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 are 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.