July 30, 2023

New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower, Empire State Plaza, Rm. 2438
Albany, New York 12237-0031

Attention: Katherine Ceroalo

Re: Proposed Regulation to Amend 10 NYCRR sections 12.2 and 405.21, and Parts 721, 754 and 795

Dear Ms. Ceroalo:

On behalf of the American College of Nurse-Midwives (ACNM), we appreciate the opportunity to provide comments and recommendations in response to the New York State Department of Health's proposed rulemaking for the perinatal system in New York State, which includes Regional Perinatal Centers (RPCs), Level III hospitals, Level II hospitals, Level I hospitals, and freestanding birth centers including midwifery-led birth centers. Improving access to evidence-based midwifery care in all settings helps ensure that all women, birthing people, and babies are served by a maternal health system that delivers safe, effective, timely, efficient, and person and family-centered care. Midwifery is part of the solution to addressing our nation's maternal health crises.

ACNM is the professional association that represents Certified Nurse-Midwives (CNMs) and Certified Midwives (CMs) in the United States.[i] CNMs and CMs are licensed and regulated as Licensed Midwives in New York state.[ii] ACNM's members are primary health care clinicians who provide evidence-based midwifery care for women and gender nonconforming people throughout the lifespan, with an emphasis on pregnancy, childbirth, gynecologic and reproductive health care. ACNM works to promote equity, diversity, and inclusion throughout the midwifery profession and across the care continuum to ensure better healthcare outcomes for the people midwives serve.

The ACNM and its members stand for improving access to quality care and coverage for women through the lifespan. ACNM supports common-sense policy solutions that improve access to care delivered by CNMs and CMs and that ensure that all people have guaranteed health coverage and access to a full range of essential health services under Medicare and Medicaid, and individual and family health insurance plans. As such, ACNM has several concerns with some of the language set forth in the Department of Health's proposal and its

potential impact on access to midwives, midwifery-led care, and freestanding birth centers in New York. Unfortunately, the proposed regulations do not honor the intent of the law and if adopted will continue to prevent midwives from serving their communities and practicing midwifery to the full extent of their education, clinical training, and certification.

To ensure equitable access to midwives and midwifery-led care, we must establish midwifery as a standard for birth and reproductive healthcare for women and gender-diverse people in New York. We strongly recommend that the Department of Health implement the following changes prior to finalization of the proposed regulation to amend 10 NYCRR sections 12.2 and 405.21, and Parts 721, 754 and 795:

- **The Department of Health should use terminology that accurately reflects the midwifery credentials that are licensed and regulated in the state, which is Licensed Midwife (LM),**
- **The Department of Health should collaborate transparently with all impacted midwifery stakeholders in New York State, including ACNM,**
- **Labor and birthing units must more accurately be renamed obstetric and midwifery units and the use of language that empowers birthing people, and the process of birth must be utilized,**
- **Accreditation by the Commission for the Accreditation of Birth Centers (CABC) criteria must be a requirement for all birth centers in New York,**
- **Licensed midwives and the practice of midwifery must be visible and included at every level of care,**
- **Hospitals must be mandated to develop transfer relationships with free standing birth centers and midwifery birth centers, and**
- **Licensed midwives must be eligible for and not categorically denied hospital clinical privileges, admitting privileges, and hospital medical staff membership.**

Birth center births and midwifery-led care are a growing choice of pregnant and birthing people today. For the essentially well person experiencing a healthy pregnancy, intrapartum, postpartum, and newborn course, childbirth with qualified providers can be accomplished safely in all birth settings, including the home, birth centers, and hospitals.[iii] The birth center is a health care facility for childbirth where care is provided in the midwifery and wellness model. A birth center is freestanding and not in a hospital. Birth centers are an integrated part of the health care system and are guided by principles of prevention, sensitivity, safety, appropriate medical intervention, and cost-effectiveness. While the practice of midwifery and the support of physiologic birth and newborn transition may occur in other settings, this is the exclusive model of care in a birth center.[iv]

