

**Before the United States
Federal Trade Commission**

Washington, D.C.

Workshop: Examining Health Care Competition

Project Number P131207

Comments of the Healthy Children Project, Inc.

Introduction

The Healthy Children Project, Inc., Center for Breastfeeding (“Healthy Children”) appreciates the opportunity to have participated in the Federal Trade Commission Workshop “Examining Health Care Competition”. Having done so, Healthy Children submits these comments on the subject matter of “Professional Regulation of Health Care Providers”.

Interest of the Healthy Children

The mission of Healthy Children¹ is to increase breastfeeding rates, to advocate for change in societal attitudes towards breastfeeding, to train health care professionals, known as lactation consultants or lactation counselors, and to assist mothers in successfully breastfeeding exclusively and for longer durations. Healthy Children is concerned that restrictions on licensure, support, and reimbursement for lactation consultants have the effect of inhibiting, rather than promoting healthy breastfeeding, and unreasonably suppressing competition among lactation consulting professionals.

Healthy Children, through the Center for Breastfeeding and the Academy of Lactation Policy and Practice, operates the Certified Lactation Counselor (“CLC”) testing and certification program. This program promotes healthy breastfeeding by identifying competent lactation professionals to expectant and nursing mothers, as well as other health care professionals. Healthy Children’s program has been accredited by the American Nurses Credentialing Center on Accreditation as a Nursing Skills Competency Program. In addition, Healthy Children has recently obtained accreditation of its Certified Lactation Counselor/CLC certification program from the Accreditation Program for Personnel Certification Bodies of the American National Standards Institute (“ANSI”).²

There is a consensus among major health profession organizations and government entities that breastfeeding provides significant health benefits to mother and child.³ Although progress in promoting rates of breastfeeding has been made, rates of breastfeeding in the United States are lower than optimum, particularly among African-American mothers and babies.⁴

¹Healthy Children, based in East Sandwich, Massachusetts, is a non-profit corporation recognized as a tax-exempt organization by the Internal Revenue Service under Section 501(c)(3) of the Internal Revenue Code. Further information about Healthy Children may be found at www.healthychildren.cc.

² The ANSI Accreditation Program is described at

<https://www.ansica.org/wwwversion2/outside/PERgeneral.asp?menuID=2>

³ See, e.g., American Academy of Pediatrics Section on Breastfeeding. “*Breastfeeding and the Use of Human Milk (Policy Statement)*.” *Pediatrics* 129, no. 3 (2012). Available at:

<http://pediatrics.aappublications.org/content/115/2/496.full.pdf+html>; U.S. Department of Health and Human Services, *The Surgeon General’s Call to Action to Support Breastfeeding [Call to Action]*, Washington, D.C.: U.S. Department of Health and Human Services, Office of the Surgeon General: 2011. Available at

<http://www.surgeongeneral.gov/topics/breastfeeding/>

⁴ Centers for Disease Control, *Morbidity and Mortality Weekly Report Progress in Increasing Breastfeeding and Reducing Racial/Ethnic Differences* (February 8, 2013), available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6205a1.htm?s_cid=mm6205a1_w.

There is a further consensus that lactation counseling and support are important components of a strategy for increasing rates of breastfeeding. The *Surgeon General's Call to Action to Support Breastfeeding* (“*Call to Action*”) reports that:

education and counseling on breastfeeding are unanimously recognized by the AAP and the American College of Obstetricians and Gynecologists in their *Guidelines for Perinatal Care* as a necessary part of prenatal and pediatric care. Similarly, the American Academy of Family Physicians and the American College of Nurse-Midwives call for the consistent provision of breastfeeding education and counseling services.⁵

The importance of counseling for breastfeeding mothers has also been recognized by the Institute of Medicine (“IOM”), which was charged by the Department of Health and Human Services with “reviewing what preventative services are important to women’s health and well-being and then recommending which of these should be considered in the development of guidelines”⁶ in implementing the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act). The IOM recommended inclusion of “[c]omprehensive lactation support and counseling and costs of renting breastfeeding equipment, among those services”, stating “[a] trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding”.⁷

The Affordable Care Act and implementing regulations did provide for expanding access to lactation counseling services. However, the regulations do not define which lactation care providers are eligible for reimbursement by insurers.⁸ Accordingly, in order to expand access to lactation counseling and support services and to meet the requirements of the Affordable Care Act, there is a need identify qualified lactation counselors. The United States Breastfeeding Committee (“USBC”)⁹ observed that:

⁵ *Call to Action* at 24.

