



June 30, 2015

Ms. Tricia Orme
Office of Legal Services
275 East Main Street 5 W-8
Frankfort Kentucky 40601

Dear Ms. Orme,

We are writing on behalf of the Kentucky Coalition of Nurse Practitioners and Nurse Midwives (KCNPNM) to submit comments regarding proposed amendments to **900 KAR 5:020:400. State Health Plan for facilities and services.**

We have carefully reviewed the above-named regulation, as well as the document, "2015-2017 State Health Plan (May 2015) Certificate of Need Review Standards". We were very disappointed to see no reference in the regulation nor in the State Health Plan to the establishment of freestanding birthing centers in Kentucky. This is a subject about which our coalition submitted extensive documentation and background information in response to the Cabinet for Health and Family Services' call for the modernization of the Certificate of Need process. Our information was reinforced by referenced statements from the American College of Nurse-Midwives and the American Association of Birth Centers.

There is no doubt that establishing freestanding birthing centers would provide desired and much-needed choice to Kentucky mothers, safe and high-quality deliveries and a reduction in unnecessary caesarean section procedures. The data is clear that the freestanding birthing centers would also save the Commonwealth significant dollars in payments made for the birth of babies whose mothers are covered by Medicaid, comprising nearly 50% of the births annually in Kentucky.

The current Certificate of Need process makes it essentially impossible for a freestanding birthing center to be approved in Kentucky. Despite a recent ruling from the Franklin Circuit Court overturning the denial of such a center, the CON process has now moved on to legal appeals at a higher level. Meanwhile, there is no choice for Kentucky mothers who want to have their babies in a birthing center, attended by a certified nurse-midwife! This is an option available to mothers in 43 other states, but not in the Commonwealth of Kentucky.

We strongly urge the addition of another subsection under **V. Miscellaneous Services** (page 52) of the State Health Plan, CON document, as circulated. This would include: **C. Freestanding Birthing Centers** beginning on page 65 or amended to the end of the current document, as circulated.

Definition

A "Freestanding Birthing Center" is an entity which provides outpatient delivery for low-risk childbirths.

Review Criteria

An application to establish a Freestanding Birthing Center shall be consistent with the Plan if the application:

1. **Proposes to establish a freestanding birthing center in an Area Development District (ADD):**
 - a. **Referenced in Technical Note 1 and defined in KRS 147A.050.**
 - b. **Where no other freestanding birthing center is established.**
2. **Meets the certification standards established by the American Association of Birth Centers.**
3. **Is staffed by Certified Nurse-Midwives who are duly licensed in the Commonwealth of Kentucky and have their certification from the American Midwifery Certification Board.**

With these changes in the State Health Plan, the regulation 900 KAR 5:020 would have to be amended to add language describing the Freestanding Birthing Centers and referencing the appropriate page numbers of the State Health Plan document. We note that the regulation as promulgated does not reference the same page numbers as are found in the State Health Plan document.

We have attached to this letter of comment the materials previously referenced and submitted to the Kentucky Cabinet for Health and Family Services, Office of Health Policy.

Thank you for your consideration of these comments. Please contact us if further information is needed. We would like to receive a written response to these comments and a copy of the final Statement of Consideration.

Sincerely,


Wendy Fletcher DNP, APRN
KCNPNM President
President@kcnpm.org


Leila Faucette
KCNPNM Executive Director
Leila@kcnpm.org

cc: Deborah Karsnitz DNP CNM, KCNPNM Board of Directors
Sheila A. Schuster, Ph.D., KCNPNM Legislative Agent



Improving Access to Freestanding Birth Centers in Kentucky

Introduction

Freestanding birth center (FSBC) care leads to improved outcomes—lower cesarean and higher vaginal birth rates, fewer medical interventions for low risk women, cost savings and higher rates of satisfaction with care. The American Association of Birth Centers (AABC) is submitting these comments with the recommendation that FSBCs in Kentucky be exempted from the Certificate of Need (CON) requirement. Taking away the CON requirement will remove a significant barrier to FSBC access for women and families in Kentucky and will help to promote improved health for women and families.

Background

FSBCs have a demonstrated track record of providing high quality, low-cost care, exactly the type of care that states are seeking to support under a variety of programs. For example:

- A 2013 study looking at 15,574 planned birth center births found a cesarean rate of 6%, as compared to an expected 25% for similarly low-risk women in a hospital setting. This same study estimated that cost savings (based on Medicare payment rates) would amount to more than \$30 million.¹
- A study by the Washington State's Department of Social and Health Services examining the cost to Medicaid of birth in various settings found that the cost of birth center birth among low-risk women was 38% less than hospital birth for women of similar risk. These savings are partially due to the fact that the state's facility fee to the birth centers was approximately \$600, an amount that is not sufficient to cover costs. When increased to a more reasonable amount, \$2,000, the total costs of birth center birth were still 13% lower than hospital birth, a very significant savings.²
- A study by the Urban Institute, published in the *Medicare & Medicaid Research Review*, found that a birth center in Washington, DC saved the Medicaid program an average of \$1,163 per birth in 2008 dollars.³

Since FSBCs collectively attend a very small proportion of births (totaling 15,577 in 2012) the opportunity to access savings generated by these high value providers is substantial.⁴ As states take steps to increase the proportion of birth center births, they will realize substantial reductions in their expenditures on maternity care. The studies mentioned above also demonstrate that high-quality outcomes can be expected. It is therefore strongly in the interest of states to create regulations conducive to the creation of more FSBCs and increased access to FSBC care.

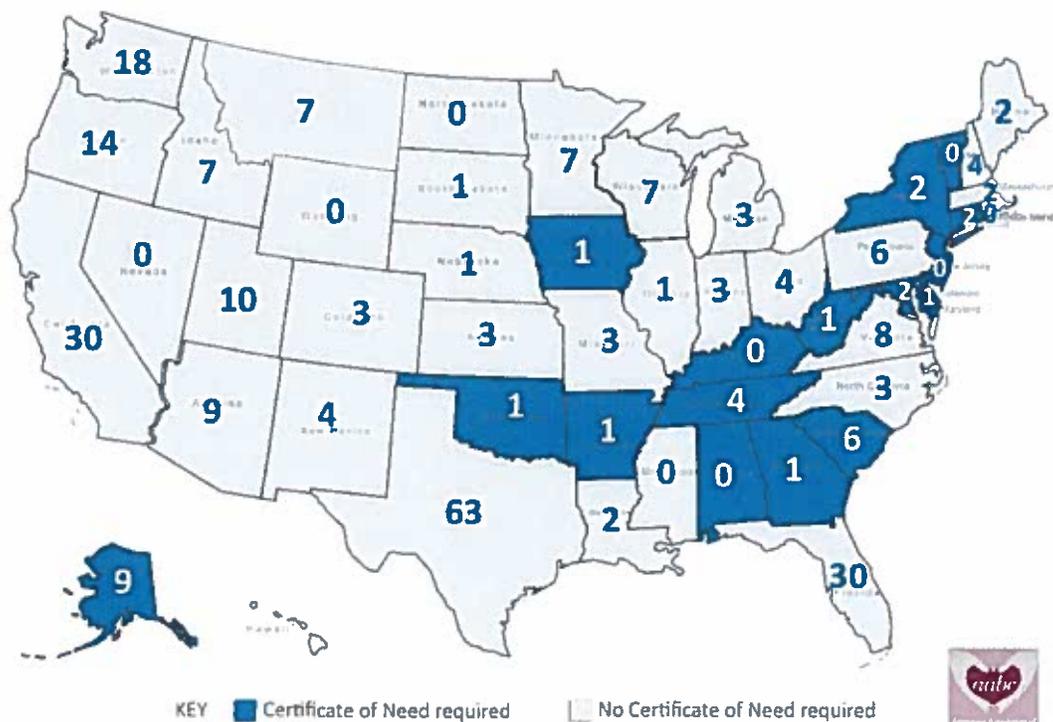
Ensuring Quality of Care

FSBCs in the United States ensure that services provided are of high quality by meeting standards of accreditation by the Commission for the Accreditation of Birth Centers (CABC) and through ongoing risk assessment and data collection for quality improvement. Birth centers collect data on the program and outcomes of care through the AABC Perinatal Data Registry. The study of birth center outcomes cited above is a testimony to the quality of care provided in FSBCs.¹

Improving Access to Care—Reducing Barriers

Access to FSBC care can be improved by reducing barriers for women seeking maternity care services in FSBCs. State regulations requiring CON can be barriers to FSBC care when other providers in direct competition with FSBCs resist CON applications. In reality, FSBCs have only 2 or 3 beds, which differ from hospital beds in that care is limited to low risk childbirth and no surgery is possible there. AABC believes that due to their small size and outpatient services, FSBCs should be exempt from the CON process. Removal of the CON process for FSBCs is one way to improve access to this option of high-quality care. Other barriers such as regulatory requirements for Medical Director, medical supervision or written agreements with hospitals can also inhibit access to FSBCs.