Most birth centers have midwives as the primary independent care providers, working collaboratively with physicians, hospitals, community care workers, and other providers in an integrated team-based approach to perinatal healthcare. Midwifery birth centers are a strong model for decreasing the high rate of cesarean birth in the United States.[v] Furthermore, midwifery services for prenatal, birth, and postpartum care, particularly when offered through birth centers, has shown promise in both improving pregnancy outcomes and containing costs. The national evaluation of Strong Start for Mothers and Newborns - a Centers for Medicare & Medicaid Services initiative that tested enhanced prenatal care models for Medicaid beneficiaries - found that people receiving prenatal care at birth centers with midwives experienced better birth outcomes compared to their counterparts in typical Medicaid prenatal care. These outcomes are due in large part to the midwifery-led model

of care provided in birth centers. Midwifery-led care has consistently achieved such outcomes in multiple studies and systematic reviews.[vi]

The Department of Health should use terminology that accurately reflects the midwifery credentials that are licensed and regulated in the state, which is Licensed Midwife (LM).

New York State licenses and regulates both CNMs and CMs as "licensed midwives." Per state statute, any reference to midwifery, midwife, certified nurse-midwifery or certified nurse-midwife, nurse-midwifery, or nurse-midwife under the provisions of this article, this chapter, or any other law, shall refer to and include the profession of midwifery and a licensed midwife.[vii] The proposed regulations reference the term licensed nurse-midwife, which is not a credential or license recognized in state statute. ACNM recommends striking use of this term from the final regulation.

The Department of Health should collaborate transparently with all impacted midwifery stakeholders in New York State, including ACNM.

As the Department of Health moves toward drafting the final regulations for implementation, we strongly encourage outreach and collaboration with ACNM's New York Affiliate, New York Midwives, and the New York State Birth Center Association. As the professional organization representing CNMs and CMs, we are disappointed and perplexed as to why ACNM was not included in a meaningful way during the information gathering phase nor are ACNM's Standards for the Practice of Midwifery referenced anywhere in the proposal.[viii] This is a missed opportunity to create equitable regulations, especially since a specific focus of the proposed regulations is integrating midwifery practices in hospital systems and establishing midwifery-led birthing centers throughout the state.

Labor and birthing units must more accurately be renamed obstetric and midwifery units and the use of language that empowers birthing people, and the process of birth must be utilized.

Language is the foundation of human behavior, expression and how we treat each other. Labor and birth are the process of human parturition and should be used instead of "deliver" LBR's should replace LDRP's. Midwifery units should be used alongside obstetrical units to acknowledge the integration of midwifery care within any birthing facility. "Client" should replace "Patient" to imply the involvement of an intelligent human who is engaged with informed choice rather than someone who should "be quiet and accept what is done to them." "Informed" rather than "shared" decision making should be used to imply that the client has been informed of their choice and potential consequences. Any unnecessary separation of the newborn from the birthing parent including the use of nurseries for healthy babies promote newborn Post Traumatic Stress Disorder and maternal postpartum depression and should be avoided at all cost.

Accreditation by the Commission for the Accreditation of Birth Centers (CABC) criteria must be a requirement for all birth centers in New York State,

ACNM strongly supports the inclusion of accreditation by Commission for the Accreditation of Birth Centers (CABC) as a requirement for all birth centers in New York. ACNM stands with the American Association of Birth Centers (AABC) in support of the CABC evidence-based standards for state licensure. Access to midwifery birth centers can be greatly improved by reducing barriers for pregnant and birthing people seeking access to maternity care services in birth centers. Barriers to care include state regulations that are not in

alignment with the CABC standards and impose unnecessary requirements on birth centers, such as requiring a written contract or agreement with a hospital while not mandating hospitals enter into contracts, requiring construction standards that are not appropriate for birth centers, and requiring a Certificate of Need (CON). The CON requirement was repealed by the federal government in 1986. Many states have since repealed their law requiring CON.[ix] New York should repeal their law requiring a CON at a minimum for midwifery practices.