⁶ Institute of Medicine, *Clinical Preventive Services for Women Closing the Gaps*, (July 2011) at 1. Available at: http://www.iom.edu/~media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf

⁷ Recommendation 5.6, *Id.* at 3.

⁸ Section 2713 of the Affordable Care Act requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage and not impose any cost-sharing on evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force. The Task Force included, among its recommendations, “interventions during pregnancy and after birth to promote and support breastfeeding” as a Grade B Recommendation.

<http://www.uspreventiveservicestaskforce.org/uspstf08/breastfeeding/brfeedrs.pdf>. The Health Resources and Services Administration of the Department of Health and Humans Services issued implementing guidelines that refer to “[c]omprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period” as including in the scope of preventative services. (emphasis supplied). Health Resources and Services Administration, *Women's Preventative Services: Required Health Plan Coverage Guidelines Supported by the Health Resources and Services Administration*, available at: <http://www.hrsa.gov/womensguidelines/>.

⁹ The USBC describes itself as “an independent nonprofit coalition of more than 40 nationally influential professional, educational, and governmental organizations, that share a common mission to improve the Nation’s health by working collaboratively to protect, promote, and support breastfeeding.” <http://www.usbreastfeeding.org/>. The Healthy Children Project, Inc. is a member of the USBC.

In the rapidly-changing landscape of insurance requirements rolling out under the Affordable Care Act (ACA), few have been more confusing than the requirement to cover "breastfeeding support, supplies, and counseling" (starting in the first plan year that began on or after August 1, 2012). The lack of guidelines or recommendations as to who may provide and be paid for lactation care, and what kinds of equipment should be covered for breastfeeding families, has created chaos for providers and patients alike.

"Many insurers have little experience with the clinical and business aspects of breastfeeding support," says Susanne Madden, chief operating officer of the National Breastfeeding Center. "Our population's health depends on insurers getting this right, but without clear guidelines we are relying on individuals that may not be qualified in breastfeeding medicine or lactation services to identify what is needed to successfully implement this coverage mandate."

As a result, families across the Nation report extreme inconsistencies in coverage and disrupted continuity of care, often being left without access to the resources they need to meet their breastfeeding goals.¹⁰

To date, efforts at the federal and state level have tended to restrict licensure, third party reimbursement and other support to one group of providers of lactation consulting services, those certified as an International Board Certified Lactation Consultant ("IBCLC") by the International Board of Lactation Consultant Examiners ("IBCLE").¹¹ For example, rather than urge access to services provided by all qualified lactation support professionals, one of the actions identified to achieve the goals of the *Call to Action* was "Action 11: Ensure access to services provided by International Board Certified Lactation Consultants".¹² At the state level, New York provides Medicaid reimbursement to "licensed, registered, or certified health care professionals who are International Board Certified Lactation Consultants (IBCLCs) credentialed by the International Board of Lactation Consultant Examiners".¹³

There is no substantive basis for restricting licensure, reimbursement, and support to individuals with IBCLC certification. No proponent of restrictions has identified any empirical evidence to suggest that restrictions on providers of lactation support services are associated with higher quality patient outcomes. To the contrary, restrictions may reduce quality of care by reducing access to lactation support services and are likely to inhibit rather than encourage healthy breastfeeding.

¹⁰ USBC, *Model Policy for Insurers Aims to Calm Chaos Surrounding Mandated Coverage of Breastfeeding Support, Supplies, and Counseling*, available at:

<http://www.usbreastfeeding.org/NewsInfo/NewsRoom/201307ModelPayerPolicy/tabid/345/Default.aspx>.

¹¹ The IBCLE operates a certification program that confers the International Board Certified Lactation Consultant ("IBCLC") credential. The IBCLE program is accredited by the U.S. National Commission for Certifying Agencies. The IBCLE program is described at: <http://americas.iblce.org/>.

¹² *Call to Action* at 48.

¹³ New York Department of Health, *New York State Medicaid Coverage of Lactation Counseling Services*, available at:

http://www.health.ny.gov/community/pregnancy/breastfeeding/medicaid_coverage/lactation_counseling_services.htm.

