwifery Birth Center
Ray Gambrill	AllCare Health
Sharron Fuchs	Public
Stephanie Bates	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
Jason Gingerich	Health Evidence Review Commission
Lacey Martinez	PHD-Health Facility Licensing and Certification
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Rebecca Long	PHD-Emergency Medical Services & Trauma Systems Program
Samie Patnode	PHD-Health Licensing Office

DRAFT

Welcome and Overview

Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and other interested parties 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.

February 15, 2022 Meeting Notes

RAC members were asked via e-mail to submit any comments on proposed changes to the February meeting notes to Mellony Bernal by e-mail. **Follow-up: Corrections have been made to list of attendees for the February 15th meeting.**

Overview of Agenda

D. Selover reviewed agenda. The goal is to get through the remainder of Table II, review some changes to administrative rule text based on previous RAC discussions, and discuss structure of next RAC meeting.

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

D. Selover reminded RAC members that Table II was revised removing references to "consideration." Therefore, for voting purposes, Table II consists of risk factors that would require transfer to a hospital.

Postpartum/Newborn
Congenital anomalies (unexpected, significant or life-threatening)

RAC member remarked that while this is a situation where the intent and prognosis is for the baby to live and need special care after birth, there are many kinds of congenital anomalies, including anomalies that are incompatible with life and which are known. It would be appropriate for a client to choose a birth center birth knowing the outcome.

Further discussion:

- RAC member concurred with comment above and asked that the wording be changed to consider scenario.
- RAC member indicated via Chat that the term "significant" is open to interpretation. "Life-threatening is meaningful but should also include known anomalies incompatible with extrauterine life."
- D. Selover inquired about the Board of DEM, Licensed Direct Entry Midwives (LDM) rules. Health Licensing Office (HLO) staff remarked and noted via Chat the LDM rules specify that "evident or suspected major congenital anomaly" is an indication for consult. D. Selover further noted that HERC requires a consult.
- Staff noted that if unexpected is modifying both significant and life-threatening than an "expected life-threatening anomaly" would not fall under this category.

- RAC member stated that if a family wanted non-intervention for an infant with, for example Trisomy 13, it would be appropriate to allow a consultation and gives the family an option to make an informed decision. An infant with a congenital heart lesion for example, should be delivered at an inpatient facility. Consult would be appropriate as each congenital anomaly is different and a plan should be developed for the family.
- RAC member remarked that criterion should be reworded or moved to consultation.
- The following comments were provided via Chat by RAC members:
  - Change risk factor to a consultation requirement
  - Language is confusing. The factors could be clearer, and consult would be a better option for families and providers
  - Move to consult to protect families' choices
  - Clearer language is needed
  - Change to "Congenital anomalies life-threatening (unless known anomaly not compatible with life)

POLL: Retain "Congenital anomalies (unexpected, significant or life-threatening)" as a mandatory transfer criterion. Results:

- 0% - 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.
- 18% - 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.
- 64% - 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.
- 9% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Excessive bruising, enlarging cephalohematoma, significant birth trauma

RAC member suggested that these criteria are very different and should be separated. It was stated that enlarging cephalohematoma or significant birth trauma would be transported; however, excessive bruising may result in a consult, treatment or watched. It was suggested that excessive bruising be removed.

Further discussion:

- RAC member also suggested removing excessive bruising stating it's a risk factor for jaundice which most midwives are aware of and follow recommendations. RAC member supported transfer requirement for both enlarging cephalohematoma and significant birth trauma.
- RAC members via Chat shared the following:
  - Should be a consult
  - Agree with moving 'excessive bruising' to consult
  - Significant birth trauma is too vague for transfer criteria; don't know what it means; depending on the actual intent could support
  - Agree with above statement; needs further clarification

- [Significant birth trauma] Needs improvement because it's too vague
- Several additional RAC members concurred that significant birth trauma is too vague.

POLL: Retain "Excessive bruising" as a mandatory transfer criterion. Results:
- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 8% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 8% - 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.
- 17% - 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.
- 67% - 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 "Enlarging cephalohematoma" as a mandatory transfer criterion. Results:
- 50% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 17% - 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.
- 8% - 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.

POLL: Retain "Significant birth trauma" as a mandatory transfer criterion. Results:
- 25% - I can say an enthusiastic yes to the recommendation (or action).
- 50% - 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.
- 25% - 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.

Hyperglycemia or hypoglycemia unresponsive to treatment

D. Selover noted that 'unresponsive to treatment' refers to both hyper- and hypoglycemia.

RAC member agreed with keeping hypoglycemia unresponsive to treatment as a transfer criterion. It was noted that clients with significant glucose issues are not seen so hyperglycemia is something that is not seen a lot.

Further discussion:

- Hyp**er**glycemia may be seen in extremely low birth weight infants or sometimes early with sepsis (glucoses of 200 or 300) which need a more thorough evaluation. It is very rare but if real can signify bad things.
- RAC member indicated support of keeping both criteria.
- RAC member via Chat indicated "I don't know what the "birth center Rx" would be for hyper- we treat hypo- KEEP"

POLL: Retain "Hyp**er**glycemia unresponsive to treatment" as a mandatory transfer criterion.
Results:
- 75% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - 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.

RAC member stated concerns with wording, 'Hyperglycemia unresponsive to treatment.' If a birth center has a hyperglycemic infant, it is not within scope to treat in a birth center. It was questioned whether the wording gives allowance for trying to bring a baby's blood sugar down in a birth center setting; stating just "hyperglycemia" should be adequate.

Further discussion:
- RAC member responded that it would be an exceedingly rare occurrence and it would be reasonable for a provider to recheck a glucose with an infant that appears to be well and not transport right away. The RAC member concurred that there is not a lot in terms of treatment that a birth center can do, but the wording and intent is appropriate.
- RAC member via Chat indicated an individual can always act more conservatively.
- D. Selover noted that the language does not say you must treat before transfer. Different actions may be taken based on whether there are multiple factors going on and clinical judgement does play a role.
- RAC member noted that she is hoping that the language does not give the impression that a birth center can delay transfer for an infant who is hyperglycemic and waste valuable time getting the infant treated.
- RAC member via Chat indicated a change in vote from a 5 to a 1.

POLL: Retain "Hyp**o**glycemia unresponsive to treatment" as a mandatory transfer criterion.
Results:
- 75% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - 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.

Hypotonia, tremors, seizures, hyperirritability

HLO staff noted that LDM rules indicate that seizures and significant hypotonia is an indication to transfer. Hyperirritability and tremors are not listed in the LDM rules for consult or transfer.

RAC member suggested via Chat that 'tremors' and 'hyperirritability' are too subjective and recommended removing. Hypotonia and seizures should be kept as mandatory transfer.

Further discussion:

- RAC member shard examples and commented that the 'immature system of the baby sometimes will do that [seizures]' and suggested that consult be considered when [seizures] are considered benign. RAC member responded that true seizures (versus tremors) likely indicate a significant need for evaluation (such as neonatal stroke) that needs intervention whereas tremors or irritability would not be an indication for any sort of mandatory consult or transfer because those can be normal in newborns. She further indicated support of mandatory transfer for hypotonia and seizures and agreed with the Board of DEM criteria that tremors and hyperirritability are very vague and should be removed.
- Another example was shared and RAC member responded that generalized seizures are more concerning for a hypoxic injury and focal seizures would be more concerning for some intracranial pathology and may not be benign. True seizures need to be confirmed with EEG criteria to confirm an electrographic correlate.
- RAC commented and shared via Chat recommendation to reword as mandatory transfer for seizures and significant hypotonia and remove tremors and irritability. Several RAC members via Chat agreed with recommendation.
- RAC member concurred with comments about keeping seizures and hypotonia and removing tremors and irritability but questioned hypotonia for example in an infant with down syndrome who might have hypotonia or hypotonia right after birth that resolves within 10-15 minutes. RAC member responded that she interpreted the text to mean unexplained hypotonia, not an infant who has hypotonia related to an infant, for example, who is given glucose gel and hypotonia resolves.
- RAC members suggested via Chat changing to 'persistent hypotonia' or 'persistent, unexplained hypotonia.'

<u>POLL: Retain "Hypotonia" as a mandatory transfer criterion. Results:</u>

- 8% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren’t necessary.

- 17% - 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.
- 33% - 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.
- 8% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>POLL: Retain "Tremors" as a mandatory transfer criterion. Results:</u>
- 17% - I can say an enthusiastic yes to the recommendation (or action).
- 8% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 8% - 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.
- 25% - 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.
- 42% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>POLL: Retain "Seizures" as a mandatory transfer criterion. Results:</u>
- 75% - I can say an enthusiastic yes to the recommendation (or action).
- 17% - 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.
- 8% - 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.

<u>POLL: Retain "Hyperirritability" as a mandatory transfer criterion. Results:</u>
- 8% - 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.
- 25% - 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.
- 33% - 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.
- 33% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>Low Apgar score - <5 at 5 minutes; <7 at 10 minutes</u>

HLO Staff via Chat noted that LDM rules specify an Apgar less than seven at 10 minutes of age is a transfer.

RAC member indicated that most birth centers have in their policies and procedures a low Apgar of 4 or less at 5 minutes, 9-1-1 is always called, but there are times that once EMS is on scene the baby is improving and is not transferred. She further indicated that less than 7 at 10 minutes should be a transfer.

Further discussion:

- RAC member via Chat concurred with comment above.
- RAC member noted that Apgar's are subjective and not firmly associated with outcomes; however, the recommendations are reasonable, and comfortable keeping both. Less than 5 at 5 minutes is most important.
- Several RAC members via Chat concurred with comment above.

POLL: Retain "Low Apgar score <5 at 5 minutes" as a mandatory transfer criterion. Results:

- 25% - I can say an enthusiastic yes to the recommendation (or action).
- 50% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 17% - 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.
- 8% - 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.

POLL: Retain "Low Apgar score <7 at 10 minutes" as a mandatory transfer criterion. Results:

- 25% - I can say an enthusiastic yes to the recommendation (or action).
- 42% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 17% - 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.
- 17% - 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.

RAC member inquired if at the time EMS arrives and the baby is stable and appears to be well, would this mean that the birth center would not need to transfer? D. Selover responded that it depends, and providers can work within their clinical practice. Providers should be watching more than just the Apgar and should be able to work with this. A complaint investigation is going to look at more than just the result of an Apgar score. RAC member suggested that additional language should be considered that clarifies that a clinician can decide not to transfer if infant is improving.

RAC member via Chat indicated:

- [Table II] were forcing functions, otherwise [risk criterion] would be recommendations.

- Adding 'not improving' makes all the difference on Apgar's. Parents won't want to send a well-baby to hospital, even if they had a low Apgar and now, they are pink and crying.
- RAC member concurred with comment above.

Respiratory or cardiac irregularities, cyanosis, pallor

HLO staff noted that the LDM rules specify the following:

- Indication for consult – Newborn includes persistent cardiac murmur, respiration rate greater than 100 within the first two hours postpartum, and greater than 80 thereafter, lasting more than one hour without improvement.
- Indication for transfer – Newborn includes central cyanosis and unresolved pallor at birth.

RAC member noted that a baby with central cyanosis is transferred. It is unclear what a baby with cardiac irregularity means (a baby with a murmur?) and should be reworded.

Further discussion:

- RAC member remarked that there is a wide variety of what that could be [cardiac irregularity] and how it would be interpreted. TPN given as an example or murmur. RAC member further indicated that some of these irregularities may be addressed through a pediatric consult.
- RAC member concurred via Chat with comment above.
- HLO Staff noted that the Board of DEM did consider certain types of health care provider requirements for consultations, however for the risk factors noted there were no specific provider requirements.
- RAC member supported the vagueness in the criterion 'respiratory or cardiac irregularities' rather than murmur. A murmur should be evaluated by a pediatrician via consult and shouldn't need to be transferred to the hospital. The respiratory rate in the LDM rules is supported and adds good clarity and is reasonable. Cyanosis should be revised to indicate 'central cyanosis.' Pallor does not add a lot and is very subjective. Maintaining cardiac irregularities is appropriate (example provided of recent transfer from midwife for evaluation of premature atrial contractions and abnormal heart rate). This would not preclude a home delivery.
- RAC member remarked and via Chat suggested that it would be helpful to add something about the Critical Congenital Heart Disease (CCHD) screen. Would failing the CCHD screen be a better indicator for the newborn who needs transfer to a hospital?
- RAC members via Chat indicated the following:
  - Adding “unresolved” would help with clarification
  - Agree that 'respiratory and cardiac irregularities' is too vague
  - Agree that 'unresolved' would help clarify
  - Agree that 'irregularities' is too vague
  - Add "central" to cyanosis vs acrocyanosis
  - Support Board of DEM language and amending to central cyanosis
  - CCHD is a consult versus transport as it is done after 24 hours
  - Agree with LDM rules
  - Change cardiac to "significant cardiac irregularities"
  - Add "or signs of respiratory distress unresponsive to treatment"

Staff noted that for purposes of polling, RAC members vote on the following:

POLL: Retain "Respiratory or cardiac irregularities" as a mandatory transfer criterion. Results:

- 8% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - 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.
- 42% - 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.
- 17% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Staff noted that for purposes of polling, RAC members vote on the following:

POLL: Retain "Central cyanosis" as a mandatory transfer criterion. Results:

- 50% - I can say an enthusiastic yes to the recommendation (or action).
- 25% - 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.
- 25% - 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.

POLL: Retain "Pallor" as a mandatory transfer criterion. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 10% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 20% - 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.
- 40% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Temperature instability, fever, suspected infection or dehydration

HLO staff noted via Chat the LDM rules state, 'persistent inability to maintain temperature between 97 to 100 degrees Fahrenheit or 36 to 37 degrees Celsius' and 'Evident or suspected infection' are indications to transfer for newborns. Dehydration is not specifically listed.

- Several RAC members via Chat agreed with the DEM wording indicating it makes it much clearer.
- RAC member commented and indicated in Chat that 'dehydration' doesn't belong with the other factors and recommended separating the risk factors. Additionally, she indicated support of removing dehydration.
- RAC member agreed with comment above and asked for clarification around time frame for temperature instability. The language is too vague.
- RAC member via Chat indicated 'leave fever and infection – the other two do not belong here.
- RAC member via Chat stated, "What is to keep suspected infection to include thrush? Too vague."

Staff noted that for purposes of polling, RAC members vote on the following:

<u>POLL: Retain "Temperature instability or fever" retain as mandatory transfer criteria. Results:</u>

- 8% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 25% - 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.
- 17% - 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.
- 17% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>POLL: Retain "Suspected infection" as mandatory transfer criterion. Results:</u>

- 75% - I can say an enthusiastic yes to the recommendation (or action).
- 17% - 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.
- 8% - 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

<u>POLL: Retain "Dehydration" retain as a mandatory transfer criterion. Results:</u>

- 0% - 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.
- 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.

- 36% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Vomiting/Diarrhea

HLO staff noted via Chat that the LDM rules indicate "persistent projectile or bilious vomiting or emesis of fresh blood" is an indication to transfer. Diarrhea is not specifically listed.

