ACOG
THE AMERICAN CONGRESS
OF OBSTETRICIANS
AND GYNECOLOGISTS

April 30, 2014

Mr. Donald S. Clark
Secretary
Federal Trade Commission
Office of the Secretary
Room H–113 (Annex X)
600 Pennsylvania Avenue NW
Washington, DC 20580

RE: FTC Health Care Workshop, Project No. P131207

Dear Secretary Clark:

The American Congress of Obstetricians and Gynecologists (ACOG) welcomes the opportunity to submit comments in response to the notice of public workshop examining health care competition, dated February 24, 2014 ("Notice").

ACOG is a non-profit professional organization. ACOG's companion charitable organization, the American College of Obstetricians and Gynecologists, was founded in 1951. Together, ACOG and the College share more than 57,000 members, representing approximately 90 percent of all board-certified obstetricians and gynecologists practicing in the United States. ACOG welcomes certified nurse midwives (CNMs), certified midwives (CMs), nurse practitioners, and physician assistants to join its membership as Educational Affiliate members. It is ACOG's mission to foster improvements in all aspects of health care for women and to promote the highest standards of clinical practice and ethical conduct. Educational Affiliate members help ACOG maintain the best standards of health care for women.

ACOG's comments respond to questions posed in the Notice regarding the extent to which professional regulation of health care providers is necessary to protect patient safety, with a focus on maternity care and midwife providers.

ACOG supports the full scope of practice for CNMs and CMs as reflected in our Joint Statement with the American College of Nurse-Midwives (ACNM).

ACOG's comments are also prompted by comments submitted by proponents of other midwives who are not CNMs or CMs. These midwives lack formal academic education and training, and provide services in home birth settings with no connection to the rest of the maternity care system, but nonetheless are legally authorized to practice midwifery in over half of the states.

Critical consumer safety concerns with this type of midwifery care are an appropriate focus for government attention. These safety concerns should take priority over considerations of cost or maximizing competition, and any consideration of expanding competition among healthcare providers must include mechanisms for protecting consumer safety.

The comments below focus on the following topics:

- Principles that ACOG holds in common with the American College of Nurse-Midwives (ACNM) for education, training, licensure, and practice of midwives.
- Recommended improvements in state licensure and regulation of midwives to benefit consumers. FTC advocacy and other actions should support—not inhibit—implementation of a single, unified regulatory framework for midwifery care in the United States.
- Critical safety data that should inform decisions by lawmakers and regulators. In any examination of the market specific to maternity care and midwife providers, the FTC should be guided by critical safety data on out-of-hospital births, and promote improvements in the collection and reporting of patient safety and outcomes data on midwife-assisted home births.

I. ACOG and ACNM: Shared Principles and Collaboration.

ACOG and its ob-gyn physician members have a close and long-standing partnership with certified nurse-midwives, certified midwives, and their professional organization, the American College of Nurse-Midwives (ACNM). CNMs and CMs can join ACOG as members; they serve on ACOG clinical committees and task forces, attend meetings of the ACOG Executive Board, and assist in training ob-gyn residents.

ACOG's and ACNM's "Joint Statement of Practice Relationships," first adopted in 1971, affirms shared goals in women's health care for overall safety and excellence of services, for ensuring access to fully qualified and skilled providers at all levels of maternity care across the United States, and for maintaining the viability of ob-gyn and CNM/CM practices. (The joint statement is attached).

ACOG and ACNM advocate for medical and midwifery practice laws and regulations that support ob-gyns and CNMs/CMs working collaboratively in an integrated maternity care system that facilitates communication and collaboration across care settings and among fully qualified and licensed providers. To establish and sustain viable ob-gyn and CNM/CM practices, ACOG and ACNM are jointly committed to advocating on behalf of members of both groups for (i) affordable professional liability insurance coverage, (ii) hospital privileges, (iii) equivalent reimbursement from private payers and government programs, and (iv) access to support services, e.g., laboratory, obstetrical imaging, anesthesia.

Recent examples of joint efforts by ACOG and ACNM include: (i) *2011 ACOG-ACNM Issue of the Year*, which recognized best practices in maternity care across the United States involving obstetrician-gynecologists and nurse-midwives, and successful models of collaborative practice in both academic and community settings; and (ii) ACOG-ACNM support for H.R. 4385 in the US Congress, which would address the shortage of maternity care providers, in particular in underserved urban and rural communities.