Licensure

It has been observed that “[a]n overarching goal of many occupations at an initial stage of regulation is to obtain licensing by a governmental entity”.¹⁴ The principal advocates for exclusive licensure of IBCLCs as lactation consultants are the IBCLE and the United States Lactation Consultant Association (“USLCA”), which is the United States affiliate of the International Lactation Consultant Association (“ILCA”) and describes itself as “the professional association for International Board Certified Lactation Consultants (IBCLCs)”.¹⁵ In a recent newsletter, the USLCA stated that:

One very important benefit of your USLCA membership that might be overlooked is continuously representing you and raising awareness of the IBCLC with policy makers and elected officials. Meetings with state legislators and lobbying visits to state capitals are essential to advancing the IBCLC credential. The USLCA’s advocacy efforts are constantly going on, any times behind the scenes, to help each of you have a more prosperous career as an IBCLC. Remember that the USLCA takes great responsibility in being a strong voice for our members!¹⁶

We currently have several states preparing for introduction of licensure legislation including Pennsylvania, New York, New Jersey, Minnesota. The Georgia Bill was already introduced and is under review. There are additional states still at the inquiry phase of licensure work including Maryland, Colorado and Delaware that are actively working on the issue none-the-less.

We are also relentlessly pursuing both private insurers, and Medicaid at the state and federal level, to educate for the need for lactation services for mothers and infants and the qualifications of IBCLCs to provide this service.¹⁷

To date, attempts to license lactation consultants in a manner that restricts licensure to IBCLCs have not been successful.¹⁶

In 2012, the Healthy Keystone Kids Initiative, representing the Pennsylvania Chapters of the United States Lactation Consultants Association, proposed legislation in Pennsylvania that would limit licensure and reimbursement for lactation consultant practitioners to IBCLCs and would penalize the unlicensed practice of lactation care services. The proposed legislation stated, in pertinent part, that:

Board standards shall be equivalent to established national standards such as those set for an International Board Certified Lactation Consultant (IBCLC) by the International Board of Lactation Consultant Examiners (IBCLE).¹⁸

¹⁴ Kleiner, Morris M., *Stages of Occupational Regulation: Analysis of Case Studies*, at 15 (2013).

¹⁵ USLCA, *Mission and Vision*, available at: <http://www.ilca.org/i4a/pages/index.cfm?pageid=3862>.

¹⁶ USLCA, eNews_February_2014 at 9.

¹⁷ *Id.* at 10.

Individuals shall not practice clinical lactation care or services or hold themselves out as lactation consultant practitioners unless licensed under this Act.¹⁹

A Scope of Practice encompasses the activities for which licensed lactation consultants are educated and which they are authorized to engage. The aim of the scope of practice is to protect the public by ensuring that all licensed consultants provide safe, competent and evidence-based care. The IBCLE Scope of Practice for IBCLCs, defined by the International Board of Lactation Consultant Examiners, fulfills the definition of a scope of practice for lactation consultants, for this board's purposes, and is applicable for board's lactation consultant licensure.²⁰

Ultimately, the request for licensure of IBCLCs was rejected on the ground that “[i]t is not apparent that licensing IBCLC-certified lactation consultants would greatly contribute” to existing efforts to support breastfeeding.²¹

Legislation was also proposed in Massachusetts in 2012 that would have required licensure of lactation consultants and would have limited licensure, with some exceptions to individuals possessing certification from the IBCLE.²² The legislation was not passed.

The Healthy Mothers, Healthy Babies Coalition of Georgia, Inc. proposed Georgia Lactation Consultant Practice Act in 2013. That legislation, known as HB363, would require individuals providing lactation care and services to be licensed, and, with some exceptions limited licensure to individuals possessing IBCLE certification. The proposed legislation was criticized by Georgia breastfeeding advocates as decreasing access to lactation care because it would deprive 900 Certified Lactation Counselors, some of whom with twenty years of experience, of the ability to practice at a time when there were only 300 IBCLCs in Georgia thereby dramatically reducing the availability of lactation support services.²³

The proposed legislation was reviewed by the Georgia Occupational Regulation Review Council, which not only obtained information from interested parties, but also “observed the work of lactation consultants in the neonatal intensive care unit, the maternity ward, and the outpatient clinics at Grady Memorial Hospital”.²⁴ Although advocates of licensure claimed that

¹⁸Preliminary Draft of Senate Bill, §X.1. Healthy Keystone Kids Initiative, *Sunrise Evaluation Report Lactation Consultants*, at 15 (March 15, 2012) (citation omitted) (emphasis supplied). A copy of the Report (which includes the Preliminary Draft of the Senate Bill) is available at http://media.wix.com/ugd/8e28ed_51b52ab30e12c20e3f1d76ea4efe59de.pdf.

