

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

32565  
No. 042422

FAMILY MEDICAL IMAGING, LLC,  
GARY L. POLING, D.O. and  
SCOTT C. LOSTETTER, D.O.

Appellants,

Circuit Court of Raleigh County  
Civil Action No. 04-AA-15-K

v.

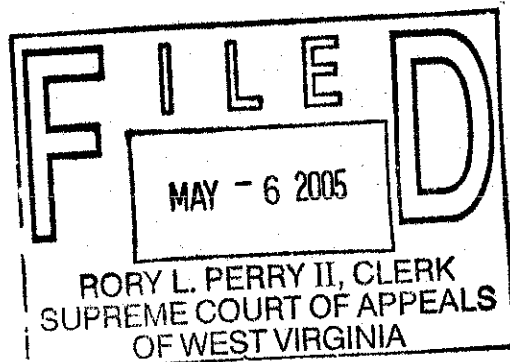
WEST VIRGINIA HEALTH CARE  
AUTHORITY,

Appellee.

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RESPONSE BRIEF ON BEHALF OF  
THE WEST VIRGINIA HEALTH CARE AUTHORITY

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Appellee, West Virginia Health Care Authority (hereinafter "Authority"), by counsel, submits the following arguments and authorities in response and in opposition to the Appellants' Brief filed on April 7, 2005, pursuant to Rule 10(b) of the Rules of Appellate Procedure.

## **I. INTRODUCTION**

The Circuit Court of Raleigh County, West Virginia, Judge Kirkpatrick presiding, properly affirmed the Office of Judges' (hereinafter "OOJ") Decision dated May 26, 2004, which in turn affirmed the Authority's Decision dated October 9, 2003, denying Family Medical Imaging, LLC (hereinafter "FMI") a Certificate of Need (hereinafter "CON") to develop a diagnostic center to offer ultrasound services on a referral basis. The Authority respectfully requests that the West Virginia Supreme Court of Appeals affirm its Decision dated October 9, 2003, for the following reasons: (1) Appellants failed to establish that the diagnostic ultrasound services were needed; (2) Appellants failed to establish the financial feasibility of the project; and (3) the testimony of both RGH's experts was properly disclosed and admitted into evidence. Accordingly, the Authority's decision should be affirmed.

## **II. STATEMENT OF FACTS**

### **A. Overview of the West Virginia Health Care Authority and the Certificate of Need program.**

By way of background, the Health Care Cost Review Authority (hereinafter "HCCRA") was created by the Legislature in 1983 as an autonomous agency within state government. W.Va. Code § 16-29B-5. The Authority, then known as HCCRA, is charged with the responsibility for collecting information on health care costs, developing a system of cost control, and ensuring accessibility to appropriate acute care beds. W.Va. Code §§ 16-29B-1, *et seq.*

This same legislation expanded the HCCRA's responsibilities to include the administration of two previously enacted cost containment programs: (1) the Certificate of Need Program, which is codified at W.Va. Code §§ 16-2D-1, *et seq.*; and (2) the Health Care Financial Disclosure Act, which is codified at W.Va. Code §§ 16-5F-1, *et seq.* In 1997, the Legislature enacted a statute renaming the HCCRA as the West Virginia Health Care Authority. W.Va. Code § 16-29B-2.

The Authority's purpose is "to protect the health and well-being of the citizens of this state by guarding against unreasonable loss of economic resources as well as to ensure the continuation of appropriate access to cost-effective high quality health care services." W.Va. Code § 16-29B-1. This statute created a three member board with power to administer, among other things, the CON program. The Authority's Board ultimately determines whether a CON application should be denied or approved based upon an evaluation of the record.

The Board has been empowered by the Legislature to promulgate legislative rules and to modify the State Health Plan, which does not go through the legislative rule

making process.<sup>1</sup> W.Va. Code § 16-2D-3(b)(5) and § 5. In 2000, the Authority amended its legislative rule which defines the services offered by health professionals, such as doctors, that are subject to CON review. These services directly impact access to health care services and the cost of those services. The legislative rule that specifies which health services offered or developed by health professionals are subject to CON review is 65 C.S.R. 17.

