



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.