¹⁹ Preliminary Draft of Senate Bill, §X.3.

²⁰ Preliminary Draft of Senate Bill, §X.7.

²¹ *Letter from Commonwealth of Pennsylvania Department of State to Judith L. Gutowski* at 2 (July 24, 2013). A copy of the letter is available at http://media.wix.com/ugd/8e28ed_3cd508d2bf20ee6884ab40fec5c6e657.pdf.

²² A copy of the legislation, the Lactation Practice Consultant Act, is included in the *Sunrise Evaluation Report*.

²³ Long and Bugg, *Unintentionally Disenfranchised?* (March 4, 2013), available at: <http://www.momsrising.org/blog/unintentionally-disenfranchised/>.

²⁴ Georgia Occupational Regulation Review Council, *House Bill 363: Georgia Lactation Consultant Practice Act A Review of the Proposed Legislation*, at 4 (December, 2013) (emphasis supplied), available at

licensure was necessary to prevent public harm caused by uneducated or inexperienced practitioners, no empirical data supported this assertion.²⁵ To the contrary, the Council stated that “[i]f this legislation prohibited CLCs from providing services, the citizens may be at a *greater risk of harm* because the majority of lactation consultant providers would no longer provide care”.²⁶ The Council also noted that services provided by Certified Lactation Counselors are less expensive than those provided by CLCs.²⁷ The Council voted unanimously to recommend against passage of the legislation on the ground that it “would not improve access to care for the majority of breastfeeding mothers”.²⁸ Healthy Children understands that revisions to the legislation have been proposed and are under review.

An Alternative to Exclusive Licensure

Healthy Children suggests that revisions to the *Model Policy Payer Coverage of Breastfeeding Support and Counseling Services, Pumps and Supplies* (“*Model Policy*”)²⁹ might serve as a better model for providing information regarding the qualifications of providers of lactation services. The *Model Policy* was issued by the United States Breastfeeding Committee (USBC) and the National Breastfeeding Center (NBfC) on July 17, 2013.

The stated aim of the *Model Policy* was “to provide clear recommendations for federal and state agencies (that oversee delivery of health care services to eligible low-income families through Medicaid or similar programs) and for private insurers (that reimburse health care services through plans offered by employers or purchased by individuals)”.³⁰ A draft of the *Model Policy, Lactation Services and Breastfeeding Equipment Guidelines* (“the *Guidelines*”), issued in May, limited reimbursement for “approved lactation professionals” which were defined as “those that hold the International Board Certified Lactation Consultants (IBCLC) designation”.³¹ Healthy Children submitted comments objecting to this limitation as unwarranted on a substantive basis and contrary to public policy.

The *Model Policy* ultimately issued no longer identified IBCLCs as the only approved lactation consultants eligible for coverage by insurance companies. Instead, the *Model Policy* stated, in pertinent part, that:

Approved lactation care providers may vary in their training, licensure, certification, level of care, and ability to deliver care. Many disciplines offer

http://opb.georgia.gov/sites/opb.georgia.gov/files/related_files/site_page/HB%20363%20Final%20Combined%20%28PUBLISHED%29.pdf. The Council’s report includes a copy of HB 363.

²⁵ *Id.* at 8. (“There are no data available within Georgia that can accurately report the scope of public harm caused by the uneducated or inexperienced practice of lactation consulting”).

²⁶ *Id.* at 13.

²⁷ *Id.* at 14-15.

²⁸ *Id.* at 17.

²⁹ USBC, NBfC, *Model Policy Payer Coverage of Breastfeeding Support and Counseling Services, Pumps and Supplies* (2013) available at: <http://www.usbreastfeeding.org/Portals/0/Publications/Model-Policy-Payer-Coverage-Breastfeeding-Support.pdf>.