RAC member commented that it is common for an infant several hours after birth to "choke up something" and questioned whether that would be considered vomiting. Support for the Board of DEM language was indicated.

Further discussion:

- Via Chat, RAC member noted that it is common for babies to vomit birth fluid and mucus.
- RAC member commented that the DEM criteria could be supported and vomiting, or diarrhea do not indicate a need for transfer.
- RAC members via Chat stated:
  - Vomiting and diarrhea are too vague. LDM rules would be ok to include.
  - Agree with projectile and bilious vomiting is being an indicator.
  - "We are LDMs (Licensed Direct-Entry Midwives not DEM's. When we discuss these rules, they are LDM rules, made by the Board of Direct-Entry Midwifery." **FOLLOW-UP – These meeting notes have been updated replacing 'Board of DEM rules' with LDM rules.**

POLL: Retain "Vomiting and diarrhea" as a mandatory transfer criterion. 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.
- 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.
- 73% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Weight less than 5th percentile for gestational age

HLO staff noted via Chat that the LDM rules indicate "weight less than 2,270 grams (five pounds)" is an indication to transfer.

RAC member commented that this factor should likely be removed. For a weight less than the 5th percentile, the provider should ensure that the infant stays normal glycemic and normal thermic and if they can do those things, it doesn't matter if their weight is less than the 5th percentile.

POLL: Retain "Weight less than 5th percentile for gestational age" as a mandatory transfer criterion. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 8% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 33% - 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.
- 33% - 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.
- 25% - 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 thanked RAC members for their comments and feedback. The OHA will take these comments into consideration. Members of the RAC and other interested parties will have an opportunity to comment on final proposed changes to the tables during the public hearing. D. Selover also thanked Samie Patnode for providing information on the LDM rules during this meeting.

OAR 333-077 Rule Text

M. Bernal provided an overview of the revised rule text which has been amended based on previous RAC discussions and input from RAC members.

- The different colors of rule text should be ignored.
- Underlined text means new language.
- Stricken text will be deleted.
- Text highlighted in yellow indicates changes from the initial version shared on May 30, 2019.

D. Selover noted that while there is a lot of highlighted yellow text, the OHA is asking for input on specific sections as noted below. Additional comments or feedback can be sent to Mellony Bernal via email at mellony.c.bernal@dhsoha.state.or.us.

OAR 333-077-0010 (6) and (7) – Definitions
OAR 333-077-0070 – Governing Body
OAR 333-077-0080 – Personnel

The terms clinical provider and clinical staff have been added and definitions proposed based on the Commission for the Accreditation of Birth Centers (CABC), Indicators of Compliance with Standards for Birth Centers. Conforming amendments using the terms have been made including in the rule related to Governing Body and Personnel.

- Clinical provider means a physician, certified nurse midwife or licensed direct entry midwife who are ultimately responsible for the clinical care of a client.
- Clinical staff means any individual among all staff who perform tasks or have responsibilities in clinical care.

Discussion:

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- RAC member stated via Chat that Naturopathic Doctor/Midwife would need to be added to the provider list unless it is included under the definition of physician. D. Selover responded that they have been included under the physician definition.
- RAC member indicated via Chat that definition of clinical provider would work for purposes of CNMs.
- No additional comments were provided by RAC members.

333-077-0100(8) – Client care services

Language has been added allowing a clinical provider to use telemedicine for prenatal and postpartum care after an initial, in-person assessment is completed and no risk factors or complications were identified. The rule further defines telemedicine and requires a set number of in-person assessments and proposes that telemedicine may not occur after 39 weeks, 6 days.

- A clinical provider may use telemedicine to provide prenatal and postpartum care to clients after completion of an initial, in-person assessment and no risk factors or complications were identified.
  (a) Telemedicine may be conducted through electronic and telecommunication technologies such as video communication, teleconference, landline or wireless communications. Synchronous communication between the clinical provider and the client is required.
  (b) A clinical provider must ensure that an in-person assessment is completed with the client at least two times between 28 to 36 weeks, and two times between 36 weeks to 39 weeks, 6 days.
  (c) Telemedicine may not be conducted after 39 weeks, 6 days.

Discussion:

- D. Selover reminded RAC members that Birth Center rules focus on patient health and safety while other agencies have rules specific for payment, insurance, etc. D. Selover asked whether Medicaid rules were reviewed to ensure there is no conflict. Staff indicated no and will follow-up.
- RAC member indicated that time periods for in-person assessment is unclear as 36 weeks is used in two places. It was also asked what the rationale was for not allowing telemedicine after 39 weeks, 6 days. Patients are being seen in person after this time period; however, if someone develops UTI symptoms after 39 weeks, 6 days a telehealth visit should be acceptable when a person can be sent to the lab and get treatment.
- RAC member noted that further clarification is needed where it states 'no risk factors or complications' have been identified. For example, a client with iron deficiency anemia can be considered a risk factor but doesn't necessarily mean that all visits need to be in-person. Consideration also needs to be given to persons who may test positive for COVID and as such needs to quarantine and couldn't have an in-person visit.
- RAC member via Chat concurred with above comment and noted that many pregnant women have been unable to come to clinic for suspected or confirmed COVID-19.
- RAC member commented that telehealth is one way to determine whether a client is a good fit for the agency and vice versa. It was questioned whether the first visit would

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need to be an in-person assessment when some first visits are a way to determine whether the client and birth center can work together. Staff noted that proposed rule language under OAR 333-077-0125 requires that an initial risk assessment be performed in-person within 21 calendar days of the initial prenatal care visit. RAC member via Chat asked that "in-person risk assessment visit" be considered for wording.

- D. Selover thanked RAC members for comments and encouraged members to submit suggested revisions to M. Bernal. She further indicated that consideration will be given to making the language more generic.
- **Follow-up – The suggested time periods for in-person visits was based on the American Academy of Pediatrics/American College of Obstetrics and Gynecologists, Guidelines for Perinatal Care, Eighth Edition – Frequency of Visits.**

333-077-0160 – Dietary Services

M. Bernal noted that the Dietary Services rule has been re-rewritten and proposed language is based on discussions with the Public Health Division's, Environmental Health Foodborne Illness Prevention Program. Consideration has been given based on previous remarks from RAC members to allow ordering from food delivery services and restaurants. Compliance with rigorous food sanitation rules, OAR chapter 333, division 150 was removed.

- RAC member asked that additional time be allowed to consider the dietary rule and bring forward additional comments at a future meeting. Some birth centers are located where food delivery is not an option and client dietary needs must be considered.
- RAC member stated that the proposed rule creates unrealistic restrictions in the birth center kitchens. When a facility is licensed, the kitchens are walked through as well. Concerns were noted about "individually packaged, single-serving foods" and "single service utensils."
- RAC member stated via Chat that single use utensils shouldn't be necessary or appropriate.

D. Selover asked that RAC members provide M. Bernal with suggested edits. She also asked whether there were additional rules that RAC members wanted to discuss.

- RAC member asked whether there is a requirement for a food handlers license in the proposed rule and staff responded no.

Planning for Future Meetings

D. Selover noted that the next meeting will be to discuss gestational age, multiple births, non-cephalic presentation and VBAC risk factors.

- RAC members were reminded that per statute, birthing centers are for low-risk births. The Health Evidence Review Commission also uses low risk births for purposes of the Coverage Guidance for Planned Out-of-Hospital Birth.
- The OHA regulates the facility, and the expectation is that policies and procedures are in place and rules are followed.
- Regulating the practitioner (MD, CNM, LDM, ND, etc.) is different than regulating the facility and investigations are substantially different between the two.

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- It's important to remember this different when approaching the risk factors, especially since there are multiple providers working in a birth center.
- D. Selover suggested one to two more meetings and suggested grouping gestational age, multiple births and non-cephalic presentation in one meeting, and VBACs in a separate meeting. It was noted that the Public Health Division does not have the same set up to look at the evidence in a rigorous way such as HERC or the Board of DEM.
- It was noted that more members will be considered including subject matter experts.
- RAC member commented via Chat that the CABC has reviewed the evidence with respect specifically to Birth Centers.
- The goal is to submit these rules for Public Hearing before the end of the year, preferably by the end of summer.
- Staff from HERC noted that they continue to monitor literature and if anything is seen that might indicate a change to the guidance would be reviewed further. Generally, guidance is reviewed every five years. Persons that wish to share literature with the HERC may do so by contacting them at HERC.Info@dhsoha.state.or.us.
- In response to RAC member who asked whether dates have been identified for future meetings including VBAC, dates have not been identified.
- RAC member asked whether HERC could have a subject matter expert available to respond to the birthing centers' subject matter expert to discuss the biggest concerns relating to VBAC. HERC staff noted that their report is posted and available for review including references to the evidence reviewed. Meeting minutes are also posted and available for review. It was noted that the February 2020 meeting minutes from the Evidenced-based Guidelines Subcommittee states: *Under delivery history, the subcommittee discussed comments which recommended allowing coverage for out-of-hospital births for women with prior successful vaginal deliveries as well as prior cesarean sections. After discussion, the subcommittee affirmed its decision to leave this as a transfer criterion based on professional guidelines and several studies associating prior cesarean with poor outcomes in the out-of-hospital setting. In addition, many Oregon hospitals lack the infrastructure and staffing to handle any emergency transfers which may occur.* HERC attendance at future meetings will be based on staff availability. RAC member stated that historically Oregon has had excellent statistics in regard to VBAC.
- D. Selover noted that Table III relating to consultation will be edited after further consideration of RAC input from Tables I and II.
- D. Selover further noted that with regard to HB 2993, there is no clear solution on how to obtain community input in the middle of a RAC process. The program is continuing to work on how to design this.

RAC adjourned at: 3:00 p.m.

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Birthing Center Rule Advisory Committee
October 4, 2022
1:00 p.m. via Zoom

RAC MEMBER ATTENDEES	
Danielle Meyer	Oregon Association of Hospital and Health Systems
Desiree LeFave	Bella Vie Gentle Birth Center (Administrative)
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
Michelle Zimmerman-Pike	Oregon Affiliate of the American College of Nurse Midwives
Sarah Wickenhagen	Oregon State Board of Nursing
Silke Ackerson	Oregon Midwifery Council
Tierra Salmón	Birth Justice Policy Committee
Wendy Smith	Legacy Emanual Medical Center
Willa Woodard Ervin	Rogue Birth Center
OTHER INTERESTED PARTY ATTENDEES	
Carrie Hertzler	Public
Debbie Cowart	Growing Family Birth Center
Dele Ogunleye	Andaluz Waterbirth Center
Elle Molokwu	Birth Justice Policy Committee
Laura Wiegand	Andaluz Waterbirth Center
Mark Buchholz	Pacificsource
Miriam Herrmann	Trillium Community Health Plan
Ray Gambrill	AllCare Health
Rebeckah Orton	Astoria Birth Center and Family Medicine
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
Kristty Zamora-Polanco	External Relations Division – Innovator Agent
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Rebecca Long	PHD-Emergency Medical Services & Trauma Systems Program

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Welcome and Overview

Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and other interested parties 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.

March 8, 2022 Meeting Notes

RAC members were asked to submit any comments on proposed changes to the March meeting notes to Mellony Bernal by e-mail.

Overview of Agenda

M. Bernal reviewed agenda. Staff will provide an update on committee activity to date and then begin reviewing three of the last four risk factors that had been deferred to discuss in the future [gestational age, non-cephalic presentation, multiples and vaginal birth after cesarean (VBAC).] The goal is to finish discussions on gestational age, non-cephalic presentation and multiples and then schedule another meeting to discuss VBACs.

Birthing Center Rule Advisory Committee Update

Dana Selover welcomed everyone and noted there are two additional subject matter experts that have been added to the RAC in response to HB 2993 which passed in 2021; Wendy Smith and Tierra Salmón.

The following overview was provided:

- 16 RAC meetings have occurred since May 2019. The birthing center administrative rules were initially adopted in 1985, amended in 1990 and risk factor tables adopted in 2006. Pulse ox screening was added in 2014. No other changes have occurred in the last 16 years.
- Meeting agendas and meeting notes for all prior meetings are now available on the web at https://www.healthoregon.org/hcrqirules.
- Future meeting notes and public hearing information will be posted on the web page.
- The RAC has completed initial review of main rule text as well as follow-up review of amended rule text.
- Risk factor Table I (exclusion at admission) and Table II (transfer to hospital) have been completed with exception of the four risk factors noted previously.
- Notices of proposed rulemaking including the public hearing will be posted and the Division will consider both written and oral comments. There will be plenty of opportunity for persons that are not on the RAC to comment on the proposed rules.
- The meeting today will focus on three of the four remaining risk factors that had been deferred from previous conversations – Multiple gestation, non-cephalic presentation, and gestational age.
- Remaining work for this RAC includes:
  - Discussing vaginal birth after cesarean (VBAC)

- Reviewing revised consultation requirement Table III
  - Reviewing the Statement of Need and Fiscal Impact, as well as consider how the rules will impact racial equity in Oregon
- The Division will be convening a community meeting to focus on Black, Indigenous, and People of Color communities; seeking review of the rules by the Department of Justice; and then will be filing a notice of proposed rulemaking with the Secretary of State
- Information about HB 2993 was shared including requirements of the 2021 Oregon Law, Chapter 463 and it was noted that the purpose of the community meeting will be to seek input on all of the proposed rule text and risk factor tables from Black, Indigenous, and People of Color communities.

Elle Molokwu, participating on behalf of Tierra Salmón, introduced self and represents the Birth Justice Policy Committee that is working with lawmakers on policy changes that are needed for black and brown bodies. E. Molokwu is a full spectrum Doula (birth, postpartum, and death) who also is a patient representative educating patients about things that happen during birth.

Dr. Wendy Smith is an OB/GYN hospitalist who works at Randall Children's Hospital at Legacy Emanuel Medical Center. W. Smith is a physician representative on the Oregon Board of Direct Entry Midwifery since 2013 who takes pride in working with community midwives to make Oregon the safest place possible for birthing people.

Follow-up - Information on Birthing Center OARs:

- 1985: Initial rules adopted
- 1990: Rules were amended adopting administrative licensing procedures; expanding policies and procedures; adding medical record requirements including consultation with Registered Record Administrator or Accredited Records Technician; and adding neonatal CPR requirements and infection control measures.
- 2006: Rules were amended adopting risk factor criteria; requiring policies and procedures to meet North American Registry of Midwives Standards; amending elements of policies and procedures relating to emergency transfers and client orientation and education; amending Vitamin K administration and newborn screening; updating infection control guidance; and amending physical environment requirements.
- 2008: Emergency preparedness requirements adopted.
- 2014: Pulse oximetry screening requirements adopted.

Risk Factor Table I – Risk Factor Criteria for Exclusion at Time of Admission

D. Selover open discussion and reminded RAC members that the rules for a licensed birthing center facility are focused on the statutory requirement that births must be low risk. Requirements from the Board of Direct Entry Midwifery (DEM) rules, guidance from the Health Evidence Review Commission (HERC) and the compliance indicators from the Commission for the Accreditation of Birth Centers (CABC) were shared for each risk factor. It was noted that the Birthing Center OARs are specific to the facility, therefore whomever has privileges at the facility would be required to comply with the proposed rule even if rules relevant to the provider's license permit a broader scope of practice. RAC member expressed concern that this does not make sense.

