HERC Coverage Guidance: Planned Out-of-Hospital Birth
Disposition of Public Comments

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Discussion Table

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1	C2, D1, D3, E1, F1, G1, I1, J1, K1, L1, O1, S1, U1, V1, Y1, AB1	Several commenters said the draft goes into much more detail than most coverage recommendations (including other HERC coverage guidance). Some said risk conditions result in uncertain or variable risk, and others requested a much shorter list of birth risk criteria. Some said the draft coverage guidance is (or has criteria more appropriate for) a practice guideline or licensing rule, and/or encroaches on the role of licensing boards. Most commenters highlighted several reasons the level of detail is problematic:	*According to the rationale for the recommendation, these criteria are more detailed than most HERC criteria because planned out-of-hospital birth is associated with a higher infant mortality rate in the United States. These recommendations aim to reduce the potential harms by clearly identifying the low-risk population for which coverage is recommended.* *In Oregon, out-of-hospital births are not universally well-integrated into the health care system, potentially resulting in delays and poor coordination of care at critical times during pregnancy, labor, and delivery, which can further exacerbate potential harms.*

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		• Some commenters said that the detailed criteria interfere with a woman's reproductive choice. • The detailed transfer and consultation criteria create an administrative burden, which may limit access to services for planned out-of-hospital birth. Limiting access discriminates against low-income women and others who are disadvantaged. • Recommendations should not cover risks which arise during labor or postpartum care as these are not relevant to selecting a planned birth location. • Uncertainty or undesired changes in planned birth location, or undesired consultations causes stress, panic or trauma for women. • Extensive limits on coverage for planned out-of-hospital birth will drive women to give birth out-of-hospital and unattended, putting out-of-hospital birth attendants in a bind.	*Standards of care and educational requirements for birth attendants are also highly variable in Oregon.* *EbGS recommendations often cover factors relating to variable or uncertain risks. See high-risk condition response table for discussion of specific factors.* *These criteria are not intended as practice standards or licensing rules (though they may be of interest to those developing such standards) but as criteria for coverage of planned out-of-hospital birth.* *To address the comments about the list of criteria being too extensive and limiting access to out-of-hospital birth for low-risk pregnancies, EbGS decided to eliminate a number of consultation and transfer criteria which appeared in the draft posted for comment. While many of the risk factors the subcommittee removed create concerning risk for labor and delivery, using them to define coverage may result in substantial clinical and implementation burden. To balance these concerns, EbGS has removed all of the criteria originating from the Board of Direct Entry Midwifery licensing rules as well as numerous criteria that were recommended only by the College of Midwives of British Columbia, otherwise had*

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		• Some consultation criteria pose an excessive burden, because potential consulting providers are too busy, refuse to consult or never recommend out-of-hospital birth. Many consultation criteria are unnecessary and wasteful and interfere with care. One commenter congratulates HERC for the exhaustive list of risks, and said the approach is similar to guidelines established in high-income countries for planned home birth.	*limited alignment across other health systems/guidelines or were based on subjective criteria that would be difficult to interpret. In addition, EbGS removed all neonatal/postpartum transfer and consultation criteria.*
2	I17	This commenter said international studies are not relevant because different standards are in place in other countries. Basing a recommendation on outcomes from places with different systems of care and regulatory standards is inappropriate. 1. The studies were mostly done in countries where there are strict guidelines for planned home births (e.g., no twins, no prior cesarean, no older women).	*EbGS acknowledges the external validity concerns for international studies, but explicitly decided to include these studies in the evidence search since they demonstrate that good outcomes are possible in the out-of-hospital setting. The factors you identified are mentioned in the draft coverage guidance.* *To mitigate the risk present in the U.S. context, this draft coverage guidance box language recommends against coverage for women with certain high-risk conditions.*

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		2. The midwives doing planned home births in non-U.S. studies are well trained and often have hospital privileges. The midwives in these non-U.S. countries are well integrated in their health systems.	*Regulation of training and systems integration are not within the EbGS's scope to change, but these considerations influenced the EbGS decision to include certain risk factors as a way to minimize risks in an environment with variable integration and training standards.*
3	C2, D1, D3, E1, L1, S1, U1, U14	Many commenters said that the draft coverage guidance is not evidence-based. An evidence-based guidance would only include risk criteria clearly identified based on evidence. Instead, some criteria are based on expert or Subcommittee opinion or external standards. Commenters said the evidence selected for this review is not appropriate to guide these recommendations. Research about hospital birth does not tell us what happens in planned out-of-hospital birth. Research specific to risks in planned, midwife-attended out-of-hospital birth is the evidence that is actually relevant to this guidance.	*Evidence was not available on all the specific risk criteria. In cases where there is little or no evidence, HERC often relies on guidelines, expert opinion and standards from other systems or payers to guide its recommendations. For this draft coverage guidance, the subcommittee based its recommendations on risk factors identified in evidence, factors that served as exclusion criteria of low-risk out-of-hospital births in available studies, and guidelines and practice standards of various bodies that regulate or make recommendations for the practice of out-of-hospital births in settings with excellent out-of-hospital birth outcomes.* *Comparative evidence sources are imperative to address the effectiveness and safety of any intervention. The HERC Coverage Guidance focused on evidence that*

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		Several commenters supported a shorter list of evidence-based exclusions in the coverage guidance.	*compared planned out-of-hospital birth outcomes to planned hospital birth outcomes. This is the most relevant evidence to understand the relative benefits and harms between the two intended birth settings.* *While the available comparative studies within the U.S. contain methodological drawbacks due to limitations of available data sources (e.g., vital statistics) and unresolved confounding or effect modification, they provide relevant evidence for this report.* *It is unclear what specific additional evidence the commenters wish to have added to the coverage guidance. The draft coverage guidance does include limited noncomparative data about out-of-hospital births for identification of certain risks associated with bad outcomes. Many of these studies excluded high-risk populations. See Appendix H.*
4	See *high-risk condition response table*	Multiple comments express concern for the addition, deletion, or modification of specific risk factors.	*See high-risk condition response table for responses to concerns about specific risk factors.*

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Commenters

Identification	Stakeholder
A	Clorissa Hecky, Stay-at-Home Mom/Doula [*Submitted December 19, 2019*]
B	Leonardo Pereira, MD, MCR, Associate Professor, Division Director Maternal Fetal Medicine, Oregon Health & Science University [*Submitted December 19, 2019*]
C	Silke Akerson, CPM, LDM, Oregon Midwifery Council [*Submitted December 31, 2019*]
D	Celeste Kersey, CPM, LDM, President, Oregon Midwifery Council [*Submitted December 31, 2019*]
E	Sarah McClure, CPM, LDM, LM, Hearth and Home Midwifery [*Submitted December 31, 2019*]
F	Whitney Wolfe, CPM, LDM, Harbor Midwifery [*Submitted January 1, 2020*]
G	Mark Lakeman, Founder, Communitecture [*Submitted January 2, 2020*]
H	Jennifer Justice Gallardo, President, Oregon Association of Birth Centers [*Submitted January 2, 2020*]
I	Amos Grunebaum, MD, Professor, Zucker Medical School, Director of Perinatal Research [*Submitted January 3, 2020*]
J	Monica Acre, CNM, Virginia Garcia Memorial Health Center [*Submitted January 5, 2020*]
K	Jessica Ruediger, LDM, CPM, Moonstone Midwifery, LLC [*Submitted January 6, 2020*]
L	Eleanor Hawkins, CPM, LDM, IBCLC, Wallowa Mountain Midwifery [*Submitted January 6, 2020*]
M	Miya Tischler [*Submitted January 7, 2020*]
N	London Lunoux [*Submitted January 7, 2020*]
O	Stephanie Dorr [*Submitted January 7, 2020*]
P	Vanessa Lyon, NP, Canyon Medical Center [*Submitted January 7, 2020*]
Q	Catherine Bailey, CPM, LDM, Member of the Oregon Midwifery Council [*Submitted January 7, 2020*]
R	Holly Nickerson, MBA, BSN, RN, CPHQ, CPPS, Asante Director of Quality, Asante Health Systems [*Submitted January 8, 2020*]
S	Nicole Bendotoff, CPM, LDM, Flourish Women's Wellness and Midwifery [*Submitted January 8, 2020*]
T	Carrie Saum [*Submitted January 8, 2020*]
U	Vileka Fisher, Naturopathic Medicine Program, Class of 2021, National University of Natural Medicine [*Submitted January 8, 2020*]
V	Karen Deon, Birth Center Manager, Canyon Medical Center [*Submitted January 8, 2020*]
W	Aimee Morrisey [*Submitted January 8, 2020*]
X	Jessica Morton, Software Validation Test Engineer [*Submitted January 8, 2020*]

Y	Sarah Dinger, Student Midwife [*Submitted January 8, 2020*]
Z	Jennifer Jensen [*Submitted January 8, 2020*]
AA	Sharron Fuchs, DC [*Submitted January 8, 2020*]
AB	Karen DeWitt, ND, Owner of Canyon Medical Center [*Submitted January 8, 2020*]

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A1	I'm here commenting on the Coverage Guidance for Planned Out of Hospital Birth to tell you my birth story in a Birthing Center and a Hospital. I have had two pregnancies, both with no complications and very healthy babies. My firstborn was brought into the world in a Birth Center in Oregon. Being a survivor of sexual assault, I knew I needed to have care where what I said was genuinely accounted for, have little to no interference, and was surrounded by women. All three of these things happened. Everything I said that I wanted in my birth happened. The pain I experienced was next to nothing while being submerged in water and knowing that I was surrounded by people who truly had my and my babies best interest in their hearts. My birth experience at the Birthing Center has been something that I treasured and revered because for once I was respected and honored. I left feeling absolutely empowered. During postpartum, my child never ever left my side..... but it truly would not have been possible without OHP. With OHP the Birth Center was able to give me a discount which made the birth affordable. At the time I left an abusive relationship, and was a single mother without a job. OHP gave me the birth that I needed to become a better person, and an even better mom. When I left the birthing center with my child tucked under my arm, I knew that giving birth at the Birthing Center was the best decision that I had ever made. Thanks to OHP and the out of hospital midwives.	*Thank you for sharing your experience. The Values and Preferences section of the draft report acknowledges the strong preferences women have for planning the location of birth.* *See response to Discussion Table item 3.* *Regarding cost, though the lower cost of out-of-hospital birth would potentially be offset by other factors including transfers and some avoidable complications, the subcommittee expects the net cost to be lower for planned out-of-hospital birth. That said, HERC uses resource allocation as only one factor in decision-making and the coverage recommendation reflects the*