When states have no CON requirement, access to FSBC care increases. As illustrated in the chart below, when FSBCs are exempt from a state’s CON requirement, more FSBCs are established, thus increasing access to birth center care. States like Texas, California, Florida, Washington and Oregon are prime examples.



Improving Value of Care

If more women had access to FSBC care, the savings would be significant both in direct and indirect costs. If even 10% of the approximately 4 million US births each year occurred in birth centers, the potential savings in facility service fees alone could reach \$1 billion per year. In addition, US spending on maternity care could decline by more than \$5 billion if only 15% of pregnant women gave birth via cesarean rather than the current rate of 32%. The cesarean rate in the National Birth Center Study II was 6%.¹ Because the cost of a cesarean birth is about twice as much as a vaginal birth, higher utilization of birth center care leads to further healthcare savings.⁵

Strong Start for Mothers and Newborns — Birth Centers Improve Health

The Strong Start for Mothers and Infants Initiative is a project of the Centers for Medicare and Medicaid Innovation (CMMI) to reduce preterm births and improve maternal and child health outcomes. One of the three models of care being studied for lowering preterm birth is the FSBC. AABC is a Strong Start awardee and collects data from over 40 birth center sites on prenatal care and outcomes of care. The extra support and relationships developed with midwives in the birth center model result in lower preterm birth rates in the FSBC, even for women with risk factors for preterm birth. Preliminary data from AABC's Strong Start project shows a preterm birth rate of 3.8% for women who are Medicaid beneficiaries with risk factors for preterm birth. Strong Start for FSBCs data collection and analysis will continue for another 2 ½ years.

Summary

The principles underlying CON statutes are based upon a health planning rather than a competitive model. AABC believes that reasonable arguments can be made for exempting FSBCs, due to their small size and the essentially outpatient nature of birth center services. Most women who give birth at a FSBC spend less than twenty-four hours there. With respect to prenatal and postpartum services, FSBC function more like a physician's or midwife's office than a health care facility. Furthermore, local levels of high demand will typically exist for a proposed FSBC, because women interested in the birth center option will strongly support adding a FSBC in the local community. FSBCs are also likely to attract women from outside the community who would never have traveled from their own community to give birth in the local hospital.

FSBCs in some states have had to go through multiple rounds of CON before approval was finally granted. These expensive proceedings constitute a significant barrier to entry for would-be birth center entrepreneurs, most of whom would be considered small businesses and some which are Federally Qualified Health Centers.

The evidence shows that FSBCs provide high-quality, high-value care with high rates of client satisfaction. Lower cesarean rates and other positive outcomes lead to immediate and longer-term healthcare savings. Removing barriers associated with the CON process would increase access to a high-quality model of maternity care.

¹ Susan Rutledge Stapleton, CNM, DNP, Cara Osborne, SD, CNM, and Jessica Illuzzi, MD, MS, "Outcomes of Care in Birth Centers: Demonstration of a Durable Model," *Journal of Midwifery and Women's Health*, vol. 58, no. 1, January 2013.

² Laurie Cawthon, MD, MPH, "Assessing Costs of Birth in Varied Settings," Washington State Department of Social and Health Services, March 7, 2013. Available at: <http://www.iom.edu/~media/Files/Activity%20Files/Women/BirthSettings/6-MAR-2013/Cawthon%20PDF.pdf>

³ Embry Howell, Ashley Palmer, Sarah Benatar, and Bowen Garrett, "Potential Medicaid Cost Savings from Maternity Care Based at a Freestanding Birth Center," *Medicare & Medicaid Research Review*, vol. 4, no. 3, 2014. Available at: http://cms.gov/mmrr/Downloads/MMRR2014_004_03_a06.pdf

⁴ Marian F. MacDorman, Ph.D.; T.J. Mathews, M.S.; and Eugene Declercq, Ph.D, "Trends in Out-of-Hospital Births in the United States, 1990–2012," *NCHS Data Brief*, No. 144, March 2014. Available at: <http://www.cdc.gov/nchs/data/databriefs/db144.pdf>

⁵ "The Cost of Having a Baby in the United States," Truven Health Analytics, January 2013. <http://transform.childbirthconnection.org/reports/cost/>



November 6, 2014

Emily Whelan Parento
Executive Director, Office of Health Policy
Cabinet for Health and Family Services
275 East Main Street, 4W-E
Frankfort, Kentucky 40621

Dear Ms. Parento,

I am writing on behalf of the American College of Nurse-Midwives (ACNM), the national professional organization representing the interests of certified nurse-midwives (CNM) and certified midwives (CM), regarding the request for stakeholder input on the proposed certificate of need modernization efforts. ACNM firmly believes that removing the certificate of need requirement for birth centers will achieve the Department's stated goal of achieving the triple aim by expanding access to midwifery care, improving maternity outcomes, and reducing cost.

An examination of perinatal outcomes in Kentucky indicates that there is room for improvement in several areas. Kentucky has one of the highest rates of preterm birth in the nation and, while the state has made efforts to decrease this rate by participating in prematurity prevention initiatives, statistics from 2012 demonstrate a preterm birth rate that still hovers above the national average.¹ In fact, data submitted to the National Governor's Association indicates that Kentucky has struggled with a higher than average preterm birth rate since at least 1999.² While preterm births have a significant impact on neonatal health and are the leading cause of neonatal death, there is an associated adverse effect on state health care spending. In 2007, for example, Medicaid financed approximately 48 percent of hospital stays for preterm infants at an average cost of \$45,900 per baby.³

Kentucky also has a higher than average rate of cesarean delivery, which was at 36 percent in 2012 versus the national average of 32 percent,⁴ and a high rate of early elective delivery (EED). Kentucky hospitals have reported EED rates as high as 45.3 percent and, while EEDs can be either vaginal or cesarean births, EEDs are more likely to result in cesarean delivery than spontaneous labors.⁵ These statistics have significant cost implications for the state. Medicaid

¹ Kentucky Cabinet for Health and Family Services, "Premature Births Can Be Prevented," November 2007. Available online at <http://chfs.ky.gov/news/Prematurity.htm>. March of Dimes Perinatal Overview for Kentucky and National Statistics available online at <http://www.marchofdimes.org/peristats/Peristats.aspx>.

² Kentucky Infant Mortality Team Report: NGA Birth Outcomes Learning Network, July 2012.

³ Association of Maternal and Child Health Programs, Report of Kentucky's "Healthy Babies are Worth the Wait" Initiative, August 2012.

⁴ Centers for Disease Control and Prevention Fast Stats, "Births – Methods of Delivery, 2012." Available online at <http://www.cdc.gov/nchs/fastats/delivery.htm>.

⁵ The Leapfrog Group, "Hospital Rates of Early Scheduled Delivery," September 2014. Available online at <http://www.leapfroggroup.org/tooearlydeliveries#kentucky>.

covers 44 percent of all births in Kentucky, and cesarean delivery is estimated to cost Medicaid programs 50 percent more than vaginal delivery. For example, a recent study by Childbirth Connection identified that the average cost to state Medicaid programs per cesarean birth is \$13,590 as opposed to \$9,131 for vaginal birth.⁶ Even a slight reduction in the state's cesarean rate would yield substantial savings.

Increasing access to midwifery services by removing the certificate of need requirement for birth centers would be an important step toward improving Kentucky's perinatal outcomes. Midwives in general and birth centers in particular have a demonstrated track record of providing high quality, low cost care. For example:

- Professional associations of midwives, nurses, and physicians have prioritized efforts to decrease the cesarean rate and recommend a national rate of 15% or less. Midwives have demonstrated that this goal is attainable. ACNM's 2013 Benchmarking Data of 232 member practices representing nearly 100,000 births demonstrated an average primary cesarean rate of 9.2%, an overall cesarean rate of 12.8%, and a preterm birth rate of only 3.2%.
- A 2013 study looking at 15,574 planned birth center births found a cesarean rate of 6%, as compared to an expected 25% for similarly low-risk women in a hospital setting. This same study estimated that cost savings (based on Medicare payment rates) would amount to more than \$30 million.⁷
- A study by the state of Washington's Department of Social and Health Services examining the cost to Medicaid of birth in various settings found that the cost of birth center birth among low risk women was 38% less than hospital birth for women of similar risk. These savings are partially due to the fact that the state's facility fee to the birth centers was approximately \$600, an amount that is not sufficient to cover costs. When increased to a more reasonable amount, \$2,000, the total costs of birth center birth were still 13% lower than hospital birth, a very significant savings.⁸
- A study by the Urban Institute found that a birth center in Washington D.C. saved the Medicaid program an average of \$1,163 per birth in 2008 dollars.⁹

Kentucky is perhaps somewhat stymied in their attempts to decrease preterm and cesarean birth rates by the low number of midwives currently practicing in the state. In 2010, CNMs attended only 5 percent of births in the state.¹⁰ Amended certificate of need requirements would make

⁶ Childbirth Connection, "The Cost of Having a Baby in the United States," January 2013. Available online at <http://transform.childbirthconnection.org/reports/cost/>. Cost figure includes care for the newborn through the first three months of life.