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Gestational age – preterm (<37 weeks, 0 days) or postdates (>41 weeks+6 days)

The proposed requirement is that gestational ages less than 37 weeks, 0 days or greater than 41 weeks, 6 days will require transfer to hospital. It was further noted that if a birthing person is in active labor at the applicable gestation dates than the transfer requirement may not apply.
Discussion:

- RAC member remarked that the current regulation, allowing delivery in the birth center at 36 weeks should be retained. Gestational age is handled on a case by case and depends on how sure the birthing person is about the conception date and the birthing person's comfort level with the higher possibility of a transfer after delivery. The RAC member indicated that there is no evidence in Oregon that the current rule is not working. Between 36 to 37 weeks the biggest concern is an increased risk of respiratory distress syndrome, which only affects about 5% of babies and is much less likely for a baby at 36 weeks, 6 days versus 36 weeks, 0 days.
- RAC member stated that one of the things that makes the risk factors being discussed today different than those previously discussed, is that these are risk factors that represent an increased risk of potential pathology but may be healthy and normal. It was further stated that pregnancies or labors with these complications face an increased risk of negative outcomes no matter how or where the baby is delivered, and there are increased risks associated with non-intervention or increased risks associated with induction or surgical delivery. RAC member further stated that while Oregon law defines a birthing center as a place licensed for the primary purpose of low-risk deliveries, that secondary purposes should be considered including deliveries that involve additional complications or risks, such as continuing to serve women based on the current gestational age rule criteria to allow vaginal birth of twins and breech babies. As indicated previously, whether to attempt birth at a birthing center in these situations should be handled on a case-by-case basis. Citizen rights should be upheld and protected. The Oregon Association of Birth Centers (OABC) has not identified any evidence of negative outcomes associated with a serving pregnant persons who go into labor between 36 and 37 weeks, or after 42 weeks to 43 with a reassuring non-stress test.
- RAC member stated agreement with the 36 to 37 weeks criteria.
- RAC members via Chat agreed with maintaining 36 weeks.
- RAC member indicated support for current rule language (greater than 42 weeks but less than 43 weeks unless there is an abnormal non-stress test or other non-reassuring fetal surveillance testing.) While there are some increased risks, there are also benefits to a baby the longer they gestate up to at least 40 weeks. There are very small increases in risk, usually a half percent, which is not substantial enough to not allow a pregnant person to labor. It was further stated that vulnerable populations, including women of color, face increased risk and increased negative outcomes when they are forced to change providers late in the pregnancy which is what would happen if the birthing person went into labor outside the limits specified.
- RAC member stated that post-dates is an important area to allow birthing people to choose with informed choice whether they give birth and what course of care they want. RAC member remarked that they are seeing a greater restriction in choice and greater pressure to induce in the hospital when someone passes their due date. With good fetal surveillance, it's important that community birth be maintained as an option for people who want to wait for physiologic labor.

- RAC member via Chat indicated that even though risks may be slightly increased, there may be an increased risk for sending people to a hospital for care (especially considering equity issues that exist in healthcare.)
- RAC member stated that persons of color with person of color providers who must change providers because of late gestation and must transfer to a hospital which might not be the safest place for them, creates more of a problem by creating an environment of trauma for those patients. It was further stated that people tend to focus on the scientific facts about what could happen and not looking at how those choices can have long term effects for black and brown bodies through the whole course of pregnancy including postpartum.
- RAC member stated that birthing persons are being sent to unnecessary or unwanted interventions in the hospital when there is no clinical reason to transfer a mom who might be early or post-dates. Many of these women end up having a C-section for no reason other than gestational age because it's outside the receiving hospital or provider's comfort zone. Many professional midwives and doulas have no clinical rights at the hospital when the birthing person would like their assistance at the hospital. Without evidence showing great percentages of birthing persons and babies being put at risk, it is uncertain what the risk is.
- RAC member indicated there is a difference between an induction at 36 weeks and physiologic labor at 36 weeks. RAC member further noted that there may be inaccuracies with dates from the Naegele's Estimated Date of Delivery (EDD) and the early ultrasound EDD, making it possible that the gestation is post 37 weeks. Additionally, a baby at 36 weeks, 3 days that is palpated small for gestational age would be treated differently than a baby that felt like a normal size.
- RAC member via Chat agreed that early babies go into labor naturally versus those being induced.
- RAC member via Chat suggested when voting to separate out 36 weeks+ and then greater than 42 weeks 0 days which aligns with the CABC. The RAC member via Chat further stated, "my personal comfort with 42+1 is less than the 36-37 weeks."
- RAC member stated via Chat further restrictions on gestational age not based on clinical backing, which borders on violating bodily integrity.
- RAC member indicated via Chat that the birth certificate data should be able to tell what the rate of neonatal transfer is for each gestational age. Comparing the rates of transfer by gestational age may be helpful to better understand absolute and relative risk by gestational age.
- RAC member via Chat indicated that midwives working in birth centers usually do not perform artificial rupture of membranes (AROM), especially within 36 weeks gestation. RAC member further indicated by Chat that AROM at term does occasionally happen, but rarely with early babies.
- RAC member stated that the proposed rule fails to account for the individual clinical profile of the patient and how potential risks playing out for the individual patient. It was further stated that birthing persons, especially historically marginalized communities, are making an informed choice and choosing an out-of-hospital birth and these choices are being taken away.
- RAC member via Chat indicated that cord prolapse is more common before 37 weeks with ROM early in labor but can be promptly diagnosed and then transferred to the hospital as it is an absolute risk factor. RAC member further stated via Chat that all birth centers have policies around increased fetal monitoring for post-term pregnancies.

- D. Selover thanked RAC members for the feedback received and noted that the issue of 'primarily and secondarily' has been discussed previously and the Division will need to seek guidance from the Department of Justice. It was further noted that the Division is balancing not just values and autonomy but patient/client safety in a birthing center as well. Furthermore, the Health Evidence Review Commission (HERC) based their decisions on patient safety as well. The proposed rules are not about taking away choice or opportunities. The proposal is based on more than just Oregon data; it's based on studies that are high quality, objective and reliable. Risks and benefits are evaluated considering the whole person, but certain situations may indicate that a transfer is indicated for safety.
- RAC member via Chat indicated that studies are frequently not done in a community setting and therefore are not a reflection of what birthing centers do and which is often quite different. RAC member further expressed appreciation for the Health Authority's desire to keep safety central and reminded those present that risks do not exist in a vacuum.
- RAC member via Chat agreed that safety is central, but that we need to remember that there are birthing people that will not access hospital-based care and if a midwife cannot legally attend their birth, they will have an unattended birth, especially if the hospital does not support their choice around things such as post-dates, breech, or twin delivery.
- RAC members agreed with above statement via Chat.

The following polls were launched:

POLL: Retain "gestational age less than 37 weeks" as a mandatory transfer criterion. 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.
- 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.
- 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 "gestational age greater than 41 weeks, 6 days unless client is already in active labor" as a mandatory transfer criterion. Results:

- 15% - I can say an enthusiastic yes to the recommendation (or action).
- 8% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 8% - 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.
- 31% - 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.
- 38% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

Multiples

Discussion ensued on the "Multiples" risk factor and the requirements from Board of DEM, the HERC and CABC were identified. Discussion:

- RAC member noted that there is not much debate about triplets in the community birth settings. RAC member stated that twin births are complex and acknowledged that there is a significantly higher risk, especially for the second twin, regardless of the setting. It was noted that having multiples is not a disease of pregnancy or something going wrong. It is one of the normal human variations of the way that pregnancy and birth happen. It is important to the Oregon Midwifery Counsel that people who are pregnant with twins have the right and ability to be able to choose physiologic birth in a community setting, especially since it is very challenging to impossible to select a vaginal birth, let alone a physiologic vaginal birth, with twins in a hospital setting. It was further stated that public safety can't just be broken down to a discussion of risk; public safety is more broad. Of particular concern is when birth centers cannot attend twin births and home birth midwives can. This means that a small population of people who choose a community birth setting to deliver twins knowing the risks, are displaced to the home setting which isn't necessarily the best option, especially if they live further from a hospital. A birth center may be the safest and best option for them. RAC member supports patient safety versus being restricted to home birth only. The same is true for breeches and VBACs.
- RAC members via Chat agreed with comment above.
- RAC member stated that if a birthing person makes a choice to deliver twins outside of a hospital, and that person understands the risks, it's wonderful to offer the option of delivering in a birthing center that has close access to a hospital. Birthing centers are in a better position to conduct case review and offer peer support. It's unclear why twin delivery is offered in the home setting and not at a birthing center. Lastly, it was stated that because the risk with twins is so nuanced, it is recommended that twin delivery be moved to the consultation criteria versus an absolute risk factor.
- RAC member concurred that twins should move to consultation.
- RAC members via Chat concurred with recommendation to move to consultation.
- RAC member via Chat stated just because someone is giving birth to twins doesn't mean that anything is going wrong, but that this is normal human variation. People deserve to be able to make the choice to have birth in a community setting. It is known that black and brown birthing people have increased risk of infant and maternal mortality in the hospital setting and that options for birthing people to have a vaginal or physiological birth of twins at the hospital is sometimes not even available at all. All birthing people, but especially people of color, should be able to have the option to choose out of hospital birth and having twins as a consultation criterion is reasonable.
- RAC member via Chat agreed with comment above.
- RAC member remarked that it is difficult trying to explain to birthing families that a provider can assist with twin deliveries in a home but not in a birthing center. Home birth clients have to be referred to other midwives because of how busy the birthing center is. It was noted in Southern Oregon many clients drive almost four hours to birth at the birth center, so to deliver at home and be far away from a hospital is unsafe.
- RAC member stated that while they appreciate the goal and purpose of these rules is not to take away access or choice, the state is hearing from RAC members whether the proposed amendments take away the option to give birth in a birth center. RAC member stated that

everyone would agree that there are times when clients should be advised, informed and even recommended to pursue a specific course of care, but under these laws, it is the client that gets to weigh the risks, choose to integrate those risks into their own values and needs, and make the decision. RAC member opined that women are facing forced surgery in the hospital, or delivery with assistance from somebody without physiological birth skills. It was further stated that injury happens when birthing persons are denied access to providers who are able to make the decision together with a birthing person on a case-by-case basis about whether and how they want to proceed. Journal article, "Maternal deaths after elective cesarean section for breech presentation in the Netherlands" referred to and can be found at: https://pubmed.ncbi.nlm.nih.gov/17364290/

- Several RAC members via Chat agreed with preceding comments.
- RAC member via Chat indicated that many birth center providers disagree with the CABC indicator, and it will likely be challenged in the coming year. Another RAC member stated via Chat that they hope the CABC makes the decision to change.
- RAC member shared their experience of home birth twins and noted they have not seen the degree of preventive care and support needed and received from midwives being offered by hospital-based clinicians.
- RAC member stated it's important that choice is placed back in the hands of birthers. They further stated that black and brown birthers in Oregon are afraid to deliver twins in hospitals. It's too often that the right to deliver out-of-hospital is taken away.

<u>POLL: Retain "Multiple gestation (two or more)" as a mandatory transfer criterion. Results:</u>

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 17% - 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.
- 42% - 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.
- 42% - 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 thanked RAC members for answering poll and asked since there is acknowledgement that there are increased risks with twins and concerns noted that transfer to a higher level of care could be far away, what other conditions could be considered knowing that you are a taking a higher risk? Discussion:

- RAC member indicated that delivery of twins may involve more equipment and more providers and resuscitation capability, including two places to receive the babies that are fully prepared for the possibility that one or more babies may need to be resuscitated. Access to equipment and access to providers is a reason to allow delivery in a birthing center. Many birthing centers are located near hospitals. There needs to be smooth integration in the event of transfer. More attention needs to be placed on ensuring that EMS providers responding to transfer are trained and equipped to handle the transfer.
- RAC member noted that each of the risks discussed are quite different. Sometimes in the HERC guidance there is an exclusion for a community birth that has a very modest increased risk and then there are a few exclusions where the relative risk is higher. The relative risk of the death of a baby in an out-of-hospital breech or twin is 8 to 12 times higher

than for a head-down baby or for singleton babies but that doesn't mean that birth should not occur in a birthing center. It was noted that this doesn't change a person's choice to give birth out of hospital and can make it less safe because this small population of people who choose a community birth, knowing the risks, will do so potentially further from the hospital or potentially with a less trained provider or with no provider. RAC member further remarked that thought needs to be given to supporting the safety of these families, such as adding an additional midwife to the team, much more attention placed on prevention and treatment of post-partum hemorrhage, significant informed choice discussion about risks so that people choosing this option really understand the risk that they're taking. (Reference to an informed choice template for twins was made and will be shared with RAC.) RAC member additionally stated that it's also important to know what kinds of twins there are and get adequate imaging to know different variations in placenta and amniotic sacs because there are really different levels of risks with twin births as well. The two topics of breeches and twins is not about whether they carry greater risk or not. The discussion should not be about whether something has inherently more risk therefore you can't do it because it won't work for the safety of birthing people in Oregon. D. Selover asked where would draw the line when dealing with a home-based birth and not feeling safe? RAC member responded that they do not attend home twin births and most midwives in Oregon would not. There are a small number of practices who have taken special care to have greater training and have more experience. Mono-mono twins would not be a good idea. Certain position combinations would be much higher risk for babies to be born in a community setting.

- RAC member noted that most of the experienced midwives who have the knowledge base to attend twin births are no longer doing them and some of the less experienced midwives are perhaps signing up for that experience for the novelty of it or zest to serve people based on their choice. Allowing twin births in a birth center that meet certain criteria, such as being close to a hospital and having proper staffing and equipment would be a safer setting than a remote home birth.
- RAC member via Chat stated that this sound like an access issue to vaginal delivery of twins. This restriction will just increase cesarean and they don't think that restricting access to midwife/birth center community is needed, rather more access of vaginal birth of multiples is needed. The same is true with VBAC. There needs to be more training across all provider types for those choices.
- RAC member stated via Chat agreement restricting access to care with physiological birth is not only a breach in the statute that was stated previously around client rights to make their own choices but is also a breach in the birthing persons human rights as well. Pushing birthing people into restricted choices doesn't increase good outcomes it just makes it harder for them to access safe choices which include the expertise of a midwife who is an expert in physiological birth as well as their access to hospitals. It's a human rights violation. RAC member via Chat agreed with this comment.
- RAC member via Chat stated agreement that the state needs to demand integration not restrict pregnant persons. RAC members via Chat agreed.
- RAC member remarked that there are a lot of nurse midwives, naturopathic physicians, and licensed midwives that have the skills to perform some of these deliveries. While birth centers that are accredited by the CABC cannot perform these deliveries, there are birth centers who are not accredited that could. It was stated that 'we' don't want to be taking care of births that have additional risk either, however birthing persons are making that choice

considering the risks and weighing the priority of keeping the birthing person as safe as possible.