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	My second born was born into a Hospital. There I was bombarded with questions, people and fingers. The pain I felt was terrible because I was overwhelmed by everyone in the room asking me questions and wanting to do internal exams. When I was literally pushing out my child, the nurses jerked back my legs (which caused a birth injury that I needed physical therapy for) and yanked out my child. In postpartum, they kept taking away my child for everything from tests to diaper changes. My newborn would cry and cry and cry. It took several months for my child to be okay with diaper changes from that experience. Also, whatever decision I made for my son was judged and ridiculed by staff..... I left that hospital with severe PTSD, flashbacks to my sexual assault, physically injured and with a child who scared to be away from his mother. It has me questioning if I'll ever be able to have another child again. Those are my birth stories. Now a few years later, I am a Doula. I know the facts and studies to an in hospital birth to an out of hospital birth..... and my in hospital birth was technically pretty good compared to what most women have had. Over regulating who gets to see a midwife is wrong because the stats and figures show that it's safer and more humane for moms and children to give birth with a midwife. Midwives are meant for ALL moms who are low risk, and actually there are very few conditions as to why a mom should go to a hospital for birth. Just look at the statistics of a birth center or midwife, they're a lot better looking the obstetricians. From a political standpoint, it's actually a lot more inexpensive to use out of hospital midwives! A 3,000 per birth cost instead of a 30,000-50,000 birth cost is a lot easier on taxpayers pockets.	*importance of maternal choice of intended birth location for low-risk pregnancies.*

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	The effects on future generations are going to be widely positive too. Think of how a drugged up baby will be 5 years down the road, or a child who hasn't had their lungs fully emptied from a cesarean birth, or the mother who had an episiotomy. Think of how much more money you could put towards cancer patients than unnecessary hospital births. Supporting the out of hospital midwives is the right answer! P.S. I did grow up out in Oregon. I'm currently living in Ohio with my husband who is from here.	
B1	I have been delivering babies in Oregon for the last 15 years and have performed over 1000 deliveries. I am proud of the collaboration that members of Oregon Health & Science University, Oregon Health Authority, and the Oregon homebirth midwife community have demonstrated in working together to maximize birth experiences and safety for Oregon pregnant patients. In addition to a familiar environment and autonomy over their birth process, Oregon's home birth consumers deserve accurate information about safety and outcomes of delivery under special circumstances. As much as we try to avoid risk in childbirth, it is impossible to eliminate risk entirely, but some factors such as breech, prematurity, prior cesarean section (VBAC or TOLAC), twins and triplets have a high rate of preventable adverse outcome which is directly tied to not only attempting delivery in a hospital, but more importantly a hospital with in house anesthesia and neonatal care unit capabilities. In Oregon, community hospitals and birth centers automatically refer these patients to more specialized OB hospital programs for care, the community of home birth providers should at	*Thank you for your comments in support of inclusion of these risk factors as transfer criteria and alignment with the community hospitals' perspective on risk.*

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	the very least follow the same safety guidelines and recommend delivery at a specialized OB hospital program to the families they care for who are planning high risk deliveries. Thanks for considering my perspective.	
C1	Public comment during HERC meetings has been limited to only a few minutes and HERC staff have repeatedly stated that we could communicate at length about the many concerns we could not express in the meetings during the public comment period yet we have now been told that we must limit our public comment to1000 words. This draft guidance is many pages long, covers a large number of new risk criteria, and has massive effects on birthing people and our profession and there is no way to respond in less than 1000 words. This limit serves to restrict public comment. Our organization is sending our letter in three sections from the executive director, president, and vice president in response to this restriction.	*Thank you for your comments. The 1,000-word limit for individual public comments is standard across all HERC Coverage Guidances and has been in place since 2012.*
C2	I am writing on behalf of the Oregon Midwifery Council to express the concerns of birthing families and midwives about the overreach of the HERC in its current draft coverage guidance on planned out-of-hospital birth. The HERC has overstepped its purpose in this document, which is not the evidence-based coverage guidance it was directed to create, but a sprawling document that encompasses everything from solid evidence to members' personal opinions about what midwives should or shouldn't do and who should or shouldn't have a planned out-of-hospital birth. The HERC must reassess its approach to this coverage guidance and come back to the scope that is appropriate to this body. Recently I have been told by HERC staff and members that the HERC is only doing what it was instructed to do by OHA, but the scope and content of the current draft document are absolutely not consistent with what OHA has actually communicated nor with the stated	*The current draft coverage guidance was developed at request of the Health Evidence Review Commission after stakeholders with diverse views requested an updated version based on evidence.* *While HERC's process is evidence-based, there are many coverage-related questions which are not adequately addressed by evidence. In that context, coverage decisions are frequently informed by expert opinion and standards from other payers,*

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	purpose of the HERC. I was a member of the 2014 LDM Staff Advisory Workgroup that directed the HERC to create coverage guidance on planned out-of-hospital birth (though I was the dissenting member on this recommendation because I feared bias against midwives and ignorance about community birth would cause the HERC to act irrationally) and I remember clearly that we simply requested that the HERC create coverage guidance on planned home birth. The primary motivation for our 2014 request was to provide an evidence review by this respected body that could help CCOs understand that covering planned out-of-hospital birth is evidence-based. We asked that the HERC review the evidence on appropriate candidates for home birth and safety criteria and assumed that the HERC would create coverage guidance, consistent with its previous work, that briefly and simply stated a recommendation for coverage and gave the short list of evidence-based risk criteria that would not be covered for planned out-of-hospital birth by OHP. In that 2014 work group we pre-identified six evidence-based risk criteria that would be excluded before the HERC process and we imagined that the HERC would add a limited number of other evidence-based exclusion criteria based on the research on planned out-of-hospital birth. Instead the HERC has created lengthy practice standards, many of which are not based in the evidence on planned-out-of-hospital birth at all but on the personal or professional opinions of HERC members, none of whom are experts in out-of-hospital birth. At this point the guidance is so comprehensive that it overrides our scope of practice, statute, and rules in many areas, and functions as regulation of the practice of midwifery in out-of-hospital settings for any midwife who is a Medicaid provider.	*professional societies and experts. In this case we have considered these factors as well as practice standards from health systems in other countries where outcomes are good for planned out-of-hospital birth. The subcommittee considered standards from the sources listed in Table 3 of the draft coverage guidance, including several midwife-led groups.* *EbGS deliberations are informed by the expert opinion of four ad hoc experts, including two midwives who have attended or continue to attend out-of-hospital births.* *The HERC Coverage Guidance is a recommendation to Oregon payers, including Oregon Medicaid which is responsible to implement coverage criteria reflected on the Prioritized List of Health Services. This report is not intended to serve as practice standards for any group of licensed providers, though it reflects risk criteria which may be of interest to some licensing bodies.*

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	It is unclear to me how things have come to this point. Was there some direction from OHA that is not part of the public record? Is the opinion of an out-of-state anti-midwife researcher so powerful that it can change the course of this body? Is there some information about decision-making in this process that we, as members of the public, have not had access to? It is hard to know who is directing this process or the OHA's internal work on the prior authorization process at this point. When asked, the HERC points to OHA as the decider and OHA points to the HERC, each body saying that the current state is out of their control and created by the other. In the end, what matters is that there is recognition that, while we all agree that standards of practice for midwifery and out-of-hospital birth are important, it is absolutely not within the purview of the HERC to create professional standards of practice. I want to be clear that we do support an evidence-based HERC coverage guidance on planned-out-of-hospital birth. However, I cannot emphasize enough how far this process has strayed from that intent. A comparative example of HERC coverage guidance that is both evidence-based and appropriate in its scope is the HERC coverage guidance on Indications for Planned Cesarean Delivery. Planned cesarean delivery has significant risks for the mother in the current pregnancy and even more serious risks for both mother and baby in subsequent pregnancies. The relevant HERC guidance restricts itself to the evidence available on this topic and, in one page, recommends coverage for planned cesarean section for 6 indications and does not recommend coverage for 6 indications. It goes on to state, "For prior cesarean delivery and other conditions for which there is insufficient evidence of clear benefit over harms, coverage may be based on an individualized treatment plan." In contrast to this clear, concise, and evidence-based guideline on Planned Cesarean, I am able to find no other HERC	*See Discussion Table items 1 and 3 for EbGS's decision to significantly reduce the number of listed risk criteria, and comment E1 below.*

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	guidance that even approaches the overreach present in the Planned Out-of-Hospital Birth guidance. Please see our continued comments in the letter from Celeste Kersey, Oregon Midwifery Council President. Thank you for your consideration,	
D1	In continuation of our concerns expressed in Silke Akerson's 12/31/19 letter: We are deeply concerned about overreach in the current HERC draft guidance on planned out-of-hospital birth. If the HERC were to assess planned out-of-hospital birth and midwifery using the standard found in other guidance such as the Indications for Planned Cesarean Delivery, the outcome would be a short coverage guidance that recommends coverage of planned out-of-hospital birth for low-risk pregnancies and names the limited number of risk factors for which there is clear evidence of increased risk in the out-of-hospital setting such as uncontrolled gestational diabetes, preeclampsia, breeches, twins, pre-term births, etc. It would not seek to cover every possible risk that midwives should assess, it would not seek to cover risks factors in labor or postpartum which are not relevant to guidance about prenatal planning for place of birth, nor would it seek to dictate the consultation relationship between midwives and receiving hospital providers. We applaud the rigorous evidence review on planned out-of-hospital birth that the HERC has undertaken which is a useful resource for us all. We implore you to step back from drafting professional practice standards, which is not your scope, and use that evidence, including observational studies, to name those limited risk exclusion criteria for which there is clear evidence from the research on out-of-hospital birth. If this does not happen and the HERC continues to create professional practice standards, of	*See responses to comment C2 above, Discussion Table items 1 and 3, and comment E1 below.*

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	the kind that are used by midwifery professional organizations in the US, Canada, the UK and the Netherlands, then you must acknowledge what you are doing, name this as something other than coverage guidance, and include Licensed Direct-Entry Midwife, Certified Nurse-Midwife, and Naturopathic Physician Midwife experts who are Medicaid providers directly in the process. Each of you who are health care providers know how absurd it would be for me to write practice standards for your profession without your input and the current process is equally absurd. Knowing that you may proceed with this process even though it is outside the scope of the HERC, [Name redacted] will also submit the public with some specific concerns about individual risk criteria included in the current draft in a separate letter. As you know, planned midwife-attended birth in the home or birth center setting is not the same as hospital birth. This is not only true in some of the ways that you have noted, such as access to a cesarean section, but also in the innumerable ways that the physiologic processes of pregnancy, birth, and postpartum are impacted by the differences in care, environment, and resources in a planned home birth. Research about hospital birth does not tell us what happens in planned out-of-hospital birth. Research specific to risks in planned, midwife-attended out-of-hospital birth is the evidence that is actually relevant to this guidance.	
D2	There are many examples that show how different outcome can be in the different settings: the rate of infection (chorioamnionitis) is lower in planned out-of-hospital birth than it is in hospital birth; the risk of 3rd and 4th degree tears is much lower for low-risk people giving birth at home than it is in the hospital; the risk of hemorrhage is lower in planned out-of-hospital birth even when risk factors are controlled for.	*As summarized in the evidence review, for several maternal outcomes the risk is similar or lower in the out-of-hospital setting compared to the hospital setting, supporting the recommendation for*