⁷ National Women's Law Center, "Women and Medicaid in Kentucky," February 2009. Susan Rutledge Stapleton, CNM, DNP, Cara Osborne, SD, CNM, and Jessica Illuzzi, MD, MS, "Outcomes of Care in Birth Centers: Demonstration of a Durable Model," *Journal of Midwifery and Women's Health*, vol. 58, no. 1, January 2013.

⁸ Laurie Cawthon, MD, MPH, "Assessing Costs of Birth in Varied Settings," Washington State Department of Social and Health Services, March 7, 2013.

⁹ Embry Howell, Ashley Palmer, Sarah Benatar, and Bowen Garrett, "Potential Medicaid Cost Savings from Maternity Care Based at a Freestanding Birth Center," *Medicare & Medicaid Research Review*, vol. 4, no. 3, 2014.

¹⁰ CDC Vital Stats – Births, available online at: http://www.cdc.gov/nchs/data_access/vitalstats/VitalStats_Births.htm

Kentucky a more hospitable practice environment and likely increase the supply of nurse-midwives, as “the single best predictor” of the distribution of nurse-midwives has been shown to be the degree to which state policies “facilitated or restricted” practice.¹¹

ACNM would argue that certificate of need (CON) requirements are one barrier that restrict expansion of midwifery practice in Kentucky. This belief, moreover, is not confined to ACNM. In 2008, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued a joint statement arguing that CON laws “impede the efficient performance of health care markets” by creating “barriers to entry and expansion to the detriment of health care competition and consumers.” The statement goes on to note that CON laws “undercut consumer choice, stifle innovation, and weaken markets’ ability to contain health care costs.” The Agencies “support the repeal of [CON] laws, as well as steps that reduce their scope.”

ACNM would heartily support efforts to repeal or minimize the scope of CON requirements as they apply to birth centers. Experts have noted that CON laws are “no longer valid” due to shifts in reimbursement methodologies that were the original impetus for such laws. Importantly, CON laws were never designed to “supplant or augment state-law licensing regulations,” although this is the precise effect the birth center CON requirements are having on efforts to expand midwifery practice. The CON process creates an inappropriate barrier to midwifery care, barring providers who would “contribute to competition and provide consumers with important choices in the market.” For this reason, the DOJ and FTC have encouraged states to consider whether such requirements do “more harm than good.”¹²

Additionally, removal of the CON process for birth centers would help achieve the state’s expressed interest in undertaking reforms that increase value of health care services while reducing costs. In a separate report, the Agencies opined that CON requirements “are not successful in containing health care costs” and “that CON programs can actually increase prices by fostering anticompetitive barriers to entry.”¹³ While supporters of CON requirements often argue that the program reduces health care costs by eliminating the duplication of services, this rationale “presumes that increased supply leads to higher costs — [a thought process] completely counter to even basic economic principles of supply and demand.” The CON process eliminates the competitive attributes necessary for an optimally functioning marketplace, leading to “fewer innovations, higher costs, and less incentive to provide quality service.”¹⁴ The FTC has found, for example, that “existing competitors have exploited the CON process to thwart or delay new competition to protect their own supra-competitive revenues.”¹⁵ In order for Kentucky to fully realize the cost-saving benefits of increased midwifery care, it is imperative for the state to remove regulatory barriers like CONs that stifle entry to practice.

¹¹ Eugene Declerq et al, “State Regulation, Payment Policies, and Nurse-Midwife Services,” *Health Affairs* 17 (1998): 190-200.

¹² Department of Justice and Federal Trade Commission, “Competition in Health Care and Certificates of Need: Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform,” September 2008.

¹³ Department of Justice and Federal Trade Commission, “Improving Health Care: A Dose of Competition,” July 2004.

¹⁴ The John Locke Foundation, “Government Trade Restraints,” November 2005.

¹⁵ *Ibid.*

For these reasons, ACNM respectfully requests the state to reconsider the CON program as it relates to birth centers. The women and babies of Kentucky deserve access to high quality, midwifery care in the setting of their choice.

Please feel free to contact me directly if you would like to discuss ACNM's position in greater detail.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. H. R.', with a long horizontal flourish extending to the right.

Jesse Bushman
Director, Advocacy and Government Affairs
240-485-1843
JBushman@acnm.org

Nurse-Midwives and Birthing Centers: Ready Solutions for Quality Outcomes and Cost Savings

*KCNPNM Comments on Core Principles in Certificate of Need Modernization
December, 2014*

KENTUCKY'S BIRTH PROBLEM:

The American College of Nurse-Midwives (ACNM) has detailed Kentucky's birth problems in its White Paper submitted to the Kentucky Office of Health Policy on November 6, 2014:

"Kentucky has one of the highest rates of preterm birth in the nation and, while the state has made efforts to decrease this rate by participating in prematurity prevention initiatives, statistics from 2012 demonstrate a preterm birth rate that still hovers above the national average. In fact, data submitted to the National Governor's Association indicates that Kentucky has struggled with a higher than average preterm birth rate since at least 1999. While preterm births have a significant impact on neonatal health and are the leading cause of neonatal death, there is also an associated adverse effect on state health care spending. In 2007, for example, Medicaid financed approximately 48 percent of hospital stays for preterm infants at an average cost of \$45,900 per baby."

ACNM goes on to point out: "Kentucky also has a higher than average rate of cesarean delivery, which was at 36 percent in 2012 versus the national average of 32 percent, and a high rate of early elective delivery (EED). Kentucky hospitals have reported EED rates as high as 45.3 percent and, while EEDs can be either vaginal or cesarean births, EEDs are more likely to result in cesarean delivery than spontaneous labors. These statistics have significant cost implications for the state. Medicaid covers 44 percent of all births in Kentucky, and cesarean delivery is estimated to cost Medicaid programs 50 percent more than vaginal delivery. For example, a recent study by Childbirth Connection identified that the average cost to state Medicaid programs per cesarean birth is \$13,590 as opposed to \$9,131 for vaginal birth. Even a slight reduction in the state's cesarean rate would yield substantial savings."

The studies described in this paper make it clear that vaginal births at full term are healthier and safer for both mother and baby. The research is also clear that the nurse-midwifery model of care and Freestanding Birth Centers (FSBCs) are dedicated to promoting full-term, vaginal births whenever possible. Kentucky is one of 17 states that retains the CON process and, as a result, has no FSBCs. Experience in other states shows that when the CON requirement is removed, access to FSBC care increases. The American Association of Birth Centers (AABC) submitted a White Paper to the KY Office of Health Policy which contains a map of CON requirements and FSBCs across the United States on page 2 that is illustrative of this point.

KENTUCKY'S UNDER-UTILIZED HEALTHCARE WORKFORCE: CERTIFIED NURSE-MIDWIVES

Nurse-midwifery began in the United States in the Commonwealth of Kentucky. Mary Breckinridge founded the Frontier Nursing Service in 1925 to meet the needs of families in Leslie County. She was the first to envision a professional trained in both nursing and midwifery. Because of the vast geographical area being served, Mrs. Breckinridge set up a model of care which included several outpost/nursing clinics, with the nurse-midwives making their rounds on horseback.

The first studies of nurse-midwifery care can also be traced back to Kentucky through Mrs. Breckinridge more than 75 years ago. She is credited with decreasing the maternal and infant mortality rate. The Metropolitan Life Insurance Program tabulated her results as described in Breckinridge, M. (1981). *Wide neighborhoods: A story of the Frontier Nursing Service*, University Press of Kentucky.

The study shows conclusively what has in fact been shown before, that the type of service rendered by the Frontier Nurses safeguards the life of mother and babe. If such service were available to the women of the country generally, there would be a saving of 10,000 mothers' lives per year in the United States, there would be 30,000 less still births and 30,000 more children alive at the end of the first month of life. The study demonstrates that the first need today is to train a large body of nurse-midwives, competent to carry out the routines that have been established both in the Frontier Nursing Service and in other places where good obstetrical care is available.

Frontier Nursing University has had a continuously operating nurse-midwifery education and training program since 1939. Both Master's and doctoral degrees are offered.

The Kentucky General Assembly established the regulation of the nursing profession by the Board of Nursing in 1914 and gave it the authority to oversee the practice of nurses. In Kentucky, Certified Nurse-Midwives (CNMs) are one of the categories of Advanced Practice Registered Nurses (APRNs) that are recognized as licensed independent providers and have never been required to work under the supervision of a physician. (KBN Counsel Nathan Goldman communication). KRS 314 defines the scope of practice of CNMs.