This rule was approved by the Legislature and became effective July 1, 2000. It defines a diagnostic center, in pertinent part, as:

[a]ny facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients that are not examined and evaluated in the same manner as any other patient of the private office practice of licensed health professionals, regardless of the cost associated with the proposal.

Once the Authority determines that the proposed action is subject to CON review, a CON application must be filed. The application states, in pertinent part, that an applicant is responsible for identifying its service area "for the proposed project as defined in the State Health Plan. If the identified service area is not defined in the State Health Plan, provide the rationale for the area proposed." CON Application, Section E.

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<sup>1</sup> Pursuant to W.Va. Code § 16-2D-5, the Authority is charged with "coordinating and developing the health planning research efforts of the state and for amending and modifying the state health plan which includes the certificate of need standards." Under section (l)(1) of this code provision "[w]hen the state agency proposes amendments or modifications to the certificate of need standards, it shall file with the secretary of state, for publication in the state register, a notice of proposed action, including the text of all proposed amendments and modifications, and a date, time, and place for receipt of general public comment." Pursuant to Section (l)(2) of this provision "[a]ll proposed amendments and modifications to the certificate of need standards, with a record of the public hearing or written statements and documents received pursuant to a public comment period, shall be presented to the governor. Within thirty days of receiving the proposed amendments or modifications, the governor shall either approve or disapprove all or part of the amendments, modifications..."

Applicants proposing the development of a diagnostic center must establish that the service is needed and must demonstrate consistency with the applicable State Health Plan Standards, which, in this case, are the Standards for Ambulatory Care Centers approved by the Governor on October 5, 1992 (hereinafter referred to as the "Ambulatory Care Standards").

The Ambulatory Care Standards set forth the need methodology for ambulatory care centers, which includes diagnostic centers, and sets forth various cost and quality standards. With respect to diagnostic centers, a general need methodology applies and in order to demonstrate consistency with the Ambulatory Care Standards an applicant "shall demonstrate, with specificity, that there is an unmet need for the proposed ambulatory care services, that the proposed services will not have a negative impact on the community by significantly limiting the availability and viability of other services or providers, and that the proposed service is the most cost effective." Ambulatory Care Standards, II.A. With respect to a service area, the applicant "shall delineate the service area by **documenting** the expected area around the ambulatory care facility from which the center is expected to draw patients." Id. (Emphasis added.) The Ambulatory Care Standards further state that an applicant "may submit testimony or documentation on the expected service area, based upon national statistics, or upon projections generally relied upon by a professional engaged in health planning or the development of health services." Id.

Once the service area is delineated, the applicant must take the population of the service area and multiply it by the use rate to determine the need in the service area. In

order to determine the amount of need currently being met, the number of scans that can be performed by a single ultrasound sonographer per day is multiplied by the amount of time the machine can provide services and this will indicate the number of scans per year of one ultrasound machine. This number is then multiplied by the number of providers in the area to determine the amount of services currently being provided. If the projected need is higher than the amount of services currently capable of being provided, then an unmet need exists.

**B. Family Medical Imaging's application for Certificate of Need to develop a diagnostic center.**

On October 29, 2002, Gary Poling, D.O., entered into a five year lease for a GE LOGIQ7 ultrasound machine. On December 3, 2002, Dr. Poling filed a request for a determination of reviewability, on behalf of FMI, for the acquisition of the ultrasound machine with an estimated capital expenditure of \$175,000.00. In this letter, Dr. Poling noted that the ultrasound machine would be purchased by a legal entity (FMI) owned by both himself and Dr. Lostetter. As indicated in the initial letter, in addition to offering ultrasound services to their own patients, which would not be subject to CON review, both physicians would accept referrals from other providers for patients needing ultrasound procedures. Since the physicians would be accepting referrals, and thus rendering ultrasound procedures to patients outside their existing office practice, the project is considered a diagnostic center under the law pursuant to 65 C.S.R. 17.

On January 8, 2003, the Authority determined the proposal to be reviewable, as a diagnostic center, and accepted the request as a letter of intent. On January 8, 2003,

the Authority received FMI's application and the appropriate application fee. In the application, FMI stated that the service area for the diagnostic center was the following West Virginia counties: Raleigh, Wyoming, McDowell, Fayette, Summers and Nicholas. FMI stated the rationale for this service area as follows: "[t]here are many rural areas that do not have ultrasound services available to them on a local level. We will serve all surrounding areas as well as the local population." CON application at p. 24.