- RAC member stated appreciation for conversation and that many providers may choose not to offer certain services. The discussion is about whether the state should have a unilateral rule that nobody may offer these services. Current rules do not allow licensed birthing centers to perform twin deliveries or breech deliveries. Maternal health care has changed in Oregon and there has been an increase in unassisted births resulting from a constricting choice in hospitals. Some midwives take it upon themselves to develop and maintain the necessary skills for twin and breech deliveries and some haven't. Just as there are a few doctors who have taken it upon themselves to learn and maintain those skills in the hospital setting, and many have not. Just because some providers may not offer this service doesn't mean it shouldn't be offered to anyone.
- RAC member commented in response to earlier question about what other conditions can be considered for allowing twin births, and that an ultrasound to determine what types of twins is important to determine if delivery would be safe to attempt out-of-hospital. Mono-mono is the riskiest type and is not allowed under the DEM Board rules. Detailed informed consent, making a detailed transfer plan, and making sure the patient understands what things to watch for during the labor process and know what their comfort level is in terms of when to transport if certain things develop. Closer to term, looking at presentation and whether the first baby is cephalic or breech or transverse which affects safety. During labor, ensuring multiple midwives are present and ensuring surveillance and monitoring for any signs of distress. This should require a consult with a provider to make sure that they are also counseling the birthing person on what their risks and concerns are and guide them through what it would be like to deliver in the hospital.
- RAC member noted that in Southern Oregon there is only one doctor in the region that will consider twin physiological birth in a hospital which is rare, making it more likely that anyone with twins will need a C-section in hospital. It was noted that it does not make sense to allow twin births in a home and not in a birthing center.
- RAC member via Chat noted that naturopathic midwives do peer review prenatally and again after delivery for all twin and breech deliveries.
- RAC member via Chat noted that the Oregon State Board of Nursing makes the distinction that nurses should only consider performing any activity, intervention, or role to acceptable and prevailing standards of safe care. Twin delivery would not be considered the prevailing standard. Another RAC member asked why twin delivery wouldn't be the prevailing standard of care? RAC member responded that it is based on the definition of prevailing standard of care, which would be what the majority of practice would do; textbook recommendation; what other level of skilled providers would perform and based on conversations, physiological twin births is controversial. A follow-up question was asked whether twin deliveries by a nurse midwife in a birthing center would be prevailing standard of care? RAC member responded from their perspective if they were asked to consult on a complaint, the nurse midwife would be found in violation of the Nurse Practice Act.

Dana thanked RAC members for comments.

<u>Non-cephalic fetal presentation</u>

Discussion ensued on the "non-cephalic fetal presentation" risk factor and the requirements from Board of DEM, the HERC and CABC were identified. Discussion:

- RAC member noted that the conversation is similar to twins acknowledging an elevated risk that requires special skill and consideration and requires in-depth informed choice with families. It was noted that there is even less access to vaginal breech birth in the hospital in Oregon than there is vaginal twin birth. There are currently no hospitals openly offering vaginal breech birth and when it is not available in the community setting, it puts more strain on birthing persons faced with only the choice of a cesarean birth which is not ethical or evidenced-based practice. It was further noted that breech and non-cephalic presentation should be separate criteria because there are a number of non-cephalic presentations that simply do not work, such as transverse. No one would advocate to provide a transverse delivery at a birth center or home. It was further stated that there is a significant risk for breech birth across the U.S. and Oregon because providers lack appropriate training and experience due to the fact that there is limited access to vaginal breech. It is imperative that all birth providers in all settings are trained and equipped to handle breech. When there is no space for people to gain experience and practice skills, then no one has anything but theoretical preparation for the surprise breech births that do happen in all settings.
- RAC member concurred that vaginal breech delivery mirrors the twin discussion with an increased risk, but the risk is not so significant that it should be excluded from a birthing person's choice. As indicated, there is no access to vaginal breech delivery in the hospital which means a birthing person's choice for a vaginal breech delivery will require an unattended, or home birth. Allowing vaginal breech in a birthing center would allow more structure and might be closer to a hospital if needed. It was noted that breech babies are not all alike, and some may be safer to delivery than others, and the Board of DEM rules should be considered such as lack of adequate progress in second stage. Detailed informed consent along with educating patients about the increased risks and informing them that cesarean is an option is needed. RAC member recommended that breech therefore be a consultation criterion.
- RAC member stated that what differs between the twin and breech discussion is the unique skills necessary for safe delivery of different non-cephalic presentations and breech positions. It was indicated that there is a "massive deskilling in obstetrics around breech delivery that is affecting women's options." RAC member stated the RAC needs to consider whether providers who have the skills to support these birthing persons may be allowed in a birth center. Personal story was shared about a pregnant person who experienced traumatic racism in hospital in another state after the midwife had to transfer client because of breech presentation and upon arrival, hospital refused to perform delivery because the patient did not want to have a cesarean. The patient was transferred to another hospital that also insisted on a cesarean, but the infant was born breech with no assistance from hospital staff. The patient was disparaged for breech delivery and reported to child welfare. Question was posed to RAC whether the rules are making birthing persons safer when the birthing person is told they are not allowed to access midwife care that a midwife, in their clinical discretion, is willing to offer in out-of-hospital spaces?
- RAC members via Chat agreed that breech and non-cephalic presentation should be separated, and that breech should be a consultation criterion.
- RAC member remarked that birthing people historically have had a lack of choice around what happens to their womb, especially birthing people of color and when we choose to restrict access to experts who have the level of skill necessary to facilitate a breech birth, we are perpetuating a system that takes away a birthing person's right to choose. More

midwives of color are needed to address the disparities in the community. If there is no access to practice in settings where people work, then the training is theoretical, and expertise in the community remains limited.

D. Selover thanked RAC members for information shared and asked whether there are any specific conditions, similar to twins, that could be considered, such as distance to hospital, system integration, agreements, etc.?

- RAC member shared that Oregon Midwifery Council's informed choice template for breeches and twins outlines those things in detail and they will send it in.
- RAC member shared that when they used to do breech, they only served pregnant people with a prior vaginal birth and would consider parity, and previous birth experience such as length of second stage. The type of breech is important as well as the size of the baby. In-depth informed consent is needed and should include the birthing person's partner. Setting expectations is important.
- RAC member via Chat indicated that if breech is allowed, they would suggest adding previous vaginal births to criteria which would reduce risk.
- RAC member via Chat indicated that conditions would be the same as for twins including extra providers and equipment.
- RAC member stated via Chat that it is not acceptable that a provider is not trained on delivering breech, it should be common, and should not be illegal to train individuals on how perform life-saving techniques. It was noted that the previous story shared is not uncommon for black and brown bodies in Oregon.
- RAC member stated that based on information provided today these categories should be allowed in a birthing center with special requirements in terms of informed consent and client education about risks. This is especially important because of inadequate and disproportionate effects on birthing people of color. These options should be available to birthing persons because they don't have the option in a hospital. The risk to birthing persons for repeat cesareans significant and a significant factor in the maternal morbidity rate in the US.
- RAC member commented that in considering the rules, the RAC needs to consider what are the other purposes for a birthing center beside low risk births. It was stated that one important purpose is the protection of the safety of birthing people and protecting rights is protecting safety. It was stated that as the risk of giving birth in the hospital setting goes up, birthing persons are willing to accept a higher level of risk outside of the hospital. It was further stated that hospital spaces and obstetric spaces have increasingly become surgical delivery spaces, and therefore birthing centers have become an important space for vaginal birth. RAC members via Chat concurred.

<u>POLL: Retain "breech or non-cephalic presentation" as a mandatory transfer criterion. Results:</u>

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 27% - 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.

- 55% - 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
D. Selover thanked RAC members for their participation. RAC members were encouraged to submit additional information to M. Bernal via email. It was noted that the Division will be planning the following: • VBAC discussion; • Community meeting.

RAC adjourned at: 3:45 p.m.

DRAFT

PUBLIC HEALTH DIVISION
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Birthing Center Rule Advisory Committee
June 4, 2024
9:00 a.m. via Zoom

RAC MEMBER ATTENDEES	
Danielle Meyer	Hospital Association of Oregon
Desiree LeFave	Bella Vie Gentle Birth Center (Administrative)
Emilia Smith	Oregon Midwifery Council
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
Megan Coppock	Andaluz Waterbirth Center
Michelle Zimmerman-Pike	Oregon Affiliate of the American College of Nurse Midwives
Sarah Wickenhagen	Oregon State Board of Nursing
Wendy Smith	Legacy Emanual Medical Center
Willa Woodard Ervin	Rogue Birth Center

INVITED SUBJECT MATTER EXPERTS	
Carrie Duncan, CPM, LDM	Andaluz Waterbirth Center
Catherine Bailey, CPM, LDM	
Jen Kamel	VBAC Facts
Melissa (Missy) Cheyney, PhD, LDM	

OTHER INTERESTED PARTY ATTENDEES	
AlexAnn Westlake	Our Community Birth Center
Charlotte Clausen	Women's Care
Christina Clay	Public
Jeanne Savage	Trillium Community Health Plan
Laura Wiegand	Andaluz Waterbirth Center
Mary Engrav	CareOregon
Ray Gambrill	AllCare Health
Rebeckah Orton	Astoria Birth Center
Sharron Fuchs	Public

OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Dana Selover	PHD-Health Care Regulation & Quality Improvement
Lacey Martinez	PHD-Health Facility Licensing & Certification
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Rebecca Long	PHD-Emergency Medical Services & Trauma Systems Program
Samie Patnode	Health Licensing Office

Welcome and Overview

Mellony Bernal welcomed Birthing Center Rule Advisory Committee (RAC) members and other interested parties and reviewed housekeeping items.

- The purpose of this RAC meeting is to hear from invited guests about their professional experience and related information about the risks related to a vaginal birth after cesarean and possible safety measures that might be considered for the health and safety of the client.
- 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.
- RAC members may choose to keep video on or off, however, if called upon to speak please turn video on. Members of the public are asked to keep video off for duration of meeting.
- Meeting is being recorded and all messages entered into the Chat are saved and subject to disclosure.
- Meeting minutes will be drafted and sent to RAC members and posted on the HFLC Rulemaking Activity website: https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/HEALTHCAREPROVIDERSFACILITIES/HEALTHCAREHEALTHCAREREGULATIONQUALITYIMPROVEMENT/Pages/proposedrules.aspx
- RAC meetings are not subject to public meetings law. Members of the public may attend but may not participate or offer public comment. A public hearing and written public comment period will be scheduled at a later time to obtain oral and written feedback from the public on final proposed rules. All information related to the public hearing and written comment deadline will be posted on the Rulemaking Activity web page.
- Interested parties will be notified about the public hearing and public comment period using our GovDelivery listserv. A link to sign-up for this listserv was shared: https://public.govdelivery.com/accounts/ORDHS/subscriber/new?qsp=ORDHS_16
- RAC members were asked to use the Chat function to indicate if they have a question or want to speak. Type the word “COMMENT” into the Chat and persons will be called upon to speak. Type the words “For the Record” or letters “FTR” and type out the information you wish to share. Persons who type For the Record/FTR will not be called upon to speak. Staff will try and call upon persons in the order they appear on the Chat.

Overview of Agenda

Dana Selover welcomed everyone and provided brief overview:

- RAC is wrapping up discussions relating to the overhaul of the Birthing Center administrative rules which will include being renumbered from OAR 333-076 to OAR 333-077.
- Rules have not been revised since 2006.
- The Rule Advisory Committee (RAC) has been meeting since 2019 and all meeting agendas and minutes are posted on the HFLC Rulemaking Activity webpage.

- This VBAC RAC meeting is the final discussion relating to risk factors. At the request of RAC members, VBAC subject matter experts in a birthing center setting have been invited to share their perspective and related information.
- This meeting is not a public hearing, nor a legislative hearing, and is not for purposes of taking formal testimony. Each invited presenter will have approximately 15 minutes to provide information from their perspective about VBACs in a birthing center. It was noted that one additional invitee contacted staff late, and if they are able to participate, time may be adjusted to accommodate. Questions and discussion will be held until after invitees have shared their information. D. Selover also requested that RAC members not use the Chat to comment on information shared by presenters until after all presenters have finished sharing.

Invited Subject Matter Experts on VBAC

D. Selover asked invitees to introduce themselves and provide information on their background.

Melissa (Missy) Cheyney, PhD

Dr. Cheney shared the following background information about herself:

- Professor of medical anthropology and reproductive health at Oregon State University;
- Midwife for 20 years (stopped practicing in 2020);
- Editor in chief of Birth Issues and Perinatal Care, one of the only journals that focuses on normal physiologic birth;
- Co-director of Uplift Lab, a research and reproductive equity laboratory at Oregon State University;
- Co-director of the Community Birth Data Registry (CBDR), an initiative through the Foundation for Healthcare Quality in Washington state, collecting pilot data on community births (home and birth center births) in the states of Washington and Oklahoma. The goal is to combine this data with the Perinatal Data Registry (PDR), developed by the American Association of Birthing Centers, so there is a national data set that can track all community birth outcomes;
- Chair of the Division of Research for the Midwives Alliance of North American (MANA) for 12 years, and during that time, wrote many articles relating to VBAC and birth outcomes in the community setting; and
- Co-director of the Quality and Maternal Newborn Care (QMNC) Alliance, a global alliance of researchers who study midwifery and physiologic birth around the world.

Dr. Cheyney noted she had three topics to cover:

1) Evidence that supports laboring after cesarean in the community setting, specifically in birth centers;
2) Importance of integration for making sure that outcomes in birth centers are as positive as possible; and
3) Autonomy and access.

Evidence

- In 2008, Dr. Cheney served on the National Academies of Science, Engineering, and Medicine, Birth Settings in America study, which was congressionally appointed to look at outcomes in the United States. One main conclusion is that increased access to nonsurgical options like labor after cesarean and external cephalic version is needed to help reduce the cesarean rate in the United States.
- Dr. Cheney was asked to serve in part due to the number of studies she has conducted using PDR data and MANAStats (which captures primarily home but also some birth center births data).
    - Study with over 47,000 pregnancies looked at outcomes by risk factors. The comparison group was multiples with no risk factors compared to individuals who had had a prior cesarean with and without another vaginal birth, gestational diabetes, breach, twins, etc.
        - The study found that the rate of success for labor after cesarean in the community setting is high. People with a prior vaginal birth and a prior cesarean had a 93 percent success rate. Individuals that had no prior vaginal birth had close to an 80 percent success rate. This helps to understand why people are wanting to attempt a labor after cesarean outside of the hospital.
        - Also found that most of the people who attempt an out-of-hospital birth for labor after cesarean have already had one vaginal birth (60 percent had already had one vaginal birth in the sample).
        - There were very low rates of individuals who had compounding risk factors.
        - In addition to laboring after cesarean, the study included other complications like gestational diabetes mellitus or post-dates, in those instances, most of the poor outcomes were actually concentrated in individuals who had additional risk factors on top of having a previously scarred uterus.
        - For persons who didn't have additional risk factors and where transfer was timely, the outcomes were really excellent.
- Dr. Cheyney noted that Oregon has been at the forefront and should be the model for a lot of other states in how VBACs are managed in a birth center setting, largely because there is a focus on additional risk factors, which has shown makes a difference in outcomes for VBAC but also because of the focus on autonomy and informed decision making.
    - In a large sample size VBAC study, poor outcomes were looked at closely.
        - One way to keep out-of-hospital VBAC safe as possible is early conservative transfer;
        - Making sure there were no other additional risk factors, or few other additional risk factors;
        - While plateaus (when labor is going along, plenty of contractions, but no change to cervix) are normal, in a previously scarred uterus, pressure from contractions is either going to help open the cervix or in some instance it affects the scar, and there is a need to pay close attention.
        - Reversals of station tended to predict poor outcomes.
        - In the absence of plateaus or reversals of station and keeping in mind risk factors and informed choice, outcomes actually look very good.