The American College of Nurse Midwives (ACNM) sets the standards of care and core competencies for certified nurse-midwives in the United States. These competencies and standards meet or exceed those set forth by the International Confederation of Midwives. Nurse-midwives must pass a national certification exam in order to be licensed in their state and must meet ongoing requirements to maintain that certification and state licensure.

CNMs are educated in the dual disciplines of nursing and midwifery. As of 2010, the minimum requirement to enter the nurse-midwifery profession is a master's degree. As reported by the American College of Nurse Midwives, almost 5% of CNMs have doctoral degrees, the highest proportion of all the APRN groups.

CNMs practice in rural, urban and suburban communities. When not prohibited by regulatory or access barriers, CNMs attend births in hospitals, freestanding birth centers and in homes, making them the perfectly trained obstetrical provider for the majority of women. However, it should be noted that in 2012, CNMs attended 5.79% of the vaginal births in Kentucky, while nationally, CNMs attended 11.8% of vaginal births. (Centers for Disease Control, 2014).

Nurse-midwives offer a wide range of obstetric and gynecologic services from treating minor illnesses to advising women on maintaining a healthy lifestyle. They perform pap smears and other screenings, order mammograms, and order and interpret diagnostic tests such as routine blood testing. CNMs also provide primary care for the newborn up to day 28, with consultation and referral to the pediatrician when necessary.

Despite being the birthplace of nurse-midwifery, Kentucky has seen these well-trained professionals leave the state to relocate in states where they can practice to the full extent of their education and licensure. From 2010 to 2014, the overall number of APRNs licensed in Kentucky increased by 53%, while the number of CNMs was stagnant over the same period of time, with approximately 102 currently licensed in Kentucky. This is all the more noteworthy in the context of Frontier Nursing University educating nearly 40% of the newly-certified nurse-midwives in the country with an average graduating class of 237 CNMs per year from 2010 to 2014. (FNU Dean Susan Stone communication)

THE SOLUTION: KENTUCKY RESPONDS TO CORE PRINCIPLES BY REMOVING THE CON BARRIER TO CREATING FREE-STANDING BIRTH CENTERS (FSBCs)

Supporting the Evolution of Care Delivery. The trend is decisively away from a high-overhead acute/inpatient model to an outpatient-centric model. Thus, the CON program will seek to give health care facilities the ability to respond to market trends in a timely fashion, enabling the continued service of local communities in a changing healthcare environment.

- The FSBC accrediting body, the American Association of Birth Centers, defines FSBCs as 2-3 bed centers that function as outpatient service delivery sites for low risk childbirths.
- FSBCs allow women to deliver their babies in a homelike environment, potentially closer to home, with the woman spending less than twenty-four hours there.
- There is demand for out-of-hospital births, as seen in the increase of both home births and birth center births by more than 40% in the United States from 2004 to 2010. (MacDorman, et al, 2014)
- In 2010, 1 in 85 US births was an out-of-hospital birth. For non-Hispanic white women, 1 in 57 births was an out-of-hospital birth. Most of the out-of-hospital birth are planned and attended by a nurse-midwife. (MacDorman, et al, 2014)
- The AABC notes that FSBCs function more like a physician's or midwife's office than like a health care facility.
- The prohibitive cost of pursuing a CON for a birthing center in Kentucky (more than \$120,000 in the most recent case), coupled with the likely denial of such a request, makes it nearly impossible for nurse-midwives in Kentucky to bring about community- and patient-driven changes to the healthcare environment.
- The costs of providing health care to the people of this nation are staggering. It is estimated that the U. S. spent 3.2 trillion dollars in 2010 on health care costs with Medicaid accounting for 13% of the overall expenditures or 404 billion dollars (Deloitte, 2013). Due to changes brought about by the Affordable Care Act, it is estimated that spending by Medicaid will rise by 12.2% this year. By 2016, another 8.8 million people will enter the system, further increasing costs (CMS, 2014). In Kentucky, Medicaid covers approximately 21% of the overall population, with women making up 55% of all beneficiaries. In 2010, Medicaid covered 44% of all births in the state, and pregnancy accounts for the largest portion of Medicaid inpatient hospital day charges (Kaiser, 2012).

What options are available to the Commonwealth to address these rising costs of births if not the opening of FSBCs and the greater utilization of CNMs?

Incentivizing Development of a Full Continuum of Care. Better care, increased value and improved population health depend on an integrated continuum of care in which providers communicate with each other and ensure that patients receive timely, coordinated care in an appropriate setting. Payment structures are evolving to reflect these goals; therefore, the CON program will work to promote and support providers and facilities that seek to develop a robust continuum of care alone or in partnership with others.

- Absence of FSBCs in Kentucky disrupts the continuum of care and takes away consumer choice.
- The cost savings for use of FSBCs over hospital deliveries is well-documented
- CNMs also care for newborns throughout the neonatal period. All newborn screening and management can be provided by CNMs, with referral to a pediatrician for deviations from normal.
- Establishing FSBCs and utilizing nurse-midwives creates a continuum of care from pregnancy through first month of the baby's life from the same CNM provider.
- In addition to attending births, CNMs provide a full continuum of primary care services to women from early teens throughout women's lives. They conduct annual exams, reproductive screening education, health exams and treatment of minor health issues. CNMs prescribe medications when needed.
- The Texas NICU Council Annual Report (2013) recommends: Identification of strategies to enhance early access and enrollment into prenatal care. "Having CNMs available to provide a continuum of care to women from early teen years throughout their lives increases the potential for early enrollment in prenatal care."
- Nurse-midwifery practices complement Kentucky's home visiting program, Health Access Nurturing Development Services (HANDS). This home visiting initiative has been shown to improve many maternal and infant health outcomes and has been endorsed by the Pew Center for the States. (2010)
- Nurse-midwifery works to complement existing programming in early childhood and can serve as a referral source for Kentucky's home visiting program, thus improving human capital development in the Commonwealth.

Incentivizing Quality. Healthcare is rapidly moving toward adoption of objective quality metrics. Thus, the CON program will seek to support those providers that demonstrate attainment of robust quality indicators.

- Quality metrics and studies abound: lower c-section deliveries, lower preterm births, lower use of NICUs, improved health of mother and baby
- Allows utilization of trained, educated, available workforce – nurse-midwives.
- US systematic review of 15 studies undertaken between 1990 and 2008 found *less* epidural use, *less* labor induction, *less* episiotomy use, *lower* perineal laceration rates and *higher* breastfeeding rates when compared with physicians. There was *no difference* in low birth weight, Apgar scores or NICU admissions among the groups. (Johantgen, 2011)
- A Cochrane review of midwifery-led care (13 studies) which included women with risk factors and those without found lower rates of instrumental births, lower epidural rates and lower episiotomy rates, plus higher spontaneous vaginal delivery rates. Those with

midwife-led care were less likely to experience preterm birth or lose their baby before 24 weeks' gestation. The conclusion of the review was that midwifery-led care should be offered to the majority of childbearing women. (Sandall, 2013)

Several landmark studies highlight the value of nurse-midwifery care. To understand how value is to be understood, one must first understand the nature of the midwifery model itself. Certified Nurse-Midwives, since the days of Mary Breckinridge, have approached the health and well-being of mothers and babies from a public health perspective. The midwifery model encompasses the woman and her family as its center, thereby allowing the midwife to take a proactive and preventative stance when it comes to health.

In addition to being patient-centered, the model is also non-interventional, using close observation and cautious, judicious use of interventions only when the condition of the mother and baby warrant it. Rather than using costly medical procedures, the model relies on low-cost interventions that over time, have been shown to have a very positive outcome on pregnancies; i.e., dietary counseling, smoking cessation, breastfeeding support and labor support, with referral and consultation when necessary.

- The Institute of Medicine (IOM), in its report "The Future of Nursing: Leading Change, Advancing Health" (2011) wrote that the APRNs and their contribution to public health are undervalued. The report goes on to say that the ability of the APRN to deliver counseling, clinical care and coordination of health services could be used as a model for policies to meet the needs of the American public.
- The Lancet's (2014) "Series on Midwifery" noted several key points worth considering relating to value. 1) Adverse effects in countries such as China, India and Brazil where there has been overuse of the medical model and loss of the midwifery model. 2) The need for integration of midwives who are highly trained and skilled at promoting optimal birth within the primary care framework. Their conclusion: Even countries with high-functioning healthcare systems would benefit from a scaled up midwifery workforce.
- Notably, Great Britain's National Health Service has just announced a significant change in their recommendations to women about to give birth: the agency is now advising healthy women that it is safer for them to have their babies at home or in a birthing center than in a hospital. (New York Times, 12/4/14)
- The State of the World's Midwifery 2014 Report states: "Every year, more governments, professional associations and other partners are acting on the evidence that midwifery can dramatically accelerate progress on sexual, reproductive, maternal and newborn health and universal health coverage." (United Nations Population Fund, 2014.)

