Comments from the United States Lactation Consultant Association

The United States Lactation Consultant Association (USLCA) appreciates the opportunity to submit comments to the Federal Trade Commission’s public workshop, “Examining Health Care Competition.” We wish to direct our comments primarily to the issue of Professional Regulations of Health Care Providers. The USLCA\(^1\) is the professional association for lactation consultants holding the International Board Certified Lactation Consultant (IBCLC) certification, however membership is open to all who support and promote breastfeeding. Recognized as the professional authority in the United States, USLCA seeks to advance the IBCLC through leadership, advocacy, professional development, and research. In doing so, USLCA promotes, protects, and supports breastfeeding by providing educational opportunities, fostering communication within the breastfeeding community, upholding high practice standards, heightening awareness of the potential consequences of artificial feeding, fostering awareness of health improvement measures related to breastfeeding, encouraging research, and collaborating with other like-minded organizations. Most importantly, USLCA protects women and infants by advocating for evidence-based practice, promoting recognition within the health care community by professionals, improving skills related to lactation care, and expanding the literature relevant to lactation management.

The US Department of Health and Human Services and the Federal Trade Commission (FTC) view competition and choice in the healthcare marketplace as desirable and beneficial for improving accessibility and quality of care, while driving innovation and reducing costs. Conversely, states continue efforts to limit and reduce professional licensure. The act of “NOT licensing” healthcare professions has the opposite effect. The prevailing and long-standing healthcare systems in the United States have designated “licensing” as the key to entering the system for legitimacy, credibility and setting minimal qualifications for professionals. To further emphasize the value of licensure, 74% of non-physician healthcare occupations are licensed.\(^2\) A healthcare professional without a license may be viewed negatively by other healthcare providers, healthcare systems, insurers and consumers because there is no accepted verification

\(^1\) The United States Lactation Consultant Association is a 501c3 non-profit organization headquartered in Morrisville, NC. See [www.uslca.org](http://www.uslca.org) for further information.

of their skill, training, and credibility in providing quality patient care. Unless the FTC and states are prepared to completely disband licensure across all healthcare systems, professions, and providers, any further impediment in the progress of issuing licensure assuredly will threaten patient safety, thwart access to high quality care, and inhibit the need for defining minimal standards for emerging providers entering the marketplace. For example, the expertise of IBCLCs is well documented and public health authorities have acknowledged the need for their services. IBCLCs have served as well as been recognized by national and global authorities as an integral part of the healthcare team since their inception 29 years ago. Recognized as the global expert in clinical lactation management, IBCLCs exercise rigorous professional standards, are mandated to demonstrate specialized knowledge and skills, and hold credentials by an independent accrediting body. These defining characteristics set them apart from other breastfeeding support personnel in providing evidence-based breastfeeding support and care.

Although breastfeeding initiation has almost quadrupled in the past 40 years, healthcare regulation is slow in making accommodations to support it. Breastfeeding is a public health issue known to unequivocally improve maternal and infant health and save billions of US healthcare dollars each year. So much so, that the Department of Health and Human Services emphasizes the significance of breastfeeding in improving the Nation’s Health clearly throughout the Healthy People 2020 agenda. In spite of the importance of breastfeeding to the Nation’s health and attempts to increase access to quality care, the process of breastfeeding is fraught with many barriers. Challenges with the process of breastfeeding and lack of knowledge in the early days and weeks after birth, combined with inability to access skilled lactation care, quickly leads to premature weaning thus halting lifelong health benefits. Unsupportive social norms, poor family and social supports, embarrassment, employment and child care, also impede mothers who wish to breastfeed their infant.