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		coverage of planned out-of-hospital birth for low-risk pregnancies.
D3	You cannot simply apply hospital-based research to an out-of-hospital setting. As you look over the numerous risk criteria in the draft HERC coverage guidance on planned out-of-hospital birth please ask yourself, "what evidence do we have about the outcomes for this risk factor in the out-of-hospital setting?" If the answer is no evidence or mixed evidence, it does not belong in this evidence-based guidance. If there is a risk factor that does not have strong evidence that you think should be in midwifery professional standards that is not already, please communicate that with the appropriate professional organizations. Thank you for your consideration,	*See response to Discussion Table item 3, and comment E1 below.*
E1	I am writing to express my concern regarding the draft of the Coverage Guidance document for Planned Out of Hospital Birth. As a Certified Professional Midwife licensed in both Oregon and Washington, I am intimately familiar with the practice of community midwifery and the risk assessment necessary to optimize safe outcomes for birthing people and newborns. My interest in maternal and neonatal safety underlines my enthusiasm for reasonable and evidence-based recommendations by professional organizations; however, the document in review by HERC is meant to be a coverage guideline and not a professional practice standards draft. It is my assessment that the document created by HERC is far too wide in its scope and attempts to enter into discussions that are meant for professional organizations. The intended purpose of this document was to create evidence-based coverage guidelines, and yet there are a number of limitations listed for transfer and consult in the guideline that are not evidence-based. They have been enumerated in other correspondences and do not	*Thank you for your comments.* *See response to Discussion Table items 1 and 3.* *These criteria are not intended as practice standards or licensing rules (though they may be of interest to those developing such standards) but as criteria for coverage of planned out-of-hospital birth. EbGS has reduced the number of consultation and transfer criteria in response to this and other similar comments.*

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	need repeating here. It is the professional obligation of midwives to perform risk assessment and that the guidelines attempt to shift the burden of risk assessments from the professionals (i.e. midwives) to the HERC organization. Home birth midwives are the specialists in assessing who is appropriate for community birth and already have professional organizations to guide us. The document fails in two key ways: a) it does not offer the guidelines it was designed to offer and b) it does not draw on relevant evidence to arrive at conclusions. The evidence that goes into drafting an out-of-hospital guideline must be primarily based on out-of-hospital research, if such research is available. The members of the committee will be familiar with the differences between planned community and planned hospital births, and relevant research must be the focal point of literature review if the guidelines are to be useful and promote safety. Please consider the numerous voices urging you to review the original intent of the document you have created and to read the document with an attuned eye for bias, over-simplification, and digression from the scope. I look forward to reading a draft in the future that meets the stated objective of creating an evidence-based coverage guideline.	
F1	As a licensed Midwife, I am governed by rules and laws that have been carefully reviewed and voted on by our board of midwifery and have been based in evidence. The HERC guidelines have overstepped our governing body and have placed rules not based in evidence, but in fear. All pregnant people deserve the chance to make informed choices for their pregnancy based on evidence. These HERC rules suggest that low income pregnant people have less of a right to make informed choices about their pregnancy that someone with the ability to pay out of pocket. Ex: A healthy active women, one Caesarian, with one subsequent healthy delivery, with no other increased risk factors, history of healthy pregnancies, and on OHP	*See response to Discussion Table item 3, and to comment E1 above.* *The draft coverage guidance is developed as a resource for all Oregon payers, not just the Oregon Health Plan. The EbGS takes into account women's values and preferences, including values around intended birth location as reflected in the GRADE table.*

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	would have the choice of home birth taken away from her. But another women with the same history, and is fortunate enough to make enough money to pay out of pocket, is able to make the choice to birth at home. This rule does not take into account the risk of hospital birth further increasing the risk of having another Caesarian, which is currently 30-50% in hospitals, which dramatically increases morbidity and mortality and other complication, at a higher rate than home birth. HERC is overstepping our Midwifery board, is discriminatory against low income pregnant people and is not based in evidence. higher risk in the out-of-hospital setting?	*The EbGS also recognizes variation in judgments related to risk. The coverage recommendations in this report balance these with concerns about fetal and infant safety, and are intended to influence coverage decisions.* *Planned out-of-hospital birth is recommended for coverage when provided according to the listed criteria, which have been reduced from the version you commented on.* *Having clear coverage rules encourages high-quality care that results in good outcomes for low-income pregnant women and infants.* *Disparities based on ability to pay for services not covered under health plans exist in Oregon, not exclusive to Medicaid.* *Oregon's legislature has designated HERC to review evidence regarding health services and disseminate evidence-based health care guidelines for use by providers, consumers*

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		and purchasers of health care in Oregon (ORS 414.698). *See high-risk condition response table for discussion of vaginal birth after cesarean.*
F2	Delivery history. The evidence I am aware of is that the outcomes are good for mothers and babies for vaginal birth after cesarean for those who have had a previous vaginal birth.	*See separate high-risk condition response table.*
F3	Fetal demise or stillbirth. What evidence is there that a history of a previous unexplained stillbirth/neonatal death is associated with increased risk in the out-of-hospital setting? What evidence is there that a previous stillbirth/neonatal death related to the difficulties of a twin or breech birth is associated with increased risks for a current non-twin, non-breech pregnancy regardless of setting?	*See separate high-risk condition response table, and response to Discussion Table item 3.*
F4	Hematologic disorders. What evidence is there that anemia with hemoglobin below 8.5 in a prior pregnancy is associated with higher risk in the out-of-hospital setting in future pregnancies? What do you mean by "history of postpartum hemorrhage requiring intervention."? What evidence is there that midwives are unable to assess a history of hemorrhage and identify those cases that need consultation or further assessment?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F5	Infections diseases. What evidence is there that out-of-hospital birth is high risk for people who are HIV positive barring other risks? Is there evidence that midwives are not capable of providing co-care with physicians to make an appropriate plan depending on the individual case?	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F6	Fetal growth. What evidence is there that midwives are not capable of assessing a history of IUGR or SGA and deciding when it makes sense to consult with another provider?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F7	Obesity or overweight. What evidence is there that shows that having midwives consult for BMI over 35 impacts outcomes? What value or safety is added by requiring this consult?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F8	Perineal lacerations or obstetric anal sphincter injury. What evidence is there that midwives are unable to properly assess the pelvic floor in someone who had a previous 3rd degree or 4th degree tear with functional recovery?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F9	Psychiatric conditions. What evidence is there that a person with a history of postpartum psychosis (or even some of the other conditions listed here) is not an appropriate candidate for an out-of-hospital birth if their mental health is currently well-managed? Many of us have seen pregnant people with significant mental health history specifically choose home birth as a way to have control over their environment, ability to sleep without interruption or other factors as a way to reduce the chance of postpartum mental health deterioration. Midwives are perfectly capable of working with a pregnant person's mental health provider(s) to come up with an appropriate safety plan. Additionally, whether a person gives birth in a hospital, home, or birth center is fairly irrelevant when it comes to postpartum psychosis as the onset is generally from 2 days to 4 weeks postpartum. All maternity care providers, including midwives, know how to assess and refer should symptoms of postpartum psychosis occur. There is no advantage to hospital birth in this situation.	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F10	Age. What evidence is there that a midwife is not capable of assessing the potential risk of a pregnant person who is 16 or 41? What value or safety is added by requiring a consult with another provider in these cases?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F11	Congenital or hereditary anomaly of the fetus. Who decides what congenital anomalies "require immediate assessment and/or management" and what happens if the parents disagree?	*See separate high-risk condition response table.*
F12	Fetal demise or stillbirth. What evidence is there that a midwife is not capable of assessing risk to the mother and developing a plan for a fetal demise after 12 weeks gestation? How is safety improved or value added by requiring a midwife to consult when a client has a 14-week miscarriage for example?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F13	Infectious conditions. What evidence is there that a person who chooses not to test for Group B strep carrier status is at an elevated risk in the out-of-hospital birth setting over the hospital setting? What evidence is there to justify infringing on the pregnant person's right to informed choice and informed refusal regarding prenatal testing and screening?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F14	Fetal growth. What evidence is there that a midwife is not capable of assessing the risk involved if there is an estimated fetal weight greater than 4.5 kg? What value or safety is added by requiring a consult in this situation especially for pregnant people with a history of a previous birth of a baby greater than 4.5 kg without complication?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F15	Meconium. What does the planned out-of-hospital birth research show about outcomes for births with meconium staining?	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F16	Parity. What evidence is there that midwives are not able to assess risk for pregnant people who have 5 or more previous births? What value or safety is added through this consultation requirement?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F17	Perineal laceration or obstetric anal sphincter injury. (Comment truncated).	*See separate high-risk condition response table and response to Discussion Table item 3.*
G1	As a recent recipient of excellent midwifery care, and now an enthusiastic supporter of this approach to birth support, I am writing to express my concerns related to HERC's current draft coverage guidance on planned out-of-hospital birth. It seems that the document is overbroad, and is not actually fulfilling the clear directives that the guidance was supposed to create. It appears to be configured to appease its members lack of familiarity with planned out of hospital birth, which may not be based in direct experience with it. Please adjust the scope of this guidance to be commensurate with the directives that it was supposed to actually serve. Please also ensure that the guidance and recommendations that are actually adopted are, in the end, actually evidence based. Thank you for your work and concern for safe and healthy families.	*Thank you for your comments. See response to Discussion Table, items 1 and 3.*
H1	Oregon Association of Birth Centers would like to formally request that you extend the public comment period to February 8, 2020 for the Health Evidence Review Commission's Planned Out-of-Hospital Birth Coverage guidance. As I am sure you know, the December holidays are the busiest season of the year, and a time when many people are trying to focus on their family's needs. Children are out of school, and many families are out of town visiting extended family.	*The length of the public comment period is determined according to administrative rule and cannot be changed without a rulemaking process. There is no provision for lengthening a comment period to accommodate holidays. Nonetheless,*

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	The birth centers and midwives are concerned that the time period for public comment on the HERC rule change was set by OHA over the holidays. The deadline over the holidays has made it impossible for many of our clients to review the materials in order to make their feedback. Oregon birth centers and providers need time to notify the public about OHA's proposed changes. Birth center clients have asked to be alerted on this issue, and would like to exercise their right to provide the state with feedback during the public comment period. Please support the public comment process by extending the public comment period to allow the families served by Oregon birth center to provide feedback and input on the rule changes that will affect them in the future.	*comments submitted outside the formal comment period will be sent to subcommittee and Commission members according to HERC policy.*
I1	I congratulate HERC for having done much work to determine risk conditions for planned home birth and to attempt an exhaustive list of conditions precluding coverage, and for determining whether a condition is a contraindication and requires transfer to the hospital or consultation. This approach is similar to guidelines established in high-income countries for planned home birth. I have met many mothers over the last years who have lost a baby at a planned home birth, so I have a very clear insight into this issue.	*Thank you for your comments. HERC adopted the original list of risk criteria based on a combination of factors including guidelines from other countries which have excellent out-of-hospital birth outcomes.* *Based on other comments, EbGS has now reduced the number of consultation and transfer criteria. See discussion table items 1 and 3.*
I2	**Recommendations to include additional coverage guidance to planned home birth** • Studies have repeatedly shown that women over the age of 34 have increased pregnancy complications and increased maternal mortality. Therefore, the cutoff of a woman's age should be red for >=40, and yellow for 35-39.	*See separate high-risk condition response table.*