The population of the six county service area, in 2002, was 214,202.<sup>2</sup> Based upon a use rate of .27 per person, FMI projected that this service area has a need for 57,835 ultrasounds. For the second step of the calculation, based upon a survey of 64 providers, some of which did not respond to the survey, FMI stated that there are 24 ultrasound providers in the six county service area. The majority of these providers appear to be located in Beckley, in close proximity to FMI. In addition, this number was not broken down on a per county basis anywhere in the application.

For the next step in the calculation, FMI concluded that a single ultrasound sonographer conducts 6-10 scans per day. FMI then stated that it would assume,

<sup>2</sup>

Information taken from FMI's CON Application at p. 24.

|                 | <u>2002</u>   | <u>2003</u>   | <u>2004</u>   | <u>2005</u>   | <u>2006</u>   |
|-----------------|---------------|---------------|---------------|---------------|---------------|
| <b>Raleigh</b>  | 77,240        | 76,251        | 75,261        | 74,271        | 73,566        |
| <b>Wyoming</b>  | 24,749        | 24,270        | 23,790        | 23,311        | 22,920        |
| <b>McDowell</b> | 25,752        | 24,964        | 24,175        | 23,387        | 22,763        |
| <b>Fayette</b>  | 46,649        | 46,183        | 45,253        | 45,253        | 44,872        |
| <b>Summers</b>  | 13,333        | 13,500        | 13,667        | 13,834        | 14,027        |
| <b>Nicholas</b> | <u>26,479</u> | <u>26,479</u> | <u>26,451</u> | <u>26,423</u> | <u>26,403</u> |
| <b>Total</b>    | 214,202       | 211,647       | 209,062       | 185,499       | 204,551       |

conservatively, that the average unit operates at 50% capacity or 250 days per year. When the average scans per day of 6 is multiplied by the average time a unit operates of 250, this equals 1500 projected scans per year, per machine. When multiplying this yearly number by the number of existing machines, which FMI stated was 24, this equals 36,000 scans per year. This number is less than the projected need in the service area; therefore, FMI projected an unmet need of 21,835 ( $57,835 - 36,000$ ) ultrasounds per year.

In order to project need, FMI made several assumptions which favorably impacted its calculation. First, FMI used the lower number of 6 scans per day rather than 10 scans per day to be conducted by the average sonographer. If the higher number of 10 were used in this calculation, rather than 6, no unmet need could be projected. For example, the number of scans capable of being performed in the service area would then be 60,000 ( $10 \times 250 = 2500 \times 24 = 60,000$ ), which is greater than the projected need of 57,835. Electing to use 6 scans per day as the multiplier, rather than 10, allowed FMI to project unmet need. Second, FMI assumed that the average machine would be used only 50% of the time.

On January 9, 2003, the Authority acknowledged receipt of the application. On that same date, Raleigh General Hospital (hereinafter "RGH") requested affected party status. On January 15, 2003, a letter of support from Anthony McFarlane, M.D., was received by the Authority. On January 23, 2003, the Authority requested additional information from FMI and received FMI's response on January 30, 2003. On January

31, 2003, the application was deemed complete and the Notice of Review was issued on February 3, 2003.

On March 7, 2003, RGH requested an administrative hearing in this matter. Shortly thereafter, FMI demanded that a speedy hearing take place in order to resolve this issue. FMI had purchased the equipment prior to filing its application and it wanted resolution of this matter as soon as possible since payments for the machine were due. In an attempt to accommodate FMI, the Authority scheduled the hearing on the matter to take place expeditiously and the Notice of Prehearing Conference and Administrative Hearing was issued on March 19, 2003. On March 28, 2003, correspondence was received from Attorney Thomas G. Casto noting his appearance as counsel for RGH.