The AABC White Paper notes: FSBCs in the United States ensure that services provided are of high quality by meeting the standards of accreditation by the Commission for the Accreditation of Birth Centers (CABC) and through ongoing risk assessment and data collection for quality improvement. Birth centers collect data on the program and outcomes of care through the AABC Perinatal Data Registry. The study of birth center outcomes cited in their paper is a testimony to the quality of care provided in FSBCs.

The Strong Start for Mothers and Infants Initiative is a project of the Centers for Medicare and Medicaid Innovation (CMMI) to reduce preterm births and improve maternal and child health outcomes. One of the three models of care being studied for lowering preterm birth is the FSBC.

AABC is a Strong Start awardee and collects data from over 40 birth center sites on prenatal care and outcomes of care. The extra support and relationships developed with midwives in the birth center model result in lower preterm birth rates in the FSBC, even for women with risk factors for preterm birth. Preliminary data from AABC's Strong Start project shows a preterm birth rate of 3.8% for women who are Medicaid beneficiaries with risk factors for preterm birth. Strong Start for FSBCs data collection and analysis will continue for another 2 ½ years.

(From the AABC White Paper): FSBCs have a demonstrated track record of providing high quality, low-cost care, exactly the type of care that states are seeking to support under a variety of programs. For example:

- A 2013 study looking at 15,574 planned birth center births found a cesarean rate of 6%, as compared to an expected 25% for similarly low-risk women in a hospital setting. This same study estimated that cost savings (based on Medicare payment rates) would amount to more than \$30 million.
- A study by the Urban Institute, published in the *Medicare & Medicaid Research Review*, found that a birth center in Washington, DC saved the Medicaid program an average of \$1,163 per birth in 2008 dollars.

Improving Access to Care. For a number of reasons, Medicaid members have, on average, a more challenging path toward access to care. Thus, the CON program will seek to incorporate strategies that will incentivize greater access to care for Medicaid members, the newly insured and the remaining uninsured.

- Establishing FSBCs increases access to low-cost, high-quality delivery services.
- In 2012, Kentucky CNMs attended fewer than one-half of the births than did their counterparts nationally. Thus, Kentuckians had significantly less access to nurse-midwife services than did women in other states.
- The Deloitte Health Care Facility Capacity Report (2013) notes: "The CON process can impact access to services." That has certainly been the case with CON and the absence of FSBCs in Kentucky.
- Another factor that affects the health of the people in our state is access to care. Currently, we have 82 primary care designated Health Provider Shortage Areas (HPSA). This problem is not simply a lack of primary care physicians. Legislative and regulatory restraints keep Certified Nurse-Midwives (CNMs) from filling these positions to the full extent of their education and training in many instances (KY Cabinet for Health & Family Services, 2014).
- The Affordable Care Act (ACA) increases health care coverage, which should result in greater access to care. In responding to the impact of the ACA, Kentucky must control the cost of care without sacrificing the quality of care. Birth Centers offer choice, increase access, decrease costs (lower cesarean rates and less use of expensive technology) and improve quality of care. FSBCs provide a low-stress, homelike environment with many non-pharmacologic pain relief measures, where care is delivered by certified nurse-midwives who know and trust their clients as much as the families know and trust their midwife.
- The "midwifery model of care" includes education, respect for the autonomy of the woman, respect for the sacredness of birth (as other than a medical/surgical event) and

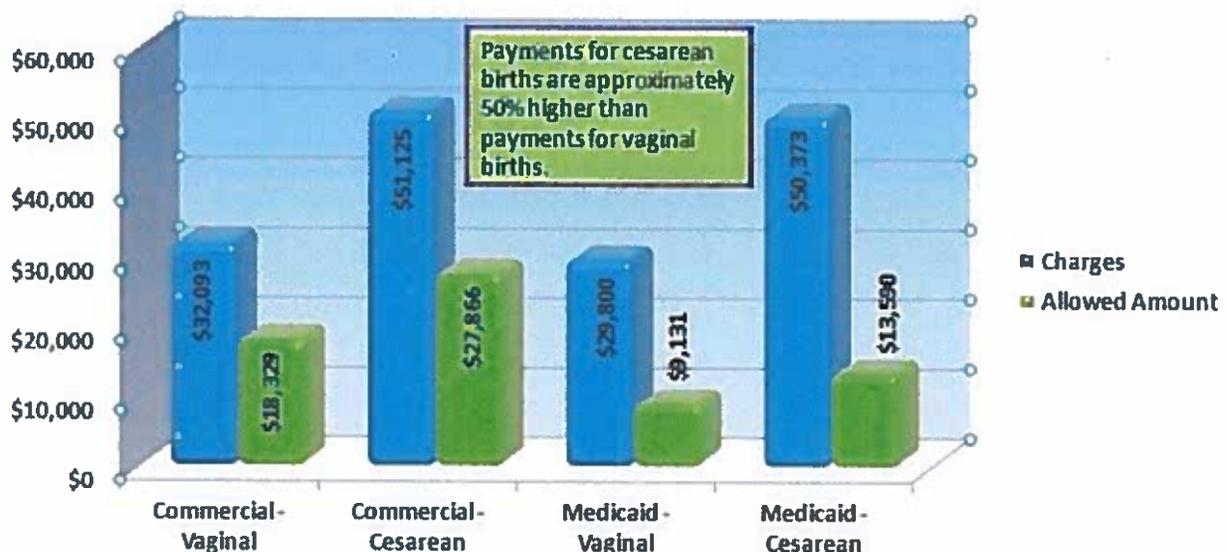
appropriate referral for sickness or high-risk situations. The midwifery model both prevents prematurity and improves outcomes of care.

- Costs are not the only issue in the state of Kentucky. Despite valiant efforts from many agencies across the state, Kentucky boasts a 32.7 % maternal smoking rate, a 36% cesarean section rate, and a 12.7% preterm birth rate. All of these are higher than the national averages. (March of Dimes, 2014)

Improving Value of Care. As healthcare transitions from a fee-for-service model to a value-based purchasing framework, payers will continue to seek evidence of value in health services. Thus, the CON program will seek to incentivize both price transparency and demonstrable value from health professionals and facilities.

- Care by CNMs has been shown to **decrease**: (1) preterm deliveries and (2) interventions (such as cesarean sections, use of episiotomies, epidural anesthesia, artificial inductions, instrumental deliveries). CNM care **increases** the likelihood of spontaneous vaginal deliveries, with **no** increase in maternal or neonatal mortality.
- Care by CNMs is safe and effective. Increased availability of services provided by CNMs could be used to address the projected workforce shortages.
- Consumers benefit when CNMs are able to practice to the full extent of their education and training. Consumers want to have a choice of a nurse-midwife for childbirth.
- Care delivered under the midwifery model offers significant cost savings, regardless of setting. The cost of a vaginal delivery is approximately one-half of the cost of a cesarean section delivery. Care in birth centers also resulted in substantial savings – an estimated \$1,163 per birth to a Medicaid member.
- Payments for cesarean births are approximately 50% higher than payments for vaginal births, as illustrated in the chart below. (Truven, 2010)

AVERAGE TOTAL CHARGES AND PAYMENTS FOR MATERNAL AND NEWBORN CARE IN THE U.S. - 2010



(Graphic: ACNM)

- The Family Health and Birth Center in Washington, DC (FHBC) has been examined both for its level of quality care and for its cost savings. In a recent report, the authors found the women receiving care there had lower cesarean rates regardless of whether they delivered in the birth center or in a hospital. They concluded that significant cost savings could be realized if more women received care under the midwifery model as delivered by the midwives at the FHBC. (Howell et al., 2014).
- The cost of maternity care in the U.S. accounts for the largest portion of Medicaid charges. With the current cesarean section rate of 36% in Kentucky, significant Medicaid dollars are being spent on both inpatient days and in additional costs to the newborn following a cesarean birth. (Truven, 2013). Several landmark birth center studies conducted over two very different time periods showed cesarean section rates in these birth centers to be approximately 6%. If one considers a 25% percent cesarean section rate in hospitals for this same low risk population, a 27 million dollar savings to the Medicaid system is estimated (Stapleton, 2013). Kentucky has the opportunity to realize similar cost savings with 44% of women utilizing the Medicaid system for their maternity care (Kaiser Family Foundation, 2012).
- Medicaid and most major health plans recognize CNM services and reimburse for them.
- The Texas NICU Council Annual Report (2013) notes: "... decreases in NICU admissions are principally achieved by reducing preterm delivery..."

Promoting Adoption of Efficient Technology. Increased adoption of technologies such as electronic medical records, participation in information sharing platforms such as the Kentucky Health Information Exchange, and participation in large-scale data projects such as an All Payer Claims Database are critical elements of a modernized, higher quality and more efficient health system. Thus, the CON program will seek to incentivize adoption of technologies deemed to further improve value in Kentucky's health system.

- CNMs have demonstrated an excellent track record of utilizing appropriate technology, particularly with regard to patient records, collaboration and coordination of care.