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I3	• Studies have repeatedly shown that women with their first pregnancy have an up to 45% transfer rate and significantly higher neonatal mortality. Therefore, nulliparity should be red and be excluded from planned home births.	*See separate high-risk condition response table.*
I4	• Twins have significantly higher neonatal morbidity and mortality at home births. Therefore, twins should be in red and be excluded from planned home births	*Multiple gestations are a high-risk criterion. See separate high-risk condition response table (multiple gestations)*
I5	• All fetal malformations should be red. Eg fewer than 3 vessels in the umbilical cord is a fetal malformation and has a higher neonatal morbidity and mortality.	*See separate high-risk condition response table.*
I6	• Coombs direct is now yellow. However, Rh disease is detected with an indirect Coomb's test (antibodies). The positive indirect Coomb's test should be a red flag but is not mentioned.	*A direct antibody test (i.e., Coombs) is performed on the newborn's blood. This condition is in the newborn conditions table. Maternal Rh disease appears under isoimmunization.* *This criterion has been removed, since it only appeared in the LDM final rule, and removed from this draft coverage guidance along with other criteria which only appear in that source.*
I7	• The term "cancer affecting site of delivery" is unclear and requires a more scientific explanation	*See separate high-risk condition response table.*

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I8	• "Cardiovascular disease causing functional impairment" is too limited as there are cardiac diseases that do not necessarily cause functional impairment (whatever that definition is) but which are a contraindication to planned home birth.	*See separate high-risk condition response table.*
I9	• Maternal seizure disorder should be red and not be permitted to be delivered at home	*See separate high-risk condition response table.*
I10	• IUGR in present pregnancy should be delivered in the hospital	*Thank you for bringing this to our attention, we have corrected the recommendation to make IUGR a transfer criterion.* *See separate high-risk condition response table.*
I11	• According to CDC guidelines Group Strep requires IV medication (https://www.cdc.gov/mmwr/pdf/rr/rr5910.pdf) which cannot be administered at home and therefore GBS positive women and those with prior GBS newborns should be delivered in the hospital to provide adequate prophylaxis.	*In Oregon, birth attendants can provide IV antibiotic prophylaxis in the out-of-hospital setting.*
I12	• Any meconium staining is of concern and should be delivered in the hospital, not only "thick" meconium (which is difficult to assert in any case and a subjective assessment)	*See separate high-risk condition response table.*
I13	• Pregnancies after 41 weeks (not after 42 weeks only) should be in red because of their increased risks. This is consistent with other countries' guidelines.	*See separate high-risk condition response table.*
I14	• An Apgar at 5-minutes below 7 requires neonatal intensive observation and should require transfer	*See separate high-risk condition response table.*

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I15	• "Abnormal fetal heart rate" is in red but it's unclear how it's being defined and what are "persistent abnormal fetal heart rate patterns during labor"?	*See separate high-risk condition response table.*
I16	• Any decreased fetal movements are of concern and should be in the hospital for more intensive monitoring, not just "abnormally decreased fetal movements"	*See separate high-risk condition response table.*
I17	**International studies do not reflect US facts** Most studies you mention as "good" studies with "good" outcomes are from high income countries (eg UK/England, Netherlands, Australia, New Zealand, Canada, Japan, Iceland). They should be excluded as a source: 1. The studies were mostly done in countries where there are strict guidelines for planned home births (eg no twins, no prior cesarean, no older women). 2. The midwives doing planned home births in non-US studies are well trained and often have hospital privileges 3. The midwives in these non US countries are well integrated in their health systems. This is similar to saying that driving a car is safe and quoting studies from countries where seat belts have been used, but then using that as an argument where seats belts are not being used. If you don't wear seat belts, you cannot argue it's safe by quoting studies where seat belts have been used. If you perform planned home births without guidelines of excluding high risk pregnancies, you cannot claim it's safe by quoting studies where high risk pregnancies were excluded. To say that "low risk patients have good outcomes at planned home births" and to then cite these other studies is mendacious and ignores that in the US there are no midwife guidelines to determine what constitutes a low risk pregnancy for a planned home birth, and which high	*See discussion guide, item 2.* *Regarding the 2019 study, upon review this is a non-comparative study looking at characteristics of intended home births in the United States.*

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	risk pregnancies should be excluded. Our studies show that planned home birth midwives in the US (contrary to other countries) deliver women who not low risk (Amos Grünebaum, Laurence B. McCullough, Francis A. Chervenak. Publication stage: In Press Journal Pre-Proof. American Journal of Obstetrics & Gynecology Published online: November 9, 2019).	
I18	**Your decision that certain studies are "poor quality"** Masking a determination of "poor quality" for peer-reviewed studies such as our own studies (and most others' eg Bachilova 2018) US studies (just because they usually used CDC data) is beyond the boundary of scientific evidence. It is inappropriate to subjectively label evidence-based peer-reviewed publications from the major ObGyn journal with a "poor quality" label. Evidence based determinations are essential, rather than to dissemble the evidence. Most well designed scientific publications show that US planned home births are associated with an unacceptably increased risk of neonatal mortality and morbidity. Adverse outcomes in US planned home births will continue as long as untrained lay midwives who are not connected to the hospital systems are allowed to perform planned home births without having guidelines to exclude risk pregnancies. Even though our and others' studies showed increased neonatal mortality at planned home births, these numbers are an underestimate of actual outcomes because adverse outcomes of planned home births transferred to the hospital (up to 45% of first pregnancies) are falsely attributed to the hospital when they should have been attributed to the planned home birth. Ignoring evidence-based home births studies that show adverse outcomes and labeling them "poor quality" and trying to dismiss them is not so different from demonizing the hundreds of	*The Methods section and Appendix B describe the assessment of methodological risk of bias. Briefly, researchers at the Center for Evidence-based Policy utilize adapted tools to assess cohort studies based on guidelines from the National Institute for Health and Care Excellence (U.K.), Scottish Intercollegiate Guidelines Network, and the National Heart, Lung, and Blood Institute (U.S.).* *Comparative cohort studies of good methodological quality have, in addition to other characteristics, a clearly defined process for the identification of confounding variables and adjustment for said confounders in their analyses.* *The concern about potential misattribution of the neonatal mortality to hospital births*

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	studies which show clear evidence that climate change is a true problem ("climate deniers: https://insideclimatenews.org/topics/climate-denial).	*rather than planned out-of-hospital births has been discussed at EbGS.*
J1	I was part of two panels that helped guide home birth rules and regulations for the state, as well as work groups that were put together by the Oregon Health Authority to guide coverage for patients planning home birth, and carrying Medicaid insurance. The work group I belonged to consistent of several types of out of hospital birth providers- CNMs, DEMs and NDs, physicians and multiple other experts in the topic. We made several recommendations that would help to improve the environment for out of hospital birth providers and moms and babies in Oregon, and asked that the state make it a priority to ensure that low-income families had the option to access home birth if they were appropriately screened for home birth and had established with a home birth provider that would accept Medicaid. This issue had become one of social justice, there were so many barriers to having Medicaid cover home birth, that the only families able to access home birth were those that could pay for the services out of pocket. Instead of opening the doors to a perfectly safe option for moms and babies in Oregon, this proposed coverage guidance has done the opposite, provide more barriers and reasons to exclude families from the services they should be getting. The most recent draft released by the HERC to guide coverage for home birth deliveries has gone way beyond the intended goals of the work group put together by OHA to inform this issue. There are multiple exclusions for families in the draft recommendations from the HERC. The document being proposed appears to be a very exhaustive list of what is and what is not in the scope of practice of a home birth provider, which is not really the intended goal. There are already many national organizations that guide the scope of practice of home birth	*See response to Discussion Table item 1. See also responses to comments C2, E1, F1, J1, K1 and Y1.* *HERC considered the available national recommendations regarding standards for planned out-of-hospital birth and included these in Table 3.* *Patients have the right to refuse health care, even when doing so places them and their fetus or infant at risk.* *Payment rates and methodologies are outside the HERC's purview.*

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	midwives and it seems like the state of Oregon is trying to re-write this scope of practice for the state of Oregon. This was not the goal of the HERCs effort. We should be looking at the HERC findings as a way to support for coverage of the services provided by home birth midwives providers and allow this service to be accessed by families of all incomes. We need to streamline the process for home birth midwives to start getting reimbursed for their services as quickly as they are being provided, so that home birth practitioners don't have to subsidize their own living and income to survive. The way home birth providers work at this time, they provide services and continue to see families throughout their pregnancy, without the assurance that those services will be covered by their Medicaid plan. Not only are home birth midwives highly qualified and guarantee fantastic outcomes compared to hospitals, they have a lot less clients and get very little reimbursement for their services, so are low income themselves. At this time, the barriers to reimbursement for home birth services have forced most home birth providers to stop accepting Medicaid. We need to provide for avenues in which the home birth provider can be reimbursed for their initial visits, in which they assess the risk factors of families and identify the needs for consults etc. They should continue to receive reimbursement for services when they are co-managed with an in hospital provider, as home birth services provide many benefits to families that are not done by traditional OB providers. They should continue to get reimbursed for home visits postpartum so that families that end up in the care of a hospital, can continue to get the benefits of the one on one personalized, timely care home birth practitioners provide families. Home birth midwives should be able to bill for newborn services both immediately after the birth and up to a month of age. The reimbursement model for home birth services	

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	should reflect that these are providers that should be intimately enmeshed and supported by allopathic and hospital services. The model of care being paid for should never exclude the other, as a way to encourage collaboration and integration of services. Please reconsider the entire goal of this effort- and instead of providing more barriers, help us ensure that families of all income levels access these services, encourage collaboration and integration into the current health care system, and stop putting barriers to this group of health care providers that have consistently shown incredible health outcomes while at the same time protecting patient autonomy and respect. I don't believe the HERC should be defining in such detail what health care conditions should or should not be managed by home birth providers, especially when the review of the evidence does not get into such specific detail for such specific conditions. We should be focusing on the issue at hand- provide an avenue to cover those services so that this delivery method is available for all patients. Patients that risk out of home birth practice will be managed by those home birth providers as they always have, by having their home birth practitioner recommend that the family access care via another avenue, while continuing to have support from their home birth practice. That home birth practice will have to document very clearly when a family declines going to another service avenue to get care despite their recommendations. This is unfortunately a common situation that puts home birth practitioners in a true bind. When this happens, home birth practitioners should not be punished for this situation, but instead supported as best we can by our system. Thank you for your time in reading my response to this coverage guidance. Please don't hesitate to call me, email me for further questions.	