Research shows that the role of the healthcare provider is critical to breastfeeding success. Systematic review further substantiates that healthcare providers lack core knowledge in the areas of breastfeeding support and management. The healthcare professional’s inability to provide appropriate care significantly impacts the care women receive and negatively affects breastfeeding outcomes. Deficiencies in the clinical management of breastfeeding have been found across all specialties of physicians and residents, all specialties of nurses and advanced

8 Perry A. Evidence-based recommendations addressing Action 9 of the Surgeon General’s Call to Action to Support Breastfeeding: A systematic review. An evidenced based capstone project presented to the Frontier Nursing University in partial fulfillment of the degree Doctor of Nursing Practice, March 21, 2014.
practices nurses, pharmacists, midwives and WIC personnel. Furthermore, non-supportive maternity care practices engrained in the system along with ill prepared professionals have been found to obstruct basic lactation care and support, consequently requiring extended visits for which most licensed providers lack the time. Most providers specialize in the care of the mother or the infant, rather than caring for them as a unit. This adds to the time and complexity of necessary lactation care, therefore disrupting continuity of care. Major health initiatives recognize the effectiveness of improving care with IBCLCs as part of the healthcare team and continue to focus on collecting accurate data and establishing guidelines to improve outcomes. Interference with that process could compromise the substantial progress made toward improving health for US mothers and infants. USLCA not only cooperates but collaborates with all those interested in breastfeeding support.

Those who complete basic training programs are an important resource for lactation support in the normal course of breastfeeding. However, mothers needing clinical management for complex problems with lactation, lack access to this level of care because insurers, including Medicaid, do not reimburse non-licensed providers. Regulatory changes that would license the IBCLC would expand the number of providers and services available to consumers, improve access, and provide a standardized, expert level of care in a cost effective manner. USLCA does not intend to inhibit competitive healthcare services but rather welcomes the strength of a larger workforce. To the contrary, USLCA strongly values full disclosure of qualifications, credentials, experience, scope of practice, practice standards, to all stakeholders but most importantly to breastfeeding mothers and their families. Careful consideration by the FTC regarding the extent to which consumers, hospitals, and physicians are fully protected, informed, and contributory to their healthcare service providers ultimately empowers our mothers in caring for their infants.

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Yardaena BO et al. Breastfeeding education and support services offered to pediatric residents in the US. Academic Pediatr 2011; 11:75-79.
IBCLCs provide safe and effective care shown to improve breastfeeding initiation, duration, and exclusivity resulting in reduced healthcare claims. Integration of lactation consultants into primary care will advance breastfeeding duration rates. Witt’s study showed improved duration with standardized IBCLC support in a pediatric practice. Qualitative evidence from two randomized control trials demonstrated that pre-and postnatal support from IBCLCs, increased breastfeeding intensity and duration at 6 months with only 3 hours of contact. The Centers for Disease Control and Prevention (CDC) considers IBCLCs as integral to the quality of breastfeeding support provided by each state. The number of IBCLCs per 1000 live births is used as an indicator in the Breastfeeding Report Card issued by the CDC each year. IBCLCs have a broad range of clinical competencies which facilitate breastfeeding success in various settings (Table 1).

There is no peer-reviewed research showing holders of a certificate from basic training programs (Table 2) obtain comparable results beyond peer support. In fact, most certificate programs do not require prior medical knowledge, education, or training but rather stand all-inclusive regardless of course length or depth of education. If certificate programs were allowed to compete for healthcare services equal to those offered by IBCLCs, it would be possible that non-professional providers could be employed in high acuity in-patient settings and consequently assigned to provide the same patient care that IBCLCs currently give. This level of practice goes far beyond the certificate holder’s scope of practice, code of ethics, or their own regulatory body. Several of the certificate programs do not practice from a clearly defined scope of practice or by a professional code of conduct or ethics because they are not healthcare professionals.