II. Improved State Licensure and Regulation of Midwives is Needed.

State licensure laws should serve as a reliable authority for consumers and regulators to understand and assess not only the cost, but also the quality and safety of services.

ACOG and ACNM support uniform state licensure and regulatory requirements to assure that consumers and regulators have a common understanding of the term "midwife" and the education and training of midwife providers.

In their joint statement, ACOG and ACNM "affirm[ed] their commitment to promote the highest standards for education, national professional certification, and recertification of their respective members and to support evidence-based practice. Accredited education and professional certification preceding licensure are essential to ensure skilled providers at all levels of care across the United States." ACOG & ACNM, *Joint Statement of Practice Relationships*, Feb. 2011, at 1.

State licensure and regulation do not presently meet these goals and should be improved.

A. The lack of a common title and scope of practice for midwives means that female consumers do not get adequate, clear information on benefits, risks, limitations, and advantages of their care location, care practices, and maternity care provider.

Midwifery groups in the United States do not accept a common definition of a midwife. Midwives use three different professional designations and numerous titles, resulting in confusion among consumers regarding the education, training, and other credentials of midwife providers.

States have not adopted a unified, transparent regulatory scheme governing midwifery care, which is necessary to assure access to safe, qualified, highly skilled midwife providers across the United States. State licensure and scope of practice laws should—but unfortunately do not—support a common minimum education and training requirement that all midwives must meet whatever their title or professional designation, and regardless of where they practice.

There are three separate midwifery credentials in the US: certified nurse-midwives (CNM), certified midwives (CM) and certified professional midwives (CPM). Each credential accepts different levels of education, training and experience. Marked variation in qualifications also exists among midwives who use the CPM designation.

Midwives also use many different titles, even within the same state, and midwives use some titles in multiple ways (e.g., Licensed Midwives, or LMs), due to variations in the level of education and training required by various states.

ACNM has a chart posted on its website that compares education, training, and other attributes of the three main midwifery credentials:

http://www.midwife.org/acnm/files/cclibraryfiles/filename/000000001031/cnm%20cm%20cpm%20comparison%20chart%20march%202011.pdf.

1. **Certified Nurse-Midwives (CNMs).** CNMs are advance practice nurses (APRNs) dually educated at the graduate level in both nursing and midwifery. CNMs are the only category of midwives that are trained and licensed as APRNs. CNMs meet educational and professional standards of the ACNM. CNMs comprise the majority of midwives in the United States and are licensed in all 50 states and the District of Columbia. CNMs practice primarily in hospitals and also birth center facilities.

2. **Certified Midwives (CMs).** CMs do not have nursing credentials and are not APRNs, but otherwise meet the educational and professional standards of the ACNM, and sit for the same certification exams as CNMs. Three states license CMs (New Jersey, New York, Rhode Island), and in Delaware CMs practice by permit.

3. **Certified Professional Midwives (CPMs).** CPMs do not meet the educational and professional standards of the ACNM. Unlike academically trained and credentialed CNMs and CMs, the majority of CPMs have only a high-school diploma or equivalent, and are trained in one-on-one apprenticeships and self-study models with no university or hospital-based education or training. In fact, the CPM apprenticeship training model does not meet accreditation standards of the US Department of Education (USDE).

Notably, CPMs who are apprentice-trained, and CPMs who have some formal university–affiliated training both use the same CPM designation without distinction. This is problematic for state legislators who must make important licensure decisions that affect public safety. This is also a consumer safety issue, particularly as CPMs practice outside of the hospital setting and are unconnected to the rest of the maternity care system, delivering babies in consumers' homes (which clearly lack the safety infrastructure found in hospitals and accredited birth centers).

Despite their lack of academic training and the absence of transparent and accredited credentials, CPMs are authorized to practice in over half of the states, either by mandatory licensure, certification, registration, permit, or voluntary licensure.

4. **Other Titles for Licensed and Unlicensed Midwives.** Compounding the problem for consumers, many midwives use a variety of other titles even within the same state. This is confusing for everyone – lawmakers, patients, consumers, and even physicians and other health care practitioners. These titles include: direct-entry midwife (DEM); licensed direct-entry midwife (LDEM); licensed midwife (LM); registered midwife (RM); lay midwife; granny midwife; traditional midwife; naturopathic midwife; and natural midwife, among others.

With some titles (e.g., LM), the level of education and training can vary among states. In some states (e.g., Hawaii), there is no state licensure, certification, or registration of midwives or other providers who deliver babies at home. Voluntary licensure of midwives who are not nurses is also permitted in a few states (e.g., Missouri, and until recently, Oregon).