Exempting Services for which CON is no longer necessary. Kentucky regulates via CON many services that even CON states exempt. Thus, Office of Health Policy will seek to focus on strategies to modernize Kentucky's CON program to be more reflective of modern healthcare trends.

A review of the Deloitte Commonwealth of Kentucky Health Care Facility Capacity Report (2013) reveals the following:

- Page 52: The primary purpose of Certificate of Need (CON) programs is to lower healthcare expenditures through the regulation of supply and to mandate the coordinated planning of new services and construction. As Figure 27 illustrates, the practice began in the 1970s and was originally mandated by Federal law; however, CON programs have been and are in the process of being repealed by a number of states.
- Twelve types of health care facilities are included in the Deloitte Health Care Facility Capacity Report (2013). There is no mention in the report about birthing centers because there were none in Kentucky to count!

- However, the Deloitte report notes the “movement toward outpatient care” and away from hospital care will drive the need for outpatient services (in the Deloitte report, the focus is on Ambulatory Surgery Centers or ASCs).
- While no surgery is performed at an FSBC, the analogy between FSBCs and ASCs is informative, as both represent movement away from unnecessary – and costly – hospital stays. The Deloitte report states: “Hospital Acute Care (including acute hospital and Critical Access Hospitals) and Nursing Facilities are projected to experience a decline in volume. This is consistent with an anticipated shift from inpatient care to ambulatory and community based health services.”
- In the case of childbirth, there is no existing alternative facility in Kentucky to which to shift patient care...thus the need for FSBCs.
- In formulating next steps for consideration for each service, the Deloitte report describes a range of potential demand and supply levers that were taken into consideration. Figure 2 shows a matrix of potential policy levers for consideration and how each lever impacts access, mix, and sustainability of health services. For example: CON is a supply-side lever. The CON process can impact *access to services* (e.g., through approval of new facilities in locations where demand for a certain service is high), as well as *mix of services* (e.g., by encouraging development of ambulatory care facilities over inpatient care).
- The Deloitte report goes on to list this next step: Consider discontinuing CON for ASC.
- “Temporarily cease CON process for ASCs in order to allow more freestanding ASCs to come online. This will increase market competition and provide consumers with viable alternatives to hospital-based care.” P. 110. **Why would we not want to do the same for women in Kentucky who are giving birth?**
- The Deloitte report also considers the challenges the Commonwealth might face in pursuing next steps. “Challenges include barriers to implementation, measures that are beyond the Cabinet’s purview, workforce limitations, and potential negative public opinion.” None of these should present a significant challenge in considering FSBCs. 29 other states have established FSBCs without the CON process. As previously noted, the workforce of highly-trained and credentialed nurse-midwives is underutilized in Kentucky, and the women of Kentucky want to have this option...thus generating positive public opinion!
- The Deloitte report also addresses another barrier – that of reimbursement and the need to assure sustainability of the facilities. It advises “Use reimbursement for ambulatory surgeries as economic lever to further encourage conducting surgical procedures in an outpatient setting rather than by admitting patients to hospitals.” Our recommendation to increase the reimbursement to FSBCs to match actual costs is consistent with the Deloitte recommendation.
- In support of this recommendation on reimbursement, the AABC White Paper points out: “A study by the Washington State’s Department of Social and Health Services examining the cost to Medicaid of birth in various settings found that the cost of birth center birth among low-risk women was 38% less than hospital birth for women of similar risk. These savings are partially due to the fact that the state’s facility fee to the birth centers was approximately \$600, an amount that is not sufficient to cover costs. When increased to a more reasonable amount, \$2,000, the total costs of birth center birth were still 13% lower than hospital birth, a very significant savings.”

- AABC recommends that the FSBCs not only should be exempt from the CON process, but should not have regulatory barriers to their operation such as a requirement for a physician director, medical supervision or written agreements with hospitals. We concur with these recommendations. We believe that FSBCs should be licensed and regulated by the Kentucky Cabinet for Health and Family Services to the same extent that physician's offices are licensed and regulated.

Health systems across the country are undergoing significant changes in response to myriad factors, including but not limited to the Affordable Care Act. In Kentucky, health reform has highlighted the need to modernize the Certificate of Need (CON) program to better enable health care providers to work toward improved health for all Kentuckians. Thus, in considering changes to the CON program and the State Health Plan in connection with the periodic update process, the Cabinet for Health and Family Services (CHFS) will adopt an holistic approach to revisions, with the vision of achieving the Triple Aim: better value, better care, and population health improvement.

In conclusion, the KY Coalition of Nurse Practitioners and Nurse Midwives (KCNPNM) in conjunction with national groups, the American College of Nurse Midwives (ACNM) and the American Association of Birth Centers (AABC) recommend that the core principles set forth by the KY Cabinet for Health and Family Services can best be met by removing the Certificate of Need (CON) process for the establishment of Freestanding Birth Centers (FSBCs) in Kentucky. We further recommend that the reimbursement schedule for FSBCs be set to match the actual cost of care at the centers and that the licensure and regulation of the FSBCs be consistent with the operation of physician's offices.

This paper and those submitted by the American College of Nurse-Midwives and the American Association of Birth Centers lay out the very strong evidence and cumulative research findings to support these recommendations made by the KY Coalition of Nurse Practitioners and Nurse-Midwives and the two national organizations:

- Eliminate the Certificate of Need requirement for the establishment of Freestanding Birth Centers (FSBCs) in Kentucky
- Establish reimbursement of services at the FSBCs to meet the cost of care
- License and regulate the FSBCs at the same level as physician offices are licensed and regulated.

Making these recommended changes will, as this paper and the accompanying White Papers demonstrate, meet all core principles delineated by the Kentucky Cabinet's Office of Health Policy and will achieve the desired Triple Aim: better value, better care, and population health improvement. Better value will be experienced by Kentuckians in:

- Safe, healthy deliveries
- Saving money
- Consumer choice

ENTERED

FEB 23 2015

FRANKLIN CIRCUIT COURT
SALLY JUMP, CLERK

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION I

CIVIL ACTION No. 13-CI-01013

THE VISITATION BIRTH AND FAMILY
WELLNESS CENTER, INC.

PETITIONER

v.

COMMONWEALTH OF KENTUCKY,
CABINET FOR HEALTH AND FAMILY
SERVICES, *et. al.*

RESPONDENTS

OPINION AND ORDER

This matter is before the Court upon Petitioner's *Petition for Review and Appeal*. Upon review of the record, being sufficiently advised, this Court hereby **REVERSES** the Final Order of the Cabinet for Health and Family Services for reasons more fully stated below.

STATEMENT OF FACTS

Petitioner, the Visitation Birth & Family Wellness Center (the VBFWC), is a Kentucky corporation which proposes to establish an "alternative birth center" pursuant to 902 KAR 20:150, in Elizabethtown, Hardin County, Kentucky. Respondent, Cabinet for Health and Family Services ("Cabinet"), is the administrative agency vested with the authority, through KRS Chapter 216B, to review applications for Certificates of Need (CON). The Office of Health Policy, Division of Certificate of Need is the division of the Cabinet that administers the CON program.

On September 26, 2012, the VBFWC filed its CON Application to establish an alternative birth center pursuant to 902 KAR 20:150. The applicable administrative regulation defines alternative birth centers as “establishments with permanent facilities which provide prenatal care to low-risk child bearing women.” (KAR 20:150 § 2). Additionally, the definition states that “an alternative birth center provides a homelike environment for pregnancy and childbirth including prenatal, labor, delivery, and postpartum care related to medically uncomplicated pregnancies.” (*Id.*).

The VBFWC’s application requested non-substantive review. Non-substantive review status is provided to applications meeting specific criteria of 216B.095(3)(a)-(e). In addition, KRS 216B.095(3)(f) allows for non-substantive review “in other circumstances the Cabinet, by administrative regulation, may prescribe.” Under 900 KAR 6:075(2)(3)(a) the Cabinet grants non-substantive review status to proposals that involve “the establishment or expansion of a health facility or health service for which there is not a component in the State Health Plan.” Since there is no component in Kentucky’s State Health Plan for alternative birth centers, the Cabinet granted the VBFWC’s application non-substantive review.

According to administrative regulation 900 KAR 6:075 § 2(7): “If an application for a CON is granted non-substantive review status by the office of health policy, there shall be a presumption that the facility or service is needed and the application granted non-substantive review status by the Office of Health Policy shall not be reviewed for consistency with the state health plan. Additionally, under 900 KAR 6:075, § 2(9), the Cabinet can only disapprove/reject an application for a certificate of need that has been

granted non-substantive review if the cabinet finds that the presumption of need has been rebutted by "clear and convincing evidence by an affected party."