CABC is the only accrediting agency that chooses to use the national AABC *Standards for Birth Centers* in its accreditation process. Research persistently demonstrates that accredited birth centers are safe places to give birth. The regulations as drafted make accreditation optional, thereby removing a recognized mechanism for ensuring safety and quality. Both ACNM and the American College of Obstetricians and Gynecologists (ACOG) recognize accredited birth centers as integral to regionalized care.

While accreditation was the basis for the 2022 *Midwifery Accreditation Act*, the regulations as proposed make accreditation optional. Accrediting and licensing all midwifery birth centers allows inclusion in the regional perinatal centers and supports ongoing learning and engagement in evidence-based birth center practices. Harmonizing the proposed regulation with CABC accreditation standard sets a high standard for ensuring quality and safety in birth centers for women and childbearing people - that is and should be the primary goal of all regulatory and policy initiatives related to perinatal care New York. ACNM proposes that the Department of Health adopt the CABC accreditation as the basis for licensing and regulation of birth centers in the state.

Licensed midwives and the practice of midwifery should be visible and included at every level of care.

Integration of licensed midwives and midwifery-led services into the perinatal system at *every* level is integral to ensuring access and equity for all birthing people in New York. Evidence supporting midwives and midwifery-led care for low and moderately risk pregnant people is vast, and for high-risk people as part of the care team. When pregnant people are placed in an appropriate level of care with the appropriate provider, maternal mortality and morbidity rates decrease. Midwifery care provided by CNMs and CMs can reduce maternal and neonatal mortality, rates of stillbirth, perineal trauma, instrumental births, rates of severe blood loss, preterm birth, low birth weight, and neonatal hypothermia. Midwifery is associated with more efficient use of resources, shorter hospital stays, and improved outcomes including increased rates of spontaneous labor, vaginal birth, and breastfeeding. People who receive midwifery care have reported higher rates of satisfaction with care, pain relief in labor, and maternal–newborn interaction.[x] In addition to caring for people during pregnancy and childbirth, CNMs and CMs conduct physical examinations; prescribe medications, including controlled substances and contraceptives; admit, manage, and discharge people under their care; order and interpret laboratory and diagnostic tests; and order the use of medical devices. However, state and hospital policies often limit the capacity of midwives to practice to their full scope. Midwives fully integrated into health systems at all levels could help reduce perinatal health disparities and address provider workforce shortages. As such, ACNM recommends incorporating the following changes to the definitions 15, 16 and 17 listed on page 7 of the proposal:

(15) Level I perinatal care service shall mean [a comprehensive maternal] an obstetrical, midwifery and [newborn] neonatal service as defined by Section 721.2([a]c) of this Title.

(16) Level II perinatal care service shall mean a comprehensive [maternal] obstetrical, midwifery and [newborn] neonatal service as defined by Section 721.2([b]d) of this Title.

(17) Level III perinatal care service shall mean a comprehensive [maternal] obstetrical, midwifery and [newborn] neonatal service as defined by Section 721.2([c]e) of this Title.

Hospitals should be mandated to develop transfer relationships with free standing birth centers.

ACNM supports the right of every family to experience childbirth in a safe environment where human dignity and self-determination are respected. Every person has the right to make an informed choice regarding the place of birth that best meets their needs. When healthy mothers plan a birth center birth, they are independently cared for and monitored by skilled midwives and other members of perinatal team. Infrequently, the mother or infant requires transfer from the birth center to the hospital to access specialized procedures or a higher level of care. Effective communication and coordination between providers during these transfers minimizes the potential for negative impact on outcomes. As the safety of the mother and infant is always of the highest priority, it is important to have detailed guidelines used by all health care providers involved in such transfers.[xi]