B. Most US home births are attended by midwives who lack the formal education, clinical training, and collaborative practice philosophy of CNMs and CMs.

See Wax JR, Pinette MG, Cartin A. Home versus hospital birth – process and outcome. Obstet Gynecol Surv. 2010;65:132-140 (CPMs attend 73.3% of US home births).

C. Current regulations in many states do not adequately restrict selection of home settings for high-risk childbirths.

Some states (e.g., Oregon), restrict birthing center facilities from performing certain high-risk births such as multiple gestations and breech presentation, but do not similarly restrict CPMs from attending high risk births in home settings.

In some states, the most highly trained midwives (CNMs), are restricted from practicing in the home setting, but less qualified, apprentice-trained, non-nurse-midwives are authorized to attend home births.

D. There are legitimate and serious consumer safety concerns with State decisions to authorize practice or permit voluntary licensure by unqualified midwives in unregulated settings, with no connection to the rest of the health care system.

CPMs are authorized to practice midwifery in over half of the states, as noted above, but women seeking a home birth in these states are unlikely to know that education and training qualifications vary among midwives—even those who use the same title—and thus that a CPM is unlikely to have the education, training, and collaborative practice experience (in particular formal academic, university and hospital-based training and experience), that the patient desires or expects.

Safety concerns for consumers of maternity care are greater in states where there is no requirement for the CPM to work collaboratively with hospital-based and privileged providers, or under state sanctioned practice guidelines and safety and transport protocols.

To ensure patient safety and the best possible care for women who are pregnant, state legislators should license only fully qualified, academically trained midwives who are credentialed by ACNM and the American Midwifery Certification Board (AMCB). ACOG supports the ACNM and AMCB standards for this purpose, as these standards are best suited to assure patient safety.

E. Effective state government oversight is critical.

State licensing agencies should verify that all licensed midwives meet minimum requirements, collect and report safety measures and outcomes for out-of-hospital births, aggregate and report this information annually to the state legislature, and monitor and act promptly on consumer complaints.

F. Uniform minimum practice standards are needed for all midwives across all states.

State regulations vary widely as to the legal status and level of practice authority of midwives. Most states lack a common minimum requirement for education and training that all midwives must meet to practice legally in the state regardless of title or professional designation.

Only one state (New York), now requires all midwives—regardless of educational pathway, professional designation, or title—to meet the same minimum level of education and training (New York Professional Midwifery Practice Act, Article 40, Sec. 6950, 1992). CNMs and CMs meet the New York standard, but CPMs do not.

1. Uniformity of regulation would greatly benefit consumers who currently may not be able to distinguish the qualifications of midwives who use different titles, and even those who use the same title.

Uniformity of regulation would mean that consumers could depend on their midwife to follow standardized safety, transfer, and transport protocols that are widely accepted and in use by the rest of maternity care providers, including other midwives. When standards of education and practice are not held in common, optimal transfer and transport systems break down. When a home birth patient's condition and risk status changes, care of the patient should be transferred to another provider in accordance with previously agreed-upon protocols to assure continuity of care. In the case of an emergency, the patient should be promptly transported to a hospital with emergency obstetric capability in accordance with system-wide safety protocols.

Consumers in New York State have a greater assurance of utilizing the services of a fully qualified midwife than do consumers in other states, due to New York State's unique and uniform midwifery licensure rules.

Federal and state governments should set minimum requirements for midwife participation in Medicaid and other government subsidized programs that include certification by AMCB.

2. Uniformity of regulation and common education and practice standards would assist state regulators to conduct appropriate oversight and hold midwifery care accountable to consumers and the public.

Evaluation by state licensing bodies of provider skills and credentials is greatly facilitated by common education standards (e.g., length of program, content of curriculum, accreditation). Information about midwives' education and training should be transparent and available to lawmakers to make sound decisions on scope of practice legislation and regulations.

3. Uniformity of regulation would assure a common scope of practice for all midwives, making it possible for outcomes data and impact studies to be correctly interpreted and tracked to a specific midwife provider.

Current limitations in the collection and reporting of data on home births (discussed below) severely compromise any analysis of safety and outcomes data on which legislators and regulators—including the FTC—rely when enacting or enforcing licensure and scope of practice laws.