On November 15th, 2012, the VBFWC's CON Application and the grant of non-substantive review of its application was placed on Public Notice. Hardin Memorial Hospital (HMH), Flaget Healthcare Inc., d/b/a Flaget Memorial Hospital (Flaget) and Grayson County Hospital Foundation, Inc., d/b/a Twin Lakes Regional Medical Center (Twin Lakes) (collectively referred to as "the Respondents") assert they are "affected persons" pursuant to KRS § 216B.015(3), and they requested a hearing on the application. Prior to commencement of the hearing, the VBFWC filed a motion to limit the hearing to the single issue of whether any "affected party" could rebut the presumption of need for the establishment of an alternative birth center in the designated service area. The administrative law judge denied this motion. A hearing was conducted on February 20th and 21st, and on March 13th and 26th, 2013 before administrative law judge Kris M. Carlton.

Because the VBFWC's CON Application was granted non-substantive review, there was a presumption that an alternative birth center was needed. In order for the Cabinet to disapprove the Birthing Center's Application, the protesting affected parties were required to show by clear and convincing evidence that there was no need for an alternative birth center in the proposed service area. At the hearing both sides presented expert witnesses and introduced testimonial evidence.

The alleged "affected parties" presented five (5) witnesses, all of whom offered expert testimony in attempt to rebut the presumption of need for an alternative birth center. The alleged "affected parties" introduced evidence intended to show, among

other things, that: (1) adequate hospital-based birth delivery services were available in the birthing center's proposed service area; (2) the Birthing Center's projected number of annual births was not reliable; (3) that it was not safe to permit low risk births in the alternative birth center setting; and (4) that the Birthing Center's financial projections were not reliable. The Petitioner, the VBFWC asserts that the administrative law judge erred by admitting all this evidence.

In defense of its application, the Petitioner presented 6 witnesses, all of whom offered expert testimony in attempt to establish the need for an alternative birth center in the proposed service area. On July 26th, 2013, the administrative law judge issued her Findings of Fact, Conclusions of Law and Final Order denying VBFWC's CON Application on the grounds that the affected parties rebutted the presumption that an alternative birth center is needed in Elizabethtown to serve the area proposed by the VBFWC. (Final Order, p.31 (2013).

Specifically, the administrative law judge found that the VBFWC did not prove that there is a need in area to be served by VBFWC for a birthing center on a volume that would support the projections made by the VBFWC. (*Id.*). The administrative law judge also found that the VBFWC did not prove, after the presumption of need was rebutted by the affected parties, that an actual need exists for an alternative birth service/facility in the proposed service area. The administrative law judge concluded that the VBFWC's CON application for an alternative birthing center must be disapproved, in accordance with 900 KAR 6:075 § 2(9)(b), since the affected parties rebuttal of the presumption of need by clear and convincing evidence was not overcome by the VBFWC.

Pursuant to KRS 216B, the VBFWC appeals the Cabinet's Final Order, disapproving its CON Application No. 047-05-5479(1). The VBFWC asserts that the manner in which the administrative law judge conducted the hearing deprived it of the statutory and regulatory presumption of need to which it was entitled and violated its statutory, regulatory, and due process rights. The VBFWC further asserts that by permitting HMH, Flaget and Twin Lakes to oppose its application as "affected persons," the Cabinet, through its administrative law judge, deprived the VBFWC of the presumption of need, acted arbitrarily and capriciously, and violated the VBFWC's statutory, regulatory and due process rights. Lastly, the VBFWC asserts that the Cabinet's Findings of Fact, Conclusions of Law, and Final Order are arbitrary and capricious, not supported by substantial evidence, are erroneous based upon a review of the record as a whole, and violate the 14th Amendment of the United States Constitution and § 2 of the Kentucky Constitution.

Furthermore, the Petitioner contends that the role of the administrative law judge was solely to determine whether the Birthing Center's CON should be granted. The requirements for *licensure* of an alternative birth center were not relevant to the CON proceeding. Petitioner argues that the administrative law judge erroneously admitted and considered evidence concerning the licensure requirements it when issuing the Final Order disapproving the Birthing Center's CON application.

Petitioner has proven beyond question that there are *no* alternative birthing centers in Kentucky. Petitioner argues that for the Cabinet to rebut the presumption of need it would need to show by clear and convincing evidence that there is not a need for an alternative birth center in the service area at issue because another alternative birth

center is already providing adequate alternative birth services to that area. Here, the evidence was uncontested that no other alternative birth centers exist in Kentucky. The proof offered by the affected parties essentially boils down to the conclusion that all women would be better served by having their babies in traditional birthing facilities operated by hospitals or other licensed providers. Under the Cabinet's final ruling, a woman who wants the services of an *alternative* birth center (as defined in Kentucky administrative regulations) is simply out of luck. She can go to another state.

Petitioner further argues that because the proof was uncontested that no one else provides the services VBFWC seeks to provide, the decision of the administrative law judge was arbitrary and capricious, against the clear weight of evidence and in violation of the regulatory and statutory rights of the applicant, the VBFWC.

STANDARD OF REVIEW

Applicants before the Cabinet have the burden of proof. The applicant has the burden of proving by a preponderance of substantial evidence that the application satisfies the statutory and regulatory standards and applicable review criteria, thereby justifying issuance of the CON. *See Personnel Board v. Heck*, 725 S.W.2d 13 (Ky. Ct. App. 1986); *see also Energy Regulatory Commission v. Kentucky Power Co.*, 605 S.W.2d 46, 50 (Ky. Ct. App. 1980). Pursuant to KRS 216B.120(2), when reviewing the Cabinet's decision to issue or deny a CON Application,

the court shall hear the case upon the certified record or abstract thereof, and shall dispose of the case in a summary manner, its review being limited to determining whether the cabinet acted within its jurisdiction, whether the decision or order was procured by fraud, and whether the findings of fact in issue are supported by substantial evidence and are not clearly erroneous based upon a review of the record as a whole.

Therefore, in reviewing the Cabinet's decision, this Court may only overturn that decision if the agency acted arbitrarily or outside the scope of its authority, if the agency applied an incorrect rule of law, or if the decision itself is not supported by substantial evidence on the record. *Kentucky State Racing Commission v. Fuller*, 481 S.W.2d 298, 301 (Ky. 1972). Substantial evidence is "evidence of substance and relevant consequence, having the fitness to induce conviction in the minds of reasonable men." *Id.* at 308. "The trier of facts in an administrative agency may consider all the evidence and choose the evidence he believes." *Bowling v. Natural Resources and Environmental Protection Cabinet*, 891 S.W.2d 406, 410 (Ky. Ct. App. 1994). In cases that contain conflicting evidence, this Court must give deference to the agency's final decision as the Court is not in a position to determine witness credibility or evidentiary weight of any exhibits or testimony. *500 Associates, Inc. v. Natural Resources and Environmental Protection Cabinet*, 204 S.W.3d 121, 131 (Ky. Ct. App. 2006) (internal citations omitted).

As long as the agency's findings are supported by substantial evidence, the Court must defer to the agency, even if there is conflicting evidence. *Kentucky Commission on Human Rights v. Fraser*, 625 S.W.2d 852, 856 (Ky. 1981). The next inquiry is whether the agency has correctly applied the law to the facts as found. *Kentucky Unemployment Insurance Commission v. Landmark Community Newspapers of Kentucky, Inc.*, 91 S.W.3d 575, 578 (Ky. 2002). Questions of law arising out of administrative proceedings are fully reviewable *de novo* by the courts. *Cabe v. Toler*, 411 S.W.2d 41, 43 (Ky. 1967); *Aubrey v. Office of Attorney General*, 994 S.W.2d 516, 519 (Ky. Ct. App. 1998). Here, the relevant question is whether the Cabinet correctly applied the law in considering this

application. Specifically, the legal question is whether the broad availability of traditional birthing options for women can defeat the presumption of need set forth in administrative regulation, for a service (alternative birthing centers) defined in administrative regulation that is not offered in the Commonwealth of Kentucky.

DISCUSSION

I. "Affected Party" Status

The parties dispute whether the opponents of the VBFWC's CON Application, HMH, Flaget and Twin Lakes, are "affected parties." "Affected persons" as defined by KRS §216B.015(3) includes health facilities located in the health service area in which the project is proposed to be located which provide services similar to the services of the facility under review. The Petitioner contends that HMH, Flaget and Twin Lakes do not provide services similar to the services under review and argues they are traditional hospitals providing only hospital-based birthing environments. The opponents of the Birthing Center's Application state they are affected parties because like the birthing center, they provide prenatal services, labor and deliver services, and postpartum services.

The Respondents argue that HMH, Flaget and Twin Lakes qualify as "affected parties." They support this argument by referring to 902 KAR 20:150(2), which defines an ABC as a permanent facility that provides "prenatal, labor, delivery and post-partum care related to medically uncomplicated pregnancies." Respondents argue that regardless of the different methods by which the alleged parties and the Birth Center provide such care, all provide "similar services" with respect to uncomplicated pregnancies.