The Time Frame Order was issued on March 31, 2003. On that same date, a Notice of Rescheduled Administrative Hearing and Cancellation of Prehearing Conference was issued. Both parties agreed to the tight time frame. The parties engaged in discovery and on March 31, 2003, the Authority received a certificate of service for the request for production of documents and interrogatories filed on behalf of RGH. On April 2, 2003, FMI filed its interrogatories and requests for production of documents. In addition, FMI requested a subpoena duces tecum for Karen Bowling and Mike Baker on April 3, 2003. On April 10, 2003, RGH filed its response to FMI's interrogatories and request for production of documents. On April 11, 2003, the Authority received RGH's witness list and on that same date, FMI filed its discovery responses.

On April 13, 2003, FMI filed a motion to exclude evidence and testimony. This motion states, in its entirety, as follows:

The applicant moves to exclude all evidence and any testimony arising from said evidence not produced or disclosed by Raleigh General Hospital in response to [sic] discovery request. Raleigh General Hospital did not identify, disclose or produce any documents or evidence other than a list of ultrasound exams and charges. I refer to a letter from the Health Care Authority titled "Notice of Rescheduled Administrative Hearing and Cancellation of Prehearing Conference", the fourth paragraph says:

The parties are directed to provide the Authority and to exchange with all affected parties a list of witnesses and a summary of direct testimony that will be offered at the hearing, as well as copies of all documents that will be offered into evidence on or before April 11, 2003. FAILURE TO PROVIDE these items will result in the refusal to admit the proposed evidence unless good cause for the failure can be demonstrated."

Introduction of any other form of evidence or testimony based thereon would be prejudicial to FMI because they were not timely disclosed.

On that same date, the Authority scheduled a telephonic conference to consider the motion. The motion did not raise any specific discovery irregularities and likewise did not indicate that RGH failed to comply with the prehearing notice. This motion was denied, but to the extent that RGH attempted to submit any new documents into evidence after this point, the objection was sustained and in fact one document offered by Lawrence Pack, one of RGH's experts, was excluded from evidence pursuant to FMI's motion.

On April 15, 2003, the Authority received a letter of opposition to the project from the West Virginia Hospital Association. On this same date, RGH filed a motion to compel and the Authority received RGH's follow up to discovery responses. This motion

was denied as being untimely because the consideration of such motion one day prior to the administrative hearing would cause unnecessary delay.

An administrative hearing was held on April 16, 2003. At that time, FMI rested on its application and did not present a case. Shortly after the conclusion of the hearing, the court reporter informed the Authority of a transcription problem. Apparently, interference, in the form of static, was simultaneously recorded on the tapes of the hearing. The tapes were filtered and the transcript was prepared. However, certain testimony was lost. The Authority placed the issue before the parties and allowed either of the parties to request a new hearing. It was anticipated that a new hearing would take approximately the same amount of time as the first hearing, one work day. On May 21, 2003, FMI and RGH indicated that they did not want a new hearing. Thereafter, the Authority received post hearing briefs from both of the parties.

**C. The Authority denied Family Medical Imaging's Certificate of Need because the six county service area was not reasonable.**

In order to be approved for a CON, an applicant must establish that the service is needed and consistent with the State Health Plan. W.Va. § 16-2D-9(b). These two findings are independent of one another; that is, both must be met and the absence of one of those criteria requires the Board to deny the application. Princeton Community Hospital v. State Health Planning and Development Agency, 174 W.Va. 558, 564, 328 S.E.2d 164, 170 (1985). On October 9, 2003, the Authority issued a decision on FMI's application for a CON to operate a diagnostic center and accept referrals for ultrasound services. The Authority's Decision denied FMI's application to operate as a diagnostic

center; however, the Decision does **not** prevent FMI from providing ultrasound services to patients of either Dr. Poling or Dr. Lostetter's practice. Based upon the Authority's decision, FMI can not accept referrals from other physicians to treat individuals who are not patients of either Dr. Poling or Dr. Lostetter.