³⁰ USBC, *Model Payer Policy Cover Letter*, available at:

<http://www.usbreastfeeding.org/Portals/0/Publications/Model-Payer-Policy-Cover-Letter.pdf>.

³¹ USBC, NBfC, *Lactation Services and Breastfeeding Equipment Guidelines* at 6, n.4 (May 13, 2013).

lactation care to the mother and infant, such as nurses, advanced practice nurses, physician assistants, physicians, registered dietitians, peer lactation counselors.³²

This statement suggested that a broad range of approved lactation care providers would be eligible for coverage by insurers. However, this suggestion was contradicted by the definition of approved lactation care providers contained in the *Model Policy*, which defined approved lactation care providers as:

those who, consistent with insurance companies' credentialing requirements, have individual certification awarded by an independently-accredited program that measures assessment of predetermined standards for knowledge, skills, or competencies in a health-related profession, substantially equal to those articulated by the National Commission for Certifying Agencies and the Institute for Credentialing Excellence.³³

Healthy Children considered the restrictions on reimbursement contained in the *Model Policy* to be significant because the Affordable Care Act and implementing regulations that provide for expanding access to lactation counseling services do not define which lactation care providers eligible for reimbursement by insurers. The USBC had indicated that the Department of Health and Human Services plans to direct insurers seeking clarification as to coverage to the USBC web-site. Healthy Children requested that the definition of approved lactation care providers be expanded in light of the accreditation of the Healthy Children program by ANSI.

Recently, in response to Healthy Children's request, a second edition of the *Model Policy* was issued. This edition expanded the definition of "approved lactation care providers" to include:

those who, consistent with insurance companies' credentialing requirements, have individual certification awarded by an independently-accredited program that measures assessment of predetermined standards for knowledge, skills, or competencies in a health-related profession, substantially equal to those articulated by the National Commission for Certifying Agencies (NCCA), the Institute for Credentialing Excellence (ICE), and American National Standards Institute.³⁴

This expanded definition encourages healthy breastfeeding by identifying qualified providers of lactation support services without the onerous effects of exclusive licensure.³⁵

³² *Model Policy* at 5.

³³ *Id.*

³⁴ USBC and NBfC, *Model Policy: Payer Coverage of Breastfeeding Support and Counseling Services, Pumps and Supplies*, 2nd rev ed. (2014) at 8 n.8. A copy is available at:

<http://www.usbreastfeeding.org/Portals/0/Publications/Model-Policy-Payer-Coverage-Breastfeeding-Support.pdf>.

³⁵ It has been noted that, "[a]lthough occupational licensing has been growing, several proposals have been made to slow the growth of occupational licensing in favor of certification". Kleiner, *supra* at 221.

Request for Commission Action

As the Commission stated in the Federal Register Notice announcing the Workshop,

Some regulations may, however, unnecessarily restrict the ability of non-physician health care professionals to practice to the full extent of their training, imposing costly limitations on professional services without well-founded consumer safety justifications or other consumer benefits to offset those costs. Such overly restrictive professional regulations are likely to suppress competition by non-physician providers (such as hospitals) from developing innovative health care delivery models that rely on innovative health care delivery models to provide efficient, safe care.³⁶

This observation applies with force to restrictions on licensure, reimbursement and support for lactation counseling services. These restrictions have the potential to cause harm by exacerbating existing access problems, thereby harming mothers and babies, and by reducing competitive pressures among providers of lactation counseling services.

In light of the Commission's extensive history of antitrust advocacy in health care markets, Healthy Children requests that the Commission continue its examination health competition. Further, Healthy Children requests that the Commission intervene at the federal and state level to address the potential for competitive harm inherent in restrictions on licensure, support, and third party reimbursement for lactation support professionals. As has been demonstrated by the analysis of the Georgia Occupational Regulation Review Council, arguments in support of restrictions do not withstand careful scrutiny. Healthy Children requests that the Commission urge federal and state officials who have adopted or contemplating restrictions on the practice of lactation support professionals to carefully consider the factual arguments advanced to support such restrictions as well as their competitive implications.

³⁶ 79 Fed. Reg. 10154 (February 24, 2014).

Healthy Children looks forward to the opportunity to assist the Commission in these efforts.

Respectfully Submitted
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