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K1	My name is Jessica Ruediger, and I am a Licensed Direct Entry Midwife and a Certified Professional Midwife providing home birth services in the Southern Oregon area. I am deeply concerned about the new HERC guidelines limiting access by low-income women to the full scope of care provided by LDMs in our state. Our licensing board already sets community birth standards. I used to be an OHP provider, but I found the restrictive guidelines set by HERC to be unfair, unclear and burdensome to both myself, as a licensed practitioner practicing within my legal scope, and to my lower income clients. Now HERC is proposing to further restrict the scope of care. This is not justified. HERC does not have the authority to re-write the midwifery licensing regulations; only our board can do that. This situation leads to licensed practitioners having to enforce a different set of protocols for poor women, which is not ethical. I am not in support of any HERC guidelines that restrict community birth standards beyond our evidence-based licensing laws. In my area, almost all of the midwives used to offer OHP. Now there are only a few community birth providers who will accept it. And if these regulations pass, even more midwives will have to discontinue as OHP providers. This is effectively eliminating low income women's access to a legal and regulated service that is a vital and important option in maternity care. Community birth is cheaper, costing the state and Oregon citizens less than hospital birth. Community birth is safe, when LDMs practice within the scope of our care. Birthing women tend to be more satisfied with midwifery care, and there is no justification for eliminating who can access this maternity care alternative in it's full scope based on economic status. Please record my dissent regarding further HERC restrictions to covering community birth. Make it simple, make it cheaper for the OHP system, and make it ethical, by allowing Oregon's low-income women access to the full scope of midwifery care.	*See response to Discussion Table item 1, and responses to comments E1, F1 and K1.* *It is not the intent of EbGS that implementation of these recommendations discourage safe, effective provision of services related to planned out-of-hospital birth. In fact, EbGS recommends coverage for low-risk births, defined according to the criteria included in the recommendation based on outcomes that show benefits to the mother and while minimizing risk to the fetus or infant. EbGS has removed a number of transfer and consultation from the coverage guidance, in response to this and other similar comments.*

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L1	I am writing in regards to the guidelines you have proposed for coverage for community birth. I have read the proposed Coverage Guidance and appreciate the work that went into the various considerations and suggestions. Many of the HERC guidelines make sense and I do not take issue with them. There are however some that seem to defy evidence and moral reality, I am not sure how they could have been included with true evidence review. I serve a rural area in Northeastern Oregon, Wallowa and Union counties, most of the people that contact me are on OHP. The unsubstantiated limitations caused by these recommendations on families of lower socioeconomic status is egregious and has created a massive barrier to access and choice for many families. The HERC claims that "Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations" did you consider rural Oregon and the impact your recommendations would have there? These guidelines seriously impact safe, evidence-based choice in most of Oregon. The cost of being licensed means that my fees are higher than the lay midwives in my area. Subsequently these guidelines have completely removed Northeastern Oregon OHP family's choice to have licensed community birth unless they are able to shoulder the cost personally. This document serves to discriminate and burden Oregonians. I remember when the first HERC guidelines were commissioned and implemented. HERC was asked to review evidence to help define prenatal assessment and risk criteria for planned home birth. I remember well the fear that this body would use the simple OHA request for guidance and instead create a president to police and overreach the objective and moral boundaries of the task at hand, this is what has happened. I grant your intention is probably good but the outcome is inappropriate and harmful. I recall when the 2015 guidelines caused	*See response to Discussion Table items 1 and 3, and responses to comments K1 and Y1.* *EbGS recognizes that access to health services, including out-of-hospital birth or higher-acuity hospital care, can be difficult to access in rural Oregon.* *Now that many criteria have been removed in response to this and other comments, the current draft has fewer consultation and transfer criteria than the 2015 coverage guidance.* *In addition, the current draft also significantly modifies the definition of consultation, now requiring the consultation to be with the appropriate provider (e.g., a hematologist for a hematologic question, a maternal fetal medicine doctor for a potential high-risk condition) rather than only a maternity provider with hospital privileges. Consultation with another LDM*

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	great disparity of access for birthing families and caused most Oregon LDMs to discontinue taking OHP. Because of your selection criteria many of the studies you have used have no bearing on homebirth or true statistics clearly provided by trained and licensed midwives. The guidance you were asked to create was not whole practice guidelines and insurance coverage does not change by actions in labor or immediate postpartum, these sections should be removed. Our OARs rightfully dictate our scope, when we transfer and when we consult. It is NOT the job of HERC to override LDMs appointed statutes, laws, scope and training. A note about consultation: Many doctors are too busy or simply refuse to consult. I happily consult when needed but consulting on many of the matters you outline is redundant to our training. Midwives are trained and can have more education and up to date continuing education regarding maternal care than many general MDs. How does consulting with people with less experience or education in some matters help anyone? Midwives are well informed to identify and manage the majority of the risks you outline. Consulting on things like these will only serve to annoy and stress relationships between LDMs and MDs. It will also serve to discredit the knowledge LDMs do have. This is especially true in rural settings. Consultation should be allowed with other LDMs as well, as defined in ourDEM OARs. Upon becoming licensed 2016 I did not even consider signing on to take OHP because I knew it was following poor evidence-based criteria and personal opinions and it had taken safe choice out of the hands of many families in Oregon. As a medical provider I can not align with the lack of ethics or evidence HERC has caused and I choose not to be involved. I would like to be able to accept OHP. As stated before I support many of the findings but the following are not items I am not willing to force on families.	*would not meet the prior nor newly-proposed consultation requirements.*

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	I believe that the HERC should adjust these in the final document: What evidence is there for the following items as outside LDM education, legal scope or as precluding homebirth? These situations are in my licensed scope of practice, I am trained to perform these types of births. It is not the place of HERC to limit DEM scope and directly alienate and discriminate Oregonians from access to licensed care.	
L2	Mandatory consults: • pregnant people >40. This is a normal age for many multiparous women. • multipara -/>5. • previous pregnancy with fetal demise after 12wks.	*See separate high-risk condition response table.*
L3	Transfer: • Breech. Frank and complete are in my scope of practice, • Multiples. In DEM scope. • VBAC. In DEM scope. There are many reviews and studies that indicate VBAC is safer and preferred to repeat c-sec, which is the only choice for rural Oregon for in hospital birth! • 36-36+6 and 42-42+6 births. In DEM scope. • GBS. It is a pregnant person's right to informed choice and informed refusal regarding prenatal testing, intervention, and treatment.	*See separate high-risk condition response table.*
L4	The following items I find noteworthy and believe they should be changed and researched further. I would not refuse to participate if they are not changed however: Transfer: • Placental delivery >60minutes. What evidence is there for this not to be a consult? Transfer seems poorly supported at this point.	*See separate high-risk condition response table.*

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	• Unknown status for various infections (HIV, Hep B, Syphilis). Many families are in monogamous relationships and have been tested in previous pregnancies for these conditions. Forcing them to do so when some have moral objections is not ethical or evidence-based but rather is overreaching and inappropriate for the scope of what the HERC was originally designed to do.	
L5	I hope that with combined effort on this document your final recommendations will allow the birthing families of Oregon to once again have access to safe and true evidence-based care. Thank you for your consideration,	*Thank you for your comments.*
M1	I have recently been made aware that midwifery care in Oregon is under threat. I think creating barriers to midwifery does a grave disservice to the women of this state who deserve the quality of prenatal and birthing care that is simply not possible in an over-medicalized obstetrical model. The safety, cost-effectiveness, and efficacy of midwifery care is undeniable and developed countries with robust citizen care models favor midwifery as a first line of care for women. Taking the freedom to choose away from the women of Oregon is wrong, and is an effort to medicalize birth and create profit. As an Oregon voter I strongly oppose this action and urge you to reconsider the motivations for such disempowering legislation and your complicity in it.	*See response to comment F1 above.* *Thank you for your comments.*
N1	I would like to comment that your current treatment of midwife care and birthing centers and the rules you place upon them is unacceptable. We the public know good and well that this is about control and putting them out of business and protecting hospital profits and not about the health and well being of women and new borns. What you are doing is a gross overreach and abuse of power. As a woman if I am pregnant it is my body and my choice to choose my	*See Discussion Table 1 above.* *See response to comment E1 above. Many criteria have been removed in response to this and other similar comments.*

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	provider and place of birth. Even women with other health issues, or previous c sections should have the right to make an informed choice without a big hassle to go through. You have put birthing centers out of business and midwives out of jobs. Stop this abuse and control of birthing people and allow them access to the birth and provider of their choice.	*Thank you for your comments.*
O1	You are not in the business of dictating health but in the business of helping people get the care they choose. You do not have authority over their decision. Your authority is how the taxpayer funds it. Individual choice and informed choice should be your number one priority. Stop mandating and dictating medical decisions for poor people.	*See response to comment F1 above.*
P1	I am writing to comment on several proposed changes to the OOH risk criteria. There are several items on this list, requiring careful evaluation and discussion between patient and care provider, but ultimately represent a theoretical or small increased risk in the pregnancy that does not translate to increased risk with choosing a midwife. By taking these choices away from women that are within the scope of out-of-hospital providers, we are unnecessarily discriminating against these women and influencing care. I would love to participate in a separate discussion about how this is implemented.	*See response to Discussion Table items 1 and 3, and response to comment F1.* *Thank you for your comments.*
P2	Collagen Vascular disease: exclusion criteria RA is a collagen vascular disease. While there is increased risk of adverse pregnancy outcomes with RA consultation would suffice. 1. Severity of RA varies. While some women do well with concervative treatment and medication, others need to work with a high-risk provider. 2. Increased risk of adverse outcomes (low birth weight, SGA, pre-eclampsia and cesarean section) are low and can be managed by skilled provider, who knows when to transfer.	*See separate high-risk condition response table.*

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	We can and should provide increased surveillance of these patients, while still providing access to midwifery care, unless complications arise . 3. Research supports midwifery care improves outcomes related to LBW, SGA and CS. Women with RA may have better outcomes when receiving care from midwives. 4. There is no evidence that patients with RA have increased adverse events when delivering out of hospital, unless additional risk factors develop to exclude them, which would require a transfer of care anyway.	
P3	Previous CS: exclusion criteria. Remove this as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. (Additional data on this available via OABC, please email.) 2. The risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. There is significant benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more cesereans increases significantly. Repeat CS is significantly more likely if TOLAC occurs in a hospital. 1 in 14 mothers with accreta die. 1 in 17 babies with accreta die. There is insufficient data showing OOH VBAC has enough increased risk to outweigh the benefits to mom and baby of avoiding repeat cesarean.	*See separate high-risk condition response table.*
P4	4. Significant Endocrine conditions other then diabetes 5. Additional clarification is needed. If hypothyroidism. If patient is seeing a CNM or ND that is trained to manage hypothyroidism in pregnancy, additional consultation is not	*Thank you for alerting us to this error in the draft coverage guidance. Hyperthyroidism*

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	necessary if patient is well managed. Requiring this consult increases cost of care and is inconvenient for the patient.	*(not hypothyroidism) was intended as a consultation criterion.* *See separate high-risk condition response table for proposed resolution.*
P5	History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Proposed change: Include as consultation criteria only. unless additional risk factors develop to exclude them. Unless there is a genetic link to the loss or an anatomical variation, there is no research showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss to remove. This simply removed choice from a patient who already traumatized.	*See separate high-risk condition response table.*
P6	History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria. This should be consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In some rural areas, having access to a midwife increases the likelihood a patient with warning signs of pre-eclampsia will be promptly referred to the appropriate provider and facility. At this time there is insufficient evidence that women with a history of pre-eclampsia requiring pre-term birth, have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy. While there is research showing that their outcomes may be improved when they received care from a midwife.	*See separate high-risk condition response table.*