As the basis for its Decision, the Authority stated that the "service area set forth in the application is not reasonable." Decision at p. 18. FMI simply failed to present any evidence in its application or develop any evidence during the hearing to establish how or why it expected to draw patients from counties such as McDowell and Nicholas Counties. In fact, the application, standing alone, did not state any justification for the service area whatsoever. Based upon a review of the hearing transcript, FMI's service area appeared even more unreasonable requiring the Authority to make the following finding:

The service area in the application includes the following six West Virginia counties: Raleigh, Wyoming, McDowell, Fayette, Summers and Nicholas. No justification for this large service area is set forth in the application. At the hearing, Dr. Poling testified that he only serves two families from McDowell County...However; the entire population of McDowell County was included in the applicant's need methodology. Likewise Dr. Poling testified that he serves "several" families from Nicholas County, however the entire population of Nicholas County was included for purposes of unmet need.

### **III. STANDARD OF REVIEW**

The standard of review applicable in this appeal is set forth in W.Va. Code § 16-2D-10, which provides that the "reviewing agency" shall review appeals from the Authority in accordance with the provisions governing the judicial review of contested administrative cases in W.Va. Code § 29A-5-4.

Thus, the review of the Authority's Decisions "at both the administrative level and circuit level, is to be conducted in accordance with W.Va. Code § 29A-5-4." Princeton Community Hospital, 174 W.Va. at 562, 328 S.E.2d at 168 (1986). See also, West Virginia Health Care Cost Review Authority v. Boone Memorial Hospital, 196 W.Va. 326, 334, 472 S.E.2d 411, 419 (1996). Specifically, in Princeton Community Hospital, this Court found that the statute grants only "limited review capacity." 174 W.Va. at 562, 328 S.E.2d at 169. The extent of such limited review is set forth in W.Va. Code § 29A-5-4(g).

The Court must evaluate the Authority's Decisions based upon the record of the Authority's proceedings to determine whether there is evidence to support the Authority's Decision and the Court shall evaluate the decision upon the Authority's findings of fact, "regardless of whether the [Court] would have reached a different conclusion on the same set of facts." Ruby v. Insurance Commission, 197 W.Va. 27, 32, 475 S.E.2d 27, 32 (1996). The Court may not re-weigh the evidence, but may only inquire into the existence of substantial evidence to support the Authority's prior determination. Only if the evidence does not, in any reasonable way, support the findings of fact or if the findings of fact do not support the conclusions of law, may the reviewing agency find the decision to be clearly erroneous and subject to reversal. Boone, 472 S.E.2d at 420; Appalachian Power Company v. State Tax Department, 195 W.Va. 573, 466 S.E.2d 424 (W.Va. 1995).

In Princeton Community Hospital, this Court held that the Authority's determination of matters within its area of expertise is entitled to substantial weight. Id.,

328 S.E.2d at 171. Further, the Court, restating prior authority, held that the review function “must be performed with conscientious awareness of its limited nature...the court must give due deference to the [Authority’s] ability to rely on its own developed expertise...” Id.

The task of the Court is to determine whether the Authority’s Decisions are based on a consideration of the relevant factors and whether there has been a clear error of judgment. Boone, 472 S.E.2d at 420. Absent a showing of prejudice to the substantial rights of the appellant, the Court has no authority under W.Va. Code § 29-A-5-4(g) to reverse the decision dated October 9, 2003. Smith v. Bechtold, 190 W.Va. 315, 319, 438 S.E.2d 347, 351 (1993).

#### IV. ARGUMENT

##### **A. The Appellants failed to demonstrate that the project was needed and the Authority acted within its discretion in evaluating the reasonableness of Family Medical Imaging’s service area.**

The Authority has been charged by the Legislature with oversight of the CON program. W.Va. Code § 16-2D-5. In addition, the Authority has power to promulgate legislative rules and to develop and amend the State Health Plan. Id. Thus, the Authority has been recognized by the Legislature as an agency with expertise in the area of the CON laws, regulations and the State Health Plan. This Court has previously held that the Authority’s determination of matters within its area of expertise is entitled to substantial weight. Princeton Community Hospital, 328 S.E.2d at 171. In addition, this

Court has held that “[a]n agency’s interpretation of a statutory provision or regulation that it is charged with administering is entitled to a high degree of deference.” Boone, 472 S.E.2d at 420. In rendering its decision, the Authority reviewed the matter pursuant to the Ambulatory Care Standards, referenced above, and determined that FMI failed to submit sufficient evidence establishing that its project was needed and that it was not consistent with the language of the Ambulatory Care Standards.