The Court is persuaded by the argument advanced by the Petitioner, specifically, that a hospital-based birth experience is not enough like an alternative birth experience to be considered similar. While there may be some overlap in the services provided, the varying methods and settings have significant differences and it is a stretch to claim that traditional hospitals providing only hospital-based birthing environments offer services similar to an ABC. The presence of a mid-wife does not transform a hospital into an alternative birth center. While the hospitals claim to offer similar services, the fact is that an attempt to honor the birth plans of pregnant women and allow for low-intervention births cannot truly be equated with the services provided by an alternative birth center. At an alternative birth center the mother is provided with an alternative birth experience that is very different from the services and care and setting a hospital can provide -even one attempting to honor the birth plan of the mother. For example, when delivering a child at an alternative birth center, the mother does not have to be in bed the whole time, she can walk around, deliver the baby in a bath or in a shower, use a ball, and attempt to deliver the baby without drugs. Furthermore, unlike the hospitals, an alternative birthing center does not provide traditional delivery services and *grant* a low intervention birth plan *exception* for some of the women at their request. An Alternative Birth Center can *only* provide alternative birthing services for women with uncomplicated pregnancies.

The parties also dispute whether the “affected party” issue should be considered as a subject matter jurisdiction issue or as a standing issue. The petitioner argues that the issue is one of subject matter jurisdiction, regarding whether the Cabinet had subject matter jurisdiction to hold a hearing on the application. Petitioner further argues that in many CON cases, the “affected party” opposing the application is itself operating under a

CON and licensure in the exact same service as the entity seeking a CON. Petitioner correctly observes that none of the Respondents claiming to be "affected parties" in this case are operating under a CON and licensure for an alternative birth center. Finally, Petitioner asserts that the Respondents are claiming the status of "affected parties" in attempt to block the CON for the VBFWC in order to prevent perceived competition from entering the service area.

The Respondents assert that the Petitioner is improperly attempting to characterize the question as a matter of subject matter jurisdiction when it is really standing that is at issue, not jurisdiction. Respondents further argue that because the Petitioner did not raise the issue of "affected party" status before the Administrative Law Judge at the hearing it effectively waived the issue. Even if the Court overlooks the Petitioner's waiver, the Respondent asserts that each of the "affected parties" offers similar services and therefore, under the statute they all qualify as "affected parties."

The law in Kentucky has long been established that a party operating a business under a license from the state has "no right to be free from competition." Lexington Retail Beverage Dealer's Association v. Department of Alcoholic Beverage Control, 303 S.W.2d 268, 270 (Ky. 1957). *See also*, HealthAmerica v. Humana, 697 S.W.2d 946 (Ky. 1985); PIE Mutual Insurance Company v. Kentucky Medical Insurance Company, 782 S.W.2d 51 (Ky. App. 1990). One exception to the rule that a state licensee lacks standing to challenge regulatory decisions to grant licenses to competitors, has been for a certificate of need (CON) for medical providers. *See* Humana v. NKC Hospitals, 751 S.W.2d 369, 371-72 (Ky. 1989). There, the Court held that the CON statute itself

explicitly grants standing and the right to appeal administrative decisions to economic competitors who are “affected persons” as defined in KRS 216B.015(3).

Here, the question is whether health care providers who do not operate an “alternative birthing center” have standing to protest an applicant for approval to operate such a facility. While the protestants provide prenatal and birthing care, this Court holds that traditional health care providers, by definition, are separate and distinct from “alternative birthing centers.” The long line of cases that holds that state licensees have no right to be free from competition applies here. The CON statute, as construed in *Humana v. NKC supra*, allows competitors to protest only when they are “affected parties.” These protestors do not operate, or even propose to operate, another “alternative birthing center.” Rather, they simply argue that all women would be better served by limiting themselves to the options currently provided. They argue that women should not have the right to select the alternative that VBFWC proposes to provide. Accordingly, the protesters, as economic competitors who do not provide “alternative birth services,” do not have standing to challenge the Cabinet’s initial determination that VBFWC qualified for a CON under the non-substantive review regulation.

III. Non-Substantive Review and Presumption of Need

The VBFWC’s CON Application was granted non-substantive review status. As a result of this non-substantive review status there was a presumption of need and the Application was not subject to the formal review criteria outlined in KRS 216B.040(2)(a) and 900 KAR 6:070. In *Baptist Convalescent Center v. Boonespring Transitional Care Center, LLC.*, the Kentucky Court of Appeals held that the presumption favoring

approval of a certificate of need granted non-substantive review may be rebutted by demonstrating that: (1) the facility/service is not required or (2) is inconsistent with the state health plan when addressed therein.” (*Baptist Convalescent Center v. Boonespring Transitional Care Center. LLC.*, 405 S.W. 3d 498, 504 (Ky. App. 2012).

The Court of Appeals decision in the *Baptist Convalescent Center* case demonstrates that under a non-substantive review of a CON application, there is a presumption of need that can only be rebutted when an affected party demonstrates by clear and convincing evidence that: (1) there is no need for the facility/service, or (2) that such a facility/service would be inconsistent with state health plan. Both parties agree that currently there are no alternative birth centers in Kentucky. Furthermore, as Petitioner correctly points out, because alternative birth centers are not addressed in the State Health Plan, the Birthing Center’s presumption of need cannot be rebutted based on an alleged inconsistency with the State Health Plan. Therefore, for the Cabinet to properly rebut the Presumption of Need granted to the Birthing Center’s Application in this case, it would need to show by clear and convincing evidence that there is not a need for an alternative birth center in the service area at issue.

The administrative law judge disapproved the VBFWC’s CON application because she found that the Birthing Center failed to prove there was a need for an alternative birth center after the presumption was rebutted by the alleged “affected parties.” Petitioner, the VBFWC, persuasively argues that the ALJ reached this erroneous conclusion after improperly admitting testimony and evidence relating to the formal review criteria despite the non-substantive review status granted to its CON Application. Despite the fact that the VBFWC’s CON Application was granted non-substantive review, the

Administrative Law Judge (ALJ) allowed testimony and evidence to be introduced by the alleged “affected parties” that concerned issues such as the safety of birthing centers, the adequacy of existing delivery services in the proposed service area, and the reliability of the Birthing Center’s financial projections.

Petitioner, the Birthing Center, further argues that in order to prove by clear and convincing evidence that there is no need for an alternative birthing center the Cabinet must show that another alternative birth center is already providing adequate *alternative* birth services. Respondents claim they only need to show that other facilities in the proposed service area are currently providing similar services and that the Petitioner’s definition of “similar” is too narrow. This Court has already stated that it is persuaded by Petitioner’s argument that the traditional, hospital-based labor and delivery services provided by HMH, Flaget and Twin Lakes are not like the alternative birth services that its proposed center would provide. As a result, this Court finds that the Respondent did not rebut by clear and convincing evidence the presumption of need granted to Petitioner’s CON Application based on its non-substantive review status.

The proof at the hearing amounted to a demonstration by the protesting health care providers of traditional birthing services that all women would be better served by using their existing options for birthing. That proof may well be correct as a matter of medical science and health policy. But those concerns raised by the proof go to the matter of licensure, not CON. As a matter of health policy, and protection of women who choose this alternative, it may well be that alternative birthing centers should be required to have established relationships with hospitals to deal with emergency situations, or that a board certified ob/gyn should be on staff. It also may be true that

there is not sufficient demand for alternative birthing services to make the VBFWC economically profitable, which was another area of testimony at the hearing. But those issues are not addressed to the need for the service under the CON statute. So long as the Cabinet's administrative regulations provide for this kind of service, an applicant who proposes to meet all applicable licensure standards cannot be denied a CON on the grounds that the Cabinet disagrees with the choice of women who want to give birth in this non-traditional setting.

Conclusion

The purpose of the Commonwealth's CON program is "to improve the quality and increase access to health-care facilities, services, and providers, and to create a cost-efficient health-care delivery system for the citizens of the Commonwealth."

KRS 216B.010. This Court is persuaded by the Petitioner's interpretation of KAR 20:150, under which, it argues alternative birth centers are to operate in addition to (i.e., as an *alternative* to) the traditional, hospital-based delivery services currently offered within the state so that women may choose how they wish to give birth.

Expanding the options for giving birth by granting the Petitioner's CON Application appears to further the purpose of the CON program by improving access to a variety of healthcare options without significantly impacting the cost of providing that care for the state. The Cabinet correctly granted VBFWC's application for non-substantive review and found that it was entitled to the presumption of need and the granting of a CON. The Cabinet erred by allowing traditional health care providers of birthing services standing to protest this finding, because traditional providers are not "affected parties" within the meaning of KRS 216B.015(3) in regard to a CON

application for an "alternative birthing center." Accordingly, the Cabinet erred as a matter of law in denying VBFWC's application for a CON.

WHEREFORE, the Final Order of Respondent, Cabinet for Health and Family Services, is REVERSED.

This order is final and appealable and there is no just cause for delay.

SO ORDERED, this 23rd day of February, 2015.



Judge A Phillip Shepherd
Franklin Circuit Court, Division 1

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