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P7	BMI ≥ 35 consult The information women receive at these consults is typically generic and no more insightful than an informed consent. It inflicts further emotional trauma and makes them less likely to seek care from providers in the future when they feel stigmatized by their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
P8	Psychiatric conditions: Schizophrenia, other psychotic disorders etc This inappropriately discriminates against women with these types of mental illness. Women with significant mental illness may choose midwifery care and home / birth center delivery. There isn't data to show this as being unsafe. In many cases this may be just the type of personal one on care these patients need. Choice in provider and the personalized care offered in this model has so much benefit, especially when they are co-managed by the appropriate psychiatric provider.	*See separate high-risk condition response table.*
P9	History of postpartum mood disorder with high risk to infant Most midwives complete a minimum of 2 home visits over the first week of life, and ongoing postpartum care with a close relationship with their provider. This allows them to closely monitor patients that are at risk for severe PPD. There is not significant evidence to show that this is a risk for these people, and therefore restricting access to this care is discriminatory.	*See separate high-risk condition response table.*
P10	Amniotic membrane rupture greater then 24 hrs. There is insufficient data to show that expectant manage of ROM > 24 hrs has enough increased risk to mom or baby that this choice should be taken away from women. As long as	*See separate high-risk condition response table.*

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	there is appropriate follow up by the provider and client, risk of infection and adverse outcomes is low.	
P11	Diabetes, gestational managed by medication. Gestational diabetes managed by metformin is within the scope of NDs. There is no data showing that these patients have worse outcomes when cared for in hospital, vs cared for by ND.	*See separate high-risk condition response table.*
P12	Thrombocytopenia Recommend 75,000 as cut off.	*See separate high-risk condition response table.*
P13	Group B strep unknown Women have the right to decline testing in pregnancy. There is sufficient data from countries that do not routinely test for GBS but used risk based protocols that not testing is a reasonable choice for an informed person and provider to make. I proprose require risk based management for women that decline GBS testing or transfer if additional risk factors develop.	*See separate high-risk condition response table.*
P14	Uterine condition: Prolapse Does not require transfer if it immediately reduces	*See separate high-risk condition response table.*
Q1	1000 words is not enough to adequately express my concerns about this exhaustive draft. This draft is too long, too detailed, and more than what the scope of coverage guidance should be. Please cut this down to basic guidelines. I have been a licensed direct-entry midwife for 6 years and have been a Medicaid Provider for most of that time and most of my	*See responses to Discussion Table item 1, and to comments C1 and K1 above.* *Thank you for your comments.*

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	clients are on OHP. This coverage guidance greatly affects my ability to give the best care to my clients and my ability to get paid for my work and I hope that you consider my feedback.	
Q2	Intro: 1) Consultation with an LDM should be one of the options for consulting provider. LDMs are capable of determining when a hospital provider needs to be the person we consult with.	*See response to comment L1 for discussion of consultation by one licensed direct-entry midwife with another.*
Q3	Medical or OB History: 1) Prior Cesarean Section - Although Prior Cesarean section has increased risks I believe that there should be coverage for all people who've had a prior c-section and a prior vaginal birth and also for all people who've had one prior c-section, with a low, transverse incision, who fully understand the risks and sign a detailed informed consent document.	*See separate high-risk condition response table.*
Q4	2) History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty - What does intrapartum difficulty mean here? Assuming a death related to an intrapartum breech entrapment is an 'intrapartum difficulty' why would someone need to have a hospital birth if they are planning a vertex birth? This should be removed entirely as an exclusion for coverage and the consult item should be clarified.	*This language was clarified to the following consultation criteria:* • Prior stillbirth/neonatal death
Q5	3) Under 'Fetal Growth' these items should all be removed. Midwives are capable of determining when they need to consult for prior IUGR, SGA and LGA babies.	*See separate high-risk condition response table.*
Q6	4) Hematologic Disorders - Midwives are capable of determining when they need to consult for all of the listed conditions - remove these items.	*See separate high-risk condition response table.*
Q7	5) Miscarriage - Remove these consult requirements. How is this evidence based?	*See separate high-risk condition response table.*

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Q8	6) Encephalopathy - what is the evidence that a prior baby with encephalopathy poses higher risks in a current pregnancy in the out of hospital setting?	*See separate high-risk condition response table.*
Q9	7) BMI>35 consult - How will this consult affect outcomes for these clients? Midwives know when they need to consult about a particular client. I have done many of these consults for my OHP clients with little to no benefit for me or the client.	*See separate high-risk condition response table.*
Q10	8) How would a consult about prior 3rd or 4th degree lacerations improve outcomes for clients in a subsequent pregnancy?	*See separate high-risk condition response table.*
Q11	9) Psychiatric Conditions - these should be removed from coverage exclusion. Midwives are particularly suited to these clients. We are capable of consulting when needed, referring for extra services, and are present much more in the postpartum period when most postpartum mood disorders arrive. I have taken care of many of these clients with great success and they have reported feeling well taken care of.	*See separate high-risk condition response table.*
Q12	Conditions of Current Pregnancy: 1) Age - Midwives can determine when they need to consult for a client <17 or > 41 years old. This should be removed.	*See separate high-risk condition response table.*
Q13	2) Pre-labor ROM >24 hours should be a consult not a requirement to transfer. While of course the risk goes up with these clients, with appropriate management and avoidance of vaginal exams, this can end in successful, healthy home vaginal births most of the time. This should be replaced with s/s of infection post-rupture.	*See separate high-risk condition response table.*
Q14	3) Consult for fetal demise after 12 weeks - There are many straightforward miscarriages after 12 weeks - midwives should determine if they need to consult for this condition.	*See separate high-risk condition response table.*

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Q15	4) Fetal Growth - midwives can determine when they need to consult for these clients - this list should be removed. For example, someone may measure size < dates for their whole pregnancy but have consistent growth and not need a consult or ultrasound. Or, someone may measure small one month and on track the next. This should be determined on a case by case basis.	*See separate high-risk condition response table.*
Q16	5) Gestational Age > or = to 42 weeks 0 days - Remove. So many clients, when given the opportunity to not be induced, ride this line of 42 weeks. Perhaps it could change to 42 weeks 3 days, or, include 'without family history of post-dates delivery.' I have many clients with family history of going post-dates go post-dates themselves with no issue.	*See separate high-risk condition response table.*
Q17	6) Group B Strep Unknown - Clients should be able to have coverage and refuse screening tests with informed consent.	*See separate high-risk condition response table.*
Q18	7) 'Genital Herpes at time of labor' - change to: 'Genital Herpes Outbreak that is uncoverable at time of labor.'	*See separate high-risk condition response table.*
Q19	8) Thick meconium staining of amniotic fluid transport requirement - Remove. What is the evidence that this is safer in the hospital? If there are ALSO abnormal fetal heart tones, this is a different story.	*See separate high-risk condition response table.*
Q20	9) 'Significant maternal confusion or disorientation' should be a consult not a transfer. This can occur when someone is feeling triggered about past abuse history in labor and it can come and go without significant safety risk to the mom or baby. What is the evidence that this would be safer in the hospital?	*See separate high-risk condition response table.*

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Q21	10) Consult for grand multiparty - how would this improve outcomes? Remove.	*See separate high-risk condition response table.*
Q22	11) Low lying placenta within 2cm of os at 36 weeks or later - should be changed to 'at last documented ultrasound before onset of labor' because someone could get an ultrasound at 38 weeks that shows it has moved.	*See separate high-risk condition response table.*
Q23	12) <5 prenatal care visits or prenatal care beginning in the third trimester should be removed as a consult requirement. Midwives can assess when they need to consult for a particular client and these are often not necessary. Evidence based?	*See separate high-risk condition response table.*
Q24	13) Psychiatric Conditions - midwives can determine when they need to consult for these clients. Remove.	*See separate high-risk condition response table.*
Q25	Neonatal Conditions: 1) Appearance - should be removed - midwives know when to consult for newborn behavior, appearance, and feeding issues.	*See separate high-risk condition response table.*
Q26	2) Weight less than 5th% for GA with no other complications or issues should be removed as a transfer requirement Thank you for your consideration..	*See separate high-risk condition response table.*
R1	In response and review of the Health Evidence Review Commission (HERC) 12/10/2019 draft for coverage guidance regarding planned out-of-hospital birth, Asante Health System would like to note the following: • There is limited to no existing regulation of training/credentials for providers assisting with deliveries outside of the acute care center.	*EbGS recognizes the value of high-quality neonatal care being critical to improving neonatal outcomes.*

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	• There is an increased risk of neonatal mortality for planned out-of-hospital births. • Neonatal resuscitation program states that "every birth should be attended by at least 1 qualified individual, skilled in the initial steps of newborn care and positive pressure ventilation (PPV), whose only responsibility is management of the newly born baby." "A qualified team with full resuscitation skills, including endotracheal intubation, chest compressions, emergency vascular access and medication administration, should be identified and immediately available for every resuscitation". A newborn with apnea, gasping, or a HR less than 100 needs PPV within 30-60sec of birth. 4-10% of births require PPV. We are unable to reliably predict prenatally which newborns will require resuscitation. Births outside of the hospital are unable to meet these immediate, lifesaving needs of a distressed newborn. Asante is committed to continuous improvement efforts related to the safe delivery inside the hospital setting and cannot recommend, with current practices and regulatory structure, any acceptable home birth. This recommendation comes with a strong care for the safety of mother and infant for the inherent risks of out-of-hospital delivery. It is imperative that the State of Oregon take significant considerations in recommendations and contracts with insurance coverages to support best practice and continue to promote safe care across Oregon.	*Although the Neonatal Resuscitation Program (NRP) is considered the standard protocol for neonatal resuscitation, HERC does not have the authority to specify neonatal resuscitation requirements as a condition for coverage.* *EbGS also does not have the authority to require an additional birth attendant whose only responsibility is management of the newly born baby.* *Thank you for your comments.*
S1	I am a Certified Professional Midwife, Licensed in Oregon. I provide evidence-based care to pregnant people, including those who are insured by the Oregon Health Plan. As a provider I am concerned about the new coverage guidance the HERC is putting out regarding out-of-hospital birth.	*See responses to Discussion Table items 1 and 3, and to comments E1, J1 and K1 above.* *EbGS recognizes the stress and anxiety caused by potential or actual transitions of*

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	My understanding is that the HERC is to create simple evidence-based coverage guidance for out-of-hospital birth; not to provide comprehensive overreaching practice guidelines. I do support an evidence-based HERC coverage guidance on planned out-of-hospital birth. However, the current draft appears to be more akin to the Oregon Administrative Rules, which already outlines safe practice guidelines and provides laws for out-of-hospital birth providers regarding when we must transfer care and consult. As providers, we are thoroughly trained to care for women the antepartum, intrapartum and postpartum. We are able to assess what constitutes a low-risk pregnancy, to decide when a consult or transport is warranted during pregnancy, birth or the postpartum and to ensure our clients are being cared for in a safe, evidence-based manner. As much as you, we do not want high-risk patients giving birth at home. Our goal is to provide birthing families a safe option for low-risk out-of-hospital birth. We work diligently to maintain good outcomes and to improve outcomes. The guidelines and process for out-of-hospital birth approval by OHP are already making it difficult for providers and patients to work together. There is increased stress on patients with the insecurity of not knowing whether their care will be covered. This is detrimental to them. Providers are declining to work with OHP patients due to the instability of the situation as well and the lack of autonomy they have in determining what is right for their patients. No other insurance company tries to define the scope of practice of a provider. They can choose not to cover something, as the HERC guidelines can outline (no twins, breeches, preeclampsia, etc), but do not require continual monitoring and review of the care being provided. My request is that the HERC stay within their scope by creating a simple, evidence-based coverage guide, not a document that will create barriers to safe and appropriate care for	*care, and balances these concerns with concerns about the safety of out-of-hospital birth for pregnant women with certain risk factors.*