III. Critical Safety Data: Improved Data Collection and Reporting of Patient Safety and Outcomes Data on Midwife-Assisted Home Births is Needed to Better Inform State Scope of Practice and Licensure Decisions.

A. Birth certificate data obscure the risks attendant to home birth.

The Centers for Disease Control and Prevention (CDC), through its National Center for Health Statistics (NCHS), compiles detailed information on the approximately 4 million US births each year. Birth certificate data for 2012 are the most recent available. Unfortunately, the CDC-NCHS data have material limitations—due in part to inconsistent, inadequate state licensing standards for midwives— that should be corrected:

1. Misclassification of the mother's intended place of delivery. For example, the CDC-NCHS data do not always distinguish between midwife-attended planned home births where the mother was transferred to a hospital due to complications, and hospital births that were planned to occur in a hospital.

2. Lack of information regarding whether a home birth was planned or unplanned.

3. Inadequate data regarding the professional designations, licensure, education, and skills level of midwives who attend out-of-hospital births. Accurate and detailed data on these metrics is especially important to identify and study instances where a mother planned a midwife-assisted home birth, but the mother was transferred to the hospital due to complications or an emergency.

These limitations severely compromise any analysis of data to evaluate the safety of home birth and the outcomes achieved by midwives with different professional and licensing designations. As a result, legislative decisions occur in a vacuum, thereby placing consumer health and safety at risk.

B. Consumer safety concerns warrant restrictions on high-risk births at home, including vaginal birth after cesarean (VBAC), twin gestation, breech delivery, and post-term pregnancy.

There are well-founded patient safety concerns with attempting a VBAC delivery at home with any provider. Indeed, the National Institutes of Health (NIH) 2010 Consensus Development Conference on VBAC summarized an imposing list of life-threatening complications to both mother and baby that can occur even for women who undertake a trial of labor in a high-volume, fully staffed hospital labor and delivery unit.

NIH recommends that VBAC should be done in well-equipped facilities ready to perform an emergent cesarean delivery with surgeons, anesthesia personnel, surgical nurses, operating

rooms, blood transfusions, and post-operative care. *See* National Institutes of Health Consensus Development Conference Statement, "Vaginal Birth After Cesarean: New Insights," March 8-10, 2010. http://consensus.nih.gov/2010/images/vbac/vbac_statement.pdf.

The attached statements of F. Gary Cunningham, MD, chair of the NIH expert panel, submitted to the Arizona Midwifery Scope of Practice Advisory Committee and the Oregon Board of Direct-Entry Midwifery, identify patient safety concerns with high-risk births at home.

C. New safety data from Oregon on out-of-hospital births supports mandatory licensure requirements for home birth providers, restrictions on high-risk out-of-hospital births, and better state oversight of safety protocols to protect home birth consumers.

Oregon ranks among the top ten states in the percentage of births that occur out-of-hospital. In 2011, the Oregon Legislature passed an ACOG–backed bill (HB 2380), requiring the state public health division to collect data on planned place of birth and planned birth attendant, and report annually on the outcomes of these births. A previous law requiring data collection on the maternal-fetal outcomes of licensed and unlicensed DEMs attending home births had not been enforced. Licensure of DEMs in Oregon has been voluntary, but as of January 1, 2015, all midwife providers except a few traditional midwives must be licensed.

The scope of practice for DEMs in Oregon includes twins, breech presentation (excluding footling), post-term pregnancies up to 43 weeks, presence of meconium, and rupture of membrane greater than 24 hours. *See* Oregon Administrative Rules (OAR). Oregon Board of Direct Entry Midwifery Act, Health Division, Risk Criteria sections 332-015-0021. (2002)

The 2012 summary report of the Oregon Health Authority, Public Health Division analyzed the data and found a much higher mortality rate for out-of-hospital births:

"Sixty-two term fetal and 30 early neonatal deaths occurred in Oregon during 2012; of these 8 (4 fetal, 4 early neonatal) occurred among planned out-of-hospital births. The term perinatal mortality rate for planned out-of-hospital births (4.0/1,000 pregnancies) was nearly twice that of in-hospital births (2.1/1,000). …6 of 8 pregnancies did not meet low risk criteria. These pregnancies included: more than 40 weeks gestation (4); twin gestation (2); morbid obesity (1). Planned attendants among these 6: CNMs (1), licensed DEMs (3), unlicensed midwife (1) and ND (1)."

http://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Pages/planned-birth-place.aspx

D. Studies from other developed countries suggesting that planned home births are safe involved only low-risk births and healthy pregnant women.

