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July 29, 2023

Katherine Ceroalo New York State Department of Health Bureau of Program Counsel Regulatory Affairs Unit Corning Tower Empire State Plaza, Rm 2438 Albany, NY 12237-0031 regsqna@health.ny.gov

RE: Perinatal Services, Perinatal Regionalization, Birthing Centers and Maternity Birthing Centers

Dear Katherine Ceroalo,

Thank you for allowing the American Association of Birth Centers (AABC) to comment on these proposed regulations for Midwifery Birth Centers. AABC has over 4 decades of experience and data collection on clinical care and outcomes in US birth centers. This innovative model of care has demonstrated improved health and patient experience for childbearing people, and leads to cost savings in reducing unnecessary cesareans and other medical interventions while decreasing the incidence of preterm birth and low birth weight. AABC has been involved in the ongoing process in New York State to increase access to high quality maternity care for at least 8 years. However, it is important to note that even though legislation was passed and signed into law in 2019 to increase access to midwifery and birth center care (Public Health Law, § 2801 and 2803(11);Part 795), there are as yet no licensed Midwifery Birth Centers, and there are currently only three licensed Birth Centers in the state. AABC's overarching concern is that these regulations add barriers to licensure of Midwifery Birth Centers rather than reducing existing barriers.

Overall, these proposed regulations do offer reasonable guidance in some areas. However, the statement on page 1 under Summary of Express Terms that these proposed regulations are aligned with AABC Standards, CABC Accreditation, and ACOG recommendations for freestanding birth centers, is simply not true.^{4,5,6} For example, AABC Standards recognize that requiring

signed *agreements* with transfer hospitals creates a barrier to birth center operations. Therefore, the AABC Standards require that written transfer *plans* be put in place by the birth center. All birth centers want to have good communication with transfer hospitals, but transfer hospitals may hesitate to enter into written agreements or collaborate with review of transfers due to unfounded concerns about increased liability for doing so. If the NYDOH decides that written agreements with hospitals will be required, then provisional written plans for transfer should meet this requirement for initial establishment to avoid unreasonable delays.

Another aspect of these draft regulations that is concerning is the inconsistent use of some key terms. For example, various terms are used for Midwives such as Licensed Midwives and Nursemidwives. When used in a list of providers that includes physicians, the term "Midwives" should be used consistently with the definition to state that Midwife means a midwife licensed to practice in the state. Licensed midwife should not be used interchangeably with midwife if you don't use the term "Licensed physician." Another example is the reference to "maternity birthing centers" instead of "midwifery birthing centers".

The following are specific concerns that are most problematic in these regulations, with page numbers where they are in the draft.

- 1) Page 1 of the proposed regulation document states that these proposed regulations "align with current standards of practice as advised by the American Association of Birth Centers (AABC)." However, there are several places in the regulations that do not align, and that will cause barriers for potential Midwifery Birth Centers and challenges to their ability to provide care appropriately.
- 2) Section 754.1, Page 105 of the draft includes a section on the definition of "low risk." The definition included here uses the term "normal," however, often patients who are appropriate to and benefit from care in the birth center model have histories of factors such as previous tobacco use, current tobacco use, previous substance use, history of domestic violence, depression, or anxiety. The Strong Start study funded by CMS demonstrated that people with psychosocial risk factors benefited greatly from midwifery care in the birth center and achieved appropriate risk status for appropriate birth center care. The birth center model (or midwifery birth center model in your case) is a holistic model of care of which a strong benefit is the holistic care with access to resources and referrals to specialty care as needed. The relationship-based support provided by midwives leads to reduced risk from these factors. To state that patients must be "normal" could lead to the understanding that certain patients are not appropriate for birth center care when research shows that they are. Our recommendation for this section is to focus on "appropriate patients for birth center admission in labor" being "those for whom an uncomplicated vaginal birth is anticipated." The screening described here, and referrals to specialty resources as needed will be provided are a part of the birth center model.