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	pregnant and birthing people. I would be happy to provide further details about what this would look like if needed. Out-of-hospital providers are 100% committed to keeping their clients healthy and safe. Please, allow us to do the job we were trained to do. Thank you for your time,	
T1	My name is Carrie and I have given birth to two healthy babies under the care of my midwives, Dr Leslie Hamlett and Karen DeWitt at Canyon Medical Center in Portland, OR. I was given the highest level of care, felt safe and relaxed, and all of my concerned were taken seriously and addressed appropriately. I have attended other births of family members and friends under Canyon's midwifery care, and observed the same attention to detail, safe practices, and gentle methods I experienced. What this comes down to, however, is choice. Regulating where a person can give birth is anti-choice, and removes autonomy from the person giving birth. This predominantly affects binary women, but also affects those who are often discriminated against in traditional medical settings. Black women, transgendered persons, fat women, financially disadvantaged families, and same sex couples will be the ones who will bear the greatest consequences by removing safe, low-cost birth options and personal autonomy. Midwifery is a valid, safe, and wonderful option for birth that should remain available to those who desire it. Please stop trying to regulate women's reproductive choices.	*See response to comment F1 above.*
U1	Several items on the proposed coverage guidance, while they should be addressed by the patient and her provider, should not preclude a patient from experiencing an out of hospital	*See response to Discussion Table item 3.*

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	birth. Many of the risks associated with those conditions are theoretical or extremely small. If anything, these proposed changes would unfairly target poor women, women with larger families, and women in larger bodies. Out of hospital providers have already seen a decrease in home and birth center births due to the current pre-approval system, which is already extremely cumbersome and convoluted. I have a problem with the process by which HERC is selecting criterion. HERC does not provide evidence for some of the conditions listed as exclusion or consultation criteria. If HERC cannot provide compelling evidence, then it should remove those conditions from its list. Those conditions are highlighted in the following chart. ***Exclusion and consultation criteria that should be revised or removed from the proposed guidelines:***	
U2	Previous C-section: CMS data indicates that VBACs are safe and successful in out of hospital settings. Women are more likely to have better VBAC outcomes if they have their babies out of hospital.	*See separate high-risk condition response table.* *It is unclear which CMS data the commenter is referring to.*
U3	Significant Endocrine conditions other than diabetes: Hypothyroidism—consult unnecessary unless not well controlled.	*Hypothyroidism was incorrectly listed in Appendix I, it is not a consult criteria in the updated draft coverage guidance. Thank you for bringing this to our attention.*
U4	History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty	*See separate high-risk condition response table.*

HERC Coverage Guidance: Planned Out-of-Hospital Birth
Disposition of Public Comments

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U5	History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria: Patients with a past hx of these conditions are not guaranteed to develop them again. They can be managed by a qualified out of hospital provider.	*See separate high-risk condition response table.*
U6	BMI ≥ 35: This is discrimination based on body size and not supported by evidence. Correlation does not equal causation. It's like saying that if you're a certain height you must have a hospital birth. Plenty of research has broken down any supposed links between health and body size.	*See separate high-risk condition response table.*
U7	Psychiatric conditions: Schizophrenia, other psychotic disorders, taking psychotropic medications, etc.: This is not an evidence-based exclusion criterion.	*See separate high-risk condition response table.*
U8	History of postpartum mood disorder with high risk to infant	*See separate high-risk condition response table.*
U9	Amniotic membrane rupture greater than 24 hrs	*See separate high-risk condition response table.*
U10	Gestational diabetes managed by medication or diet.: If well managed by oral meds or diet, GD patients should not be denied out of hospital births.	*See separate high-risk condition response table.*
U11	Group B strep unknown: Providers can use a risk-based protocol if testing is declined. Providers are trained in monitoring the mother and baby for signs of infection. Furthermore, patients are allowed to exercise autonomy and decline tests after being informed about the risks.	*See separate high-risk condition response table.*
U12	Uterine Prolapse: If immediately reduced, it does not require immediate transfer.	*See separate high-risk condition response table.*

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U13	Prenatal Care, <5 visits in the 3rd trimester: Patients have a right to autonomy, meaning every patient should be able to choose who they see for prenatal care.	*See separate high-risk condition response table.*
U14	It's hard to provide research when it doesn't exist or when only poor research is available. In addition, out of hospital care that is supportive of physiological birth is inherently different than hospital-based birth. It's apples and oranges. The data is too heterogeneous. Ignoring available evidence or making biased inferences from available evidence and ignoring the clinical expertise of out of hospital birth providers will not improve current guidelines. Moreover, much of the proposed guidelines disregard reproductive rights. We can trust pregnant women to make the best decisions for themselves, and if a woman wants to have an out of hospital birth with a qualified provider, then she should have that opportunity.	*See responses to Discussion Table item 3, and to comment F1 above.*
V1	I have been in Oregon for almost two years, finishing up my midwifery training, I came here to do so because people still had choices for out of hospital births. I am getting ready to sit for NARM. Currently I am the Birth Center Manager at Canyon Medical Center. There are several items on this list, that while they require careful evaluation and discussion between the patient and care provider, represent a theoretical or small increased risk in the pregnancy that does not translate to increased risk with choosing a midwife. By taking these choices away from women that are within the scope of out-of-hospital providers, we are unnecessarily discriminating against pregnant people. The actual enforcement of this PA process has lead to a significant decrease in the number of out of hospital births, because midwives are not paid for PN care when a client is not approved; the process is cumbersome due to the amount of documentation required.	*See responses to Discussion Table item 1, and to comments F1 and K1 above.*

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	Approval needs to be given at the beginning of pregnancy, and then can be re-evaluated later if needed.	
V2	Topic: Previous CS: exclusion criteria. Remove this as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. 2. The risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. There is significant benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more.	*See separate high-risk condition response table.*
V3	Topic: History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Women with previous loss are capable of understanding risks and benefits to choosing their provider and place of birth. Restricting access to coverage based on this history is traumatic for women with that history. They may choose out of hospital birth for a variety of reasons. It also may drive patients that are not comfortable in a hospital to birth unassisted at home, increasing the risk to mother and baby. There is insufficient data showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss to remove this choice for birthing people.	*See separate high-risk condition response table.*

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V4	Topic: History of preeclampsia requiring pre-term birth and HELLP as exclusion criteria. This should be consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In some rural areas, having access to a midwife increases the likelihood a patient with warning signs of preeclampsia will be promptly referred to the appropriate provider and facility. There is no evidence that women with a history of preeclampsia requiring pre-term birth have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy, and in fact the opposite may be true.	*See separate high-risk condition response table.*
V5	Topic: BMI ≥ 35 consult Information women receive at a consult is not so nuanced as to need an in-person consult. It does not justify the cost and the emotional expense to these women. They have already educated themselves and there is no added improved outcome by having a consult. It does further stigmatize their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
V6	Topic: History of postpartum mood disorder with high risk to infant Midwives complete a minimum of 2 home visits over the first week of life, and ongoing postpartum care with a close relationship with their provider, most of the time they don't see an OB for six weeks.	*See separate high-risk condition response table.*
V7	Topic: Group B strep unknown Women have the right to decline testing in pregnancy. There is sufficient data from countries that do not routinely test for GBS but used risk based protocols that not testing is a	*See separate high-risk condition response table.*

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	reasonable choice for an informed person and provider to make. I propose require risk based management for women that decline GBS testing or transfer if additional risk factors develop.	
V8	Topic: Uterine condition: Prolapse Does not require transfer if it immediately reduces.	*See separate high-risk condition response table.*
W1	I was denied coverage for my planned birth center birth in June 2019. The reason for denial was a previous cesarean in 2018. I went on to have a successful vaginal birth after cesarean at a birth center. I was forced to pay out of pocket for my care because OHP denied my chosen delivery method. The care I received at the birth center was by far superior to the care I received at the hospital after my first birth. Every woman who has had a previous cesarean should have every right to make an informed decision about how and where she gives birth. Studies have shown a higher success rate of VBAC in a birth center setting then a hospital setting. There has also been studies showing that a vaginal birth after a cesarean is safer for the woman and baby. Studies have also shown that 80% of women who attempt a vaginal birth after cesarean are successful. Women are being traumatized with lack of evidence based care. The most empowering thing that can be given to pregnant women is a voice.	*Thank you for your comments.* *See separate high-risk condition response table.*
X1	There should be safe and affordable midwives and birthing centers available for all pregnant women. Several birth centers in Oregon have closed because of this policy and Medicaid is covering drastically less out of hospital births because of it. In cases where the medical risk is small, it's important to maintain patient autonomy and I'm gravely concerned that these requirements create discrimination against out of hospital providers and their Medicaid recipients that seek an out of hospital birth. If a provider is already contracted with OHA, why	*Thank you for your comments.*

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	are we requiring such lengthy, involved process for them to be approved to birth with their chosen provider. Pregnancy and birth are normal events in a woman's life, not unique conditions. I suggest a single page document, with patient's demographics and a signature from their midwife that says they don't have certain high-risk conditions. This should be adequate to approve out of hospital delivery, and approval be offered as early as the first trimester so there is not an obstacle to them having complete prenatal care with their chosen provider.	
Y1	I am writing in regard to the proposed coverage guidance for planned out of hospital birth. I am deeply concerned and frustrated by the extensive and detailed list of indications for consult and transfer of care. I find myself wondering whether it is possible that the HERC is unaware that LDMs in Oregon already practice according to a detailed set of rules? I do not disagree with many of the indications listed, but because these rules already exist, much of the proposed draft is, in fact, redundant. Additionally, the proposed draft lists indications for consult that should be left to a midwife's discretion. Whether an LDM needs to consult depends on the specifics of the situation, and on that person's experience with similar situations. For example, as required for OHP coverage, I recently consulted for a history of macrosomic babies. The client had two truly uncomplicated home births with large babies and a negative test for gestational diabetes. The CNM with whom I consulted seemed confused by what I was asking; she replied that "obviously" this person is an appropriate candidate for home birth. This was obvious to me as well. The required consult in these situations is a waste of time for the LDM, for the CNM, and even for the person who is reviewing the chart to determine OHP coverage eligibility. At the same time, consult and sharing of information is an important part of midwifery practice among LDMs. Every midwife	*See response to Discussion Table items 1 and 3.* *EbGS has selected its consultation criteria based on evidence and on criteria used to guide care in various settings. The consultation criteria differ from the 2015 coverage guidance in that consultation can be with a specialist not credentialed to deliver babies at a hospital.* *See separate high-risk condition response table.*