- Dr. Cheney indicated that she couldn't find any good evidence for restricting access in the birth center setting.

Integration

- Dr. Cheney indicated integration as being key. She noted that there's a lot written globally about systems that do too much too soon, and too little too late. The hospital-based system is often thought of as being a too much too soon system, and what we're looking for is the right amount, at the right time, and the right place.
- Birth center data shows that birth center midwives are able to identify when someone needs to be triaged to a higher level of care when a complication arises. With good risk selection, informed consent, respect for autonomy and triage to a higher level of care, when needed, in a collaborative manner, excellent outcomes are seen.
- In a study that mapped levels of integration across the United States, how integration of home, birth center birth, midwives into the larger system of hospital-based care on how outcomes were affected was looked at. Integration was the best predictor next to race on birth outcomes. Race was the biggest predictor of birth outcomes and second was level of integration.
- Recommendation would be not to restrict access to labor after cesarean in a birth center setting, but to focus on building relationships and integration across systems so there can be an appropriate and smooth transfer.
- There is a huge body of literature suggesting that midwives are well-placed to offer this kind of care in birth centers as well as in the hospital.

Autonomy and Access

- Dr. Cheney remarked that VBAC rates in the United States have remained low and quite stable. Since 2022, they are under 15 percent.
- In a project where people from across the nation were invited to talk about their experience of seeking VBAC care, it was found that people face enormous, extraordinary challenges in getting access to vaginal birth after cesarean.
    - People traveling long distances, including going to other states;
    - Sometimes having unassisted birth;
    - Giving birth at home sometimes with credentialed providers, sometimes not;
    - Giving birth in hotels in other states to get access to VBAC.
- Dr. Cheyney recommended against doing anything that restricts further access to VBAC outside of the hospital.
    - Looking at the American College of Obstetricians and Gynecologists statement on maternal autonomy, she indicated that they are unequivocal in their support for people's right to make decisions about their own body, and they say that while birthing people have to be given appropriate, complete information about risks, benefits, choices, the potential consequences of their choices, maternal autonomy can never be overridden even if there was clear evidence of potential fetal harm incurred by their choice.
- It was noted that in terms of access, access is really inequitably distributed. People choose birth centers for labor after cesarean because they can't always find a provider who is supportive or a hospital that will allow it.
- It was stated that in addition to just choosing a birth center because there is no hospital, there's also similarly alarming data on rates of mistreatment and inequity due to systemic

racism in the United States. Thus, it's understandable why people, especially people of color, might choose to give birth in birth center where they have a known number of carers. Every interaction in the hospital means a person may interact with someone who's incredibly supportive, loving compassionate, but persons may also face either explicit or implicit racism.

  - In the 'Giving Voice to Mothers' study in 2019, privileged voices of under-served communities, with over 2,000 respondents to the survey:
    - One in six birthing people in the United States experienced some kind of mistreatment while giving birth in the hospital;
    - The rate for the community setting (home and birth center births) was 5% experienced mistreatment compared to 28.1% in the hospital.
    - Identities including race, ethnicity, and socioeconomic status also intersect, and it was found, for example, that women of color, who also had low socioeconomic status, had a 27% chance of experiencing some form of mistreatment. While white woman who had low socioeconomic status had about an 18% chance. There are intersecting identities that affect people's ability to access care.
  - There is a lot of evidence that cesarean birth, especially if the birthing person feels it was unnecessary, can be extremely traumatic and is associated with post-traumatic stress syndrome. It's not appropriate for every person who gets pregnant again and is wanting to attempt a labor after cesarean to have to go back to a hospital that may be associated with that trauma.

Dr. Cheyney concluded her comments stating that attempts across the United States to restrict access to care in certain settings or to narrow the range of practice for midwives or to reduce choice for birthing people is motivated by a misplaced desire to protect people. Just not dying in birth or not having some kind of injury is a low bar – the floor, not the ceiling - of what we're trying to achieve. People should have not only a live, healthy baby and a healthy body, but also a positive experience going into parenting, from a position of power, support, compassion and, not one of victimization. In order to do that, there needs to be a full range of options open to birthing people in the United States.

Carrie Duncan, LDM

Carrie Duncan shared the following background information about herself:

- Midwife in the Portland area for over 23 years, and most of that time has been serving in a birth center setting.
- For the last two years, serving as the Midwife Director at Andaluz Water Birth Center.

C. Duncan noted that the Andaluz Waterbirth Center has a successful VBAC rate of about 89% with two additional successful VBACs in one day last week. They are proud of the success.

It was noted that the birth center uses a robust intake screening process and continued evaluation for comorbidities and compounding risk factors, as well as the current state guidelines and CABC guidelines, backed by an equally robust process for continued quality improvement. Peer review of serious and sentinel events are conducted both in community setting as well as professional setting by the Oregon Midwifery Council and the Commission for the Accreditation of Birth Centers. This is how Andaluz ensures that they are continuing to improve the quality of the care delivered, including compliance with regulatory guidelines, and

staying up to date with new shifts in the evidence. They are proud to use a shared decision making to honestly inform clients.

C. Duncan stated that clients choose Andaluz for their years of experience and expertise. Andaluz has a lot of experience and C. Duncan can speak to many years of serving VBAC clients which is something that people are looking for.

C. Duncan remarked that Andaluz's success rate of almost 90% is on par with the rest of the birth centers which tend to land around 90% on average and is why birthing persons are choosing birth centers for a trial labor of after cesarean. Most clients are choosing the birth center from a place of conservatism not to take extra risk:

- Clients are trying to avoid a medicalized induction, and want to avoid interventions such as Pitocin, misoprostol and induction.
- Clients want to labor biologically which minimizes their chance for uterine rupture and other complications.
- Clients want extra attention and one-on-one care; they want a smaller practice with more individualized attention.
- Clients want a relationship with their provider and continuity of care.
- Clients are more compliant with provider recommendations based on more attention paid to them.
- If risk factors are found, they are happy to go to the hospital and receive the care they need.

C. Duncan has served over 1,000 women in a birthing space, and VBACs are some of the most impassioned folks served. Regardless of the method of birth, the birth center is able to make a huge impact and has a high satisfaction rate among the people served. Even if a client ends up transferring for a repeat cesarean or for another reason, clients are still more satisfied with their birth because they were able to receive midwifery care with longer appointment times, more individualized attention, and better follow up. C. Duncan further stated that clients are less likely to have postpartum depression.

C. Duncan shared the concern that when choices are limited, services are pushed further underground (example VBAC). A story was shared of someone who traveled from a Southern state to come try for VBAC with Andaluz. Clients will not stop seeking the service, rather will travel farther and take bigger risks. There is evidence that people are choosing unassisted birth due to limited options and traveling long distances to receive care. There is then no continuity of care with a provider which has its own risks. People who are often traumatized by the experience will still seek the care that they deserve or seek the experience that they want, one way or another. Providing an avenue where individuals can have a well-informed, expert provider, individualized care, in a safe setting is the only ethical way to proceed and statistics have demonstrated that this is being done.

Catherine Bailey, LDM

Catherine Bailey shared the following background information about themself:

- Licensed midwife in Portland attending home births currently since 2011;
- Current president of the Oregon Midwifery Foundation focusing on giving grants to new midwives and student midwives who are black, indigenous, or people of color;
- Involved with the Oregon Midwifery Council for a long time and organized continuing education conferences for midwives for about 10 years.

C. Bailey shared that she has attended many VBAC births both at home and in the birth center setting, both as a student and as a licensed midwife and noted that they attended VBACs with Carrie Duncan as a student 12 and 13 years ago, has consulted with Melissa Chaney about more complex VBAC cases in the past, and has organized a CEU conference inviting Jen Kamel to come out to Oregon to speak to midwives. It's a reminder that midwives need community, and midwives need each other to keep their clients safe, they do not need more restriction.

It was stated that midwives should be allowed to attend VBAC births at birth centers. As a licensed midwife, C. Bailey has been practicing with the Oregon licensed direct entry midwifery (LDM) rules and has appreciated having those rules which are appropriate for keeping clients safe.

- Currently, the LDM rules state that licensed midwives can attend home birth or a birth center birth for clients who have had a previous C-section.
- Additional LDM regulations state clients with a history of four or more C-sections must be transferred; or clients with three C-sections without a previous successful vaginal birth.
- LDMs are not allowed to attend births where people have had a previous classical incision, T incision or other extensive transfundal surgery or a prior uterine rupture.
- LDMs are required to transfer care with any signs or symptoms of uterine rupture.
- LDMS are required to consult with another provider for people who had any prior cesarean section.
- If a client has had one or two prior C-sections with no prior vaginal birth, the LDM is required to consult specifically with an OB who provides cesarean sections.
- Clients with a history of three C-sections with a previous successful vaginal delivery must have consultation with a physician who provides C-sections.

C. Bailey noted that midwives have benefitted from these consults especially with more complex VBAC cases where clients who've had two prior cesarean sections or one or two previous C-sections with additional risk factors. Consults with another provider, even if it's with another midwife, is an important way to be in touch with any compounding risk factors to help people think more broadly about their clients and to help plan to keep clients safe. Specific plans are made with VBAC clients including plans about care, making sure a client understands that because there's increased risk, there is a need for more frequent vital signs checks, more frequent fetal heart rate checks, if there's a plateau in labor there might be more cervical exams than otherwise done to know if a plateau is occurring, and making more conservative plans for transfer to the hospital if indicated. C. Bailey remarked that midwives are capable of taking risks seriously just like any other risk that midwives interact with.

It was stated that having access to VBACs in free-standing birth centers is a big equity issue for many clients. There are all kinds of reasons why someone choosing a VBAC might not want to deliver in a hospital including:

- Difficulty in finding a truly supportive VBAC provider;
- Fear of being treated poorly with racism or homophobia;
- Fear of being misgendered;
- Fear of fat bias.

C. Bailey stated that they have served many Black, Indigenous, People of Color clients, many queer and transgender clients and they hear about how people don't feel safe in the hospital, need choice in their care and where they want to have their babies.

As an OHP and Medicaid provider, OHP will not pay for a VBAC at home and as such, many clients who are on OHP who choose to have a home birth have to pay out of pocket for their care. This is a huge problem because a lot of people cannot afford it. This means that clients who can afford it can have access to a VBAC with a licensed midwife, while for those who cannot afford the out-of-pocket cost, the only option is to go to the hospital.

Based on their experience with clients who are planning a VBAC, they are a lot more in touch with safety and with risk than any other client. They understand that there are increased risks with their birth. These individuals know about the risks, know what they are choosing, and to not be able to choose is a big deal.

It was stated that if the advice is that persons are not allowed to attend VBACs in birth centers, people not being able to afford the care is more exaggerated because there's a lot of people who choose a birth center birth over a home birth because of in-network options for insurance to pay for that birth and it may not be an option with a home birth midwife.

C. Bailey remarked on how important it is to have skilled providers who know about VBAC and who have trained in it and expressed a lot of gratitude and appreciation for a birth center apprenticeship experience. Having access to training, having attended several VBAC births as a student midwife is important, as lack of experience or training presents additional risks to clients. Many midwives will train at birth centers because birth centers often see a higher volume of clients, and often have more midwives than smaller, home birth practices. More high-risk births become unsafe with a lack of, or loss of, training and ability for people to be skilled providers.

It was further noted that in the past, consults for clients planning a VBAC would be sought from the Legacy Emanuel, Maternal Fetal Medicine clinic; however, it was recently heard that the Legacy clinic's policy has been revised to not accept VBAC consults anymore because they're too low risk and a waste of time. The point of consults is for those providers to repeat what has already been done in terms of talking to the clients about the risks which they already know. (It was stated that a consult would likely occur if it was two or more C-sections with additional risk factors.) It seems like the general understanding in the community, is that people believe that midwives can handle the VBAC client.

It was stated that midwives are really good at informed choice and informed consent, and it is believed that clients should be able to have choice about where they want to give birth.

Jen Kamel

Jen Kamel shared that she is the founder and CEO of VBAC Facts. For the last 16 years, VBAC Facts has worked to provide accurate information on the medical research, medical ethics and political realities to parents, professionals, policy makers and the court so all parties can make informed decisions on this nuance topic.

J. Kamel stated that she will review the following topics:

- Data on VBAC;
- The current state of VBAC access in Oregon;
- What is important to consumers during this work.

<u>Data</u>

J. Kamel stated that the data on VBAC is complex, and there is a lot to consider.

- Wide range of risks at stake, and the choices available to pregnant patients assessing their options for birth after a cesarean.
- Perinatal mortality and morbidity in the current pregnancy and the next pregnancy, maternal mortality, maternal morbidity, and maternal mental health are all factors that play a role which parents are aware of. Parents weigh the risks and benefits of their options in highly individualized manners, and through a variety of personalized filters, including their clinical profile, mental health experiences, past trauma and intended family size.
- Both VBAC and elective repeat cesarean section carry distinct and different risks and ultimately it is the parents' right to decide which set of risks are acceptable.
- Summation of VBAC research in four sentences:
  - The National Institutes of Health stressed back in 2010, VBAC is a reasonable and safe choice for most women with prior cesarean.
  - There is emerging evidence of serious harms related to multiple cesareans.
  - Most women who labor after a cesarean, will have a VBAC, and they and their infants will be healthy.
  - There is a *minority* of women who will suffer serious adverse outcomes of both planned VBAC and elective repeat cesarean section.
- It was stated that this is why no major medical organization supports the idea that a prior cesarean is a reason for a repeat cesarean.
- 2013 to 2020 - the VBAC rate at Oregon Birth Centers was 91 percent, which is higher than any individual Oregon hospital and a stark contrast to the 19 percent VBAC rate statewide.
- It is access to vaginal birth after one cesarean that mitigates the risks of multiple prior cesareans because once someone has two prior cesareans, the odds of ever having a VBAC diminish dramatically.
- Safety or risks involved with out-of-hospital VBAC cannot be understood without understanding risks associated with diminished availability of VBAC in the hospital setting:
  - Maternal morbidity and mortality are strongly associated with cesarean birth, and the odds of repeat cesarean are dramatically higher in the hospital.
  - Per Dr. Elliott Mane, Medical Director of the California Maternal Quality Care Collaborative, there are a lot of hysterectomies, accreta and significant blood loss due to multiple prior cesareans. The biggest risk of the first cesarean is the repeat cesarean. Research clearly ties cesarean to these specific outcomes.
  - Accreta, when the placenta abnormally attaches to the uterine wall, is associated with significant risk of maternal and fetal complications including death. The current recommendation for accreta management is a cesarean hysterectomy ending the fertility of that individual.
  - It was stated that a labor and delivery nurse stated that it is not uterine rupture killing patients, rather it is accreta, increta, and percreta.
  - Per the National Institutes of Health, the risk of maternal death among those who schedule an elective repeat cesarean section is five times higher than those who labor after a cesarean. It was stated that this is important because that group labors after a cesarean, includes those who have a VBAC, as well as those who have a repeat cesarean during labor, including emergency cesareans.
  - When comparing those who plan VBACs to those who schedule repeat cesareans, the risk of maternal death is five times higher in the elective repeat cesarean group,

but it's not just the risk of maternal mortality that is higher with cesareans, it's maternal morbidity as well.
  - The likelihood of many cesarean-related complications increases with each prior cesarean, including uterine rupture, whereas the rate of uterine rupture drops by 50 percent after the first VBAC.
  - Black women have a higher overall cesarean rate and are more likely to plan a VBAC, but are less likely to have a VBAC. As such, they are at a greater risk to experience the short and long-term cesarean complications up to and including death.
  - When talking about safety, we must remember safety for all our citizens with a special focus on marginalized communities. These communities are entitled to respectful, evidence-based care.