- 3) Section 754.2 and 754.3, page 108 and page 123 of the draft Transfer Indications and Written Transfer Agreement. These sections state that the birth center shall work out an agreement with the transfer hospital or hospitals concerning the possible indications for transfer. This seems an unnecessary step and creates a burden on the birth center or midwifery birth center in time and potential negotiations about the situations that are appropriate for transfer. Clinical guidelines for transfer are the responsibility of the birth center or midwifery birth center and they are the experts in birth center care. It is not appropriate for hospitals to arbitrarily set transfer requirements for patients at the birth center. All birth centers that follow AABC Standards operate under Clinical Practice Guidelines that are agreed upon by all clinical staff and the Clinical Director and updated as needed due to new evidence. When birth centers around the US have a good working relationship with their transfer hospitals, they simply share the Clinical Practice Guidelines with appropriate clinical staff at the hospital so the transfer hospital is aware of indications for consultation, collaboration and transfer. In addition, in Section 754.2, page 107, the proposed regulations state that transfer arrangements must be made during each transfer in collaboration and coordination with the RPC. There are times when the ideal option for the patient transferring would be to transfer to the nearest hospital with midwifery providers for continuity of care in the midwifery model. Birth Centers and Midwifery Birth Centers should have the option of making transfer arrangements with other area hospitals for transfers requiring such care as pain management or augmentation of labor without the presence of other risk factors. It seems burdensome to require consultation with the RPC for every transfer of care if the transfer is being made to a different hospital.
- 4) Impact Statement p. 140. Additionally, regulations related to accreditation and establishment of midwifery birth centers have been added to address regulatory items noted in the Midwifery Birth Center Accreditation Act (Public Health Law § 2803(11)).
- Midwifery Birth Center Accreditation Act (see Public Health Law § 2803(11)). Page 149. "Midwifery birth centers under 10 NYCRR 795 who choose to become accredited through a recognized accrediting organization will be required to comply with all requirements of accreditation and maintenance of accreditation and will need to submit proof of accreditation to the Department as a condition of establishment" making CABC accreditation optional for Birth Centers and Midwifery Birth Centers. Decades of research has shown that birth centers that follow AABC Standards of care have excellent clinical outcomes. The best way to ensure that birth centers follow these Standards is to require CABC accreditation. These Standards and CABC accreditation have been utilized for many years and have a proven research record. Why would the DOH not require accreditation of Midwifery Birth Centers if the goal of the regulations is to "harmonize" with the standards and guidelines of the AABC, ACOG, and ACNM, which all support and recommend accreditation of birth centers?

- 6) Section 795.12 Application for Establishment, p. 136, and Certificate of Need. Pages 136, 142, 148. The stated goal of the Midwifery Birth Center bill passed in 2021 was to decrease the overwhelming costs and challenges for midwifery birth centers to attain licensure. These regulations lack details about the establishment process but imply that the process will include many complicated forms and costly requirements which are unnecessary according to AABC Standards and CABC indicators.
- 7) Section 795.12 Design. Top of page 148. Life Safety Codes and Facility Guidelines. Birth Centers and Midwifery Birth Centers are classified as outpatient facilities. NFPA 2021 Facility Guidelines Institute for birth centers is the most current and the most relevant to the needs of regulations for Midwifery Birth Centers. The proposed regulations refer to an outdated version of the FGI from 2012. People who are patients in a birth center or a midwifery birth center are not sick patients requiring hospital level care. They are experiencing pregnancy and are expected to have an uncomplicated vaginal birth. They are ambulatory. The codes and guidelines should specify business level occupancy, not that of a hospital.
- 8) Section795.12. pp. 136, 142, 148. Requiring a Certificate of Need process for Midwifery Birth Centers that is not fully described in the regulations. The proposed regulations for midwifery Birth Centers mention the CON in several places (pp. 136, 142, and 148). Midwifery Birth Centers should be exempt from the Certificate of Need process because there are currently no Midwifery Birth Centers licensed in the state. Because the birth center (and midwifery birth center) is an evidence-based model that has been shown to improve maternal and infant outcomes and access to care, and there are areas of NYS with shortages of reproductive health care providers and facilities, there is a need for Midwifery Birth Centers in the state. Multiple states have removed the CON requirement for birth centers, and most recently Connecticut passed legislation that licenses freestanding birth centers and exempts them from a CON. (Public Act No. 23-147, "An Act Protecting Maternal Health."), https://www.jdsupra.com/legalnews/connecticut-governor-signs-bill-3733095/

We thank you for the opportunity to comment on these proposed regulations for Midwifery Birth Centers. We ask that you make further amendments to reduce the significant barriers to operation faced by birth centers in New York State. If you have questions, please do not hesitate to contact us.

Sincerely,

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President, AABC

Jill Alliman, DNP, CNM

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Government Affairs Chair, AABC

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- 3. Jolles, D. (2019, June 12). Rural resilience: Lessons from the Center for Medicare and Medicaid Innovation Strong Start for Mothers and Newborns. A Conversation on Maternal Health Care in American Association of Birth Centers (1.13.2023) pg. 6 Rural Communities. Charting a Path to Improved Access, Quality and Outcomes, Kaiser Family Foundation, Washington D.C., United States.
- 4. AABC Standards for Birth Centers (https://www.birthcenters.org/page/Standards)
- 5. CABC Indicators for Compliance with Standards for Birth Centers, Reference Edition 2.2 (https://birthcenteraccreditation.org/go-get-cabc-indicators/)
- 6. ACOG and SMFM Consensus Statement 2. Levels of Maternal Care, 2019 (https://www.acog.org/clinical/clinical-guidance/obstetric-careconsensus/articles/2019/08/levels-of-maternal-care)