The burden to establish a justifiable service area clearly rests on FMI. See, CON Application at Section E; Ambulatory Care Standards, II.A. The Authority, which has been charged by the Legislature with oversight of the CON program, is within its discretion to test the reasonableness of the information submitted. The Authority determined that FMI did not meet its burden under the Ambulatory Care Standards to justify its large service area and that this overstated service area skewed, in its favor, all of its need calculations. The Authority acted well within its discretion in making this determination since part of its essential core function is to evaluate and render decisions on CON applications.

FMI contends that the Authority ignored the service area definition set forth in the Ambulatory Care Standards and rather held it to a 25/10 service area. It further argues that the 25/10 service area that the Authority used in this case was not properly promulgated and is, in fact, contrary to the more general, plain language of the Ambulatory Care Standards. This argument fundamentally mischaracterizes the Authority’s actions.

The Authority did not create a new standard or policy to evaluate this case, rather the Authority evaluated FMI's application under the language of the Ambulatory Care Standards, which were promulgated in 1992 as FMI concedes, which provide that an applicant must "demonstrate, with specificity, that there is an unmet need" and must do this by "documenting the area around the ambulatory care facility from which the center is expected to draw patients." Ambulatory Care Standards, II.A.

Contrary to FMI's assertions, this language does not give FMI unfettered discretion to select any service area that it wants; otherwise every applicant would submit the entire state as its service area. Rather, an applicant must document the area from which it expects to draw patients. The Authority found that it was not reasonable for FMI to expect to draw patients from such a large service area when other providers for the same services currently exist and FMI has no on-going relationship with either the potential patient or the referring physician.

FMI attempts to mischaracterize the Authority's discretion to critically evaluate applications, under the language cited above, as somehow altering the legal standard that it must meet in order to be approved for a CON. However, this is simply not the case. The Authority is entitled and, in fact, must critically evaluate CON applications in order to determine if they merit approval. If the Court were to accept FMI's argument, it would deprive the Authority of discretion to critically evaluate CON applications and eviscerate the Authority's legislatively conferred powers. Essentially, adopting FMI's argument would allow applicants to project need without restriction in all cases before the Authority where no specific service area is defined. The Authority could only rubber

stamp such applications and not delve any deeper or perform any analysis. This was clearly not the intent of the Legislature when it empowered the Authority to administer the CON program and it was likewise not the intent of the Authority to allow unmet need to be manipulated under the Ambulatory Care Standards, as FMI did in this case.

It is essential that the Authority has discretion to critically evaluate applications or the entire mission of the Authority is in jeopardy. The Authority was created, in part, to help restrain the costs of health care. This is accomplished, in part, by not allowing the duplication of services in a service area. If the Authority were deprived of the ability to critically evaluate applications, it would become a rubber stamp approving anything that is filed. This would result in skyrocketing health care costs and would not benefit the health care consumers that the Authority is charged with protecting.

The importance of recognizing the Authority's discretion to critically evaluate applications is highlighted by a review of the facts of this case. FMI set forth a six county service area. The only justification for this large service area, in the application, was the assertion that "there are many rural areas that do not have ultrasound services available to them on a local level and it [FMI] will serve all surrounding areas as well as the local population." This service area is not reasonable for several reasons.

First, in evaluating the service area, the Authority considers the type of service being offered. Here, FMI is proposing offering diagnostic imaging services to not only its own patients, but also to treat patients on a referral basis. This distinction is important because when accepting referrals, a physician will be providing services to patients not currently being treated by his or her office practice. In this case, FMI did

not demonstrate why patients, who are currently not being treated by either practice, and in some cases are actually located closer to existing providers, would seek out its services for treatment. In addition, there is simply no evidence, of record, indicating that physicians in Nicholas, Summers and Wyoming Counties will send their patients to FMI to receive treatment. Indeed, FMI had the opportunity to submit letters from physicians in these areas indicating their support of this project and it failed to do so. Additionally, the financial information submitted indicates that no advertising will take place. This would make it even more difficult for physicians and their respective patients in Nicholas, Summers and Wyoming Counties to even be aware that FMI is offering ultrasound services.