<u>VBAC Access in Oregon</u>

- J. Kamel shared that despite the evidence and national recommendations supporting VBAC, medical ethics stating that people have the right to make this choice and repeat cesareans in particular contributing to excess maternal death and morbidity, people do not have the ability to plan a VBAC and avoid repeat cesareans and unnecessary surgery.
  - VBAC is difficult to access across the country, including Oregon. A 2022 study summarized alarm about the risk of uterine rupture, liability concerns, and increasingly stringent standards for surgical readiness overshadow the benefits of successful VBAC, and the risks of repetitive cesarean.
  - Women seek out-of-hospital midwifery support for VBAC, because they have a higher chance of VBAC with midwives, and the best support for physiological birth is with out-of-hospital midwives.
  - In many settings, hospitals do not offer support for physiological birth and do not even offer support for vaginal birth. Out-of-hospital midwifery care is therefore the only option available and the only supported space for vaginal birth after cesarean.
  - The repeat cesarean rate in Oregon is 81%, despite research and guidelines encouraging VBAC access.
  - 69% percent of Oregon counties reported fewer than 10 VBACs during 2023, even though 72% of those counties had at least one hospital.
  - Many hospitals do not offer VBAC, and even among those that do, the odds of having a VBAC in the hospital are far lower than the odds with an out-of-hospital midwife. Women choose out-of-hospital birth because they want to give birth vaginally without medication and this setting is their best choice.
  - One study referenced that some women with higher risk pregnancies will, even with full understanding of the evidence and current recommendations against, seek a community birth, midwife attended, or unassisted birth when they do not have access to vaginal delivery in the hospital, because they do not see cesareans as risk free.
  - Only 19 percent of person with a prior cesarean have a VBAC in Oregon, because hospital VBAC is difficult, if not impossible for many to access, especially in rural areas. While rural hospitals that require repeat cesareans claim this is for patient safety, a recent study on VBAC in community hospitals reported no increased maternal or severe neonatal risk at Tier 1 facilities in comparison to larger hospitals. The resource limitations cited by hospitals as a justification for refusing VBAC, ultimately reflect a financial analysis related to issues like staffing costs.

- Integration and communication between all parties is key to generating the best outcome. Rural hospitals with labor and delivery units have emergency protocols. These same protocols are engaged if someone transfers into their care from a community setting, or if they call in a physician for someone laboring at their facility. That same study advised overemphasizing hospital tier and volume about the safe delivery of women with a previous cesarean delivery may be displaced and parallels can be seen between community hospital research and birth center VBAC.

- J. Kamel noted that smaller hospitals can and do offer VBAC safety. The same drills and skills' training that makes all births safer, also benefits those planning VBACs. Another study on VBAC in rural hospitals found that while mothers were more likely to experience an infection, hemorrhage, or operative vaginal delivery at urban centers, there was no difference in severe neonatal outcomes by hospital type. A third study found that 42% of rural community hospitals surveyed attended VBAC, illustrating that hospitals with fewer resources can and do offer VBAC.
- It was noted that hostility towards midwives and those who plan birth center VBACs can delay care and contribute to adverse outcomes during hospital transfers. The way to make VBAC safer in all settings is integration and collaboration.
    - In a recent survey of OB residents, only 59% reported that offering planned VBAC was important to them.
    - High repeat cesarean rates and their associated complication rates is a problem OBs and hospitals alone cannot fix.

<u>What is important to consumers?</u>

- Midwifery care at a birth center is vital to Oregonians and represent an opportunity to avoid a repeat cesarean mandated per hospital policy.
    - Restrictive hospital VBAC policies, the impact of prior psychological trauma that occurred during childbirth, and the routine violation of informed consent in hospital labor and delivery units are a few reasons why people seek out-of-hospital birth with midwives.
    - Midwifery care is a refuge from hospital policies that leave them no choice, but a repeat cesarean.
    - Midwifery care is an opportunity to access trauma informed care and to avoid a repeat of the trauma they experienced the first time.
    - Midwifery care represents the best support available for physiological birth. Midwives are the experts of physiological vaginal birth and thus offer the greatest probability of avoiding a repeat cesarean.
    - The out-of-hospital setting is the space in which midwives are best able to support the individual needs of birthing patients.
    - Those in rural communities seek out VBAC at birth centers rather than labor at their home because they want access to midwifery care and want proximity to a hospital.
- The Health Evidence Review Commission (HERC) states in its out-of-hospital birth recommendations, they are weighing rare, but sometimes severe risks to the infant against less severe, but more common maternal harms based on very low-quality evidence. Thus, HERC describes their own recommendations against out-of-hospital birth for those with a prior cesarean as weak.
- Considering the recommendations by the American College of OB/GYNs and the National Institutes of Health relative to the VBAC evidence and medical ethics, VBAC access is

encouraged, and considering the realities of increasing maternal mortality and morbidity rates associated with multiple repeat cesarean sections the objective should be making VBAC more accessible, not less.

- The data and evidence support including safe VBAC access in the freestanding birth center setting as important to protecting public health. J. Kamel urged the State to include consideration of the full range of short and long-term risks that pregnant people face when they navigate the choice between vaginal birth and planned repeat cesarean section to protect their right to weigh the risks and benefits as they apply in their case, and to make the decisions that are best for them.

DISCUSSION

D. Selover opened discussion for questions and comments based on the information shared by the presenters.

- RAC member asked C. Bailey whether they felt like midwives with their training and model of care are skilled at the ongoing risk assessment that is necessary with attending a VBAC in the community setting. Also, is there a benefit to the typical provider to patient ratio (at a home birth or birth center) where it's often 1:1, or 1:2 at the most, providers per patient actively laboring. Is there a benefit for patient safety and women seeking a VBAC. C. Bailey responded that even if there is something high risk or complications that wouldn't be safe to attend at home or in a birth center, having midwifery care, which is more personalized, slowed down, emphasizes continuity, a smaller care team, and longer appointments, makes the care safer for clients.
- RAC member expressed frustration that meetings in the past have been canceled by the OHA due to the lack of BIPOC representation and there is no BIPOC representative at today's discussion which was understood as a requirement. It was further noted that the other subject matter expert who is also a BIPOC participant was told that they couldn't attend. Staff responded that the last few meetings have been canceled at the request of the Oregon Association of Birthing Centers not the OHA. Furthermore, the subject matter expert who responded late was notified that while the agenda had been set, the OHA would have them share their information as time allowed. Staff further noted that passage of HB 2993 requires state agencies to invite communities to participate. With the assistance of RAC members, a BIPOC representative was identified to serve on the RAC, however, because the Birthing Center RAC had already been meeting prior to passage of HB 2993, the program received direction from the Department of Justice and OHA leadership to convene a separate meeting specifically to obtain feedback from communities with a specific emphasis on communities of color. This will allow multiple communities an opportunity to see the entire set of revised rules and provide feedback. This plan to comply with HB 2993 requirements in an existing RAC has previously been shared with the Birthing Center RAC. **FOLLOW-UP – ORS 183.333 states in part that an agency may appoint an advisory committee or use any other means of obtaining public views that will assist the agency in drafting the rule and the membership of an advisory committee appointed under the subsection must represent the interests of persons and communities likely to be affected by the rule.**
- RAC member asked C. Duncan is she could explain to RAC members what it looks like when people receive informed choice in the birth center setting regarding VBAC; options; pros and cons, whether it is a one-minute conversation or five minutes? C. Duncan

responded that it is an ongoing conversation. When someone comes into care an intake risk assessment appointment is made and persons complete a health history. Persons who indicate prior cesarean are asked questions about circumstances of the surgical birth, what happened, did they labor, was it for breach, etc. and that surgical records need to be obtained. Information is shared about increased risks for uterine rupture and that the client will need to be monitored more closely. A third trimester ultrasound is required. It was noted that a lot of clients do not start at 6-weeks, rather they start midwifery care later in the pregnancy when they have already received a lot of information about risk related to a VBAC. Discussions are frank including data and other factors that may contribute to risk. Clients are talked with about what the assessment might look like, how the baby will be listened to more frequently, and there may be need for additional vaginal exams. Client testimony was shared previously and was noted for reference. Individualized plans of care are created with ongoing education and risk mitigation.

- RAC member inquired whether C. Duncan had experience with a hospital provider giving informed choice/informed consent for persons who have been followed by a birthing center but based on agreement with birthing center and client, that a cesarean is needed. C. Duncan responded that conversations are limited with hospital providers, but explained informed choice and informed consent are two different things, especially in the case of an emergency.
- The following comments by RAC members were entered into the Chat:
  - Black and brown women are the ones more likely to die after pregnancy. We need to be hearing from them.
  - Agreement on the importance of always having full BIPOC representation present.
  - Seconding statement about the importance of BIPOC input and needs to be done in a meaningful way.

Current Regulations and Polling

D. Selover shared current regulations based on the requirements of the HERC, the Board of Direct Entry Midwifery, the Health Care Regulation and Quality Improvement Program and the Commission for the Accreditation of Birth Centers. Polls were created to gauge RAC members' feelings about whether the rule should be aligned based on each of the regulatory body's requirements.

Based on the initial set of proposed rules, the Oregon Health Authority (OHA) had aligned language with the Health Evidence Review Commission to require transfer of a care for any client with a history of previous caesarean section. As such, the first poll is whether the OHA shall retain the proposed rule text that requires a person with previous cesarean history to be transferred to a higher level of care.

- For purposes of polling, only RAC members are allowed to vote so the percentage of participation displayed will not align based on the number of attendees in the meeting.
- In response to question on the Chat, staff noted that there is no significance with the coloring scheme of the Chart – it was only to clarify the different regulatory bodies.
- Public member asked via Chat whether the results of the polling could be read aloud for persons participating on the phone. Staff agreed.

POLL: Retain VBAC as a mandatory transfer criterion. Results:

- 0% - 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.
- 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.
- 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.
- 82% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

The following poll was conducted asking whether the OHA should consider adopting the CABC compliance indicators which allow a trial of labor after cesarean in a birth center if certain criteria are met (client has had only one prior cesarean birth; client has a documented low transverse incision; ultrasound demonstrates placental location is not anterior and low lying; client remains consistent with all other risk factor criteria of the birth center). RAC member noted that one criterion, informed consent, was missing. Staff noted that the OHA will require that informed consent be obtained.

POLL: Align requirements with the CABC indicators for accreditation. Results:

- 18% - 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.
- 18% - 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.
- 27% - 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 for comments from the RAC regarding the risks and benefits relating to the CABC indicators. Discussion:

- RAC member stated that the American Association of Birth Centers (AABC) sets the standards for birth centers and the CABC defines the indicators for meeting those standards.
  - Most birth centers in Oregon are AABC members, as well as accredited by the CABC.
  - The current CABC indicators support labor after cesarean in a birthing center with the identified risk criteria, as well as comprehensive informed choice specific to risks associated with labor after cesarean; resources for managing emergencies in the birth center; and resources for managing emergencies at the nearest hospital considering the impact of timeliness of access to those resources.
  - The AABC clinical bulletin on VBAC, and position statement on VBAC, and the sample VBAC consent documents were published in 2019.
  - The CABC has supported labor after cesarean in birth center settings since 2014, and the indicators were last updated in 2023 and continue to be supportive within the risk criteria state above.

- Evidence supports that labor after cesarean is consistent within the definition of low risk when provided within the established risk criteria from other local and national professional organizations, regardless of delivery setting.
- When support for labor after cesarean is removed from the communities, families will continue to opt for labor after cesarean, but without the guidance of trained and licensed providers in attendance, and further from emergency care. This dramatically increases risk and potential of harm to the residents of Oregon.
- Duty to protect Oregonians extends to continuing to protect their right to choose labor over repeat cesarean with licensed providers in all settings.
- Echoing what other subject matter experts have already stated. There are guidelines that help make labor after cesarean in any setting safe. The CABC has used evidence to support their recommendations and that evidence is regularly reviewed and updated.

- RAC member noted that there are eight accredited birth centers in Oregon. There are a total of 12 licensed birth centers in Oregon.
- RAC member expressed via Chat concern with the CABC indicators as it does not allow a trial of labor for a person with two previous cesareans and a prior vaginal birth. Depending on timing and other factors, this is not significantly higher risk, and they should have access to delivery at a birth center. No evidence was presented today that would necessitate removing this requirement which is currently allowed under Oregon birth center rules. RAC members via Chat concurred.
- RAC member further stated that this could present a safety issue as birthing people seeking a VBAC after two cesareans would have to birth at home or have unattended birth as their only option. This will have a greater effect on people in rural areas and potentially BIPOC women as well. RAC member remarked that the CABC indicator may be why other birth centers in rural Oregon are not seeking accreditation. RAC members concurred via Chat.
- RAC member further stated that there is inadequate access to VBAC care in rural communities, but there are small birth centers where people can travel from their home, 2-3 hours from a hospital, and have a VBAC in a birth center with a skilled provider often less than five minutes from a hospital. Making the rule more restrictive will decrease safety.
- RAC member stated that in Josephine County half of the VBACs were in a birth center. Most women in Oregon don't plan to have a VBAC in a birth center. There are only 35 to 40 women a year seeking a VBAC; but for those women, they will be the most affected. It was noted that autonomy is very important.
- RAC member stated that any further restrictions, specifically for Josephine County, would result in additional barriers as there are no providers that will attend a VBAC. It was stated that people will drive four hours, coming from other states, to have the option for a VBAC. A birth center is not going to be the perfect location for every single birthing person, but every pregnant person should have a choice as to where she's going to birth which would be further restricted by aligning with the CABC indicators.
- RAC member indicated they would submit their comments after the RAC meeting. Those comments are attached as Attachment 1.
- RAC member stated via Chat that "out of 37 total counties in Oregon, 26 do not have even one VBAC provider."
- RAC member indicated via Chat "it would not be in support of ACOG guidelines to support patient autonomy."