In-patient settings continue to transition to higher and higher levels of acuity with more care provided in an outpatient or home setting. Still, as a part of a fragmented health system, women and infants continue to be the most vulnerable population. As seen with other non-professionals, credentialing by unregulated bodies not only confuse and convince consumers that their services and expertise are equivalent but can reach beyond the consumer to all those involved within the healthcare team, healthcare systems, and healthcare provision. No longer will the professional credential be publically recognizable or administratively desirable with disputable claims of skill and knowledge equality by non-professionals. In some certificate programs (such as the Certified Lactation Counselor-CLC) there are claims that participants in a 5 day course possess the ability to conduct a comprehensive assessment on the breastfeeding mother and her infant, yet are not required to have prior knowledge of anatomy and physiology which is concerning. Also, according to Healthy Children, CLC’s have the ability to integrate evidence-based practice although there are no prerequisites of research knowledge required or additional licensing prior to the certificate training program. Additionally, the overwhelming flood of non-professionals into the healthcare market could result in a much greater risk to women and infants with differing scopes of practice, code of ethics,

and lack of independent regulatory bodies that monitor practice standards. The quantity of non-professionals cannot outweigh the quality of care provided by IBCLCs in the healthcare market.

A worst case scenario for example, would be a certificate holder with or without a high school diploma could be placed in a neonatal intensive care unit to care for an infant without any prior medical training or knowledge of at-risk infants.

<table>
<thead>
<tr>
<th><strong>Table 1</strong></th>
<th>Effectiveness of IBCLCs</th>
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<tr>
<td><strong>Setting</strong></td>
<td><strong>Effect of IBCLCs on initiation and duration of breastfeeding</strong></td>
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<tr>
<td>WIC</td>
<td>More mothers initiate breastfeeding&lt;sup&gt;14&lt;/sup&gt;</td>
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<tr>
<td>Community Clinic</td>
<td>Access for lactation consultants facilitates mothers achieving their breastfeeding goals&lt;sup&gt;15&lt;/sup&gt;</td>
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| Primary Care | Promote a longer duration of breastfeeding<sup>16</sup>  
LCs help overcome barriers and sustain breastfeeding<sup>17</sup>  
LC integrated into routine care increase breastfeeding intensity at 3 months<sup>18</sup> |
| NICU | Breastfeeding rates 50% compared to 36% without an IBCLC<sup>19</sup>  
NICU dedicated lactation consultant increases babies receiving human milk<sup>20</sup> |


<sup>16</sup> SE Thurman and PJ Allen, “Integrating lactation consultants into primary health care services: are lactation consultants affecting breastfeeding success?” Pediatric Nursing 34, no. 5 (2008): 419-425.


IBCLCs are the only lactation service provider with a pre-requisite of clinical experience to qualify for examination by the International Board of Lactation Consultant Examiners, currently 300-1000 hours of clinical practice. Other training programs provide knowledge of basic lactation support for the normal course of breastfeeding. These are generally 15 to 45 hour courses with no prerequisites and limited continuing education requirements.

### Table 2

**Landscape of providers**

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<tr>
<th>Title</th>
<th>Training time</th>
<th>Skills</th>
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| International Board Certified Lactation Consultant | Usually around 5 years, of preparation | • 90 hours lactation specific education,  
• 8 college level health professional courses,  
• 6 health related continuing education courses,  
• 300-1000 clinical practice hours  
• Pass a criterion-reference exam  
The International Board Certified Lactation Consultant possesses the necessary skills, knowledge, and attitudes to provide quality breastfeeding assistance to babies and mothers. IBCLCs specialize in the clinical management of breastfeeding which includes: preventive healthcare, patient education, nutrition counseling, and therapeutic treatment. |
| Certified Lactation                        | 45 hours             | Designed for the aspiring lactation consultant or |

