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

Oregon Health Authority

800 NE Oregon Street, Suite 465
Portland, OR 97232
Voice: (971) 673-0540
FAX: (971) 673-0556
TTY: 711

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.

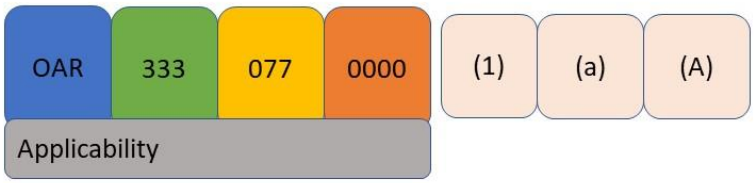
- Health Policy and Analytics, Health Evidence Review Commission (HERC): Reviews clinical evidence to guide the OHA in making benefit-related decisions for its health plans. Risk factor guidelines were developed in November 2015 and are currently under reconsideration. A meeting is scheduled for Thursday, 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 <u>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.</u> 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.