- RAC member remarked about the general discussion and commented about changing regulations relevant to scope. Those comments are attached as Attachment 2. RAC members concurred with this statement via Chat.

The following polls were conducted with respect to the current Oregon Birth Center administrative rules for a client with a previous uterine wall surgery, including cesarean if certain risk factors are present:

<u>POLL: Retain “conception occurred less than 12 months following surgery or uterine procedure” as mandatory transfer criterion. Results:</u>

- 9% - I can say an enthusiastic yes to the recommendation (or action).
- 45% - 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.
- 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.
- 18% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

<u>POLL: Retain “absence of ultrasound to rule out placenta previa or placental attachment to surgical site” as mandatory transfer criterion. Results:</u>

- 36% - I can say an enthusiastic yes to the recommendation (or action).
- 27% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren’t necessary.
- 18% - 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.
- 0% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- RAC member stated via Chat that for people who are very uncomfortable with having an ultrasound to determine placenta location, placentas can sometimes be heard with a fetoscope.

<u>POLL: Retain “history of two or more c-sections without a prior successful vaginal delivery” as a mandatory transfer criterion. Results:</u>

- 9% - I can say an enthusiastic yes to the recommendation (or action).
- 27% - 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.
- 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.

- 27% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

- RAC member stated that there is sufficient evidence that this is not a problem that needs to be fixed, and the current criteria are supporting women having access to VBAC. RAC member reiterated that anything that restricts the current regulations in place is going to be problematic, pushing pregnant persons to free birth which is essentially an unattended birth. It would push women further away from skilled providers and make birth more dangerous. Women need to be given more autonomy; they can understand and make their own choices about risks. Reference was made to the Strong Start for Mothers and Newborns study and all the benefits of being in birth center care in terms of less preterm birth rate, having higher breastfeeding rates, and a much higher level of satisfaction of care. Compelling evidence is needed to take choice away from women and that evidence does not exist.

POLL: Retain "history of myomectomy which invaded the endometrium" as a mandatory transfer criterion. Results:

- 0% - I can say an enthusiastic yes to the recommendation (or action).
- 55% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 36% - 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.
- 0% - 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 "history of c-section which included classical incision" as a mandatory transfer criterion. Results:

- 42% - I can say an enthusiastic yes to the recommendation (or action).
- 50% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.
- 8% - 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.

POLL: Retain "history of c-section and complications including postoperative infection, diabetes or steroid use" as a mandatory transfer criterion. Results:

- 27% - I can say an enthusiastic yes to the recommendation (or action).
- 45% - I find the recommendation acceptable and have no serious objections. Improvements could be made but aren't necessary.

- 18% - 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.
- 9% - I do not agree with the recommendation and will actively block its movement. More discussion is necessary, or an alternative resolution is needed.

The following polls were conducted with respect to the current Board of Direct Entry Midwifery requirements related to c-section(s) and transfer requirements or consultation requirements.

POLL: Align requirements with the Board of Direct Entry Midwifery rules for transfer and consultation. Results:

- 67% - I can say an enthusiastic yes to the recommendation (or action).
- 33% - 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.

Further comments via Chat:

- Data gathered by Oregon association of birth centers show that from Jan 2013- Feb 2020, Oregon birth centers cared for 271 people planning VBAC, 247 of whom had a vaginal birth. That means 35-40 people plan a VBAC in an Oregon birth center each year, with an overall VBAC rate just over 90%.
- Nationwide data from the Strong Start for Mothers and Newborns study showed a more modest rate of VBAC in birth centers, yet still double the rate of a matched cohort planning a hospital VBAC. (24.2% compared to 12.5%) https://www.birthcenters.org/news/strong-start-national-report.
- 52% of people who die subsequent to pregnancy are due to mental health. The way women give birth matters profoundly.
- Strong Start for Mothers and Newborns data - all those benefits of having care in a birth center (lower rates of preterm and low birth weight infants, higher rates of weekend deliveries, higher rates of breastfeeding) - these findings all apply to clients seeking VBAC as well. This study also showed a reduction in racial/ethnic disparities via the birth center model of care. Another finding in that study is higher rates of extreme satisfaction with their overall care. We sometimes forget to talk about maternal mental health, despite that being the leading cause of perinatal mortality for women in the United States. This study also showed a reduction in racial/ethnic disparities via the birth center model of care as well.
- There is not adequate evidence that all women with two previous cesareans and a vaginal birth should not have the choice to deliver in birth centers. Risk assessment needs to be individualized, and not all VBAC after two c-sections are the same risk profile.

- As a woman forced into a 3rd C-section because of hospital policy, the PTSD and trauma is long-lasting. As a midwife and licensed Perinatal Mental Health Professional seeing women referred to me from our local OB providers after their 6-week checkup for concerns, I see these women for a very long time after their traumatic births. These traumas inflicted upon women leave them feeling helpless, alone, abused, and then with a loss of confidence in not only the medical field but also themselves as mothers. As safe, skilled midwifery providers we fill these huge gaps that Oregon is missing entirely.
- There is an overwhelming amount of data that everyone that meets the current birth center risk criteria should be offered VBAC. For people that choose to have their VBAC in the community setting, birth centers have a demonstrated record of safety and a significant benefit in avoiding repeat cesarean. This is based on the current risk criteria which includes VBA2C with a previous vaginal birth.
- There is a Study on gap between price of vaginal birth vs. price of c/s. Looks like Alaska has passed Oregon in having the widest gap in the price, but Oregon's is still a gap of almost $10K on average. https://healthcostinstitute.org/hcci-originals-dropdown/all-hcci-reports/the-price-of-childbirth-in-the-u-s-tops-13-000-in-2020#:~:text=We%20examined%20the%20price%20of,%2411%2C453%20for%20a%20vaginal%20delivery.
- There is no evidence that VBAC birth is less safe in a birth center than it is in a home birth.
- Birth centers have the potential to be safer due to proximity to the hospital, requirement of transfer protocol for licensure and comprehensive chart and peer review ensure ongoing risk assessment.

RAC member inquired via Chat about financial implications. Staff noted that RAC member will be given an opportunity to review a Statement of Need and Fiscal Impact (SNFI) which includes an equity impact statement. Staff plan to seek input on the potential equity impact during the community meeting and the final draft of the SNFI will be shared with the RAC afterwards.

RAC member shared information on the collection of information related to the benefits of using birth centers including the safety and cost effectiveness. It was noted that there is a disparity between the cost of vaginal birth and the cost of caesarean. When hospitals get more money for a caesarean, they are way more likely to do one. Hospitals prioritize surgical birth and Oregon has the biggest disparity in the nation. RAC member further stated that per a discussion with "Medicaid Oregon," one-third of critical access hospitals in the western United States are expected to close in the next three years so VBAC access in hospital settings will be further reduced. Free birth has been mentioned frequently in part because the Oregon Health Plan does not pay for VBAC. This is something that must be addressed.

RAC member stated that the US is incredibly high with respect to people dying in the process of pregnancy or childbirth. Thirty-two out of 100,000 women are dying after pregnancy and a contributing factor is mental health. People are affected emotionally when they have a birth that feels out of their control when they're not regarded in their birth.

Wrap-Up
D. Selover thanked RAC members for their participation. RAC members were encouraged to submit additional comments to M. Bernal via email. • Goal is to get a complete set of draft rules out to the RAC and get feedback. • Staff will consider all comments received over all the RAC meetings. • The Department of Justice will be considering proposed rules for legal sufficiency based on statutory requirements. • A community meeting will be convened to obtain feedback from communities of color on the proposed rules. It was noted that staff will be working with the Office of the State Public Health Director's, Community Engagement Liaison in identifying communities of color and other communities to invite to the community meeting. RAC members were encouraged to submit their suggestions on community organizations to invite to the community meeting. In response to question posed in the Chat, the community meeting will be a separate meeting from the public hearing. • The RAC will be given an opportunity to review and provide feedback on the Statement of Need and Fiscal Impact (SNFI). • A notice of proposed rulemaking hearing will be filed with the Secretary of State's office along with the final draft rules and the SNFI. Interested parties via the listserv and RAC members will be notified via the birthing center listserv about the public hearing date and written public comment deadline.

RAC adjourned at: 11:58 a.m.

ATTACHMENT 1
Follow-up Comments from RAC Member to 06/04/2024 RAC Meeting

Mellony Bernal

From:	K. And <andekaylosu@gmail.com>
Sent:	Tuesday, June 4, 2024 12:01 PM
To:	Mellony Bernal
Subject:	Re: 6/3/2024 meeting FTR Comment

Think twice before clicking on links or opening attachments. This email came from outside our organization and might not be safe. If you are not expecting an attachment, contact the sender before opening it.

My apologies for the mistype, 6/4/2024 RAC meeting, not 6/3.

On Tue, Jun 4, 2024 at 11:57 AM K. And <andekaylosu@gmail.com> wrote:

Please add this to the record for this meeting.

My points were going to be that limiting access to VBAC in Oregon could have wide-ranging implications for consumers, including impacts on autonomy, maternal health outcomes, psychological well-being, financial considerations, and disparities in access to care. It's essential for policymakers, healthcare providers, and stakeholders to consider these implications when making decisions about maternity care policies and practices.

From a consumer perspective, ensuring access to VBAC involves advocating for policies and practices that support informed decision-making, patient-centered care, and equitable access to maternity services. This may include efforts to address barriers to VBAC, such as limited provider expertise, institutional policies, and reimbursement issues, and to promote shared decision-making between pregnant individuals and their healthcare providers.

ACOG's stance on VBAC emphasizes the importance of individualized care and shared decision-making, with the goal of promoting the best possible outcomes for both mothers and babies while respecting patient preferences and autonomy.

These conversations are not happening through Oregon and we as a committee have failed these women by not prioritizing this conversation in the committee. I have gone through a whole pregnancy and birth since starting this RAC. My baby turned 4 in April this year.

Nearly half of Oregon's births were paid for by Medicaid for the last 5 years. It's been a steady 3% of those births happened out of hospital and a steady 2.5 % in hospital. Again, for the last five years. There are women that want this option and deserve to have VBAC in AND out of the hospital offered.

These women deserve true informed choice and respect for their autonomy. I This isn't a matter of yes So what is the compromise and safeguards that we can put in place to ensure the mothers of Oregon have informed choice for VBAC in and out of hospital? We can all agree it's happening and has been so what's the next step to support them? The mothers of Oregon look forward to increase of access in hospital if Vbac was removed/restricted as an option for out of hospital birth.

Thank you,

Kaylyn

ATTACHMENT 2
RAC Member Comments on 06/04/2024

"On behalf of Oregon Association of Birth Centers and as an attorney speaking in a meeting about changing regulations relevant to scope, I think we need to bear in mind that the proposal we're discussing here is only relevant to circumstances in which pregnant people make an informed choice to give birth vaginally at a birth center, and the proposal we're discussing is whether the state should order midwives to refuse to support women in that choice and to use the power of law to take that choice off the table."

"In the case of CABC, it's a choice to give birth vaginally after two cesareans. We've heard a lot of information about the full spectrum, the full constellation of risks at stake in that choice, and we are very clear the data is extreme. The data on out-of-hospital VBAC may be weak, but the data on the risks of cesarean is very strong. There is no question that repeat cesarean increases the risk of maternal death, and there is no question that our rising maternal mortality crisis in the United States is a product of, in large part, birthing people's inability to make a free choice about whether to give birth surgically or whether to give birth vaginally. What we're again discussing here is the role that the law plays in that choice. The law without regulations that restrict choice gives pregnant people the right to weigh risks and make decisions."

"Under ORS 677.097, an Oregon statute, doctors have an obligation to inform all patients, everybody seeking health care, about the viable alternatives for treatment and to support the patient in weighing the risks and benefits of their options and making that decision. Vaginal birth is certainly a viable alternative to surgical delivery after one cesarean, after two cesarean, after numbers of cesareans. What just happens is the risk analysis changes; but it is a viable alternative. If ORS 677.097 were being followed, it would mean that after each cesarean, the increased known risks based on data of that increased cesarean for vaginal birth - that information would be provided to the pregnant patient, and the pregnant patient would be able to weigh that information in balance with things like risks to their downstream pregnancies. Only they know how many babies they want to have, their postpartum support situation, and very importantly, their mental health, which we now recognize as a salient health, measurable aspect of health and of public health and one that should be relevant to this discussion."

"Given the statute, every childbirth provider has a statutory obligation to inform pregnant patients about the options of both VBAC and repeat cesarean, and support the pregnant person to weigh the risks and make their own best decision. Yet, as we've heard today, that is not what's happening for reasons that are cultural rather than legal. But the state is supposed to be the enforcer and protector of its own laws, and so my comment here is the question of, is the state protecting the rights of pregnant people? The risk analysis we're discussing here gets to, when is the state justified in ordering providers to take the option of non-surgical birth off the table, as they would do to birth center midwives through the proposed rule change. Throughout the RAC meetings that have reviewed the proposed rule changes that would essentially replace the current birth center tables on scope of services with OHA's HERC guidelines for coverage of out-of-hospital birth, OABC and our members have said if OHA is aware of evidence or events relating to freestanding birth center births in Oregon that justify the proposed restrictions on access to those services, please put that evidence on the table so that we can figure out whether there is a safety gap that would potentially be closed by the proposed changes. At no time has any evidence been presented of any negative outcomes that justify the proposed changes, and so it is for VBAC."

"OABC's data on VBAC in the birth center setting, over all the years that our members have been providing these services, shows that Oregon birth centers have a much, much higher success rate in helping birthing folks give birth vaginally after a cesarean section without negative outcomes that would suggest that those services and those increased improved rates of success are correlated to a safety gap."

"If OHA's focus is on the protection of public health and the safety of birthing people and their babies, they are going to ensure that nobody ever tells a birthing person that the only medical support available to them for childbirth is surgical delivery. And on that front, OHA has a lot of work to do. Hospitals and obstetricians are never ethically or legally justified in taking the viable alternative of vaginal birth off the table for pregnant patients on the basis of prior cesarean. Any effort to increase public health outcomes around childbirth after cesarean section should focus on protecting pregnant patients' rights to supported vaginal birth in the hospital setting. Evidence does not support taking VBAC off the table. OHA's HERC guidance on payment for repeat cesarean reflects its understanding that VBAC should be supported, and I quote from OHA, 'the majority of planned cesareans in the United States are performed for women who have a prior history of cesarean birth.' That's what we're talking about here. A 2010 AHRQ systematic review reports stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean and that there is emerging evidence of serious harms related to multiple cesareans. That evidence, that study is 14 years old. OHA goes on, 'planned cesareans without an evidence-based indication may increase neonatal and maternal harms, increase costs and result in unnecessary procedures.' We now know that they do, for sure, increase neonatal and maternal harms, as well as those neonates downstream in future pregnancies, and yet, there are hospitals in this state that tell patients that their only option is repeat cesarean section on the explicit basis that supporting physiological childbirth or even vaginal birth at that hospital after cesarean would make them feel that they should pay an obstetrician or an anesthesiologist to be available for the possible need for an unscheduled surgery."

