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 no 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.

II. 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

DISTRIBUTION:

J. Guthrie True
Whitney True Lawson
124 West Clinton Street
Frankfort, KY 40601
Counsel for Plaintiff

Matthew R. Klein
Ellen Houston
DRESSMAN, BENZINGER, & LAVELLE, PSC
207 Thomas More Parkway
Crescent Hills, KY 41017-2596

Jenny Oldham
Hardin County Attorney
109 East Dixie Avenue
Elizabeth, KY 42701

Michael D. Baker
Wyatt, Tarrant & Combs, LLP
250 West Main Street, Suite 1700
Lexington, KY 40507

Mary Stewart Tansey
Cabinet for Health and Family Services
Office of Legal Services
275 East Main Street, 5th Floor West
Frankfort, KY 40621