For example, Canada and the Netherlands have strict criteria for selecting appropriate low-risk candidates for planned home birth, e.g., no pre-existing maternal disease; no disease arising during pregnancy; singleton fetus; cephalic presentation; gestational age greater than 36 weeks and less than 41 completed weeks of pregnancy; labor that is spontaneous or induced as an outpatient; mother has not been transferred from a hospital.

See Johnson KC, Daviss BA. Outcomes of planned home births with certified professional midwives: large prospective study in North America. BMJ. 2005;330:1416; de Jong A, van der Goes BY, Ravelli AC, et al. Perinatal mortality and morbidity in a nationwide cohort of 529,688 low-risk planned home and hospital births. BJOG. 2009;116:1177-1184; Amelink-Verburg MP, Verloove-Vanhorick SP, Hakkenberg RM, Veldhuijzen IM, Bennebroek Gravenhorts J, Buitendijk SE. Evaluation of 280,000 cases in Dutch midwifery practices: a descriptive study. BJOG. 2008; 115:570-578.

While women in Canada with one previous cesarean delivery are considered candidates for home birth, no safety data exists to support this practice. Canadian studies do not provide details on outcomes of women who have attempted a vaginal birth at home after a prior cesarean birth. *See* Janssen PA, Saxell L, Page LA, Klein MC, Liston RM, Lee SK. Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician. CMAJ 2009;181:377-83; Hutton EK, Reitsma AH, Kaufman K. Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in Ontario, Canada, 2003-2006: A retrospective cohort study. Birth 2009;36:180-9.

E. Conditions that make home birth relatively safe in some countries are not applicable to much of the United States.

For example, the Netherlands has a long tradition of optimally organized home birth. Well-trained midwives provide care only for low-risk births and they practice in an integrated maternity care system with a highly-developed transport system. High-risk births are not performed or sanctioned out-of-hospital in the Netherlands.

These conditions do not exist today in the United States. Several states (including Oregon), permit midwives to do high-risk births at home (e.g., VBACs, breeches, twin gestations, post-term pregnancies), despite evidence against the safety of a home setting for these births. The United States has emergency services but lacks a well-developed system of dedicated maternal transport services. Notably, the Netherlands is geographically small and densely populated, with virtually the entire population living within 20 minutes of a hospital, far shorter than in much of the United States.

F. The 2011 ACOG Committee Opinion, "Planned Home Birth," provides a useful review of the safety data on home birth.

"Although the [ACOG] Committee on Obstetric Practice believes that hospitals and birthing centers are the safest setting for birth, it respects the right of a woman to make a medically informed decision about delivery. Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence. Specifically, they should be informed that although the absolute risk may be low, planned home birth is associated with a twofold to threefold increased risk of neonatal death when compared with planned hospital birth. Importantly, women should be informed that the appropriate selection of candidates for home birth; the availability of a certified nurse–midwife, certified midwife, or physician practicing within an integrated and regulated health system; ready access to consultation; and assurance of safe and timely transport to nearby hospitals are critical to reducing perinatal mortality rates and achieving favorable home

birth outcomes." Planned home birth. Committee Opinion No. 476. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;117:425–8.

The complete ACOG Committee Opinion on Planned Home Birth is available at the link below:

http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Obstetric%20Practice/co476.pdf?dmc=1&ts=20140424T1343517701

Conclusion

ACOG and its members have long-standing and positive working relationships with certified nurse-midwives and certified midwives, and with ACNM, their principal professional organization.

ACOG's recommendations stated above for broader and uniform state licensure and regulation of midwives are grounded in legitimate and serious patient safety concerns. The recommendations warrant prompt attention by state regulators and other constituencies, including private and government payers, hospitals, and other organizations that set credentialing standards for midwives, monitor the manner in which they provide services, and evaluate outcomes for out-of-hospital deliveries.

ACOG's recommendations for limits on out-of-hospital births for high-risk pregnancies seek to avoid unwarranted risk and confusion to women who may consider home birth, and establish limits on out-of-hospital deliveries for high-risk pregnancies where the risk of complications is great.

Such measures will eliminate consumer confusion and ensure that all patients receive health care from providers with the essential education, training, experience, and collaborative arrangements with other health care providers that are needed to meet the critical patient safety considerations inherent in childbirth.

Sincerely,

Hal C. Lawrence, III, MD, FACOG
Executive Vice President and
Chief Executive Office