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August 2, 2023

Jacqueline D. Milledge
Bureau of Health Provider Standards
Department of Public Health
P.O. Box 303017, Montgomery, AL, 36130

Re: Comments for Alabama Proposed "Birthing Center" Freestanding Birth Center Regulations 7-13-2023 Chapter 420-5-13 Birthing Centers

Dear Ms. Milledge,

Thank you for allowing us the opportunity to comment on these proposed regulations for freestanding birth centers in Alabama. American Association of Birth Centers (AABC) holds national expertise and decades of experience in the safe operation of birth centers. We are available to consult with the state DPH or to provide information or resources as needed in your work to license birth centers in Alabama.

Freestanding birth centers have demonstrated excellent outcomes for birthing people and infants including reduced preterm and low birthweight rates, decreased cesarean rates, increased breastfeeding rates and over \$2000 cost savings to Medicaid for every mother/baby pair when compared to typical care.¹

AABC recommends that birth center regulations state very clearly that when a birth center is accredited by the Commission for Accrediting Birth Centers (CABC), that birth center will be deemed licensed in the state of Alabama. AABC has model regulations that can be utilized with CABC accreditation as a basis, simplifying and ensuring birth center regulations' safety and consistency.²

The AABC Standards are the evidence-based standards that are recognized by national partners including the Society of Maternal Fetal

Medicine (SMFM) and American College of Obstetricians and Gynecologists (ACOG).³ In the Levels of Maternal Care (2019), ACOG recognizes the freestanding birth center as a level of care within the larger perinatal care system and states that the AABC Standards should be followed as the basis for that care and that CABC Accreditation be a requirement for licensure (Levels of Care).⁴

Many of the provisions outlined in the proposed regulations do not align with current evidence based national standards or CABC accreditation. Since CABC accreditation will be required for all licensed birth centers in the state, CABC indicators should be used for licensure.⁵

Including provisions in the regulations that are not aligned with AABC Standards or with evidence-based care could lead to confusion about required components of care and to potential problems with patient safety. When AABC Standards and CABC Accreditation are used as a basis for licensure, then the state is not required to add new staff and cost for site visits. For example, Minnesota uses CABC accreditation to deem licensure and when a birth center becomes accredited, notification is sent to the state, then that birth center is deemed licensed.⁶

AABC has thoroughly reviewed these proposed regulations both as an independent organization and in partnership with multiple AL stakeholders. Unfortunately, these regulations are significantly out of step with both AABC and CABC recommendations, standards and indicators. Together, we have compiled a list of the five most egregious concerns to highlight the overall non-functionality of the document. We will present them here.

First, requiring a physician as birth center staff or consultant. This is referenced several times in the proposed regulations, 420-5-13-01 in the General definitions section:

b. lists licensed physicians as required staff

f. consultant physicians are required if there is no staff physician and the physician is required to be "available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing facility when called"

The presence of a medical director or supervising physician in the facility is not associated with better outcomes.² Further, the requirement to have a physician go to the birth center to provide hands-on care goes against all known and accepted safety plans and could cause delay in care and harm to the patient. In the event of a clinical situation requiring physician involvement, the safest course of action is to transfer the patient to a hospital where a physician is ready and able to intervene as needed. This proposed requirement highlights the necessity of including birth center experts who will share best practices

around clinical safety, provider scope and specialty, and appropriate utilization of the levels of care.

The second major issue of concern is related to how Certified Professional Midwives (CPM's) are defined in the document.

General Definitions section, (b) states "Certified Professional Midwives may also provide care as assistive personnel to staff certified nurse midwives and registered nurses in a birthing center".

This is in direct contradiction to known and established national birth center standards and the state of Alabama's own rules. These AL Regulations for Licensed Midwives state they may practice "in the setting of the client's choice except a hospital". The Alabama Attorney General provided further confirmation that CPMs are appropriate care providers in the birth center setting in his December 2022 Opinion in which he stated, "a licensed midwife may provide midwifery care in a licensed freestanding birth center." The education and training of CPM's makes them appropriate providers for birth center practice. In fact, Certified Professional Midwives are the only perinatal care provider type with an educational pathway that requires training and demonstrated expertise in the out of hospital setting. Over half the birth centers in the US are owned and/or staffed by CPMs. This designation as "assistive personnel" is out of alignment with AABC Standards. Current studies that show improved outcomes with birth center care include birth centers led by Certified Professional Midwives, Certified Nurse-Midwives, and Certified Midwives. 1,9

The third area of concern relates to the use of Registered Nurses (RN's) in the staffing model. This can be found in 420-5-13-01, page 14:

(d) Staffing. There shall be a minimum of two licensed RN's at the birthing center at all times when patients are present

This requirement is in direct contradiction to AABC and CABC standards and indicators. While RNs are valuable care givers and highly regarded professionals in their own right, they are not required staff for birth centers. The Standards require two staff at each birth trained in Adult Cardiopulmonary Resuscitation and Neonatal Resuscitation – there is no requirement that birth assistants be RNs. Birth assistants may be paramedics, midwifery students, or other personnel who are trained to provide assistance at a birth outside the hospital setting such as those who've completed AABC's Community Birth Assistant Training.

Furthermore, fulfilling this requirement in the midst of a national nursing shortage will be a barrier to operating a birth center. According to the president of the Alabama Hospital Association, many Alabama hospitals are still relying on traveling nurses after the pandemic

significantly depleted the workforce.¹⁰ Freestanding birth centers are small businesses, they cannot compete with hospitals to maintain the proposed level of RN staffing. Consider a clinic day when no patients are admitted in labor – an MA or the midwife themself can take vitals and draw labs – this is standard operating practice in birth centers. Additionally, there is no need to have two RNs present if there is only one laboring patient in the building, as may often be the case in a low volume birth center.