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	I have met is deeply committed to providing excellent care to their clients. As such, if a midwife does not have experience with a situation or condition, they will consult with one or more practitioners who can provide recommendations. It is condescending for the HERC to enumerate every specific case in which consult is required. This same reasoning applies to indications for transfer of care in the proposed draft for coverage guidance. Midwives are trained and licensed professionals AND are already practicing according to a detailed set of practice standards created by the Oregon board of direct entry midwifery. I am currently a student midwife nearing the end of my training, and feel strongly that it is important to accept clients who have OHP coverage. However, it is discouraging to be faced with the additional restrictions and requirements detailed in the proposed draft. These not only dictate how a midwife can practice, but also necessitate extra work and time. I know that many midwives do not accept OHP clients because they are not comfortable with letting the coverage guideline dictate their care and infringe upon their ability to provide true informed choice to clients. A simplified and evidence-based coverage guideline could go a long way toward increasing the number of midwives willing to accept OHP clients. I strongly request that the HERC create a concise list of evidence-based recommendations for coverage guidance, rather than attempting to create a midwifery practice standard.	
Z1	In November of 2018, when I was 36 weeks pregnant, I was forced to undergo an OHP Prior Authorization ultrasound. It was supposedly because I had 3rd degree lacerations with my first pregnancy, which was 18 years ago. After the ultrasound, which lasted a full hour, the doctor who came to speak to me was rude, abrupt, and didn't listen to anything I said. She told me that I was going to be forced to	*Thank you for sharing your experience.* *See responses to comments S1 and Y1 above.*

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	change providers, at 36 weeks, and that I was "taking (my) baby's life in my hands" and that a vaginal birth, let alone a birth center birth, was out of the question. I was actually able to transfer care (unheard of at that late stage) and gave birth, vaginally, unmedicated, and out of hospital just a couple of weeks later. He was a perfectly healthy, beautiful baby boy who is now a year old. While I WAS able to transfer care, it was ONLY because of my fantastic midwife, who I trusted and had developed a relationship with. She was able to pull some strings and get me in to a different place, with some more stringent rules. This is an incredibly important time in a woman's life, and pregnancy. In a time when I SHOULD have been the happiest, secure in my birth team, happily preparing to give birth, I was having severe panic attacks, and sobbing regularly, not knowing who would help deliver my child, where I would give birth, or how it would be paid for. This is a time when blood pressure is important, yet I had panic attacks, induced by this ridiculous, asinine process, which (obviously) caused my blood pressure to rise. That can't be healthy. This process robs the mother to be of her security, making her pregnancy more at risk, and her labor longer. The providers who have known the patient, developed a relationship with her, and helped her plan, know the patient, and her pregnancy, including any extenuating circumstances FAR better than the one off doctor who is supposed to come in and tell them what is going on, without ANY knowledge of the patient. Yet this one off doctor (who was incorrect on all accounts) made my last few weeks of pregnancy hell. A lawsuit was considered but ultimately decided against.	

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	The prior authorization protocol of OHP robs patients of their choice and makes medical induced interventions far more likely with worse outcomes for both mother and child.	
AA1	As an Oregon Doctor of Chiropractic trained in out of hospital births I ask for the following additions to the draft Medicaid Guidance for Planned Out of Hospital Births: Mandatory fetal and infant mortality reporting to Oregon Medicaid for sentinel event review by a multidisciplinary team to include medical physicians (MD). Deidentified data collected from these reports to be organized and made publicly available. Mandatory reporting to Oregon Medicaid the outcomes for all births including but not limited to all injuries , no matter how slight, to birth mother or baby with those injuries attached to both birth mother and baby records . Meaning, an injury to birth mother is noted in the babies Medicaid report records. Deidentified data collected from these reports to be organized and made publicly available. Mandatory reporting to Oregon Medicaid circumstances of all transfers from home or birth center to a hospital. Deidentified data collected from these reports to be organized and made publicly available.	*Mandatory reporting of sentinel events and data collection and analysis by health plans are outside the scope of this report.*
AA2	Advanced maternal age ,greater than 35, as a high/ higher risk factor precluding planned out of hospital birth. (Advanced maternal age is not low risk).	*See separate high-risk condition response table.*
AA3	Post dates, beyond 41 completed weeks, as a high/ higher risk factor precluding planned out of hospital birth. (Post dates is not low risk).	*See separate high-risk condition response table.*
AA4	All births in early labor to be confirmed by ultrasound that fetus is in the cephalic presentation. No payment for 'surprise ' breech.	*See separate high-risk condition response table.*

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AA5	All Medicaid records , including labor and delivery records, to be completed on Oregon Medicaid standardized forms. No 'draft' or rewriting of any record at anytime.	*Documentation requirements are determined by health plans and are outside of the scope of this report.*
AA6	The scope of practice and the standards of care for All planned out of hospital births in Oregon is the same for all professions. Meaning, all planned out of hospital births are to be low risk as defined by the Oregon Health Evidence Review Commission under the Oregon Health Authority. No Oregon licensing board, especially one who is also under the purview of the Oregon Health Authority, can independently decide that a planned out of hospital birth can be anything other than low risk as per the Oregon Health Evidence Review Commissions' definition of low risk. To intentionally practice anything other than low risk care and attend births that are anything other than low risk jeopardizes the health and safety of the patient(s) and is considered unprofessional conduct under Oregon law.	*Licensing standards are outside the scope of this document. They are determined by licensing boards as required by law.*
AA7	The question of maternal choice has come up as a reason for the EBGSs to not fully investigate and define some factors as high / higher risk ie nulliparity. Maternal choice is of significance only as to the 'consideration' of place of birth NOT as to maternal personal choice of what the definition of low risk is and thus demanding a payor conform to their personal choice of definitions. Safety of mother and baby is not a question of choice.	*See response to comment F1 above.*
AB1	There are several items on this list, that while they require careful evaluation and discussion between the patient and care provider, represent a theoretical or small increased risk that does not translate to increased risk with choosing OOH birth.	*See responses to Discussion Table item 1, and as to comments F1, K1, and S1 above.*

ID/ #	Comment	Disposition
	To take this choice away from women that are within the scope of out-of-hospital providers, unnecessarily discriminates against these women by restricting their access to the provider of their choice. Oregon decided many years ago to provide access to out-of-hospital birth for women on Medicaid, and that right is legally protected. The implementation of these guidelines has drastically reduced the numbers of out-of-hospital births in Oregon. If OHA truly wants to provide access to this care, they need to allow their contracted providers to provide maternity care without a cumbersome and restrictive prior authorization process. In my experience since HERC was implemented the majority of patients that undergo the PA process find it stressful at best and at times traumatic and demoralizing. My clients have stated they feel like they are being discriminated against for being poor, or fat, or having too many miscarriages, etc. I have seen patients make significant sacrifices to pay for their birth out of pocket after OHP denied their PA, when they were in fact low-risk and a candidate for delivery at the birth center.	
AB2	Topic: Collagen Vascular disease: exclusion criteria. Change to consult only. RA is a collagen vascular disease. 1. Severity of RA varies. 2. The increased risk of adverse outcomes (low birth weight, SGA, pre-eclampsia and cesarean section) is minimal. 3. Research supports midwifery care improves outcomes related to LBW, SGA and CS.	*See separate high-risk condition response table.*

ID/ #	Comment	Disposition
AB3	Topic: Previous CS: exclusion criteria. Remove as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. 2. Risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care; it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. Benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more cesereans increases significantly. Repeat CS is significantly more likely if TOLAC occurs in a hospital. 1 in 14 mothers with accreta die. 1 in 17 babies with accreta die. There is insufficient data showing OOH VBAC has increased risk to outweigh the benefits to mom and baby of avoiding repeat cesarean, which midwives excel at.	*See separate high-risk condition response table.*
AB4	Topic: Significant Endocrine conditions other then diabetes Please clarify that if patient is seeing a CNM or ND that is trained to manage hypothyroidism in pregnancy, additional consultation is not necessary if patient is well managed. Requiring this consult increases cost of care and is inconvenient for the patient.	*See separate high-risk condition response table. See hypothyroidism response in comment P4.*
AB5	Topic: History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Women with previous loss are capable of understanding risks and benefits to choosing their provider and place of birth. Restricting access to coverage based on this history is traumatic for women. They may choose OOH birth for a variety of reasons.	*See separate high-risk condition response table.*

ID/ #	Comment	Disposition
	There is insufficient data showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss. Proposed change: Include as consultation criteria only, unless additional risk factors develop.	
AB6	Topic: History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria. Consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In rural areas, having access to a midwife increases likelihood a patient with early signs of pre-eclampsia will be promptly referred to the appropriate provider and facility. There is not evidence that women with a history of pre-eclampsia requiring pre-term birth have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy.	*See separate high-risk condition response table.*
AB7	Topic: BMI ≥ 35 consult Information women receive is not so nuanced as to need an in person consult. It does not justify cost and emotional expense to these women. There is no added improved outcome by having an in person consult. It does further stigmatize their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
AB8	Topic: Psychiatric conditions: Schizophrenia, other psychotic disorders etc Inappropriately discriminates against women with mental illness. Women with significant mental illness may choose OOH birth. There is not data to show this as being unsafe, and rather having a choice in their provider and the personalized care offered in this model has benefit for these patients when they are being co-managed by the appropriate psychiatric provider.	*See separate high-risk condition response table.*

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ID/ #	Comment	Disposition
AB9	Topic: History of postpartum mood disorder with high risk to infant Remove as exclusion criteria. Personalized care and close follow up by midwives including home visits are one of several reasons women with PPD hx may choose a midwife. Also in may be important to choose the same provider in a subsequent pregnancy as they are already familiar with their history.	*See separate high-risk condition response table.*
AB10	Topic: Amniotic membrane rupture greater then 24 hrs. There is insufficient data to show that expectant manage of ROM > 24 hrs has enough increased risk to mom or baby that this choice should be taken away from women.	*See separate high-risk condition response table.*
AB11	Topic: Diabetes, gestational managed by medication. Gestational diabetes managed by metformin is within the scope of NDs. There is no data showing that these patients have worse outcomes when cared for in hospital, vs cared for by ND.	*See separate high-risk condition response table.*
AB12	Topic: Thrombocytopenia Recommend 75,000 as cut off.	*See separate high-risk condition response table.*
AB13	Topic: Group B strep unknown Women have the right to decline testing in pregnancy. Recommend risk based management for women that decline GBS testing or transfer if additional risk factors develop.	*See separate high-risk condition response table.*
AB14	Topic: Uterine condition: Prolapse Does not require transfer if it immediately reduces.	*See separate high-risk condition response table.*

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References Provided by Commenters

ID	References
I	Grunebaum A, McCullough LB, Chervenak FA. Most intended home births in the United States are not low risk: 2016 – 2018 [published online ahead of print November 9, 2019]. *Am J Obstet Gynecol.* doi: 10.1016/j.ajog.2019.11.