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22 Ibid.
| Specialist Breastfeeding Specialist | nurses, physicians, midwives, dieticians, breastfeeding assistants or others desirous of improving their knowledge base and skills in working with the breastfeeding dyad. This certification is a stepping stone to the IBCLC credential. |
| Lactation Educator Counselor | 45 hours | This university based program trains participants to be Lactation Educator Counselors. Lactation Educator Counselors are typically entry level practitioners and deal primarily with the normal process of lactation. This course is the required prerequisite to the Lactation Consultant course. |
| Breastfeeding Counselor | 10-14 months, Provide 30 hours of support | 2-3 day workshop, self-evaluation, one written paper & case studies, read and review 5 books, submit one survey on breastfeeding support available in your community, open book online tests (multiple choice) to cover physiology & anatomy. |
| Breastfeeding Educator | 1010 hours | Qualified to teach, support, and educate the public on breastfeeding and related issues and policies. Workbook activities, required reading materials, attend 8 breastfeeding meetings, research paper, submit a class presentation, work for clients in their community. |
| Community Breastfeeding Educator | 20 hours | “Does not issue Lactation Consultant status. For community workers in maternal child health, focuses on providing services to pregnant women to encourage the initiation and continuation of breastfeeding.” |
| Certified Lactation Counselor | 45 hours | “This comprehensive, evidence-based, breastfeeding management course includes |

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<tr>
<th>Curriculum</th>
<th>Hours/Details</th>
<th>Description</th>
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<tbody>
<tr>
<td>Baby Friendly Curriculum</td>
<td>Approximately 20 hours</td>
<td>Used by facilities to strengthen the knowledge and skills of their staff towards successful implementation of the Ten Steps to Successful Breastfeeding.</td>
</tr>
<tr>
<td>WIC Peer Counselor</td>
<td>30-50 hours, Varies by state, some states have quarterly training</td>
<td>Must have successfully breastfed their infant. Provide information to help mothers make an educated choice about how they will feed their babies, share tips for helping mothers get off to a good start with breastfeeding, answer common questions, and encouragement for challenges. Will also refer mothers who have challenging questions and concerns.</td>
</tr>
<tr>
<td>Certified Lactation Educator</td>
<td>20 hours total, some have 8 hours clinical</td>
<td>Qualified to teach, support, and educate the public on breastfeeding and related issues. Complete course training, attend support group meetings, observe consultation or videos, review research studies and other requirements, including a test.</td>
</tr>
<tr>
<td>La Leche League Peer Counselor (volunteer)</td>
<td>18-20 hours</td>
<td>Have successfully breastfed their infants for 6 months. Program developed to provide support systems within targeted communities that will provide ongoing access to breastfeeding information and support.</td>
</tr>
<tr>
<td>La Leche League Leader (volunteer)</td>
<td>Approximately 1 year of self-study training</td>
<td>An experienced breastfeeding mother, familiar with research and current findings dealing with breastfeeding, who offers practical information and encouragement to nursing mothers through monthly meetings and one-to-one help.</td>
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Without question “The Surgeon General’s Call to Action to Support Breastfeeding” specifically recommends services provided by IBCLCs because of the evidence-based care known to make

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a difference in maternal and infant health outcomes. The USLCA urges private third party payers and Medicaid to include standard coverage for IBCLCs as covered providers independent of their having other professional licenses. Licensing of IBCLCs would in no way restrict the practice of other lactation service providers. Licensure protects consumers, encourages quality, assigns responsibility, raises professional standards of practice, and prevents unqualified individuals from practicing. It provides consumers with the tools needed to evaluate the preparation and skills of practitioners. Currently, the public has little in the way of resources to evaluate the type of lactation services they may need as well as the most appropriate provider of those services. IBCLCs across the country currently serve an important role as part of the healthcare team for both the mother and infant, and stand committed to providing professional, evidence-based, accessible, available, and affordable lactation support. Healthcare systems, professions, and providers have been charged by the Institute of Medicine to maintain the value of quality over quantity in order to advocate for the public’s welfare for which they are committed to protect.

Other than the IBCLC credential, the remaining programs resemble certificate programs as defined by the Institute for Credentialing Excellence (ICE).35

Certificate Programs
- Provide education and training to individuals
- Are generally associated with a particular course or program
- Are not independent of any provider of classes, courses, or programs
- “Certificate holders “shall not say that they are ‘Certified in…” and “shall not use acronyms or letters after their names to reference the certificate they hold” or “make claims or imply that the certificate is a professional certification.”