The goal of creating an RPC system is to maintain and increase access to care by developing, strengthening, and better defining relationships among facilities within a region. Central to a healthy RPC system is the development of collaborative relationships between hospitals of differing levels of care in proximate regions. This ensures that every birthing facility (i.e., hospitals and all birth centers) are fully integrated into the RPC system and the personnel and resources to care for unexpected obstetric emergencies, that risk assessment is judiciously applied, and that collaboration, consultation and referral are available as needed. These relationships enhance safety and quality of care for all women and birthing people at all levels of care (midwifery birthing centers and at Level 1, 2, and 3, and RPCs) while providing support for circumstances when higher-level resources are needed. ACNM recommends that transfer guidelines be designed to facilitate the safe and mutually respectful transfer of care of a birthing person from a birth center to the hospital. These guidelines must be enforced and facilitated by the RPC between both the midwifery birth center and transfer hospital.

Licensed midwives should be eligible for hospital clinical privileges, admitting privileges and hospital medical staff membership.

The ACNM strongly supports institutional bylaws and guidelines that foster cooperation and facilitate consultation, collaboration, and referral, as indicated by the condition/status of the person under a midwife's care. Mandatory integration of midwives and the midwifery model of care is essential to the provision of quality of care in all settings, including the hospital. As such, state regulations and hospital bylaws should mandate that licensed midwives in New York have access to hospital privileges, including admitting privileges, as well as full participation and voting privileges on hospitals' medical staff. Ensuring access to hospital privileges and full participation on medical staff will address a significant barrier to midwifery care in New York and will also help hospitals perform well on a number of quality measurements related to maternal and newborn care and outcomes.

We appreciate the opportunity to provide comments on the proposed regulations to amend 10 NYCRR sections 12.2 and 405.21, and Parts 721, 754 and 795. ACNM looks forward to working with the Department of Health to adopt birth center rules and regulations that ensure quality, safety, and equity for people seeking birth and reproductive health care as provided by licensed midwives and expand access to birth centers and the midwifery

model of care in New York. Please do not hesitate to contact ACNM's Director, Advocacy & Government Affairs, Amy Kohl at akohl@ACNM.org with any questions regarding the role of Certified Nurse-Midwives and Certified Midwives in the health care continuum.

Sincerely,

Michelle Munroe, DNP, CNM, APRN, FACNM, FAAN
Interim Chief Executive Officer
American College of Nurse-Midwives

Heather Clarke, DNP, CNM, APRN, LM, FACNM
President
American College of Nurse-Midwives

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[i] CMs differ from certified nurse-midwives (CNMs) *only* in that they are not also licensed as nurses. CMs and CNMs have the same master's and/or doctorate level education, meet the same core competencies, sit for the same board exam, and have identical scopes of practice including prescriptive privileges.
[ii] NYS Midwifery:Laws, Rules & Regulations:Article 140 (nysed.gov)
[iii] http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000251/Planned-Home-Birth-Dec-2016.pdf
[iv] American Association of Birth Centers. Definition of Birth Center. Accessed July 18, 2023. Available at: What is a BC - American Association of Birth Centers.
[v] Stapleton SR, Osborne C, Illuzzi J. Outcomes of care in birth centers: Demonstration of a durable model. Journal of Midwifery and Women's Health. 2013. Available at: http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12003/full
[vi] Strong Start for Mothers and Newborns Initiative (medicaid.gov)
[vii] NYS Midwifery:Laws, Rules & Regulations:Article 140 (nysed.gov)
[viiiviii] 2022_standards-for-the-practice-of-midwifery.pdf
[ix] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://assets.noviams.com/novi-file-uploads/aabc/pdfs-and-documents/PositionStatements/AABC_PS_-_Certificate_of_Nee.pdf
[x] https://www.midwife.org/acnm/files/ccLibraryFiles/Filename/000000004184/Midwifery-Evidence-Based-Practice-March-2013.pdf
[xi] Midwifery Provision of Home Birth Services - 2016 - Journal of Midwifery & Women's Health - Wiley Online Library