"Why are those cesareans covered by OHA, particularly in settings that openly refuse support for vaginal birth to women for no other reason than a prior cesarean, when doing so conflicts with OHA's coverage guidance for planned repeat cesarean? The basis for the hospital policy refusing support of VBAC is therefore transparently financial and also happens to profit many hospitals because of the increased provider and facility fees associated with surgical delivery. Yet, the government agencies creating the policies that are supposed to protect the rights of birthing people sometimes state sympathetically that you can't make a doctor or a hospital support a non-surgical birth if they're not comfortable doing so without concern for whether it is ethically or legally permissible to subject a pregnant patient to a surgery that they aren't comfortable receiving as their only option for supported childbirth, even though the evidence is crystal clear that that surgery increases the pregnant patient's risk of mortality and morbidity. In other words, the risks of death."

"In conclusion, nobody works harder than out-of-hospital midwives to protect the physical health, mental health and human rights of birthing people and their babies. When the state uses the power of law to cut off access to out-of-hospital midwifery, it's doing nothing more than enforcing a medical monopoly over obstetric services. This is true now, and it was true 100 years ago when midwives were being pushed out of maternal health care in the USA. In the case of vaginal birth after cesarean it means that forbidding midwives to support VBAC amounts to leveraging the power of law to push pregnant people into surgeries that they neither want nor need. The data is clear that doing so is causally linked to the maternal mortality crisis in the USA. The data is also crystal clear that access to out-of-hospital midwifery care is critical to eliminating the racial mortality disparities that increase the risk of death for black women in the hospital setting. OABC sincerely hopes that OHA will honestly pursue the lodestar of safety and public health by protecting the ability of pregnant Oregonians to access VBAC in the birth center setting."

Birthing Center Rule COMMUNITY MEETING
November 15, 2024
10:00 a.m. via Zoom

ATTENDEES	
Cynthia Luxford	Nova Vida Midwives Freestanding Birth Center
Danielle Meyer	RAC member, Hospital Association of Oregon
Desiree LeFave	RAC member, Bella Vie Gentle Birth Center (Administrative)
Holly Jo Hodges	Moda Health
Kaylyn Anderson	RAC member, Consumer
Laura Weigand	Andaluz Birth Center
Mika Ingram	Oregon Advocacy Commission Office
Miriam Herrmann	Trillium Community Health
Rebeckah Orton	Astoria Birth Center
Sharron Fuchs	Public
Terrence Saunders	Oregon Advocacy Commission Office
Tierra Salmón	SMC Full Circle Doula; Birth Assistant @ Canyon Medical Center

OHA Staff	
Anna Davis	PHD-Health Facility Licensing & Certification
Brittany Hall	PHD-Policy and Partnership
Dana Selover	PHD-Health Care Regulation & Quality Improvement
Mellony Bernal	PHD-Health Care Regulation & Quality Improvement
Rebecca Long	PHD-Emergency Medical Services & Trauma Systems Program

Welcome, Housekeeping and Agenda

Mellony Bernal welcomed attendees to this community meeting to discuss how proposed Birthing Center administrative rules may impact health equity in Oregon. The following information was shared:

- Instructions on how to navigate the Zoom tool bar;
- Meeting procedures and expectations on use of the Chat;
- The meeting is being recorded and all information is considered a public record and may be disclosed; and
- Meeting notes from this meeting will be posted at http://www.healthoregon.org/hcrqirules under Rulemaking Advisory Committees in Progress.

The meeting agenda was reviewed.

Overview

Dana Selover welcomed everyone and provided a brief overview on the following:
• Birthing centers per statute are licensed for the primary purpose of performing low risk deliveries;
• Administrative rules are over 17 years old and out-of-date.
• The reason why we are obtaining input from the community in this manner versus through the Rule Advisory Committee (RAC) is due to passage of HB 2993 (2021 Oregon Laws, Chapter 463) which requires that a RAC include members of the community. Because the Birthing Center RAC had already met multiple times over a two-year period before the law became effective and has continued meeting since the law passed, through guidance from Department of Justice and discussions with leadership, a decision was made to convene a community meeting at the end of the RAC process to gather input.
• Initial rules were drafted modeling the criteria identified in the 2015 Health Evidence Review Commission's (HERC), Coverage Guidance for Planned Out-of-Hospital Birth. Over the course of multiple RAC meetings and revisions made to guidance received from HERC, as well as considering current Board of Direct Entry Midwifery (DEM) rules, the proposed rules were amended.
    – Health Evidence Review Commission – Serves Oregon citizens by ensuring that certain medical procedures, devices and tests paid for with Medicaid health care dollars are safe and proven to work. This includes not only birthing center births but home births as well and it was noted that prior authorization is required.
    Coverage Guidance: Planned Out-of-Hospital Birth (updated – 08/13/2020)
    – Board of Direct Entry Midwifery (DEM) – Oversees the practices of licensed direct entry midwives in the state. It was noted that there is overlap between HERC, DEM and Public Health Division (PHD) birthing center rules.
    OAR chapter 332, divisions 010-040 (unofficial copy – 06/29/2023)
    – Public Health Division, HCRQI - Regulates non-long term care facilities and agencies to ensure that facilities comply with all federal and state requirements to ensure the health and safety of clients or patients being served. The PHD looks primarily at health and safety requirements and does not oversee payment requirements or individual scope of practice.
• The Birthing Center RAC was initially convened in May 2019 and finished obtaining input in June 2024.
    – Meeting notes from the Birthing Center RAC meetings can be found at: http://www.healthoregon.org/hcrqirules under Rulemaking Advisory Committees in Progress.
• The purpose of convening this community meeting is to hear from racial, ethnic and immigrant communities, persons with lower incomes, and organizations that serve these communities, about their experiences and concerns and to get direct feedback on the proposed rules from those populations and communities.

- Our goal is to ensure that the rules are both equitable and provide for the health and safety of birthing persons and newborns in Oregon.

Orientation for Health Facility Licensing Rules

D. Selover reviewed the general structure of licensing rules for facilities. Rules generally begin with an applicability statement, definitions, and then proceed with the application process (submission, review, approval, denial, etc.) Following the application process are rules related to licensing requirements such as on-site surveys, complaints, and investigations. Enforcement requirements are found at the end including issuing statements of deficiencies, plans of correction, re-survey, suspension, revocation, civil monetary penalties, etc. The core of the rules, in terms of health and safety requirements, are the bulk of the rules.

Health and safety requirement rule categories include:

- For all health facilities – generic: such as physical environment and emergency preparedness requirements.
- For all health facilities – special: such as medical records, lab and pharmacy services, equipment and supplies, infection control, quality assessment and performance improvement requirements.
- Client care for birthing centers – policies and procedures, client services, admission and discharge, client transfer, risk status assessment, newborn care, and screening.

D. Selover shared information related to the facilities' policies and procedures. An exhaustive list was not reviewed rather a subset for purposes of orienting attendees to the administrative rule requirements. Facility standard policies include, but are not limited to:

- Staff training requirements.
- Admission and discharge criteria.
- Client grievance procedures.
- Assessment of risk and consultation.
- Medical record content.
- Infection control requirements.
- Equipment storage, maintenance, and sterilization.
- Provision of life saving measures.
- Availability of emergency transportation.
- Orientation and education of clients and families.
- Performance of laboratory services.
- Procurement, storage, and administration of drugs.
- Procedures for notifying clients of any financial interest.
- Procedures for providing health care interpreter services to clients who prefer to communicate in a language other than English.

Highlights of client service requirements include:

- Receiving an orientation and written information about services to be provided and a statement of client rights.
- Disclosure requirements.

- Minimum services that must be provided including intrapartum and postpartum care.
- Risk status assessment throughout pregnancy, labor, and delivery to determine if receiving care at the birthing center is appropriate.
- Consultation with perinatal care or other specialty care providers.
- Provisions for the use of telemedicine through real-time communication.

Admission and discharge highlights:
- Admitting only clients for whom medical history, physical exam, laboratory screening and risk assessment do not exclude them from receiving care and services.
- Referral to appropriate providers or health care facility when clients meet certain risk factor criteria.
- Developing and communicating discharge plans including provisions for newborn screening follow-up care and whether a follow-up visit is necessary.

Client transfer highlights:
- Policies for essential lifesaving measures, stabilization and immediate transfer of a client or newborn to a hospital for medical care that exceeds the capability of the birthing center.
- Imminent fetal delivery may delay or preclude transfer prior to birth.

Risk status assessment and consultation highlights:
- A clinical provider at the birthing center must assess a client's risk status throughout pregnancy to determine whether the client may continue to receive care and services, including delivery, in a birthing center based on adopted risk factor tables.
- Risk factors identified in tables are not comprehensive and other conditions may arise that may require further consultation or transfer to a hospital.
- In-person risk assessment must be completed within the first 21 days after the first prenatal care visit. Risk assessments must be updated throughout the pregnancy, labor, and delivery.
- Appropriate referral to a hospital must be prompt if the client, fetus, or newborn meet any of the exclusion criteria identified in the relevant risk factor table.
- Based on the risk assessment findings and associated risk factor tables, a birthing center provider may be required to consult with a certified nurse midwife, licensed direct entry midwife, physician, physician associate, or nurse who has experience handling complications of the risk factor(s) found.
- The client must be present for the consultation or if the client is unavailable, the client must be notified about any findings and recommendations suggested by the consultant.
- Outcomes of the consultation and decisions made about the plan of care must be implemented and documented.
- Client who must be referred or transferred to higher level of care based on a risk assessment may continue to receive prenatal care at the birthing center if certain criteria are met.

Newborn care and screening highlights:
- Various newborn screenings that are required by other OHA rules are reiterated including:
  - Vitamin K
  - Metabolic disease screening
  - Newborn hearing screening
  - Gonococcal conjunctivitis evaluation and treatment

- Pulse oximeter screening

Open Forum Discussion

Participants that were not RAC members were asked to share their feedback on:

- How might the proposed rules impact services to communities?
- How might the proposed rules affect racial equity in Oregon?
- How might the proposed rules reduce barriers to health equity in birthing care?
- What changes can be made that would support more equitable birthing center services?

D. Selover reminded attendees that the purpose of this meeting is to gather input on how the rules may impact health equity in Oregon. An opportunity to provide feedback on the rules will occur after the OHA files a Notice of Proposed Rulemaking Hearing with the Secretary of State's Office. A public hearing will be scheduled where persons may provide oral testimony or written public comment about the rules. The public comment period for submission of written comments will be open for several days. The OHA will review the oral testimony and written comments, consider possible additional changes, and then will file permanent rules.

It was further noted that RAC members will have an opportunity to comment on the Statement of Need and Fiscal Impact prior to the Notice of Proposed Rulemaking Hearing being filed.

Comments:

- Attendee asked that the OHA consider data obtained from the Strong Start for Mothers and Newborns initiative funded by the Centers for Medicare and Medicaid Services (CMS) and how birth outcomes were impacted as well as how it impacted reduced racial inequities with care at birth centers. This initiative identified reduced cost, reduced stress, reduced c-sections, client's 'being heard, understood and respected.'

  https://www.cms.gov/priorities/innovation/innovation-models/strong-start#:~:text=Two%20Strong%20Start%20Strategies&text=Building%20on%20the%20work%20of,Learn%20more...

  Dana asked attendee to identify anything specific in the Strong Start study that can be called out for purposes of the proposed rules that will ensure health equity in Oregon. Attendee indicated that they will consider further.

- Attendee asked how many midwives or staff members of color are in the virtual meeting right now. Staff responded that this information is not collected. Attendee further questioned how and to whom notice was sent. Staff shared that they worked with the Public Health Division's, Community Engagement Team on sending out the flyer. Additionally, staff reached out directly to the following communities:

    - Asian Pacific American Network of Oregon
    - Coalition of Communities of Color
    - Community Care Organizations
    - Community Doula Program
    - Every Mother Counts
    - Forward Together – Birth Justice Committee
    - Healthy Birth Initiatives
    - Oregon Latino Health Coalition
    - Oregon Perinatal Collaborative

- Health Care Coalition of Southern Oregon
- Southern Oregon Perinatal Task Force
- Oregon Health Equity Alliance
- Oregon Advocacy Commission Office

It was noted that there were several persons/organizations that had registered to attend today's meeting, including persons representing the above groups, but are not on the call.

Attendee further inquired what is the deadline to receive feedback. Staff indicated that comments on the specific equity questions may be sent to mellony.c.bernal@oha.oregon.gov and the deadline to receive comments is by 5 p.m. December 2, 2024. It was further noted that these comments will help inform the health equity impact statement that is part of the Statement of Need and Fiscal impact which RAC members will have an opportunity to review.

- Attendee inquired whether the OHA would be reading through all the proposed rules changes during this meeting. D. Selover responded no. The PowerPoint just shared and related material on the webpage summarizes the rules and activities to date. The full rule set was linked in the materials sent in advance of the meeting.
- Attendee inquired about the 21-day assessment requirement in the rules and what if any exceptions can be considered. D. Selover asked for clarification whether they believed the 21-day assessment may impact health equity and attendee responded yes. Another attendee via Chat indicated that that there are military families or others moving that want to meet with birthing centers and establish care to make sure they can find care when they arrive which is sometimes late in pregnancy. **Follow-up – The 21-day assessment is required following the initial prenatal care visit. The 21-days was suggested by RAC members in lieu of 14 days initially suggested. Reference BC RAC meeting notes dated July 21, 2021.**
- D. Selover remarked that should attendees have additional suggestions on who the OHA should seek input from relating to health equity to share information with mellony.c.bernal@oha.oregon.gov. Attendee inquired whether the heath equity questions, and the proposed rules can be shared with national organizations including the AABC and CABC. Staff responded yes. Post community meeting information will be added to the HCRQI rules webpage.
- Attendee stated that they came unprepared as they thought the rules would be reviewed section by section and will review more thoroughly to respond to the questions and invited other members of the OABC to participate.
- Attendee stated via Chat, "We know by the Strong Start data that black and brown people are statistically much safer in birth centers. Any rule that limits people from coming to birth centers has the potential to affect safety for those most at risk in birth (black and brown people)."
- Attendee expressed appreciation for comments previously shared about other programs responsible for reimbursement and payment. Attendee stated there is a continuing crisis of people dying during birth, it was strongly encouraged that all agencies work on making reimbursement sustainable for birth centers and being able to provide more access to Medicaid clients for better outcomes.
- Attendee asked for clarification on where to access the documents. Staff walked attendees through the webpage to identify where documents can be found.

Wrap-Up
Staff shared that the goal is have final draft rule language submitted mid-December 2024 to hold a public hearing in mid-January 2025. OHA policy does not allow PHD programs to hold public hearings during legislative session. If a public hearing does not occur in January, the earliest it could happen would be June or July 2025. Depending on comments received about health equity and possible changes needed to rule, the program may need to delay filing.

Community meeting adjourned at: 11:21 a.m.