Certification Programs
- Assessment of knowledge or skills which is completely separate and independent of training or education
- Individuals must meet predetermined criteria (education, professional experience, supervised clinical experience) to be eligible to sit for an exam
- Must pass a professionally developed exam
- Is time limited and requires periodic renewal

In general, lactation consultants hold the IBCLC certification and are paid healthcare professionals trained to provide specific clinical expertise in the management of complex problems with lactation. Counselors usually have less training and handle basic problems while providing encouragement, emotional support and promoting self-efficacy. For example, the Certified Lactation Counselor (CLC) may be an additional credential for other health care providers, signifying additional training in lactation care. Depending on their educational and professional background, IBCLCs are required to accrue 300-1000 hours of supervised lactation-specific clinical experience and 90 hours of didactic education in human lactation and breastfeeding as well as training in another healthcare field, or 14 general education, college

level classes in health sciences. Following this education and training, they must pass an independent criterion referenced exam which provides a standard for IBCLC certification. The exam is administered by the International Board of Lactation Consultant Examiners (IBLCE). IBLCE is an independently accredited organization that determines prerequisites to sit for the exam and assures its validity through the use of an independent psychometrician. IBCLCs are the only lactation service provider with the pre-requisite of clinical experience and college level health-related coursework to qualify for examination by the IBLCE. There are no prerequisites needed in order to acquire a certificate in lactation, such as with the CLC training program. This program consists of the same organizational body supplying their own accreditation, training, exam, and maintenance management. Ultimately, the concern would be whether or not the organization can objectively enforce unbiased disciplinary actions, create on-going accountability measures for personal development, serve as their own regulatory body in which to monitor quality of evidence-based patient outcomes, and avoid a conflict of interest.

Additionally, the widespread use of terms such as “counselor,” “specialist,” “educator,” and “consultant” are often misused and mistaken to mean the same thing. Potential risks include misrepresentation and deception of qualifications which confuses hospitals, healthcare systems, policy makers, and consumers into erroneously thinking that all of these terms are equivalent.

Currently, all women and particularly vulnerable and underserved populations lack access to the level of lactation services that they require. As long as insurers follow the prevailing system requiring licensure for the reimbursement of healthcare providers, impaired access to lactation care and services will continue. In 2013, CMS issued an “Update on Preventive Services Initiatives” informing states of a new option for offering only preventive services in state Medicaid plans that is applicable to inclusion of IBCLC services. The letter says, “In particular, the statute at section 1905(a)(13) indicates that services must be recommended [not provided] by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law…” “Preventive services may be provided, at state option, by practitioners other than physicians or licensed practitioners” effective January 1, 2014. This can be accomplished by including the preventive service providers in the State Plans. However, this process is arduous, can still require passing legislation and would only be applicable to Medicaid, making licensure still the preferable course of action.

In summary, competitive harm currently exists when only licensed providers can deliver reimbursable lactation services. The consumer suffers when current providers are ill prepared to deliver evidence-based care regardless of the quantity of providers delivering services. Licensure of the IBCLC will help to maintain the rigorous professional practice standards as well as expand access to lactation care to all women and infants. Licensure will in no way hinder the role of breastfeeding support personnel who work within their own scope of practice.

USLCA urges the Federal Trade Commission and states not to summarily limit or eliminate healthcare professional licensure for political reasons when evidence of effectiveness of the provider and needs of consumers exists. USLCA also recommends consideration of the following:

36 www.IBLCE.org
• Recommend that state and Federal officials take prompt and aggressive action to facilitate the licensure of the IBCLC
• Urge CMS and private insurers to reimburse for lactation services provided by IBCLCs

Thank you so much for this opportunity to provide comments. USLCA stands ready to assist the Commission in moving forward on the issues brought forth in this workshop and on expanding access to lactation services provided by the only internationally certified lactation healthcare professional, the IBCLC.

Submitted respectfully,

Alisa Sanders, RN, IBCLC
President
United States Lactation Consultant Association