Our fourth area of concern surrounds the requirement of a written transfer agreement with a hospital.

This can be found in 420-5-13-01, page 7:

(x) A birthing center is ineligible for licensure unless it has a Transfer Agreement with a licensed, qualified hospital.

The requirement that licensed birth centers obtain a written transfer agreement with a hospital constitutes a barrier for birth centers within the state. 37% of Alabama counties are Maternity Care Deserts where there are no midwifery or obstetric services. 11 Childbearing people in these parts of the state must drive long distances for care. Freestanding birth centers can fill vital gaps in the state's perinatal care infrastructure, especially in the context of rural L&D unit closures 12 – ADHP should write regulations that reduce rather than impose barriers for birth centers to open and operate. Additionally, the federal Emergency Medical Treatment And Labor Act (EMTALA) is a law, already in place, that requires hospitals to treat people in active labor, 13 therefore written transfer agreements are unnecessary.

Birth centers desire effective collaboration with local transfer hospitals. Appropriate integration with higher levels of care supports the midwifery model and improves outcomes. Many birth centers enjoy robust working relationships with their transfer partners, including practice of emergency and non-emergency drills to ensure seamless transfer of patients when necessary. The ACOG/SMFM document—Maternal levels of care states that accredited birth centers are part of the healthcare system and promotes communication between the various levels of care. Unfortunately, where birth centers are not yet integrated into the healthcare system, hospitals may refuse to enter into signed transfer agreements. Thus, the AABC Standards and CABC Accreditation require the birth center to have written policies and procedures for collaboration and safe transfer of care.

Lastly, our fifth area of concern relates to the definitions of a "Low Risk Patient", often referred to as the Eligibility Criteria continuing through to active labor.

These criteria are listed in 420-5-13-01 on pages 4-5.

A sampling of some of the risk criteria we disagree with are as follows,

- 1) Reference to the condition "toxemia" (page 4, in number 4) this is extremely antiquated terminology that is no longer in use clinically. The current accepted terminology is Pre-eclampsia. This term once again demonstrates the need to involve midwifery and birth center experts in the drafting of these regulations.
- 2) Has no history of fetal wastage (page 4, number 5). This terminology is not only offensive, it is also antiquated and for good reason, is no longer utilized in any professional manner. The current accepted terms are miscarriage and spontaneous abortion. We not only find this language deeply problematic, it is also unreasonable to suggest that anyone with a history of miscarriage is ineligible for birth center care given that one in four pregnancies end in miscarriage. It's critical that Alabama's birth center regulations be up-to-date and evidence-based. In order to write regulations, it is necessary to involve birth center experts who are familiar with the provision of perinatal healthcare in the creation of the document. The draft regulations as written do not exemplify experience or expertise in midwifery or obstetrical care.
- 3) Has given birth to fewer than five children (page 4, number 6), in line with national standards, birth centers may care for those with five or more term pregnancies if they have a low risk medical and obstetrical history.
- 4) CABC Accreditation does not prevent birth centers from providing care for those choosing vaginal birth after a previous cesarean if other risk factors do not complicate the pregnancy or birth.
- 5) Birth centers may also care for a nullipara over 40 years of age and will use clinical judgment on this risk factor for appropriateness for birth center admission in labor.
- 6) For a pregnancy impacted by congenital anomalies, , there may be cases where a condition is not compatible with extrauterine life. In these cases, the birth center should be an option as a place for birth of that fetus if the family chooses.

We have listed here some of the proposed regulations that are out of alignment with the current evidence and practice of birth centers in the US. These five main areas of concern are not all inclusive of the concerns we have with these regulations. Rather they are representative of the overall issues with the regulations. In fact, the current requirements related to physician staffing and oversight, written transfer agreements with hospitals, exclusion of CPMs, and the nurse staffing could effectively prevent any birth centers from opening in Alabama. For these reasons, we respectfully and formally request that this current version of Proposed Regulations Birthing Centers in Alabama (420-5-13) be discarded altogether. Furthermore, we recommend the formation of a committee or taskforce of both local and national birth center experts, perinatal care providers and other stakeholders to draft new regulations for review. Some key stakeholders to include would be:

- Alabama State Board of Midwifery
- Alabama Midwives Alliance
- Alabama Chapter of the American College of Nurse Midwives (ACNM)
- The American Association of Birth Centers (AABC)
- The Commission for the Accreditation of Birth Centers (CABC)
- National Association of Certified Professional Midwives
- Alabama Birth Coalition
- Safer Birth in Bama
- Consumer representation through the inclusion of Alabama residents of childbearing age

If further information is needed, please do not hesitate to contact us for questions or clarification. We encourage you to bring all the stakeholders to the table to work on evidence-based and current birth center regulations, with a focus on the developing birth centers, midwives -- both Certified Professional and Certified Nurse-Midwives, and the physicians who are already working in collaboration with midwives.

We also encourage that the community groups working to reduce perinatal health disparities and improve outcomes for all be invited to work together on these regulations. These are the experts in community birth, and they can help to improve access and health. AABC would be happy to participate in any way we can to help.

Sincerely,

Aubre Tompkins, MSN, CNM

President, AABC

Jill Alliman, DNP, CNM Government Affairs Chair, AABC

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