Second, it is clear from a review of the hearing testimony, that the existing office practices of Dr. Poling and Dr. Lostetter treat a statistically insignificant number of patients from Nicholas and Summers Counties to reasonably include these counties in the service area. For example, in the hearing, Dr. Poling testified that he only served "two families" from McDowell County and "several families" from Nicholas County. Hearing Transcript at p. 19. In 2002, the population of McDowell County was 25,752 and the population of Nicholas County was 26,479. Therefore, it is unreasonable for the applicant to assume that the entire population of these counties will travel, in some cases great distances, and forgo treatment by closer existing providers to receive treatment from FMI.

However, despite the fact that FMI had no reasonable basis to expect to draw patients from these counties, it included these counties and their populations in its

service area. It is simply not reasonable to expect to draw patients from these counties, when the existing practice has so little presence in the area. The residents of these counties would need to travel to Beckley and presumably pass existing providers to receive treatment from FMI.

Third, the service area proposed by FMI is three times larger than that of RGH, an acute care hospital. This fact, alone, demonstrates the unreasonableness of the proposed six county service area. RGH offers more services than FMI and thus would reasonably have a larger, not smaller, service area than FMI. In making this comparison, the Authority is not holding FMI to a 25/10 service area, as has been repeatedly contended by FMI, but rather is pointing out the glaring deficiencies in FMI's proposed service area.

After reviewing the application and the hearing testimony, the Authority found no reasonable justification for such a large service area. Therefore, it turned to an examination of type of service being proposed to determine if the proposed service is considered specialized care which generally necessitates a larger service area. Typically, specialized care services, such as open heart surgery, angioplasty and long term acute care, are considered specialized services because these services are available at a limited number of locations throughout the state. Since these services are only offered at a limited number of locations, patients are forced to travel great distances to receive treatment and this increases the size of the service area.

In the instant case, the ultrasound services cannot be considered specialized. These services are currently available by at least 24 other providers in the service area

alone, unlike open heart which is only offered by six providers in the state. Therefore, there is no reason for people to travel to receive these services. Accordingly, FMI's service area could not be justified based upon the type of the services being offered.

Contrary to the Appellants' assertion that there is no case law to support the Authority's service area analysis, the Authority has previously considered this issue. In Raleigh General Hospital v. West Virginia Health Care Cost Review Authority, Civil App. No. 97-AP-09-B, *affirming*, Raleigh General Hospital, App. Docket # 95-HC-14, *affirming*, Raleigh General Hospital, CON File # 92-1-3872-H (denying a CON to develop open heart surgery services and holding that the applicant, RGH, failed to provide a reasonable justification for the inclusion of a secondary service area when a statistically insignificant number of patients from the secondary service area utilized the current cardiac catheterization services offered by the applicant), the Tenth Judicial Circuit affirmed the Authority's Decision to disallow RGH's use of a secondary study area. The Circuit Court stated that use of RGH's existing cardiac catheterization services by "patients in the proposed secondary service area is insignificant and HCCRA's [now known as the Authority] conclusion that this is a valid indicator of the probable use of the proposed open heart unit is sound."

In both the above referenced case and in the instant case, the Authority conducted the same analysis of the facts. In the Raleigh case, the applicant tried to justify using a larger service area than set forth in the State Health Plan. In evaluating this secondary service area, the Authority considered the number of patients currently using the applicant's cardiac services from the secondary service area and determined

that use in the secondary service area of existing cardiac catheterization services currently offered by the applicant was so insignificant, that inclusion of the additional counties was not reasonable or justifiable. Thus, since patients from the secondary service area were not currently utilizing the applicant's service, it is unreasonable to assume that approval of the project will change this treatment pattern.

In the instant case, the Authority evaluated the evidence and, like the Raleigh case, determined that Dr. Poling and Dr. Lostetter are treating a statistically insignificant number of patients in McDowell and Nicholas Counties to justify the inclusion of these counties in FMI's service area. At this point, it is important to note, that the application submitted by FMI is much weaker than that previously considered in the Raleigh case. In the present case, FMI failed to submit any data whatsoever indicating the number of patients currently served by its family practice in any county in the proposed service area, including McDowell and Nicholas Counties. In fact, FMI objected in discovery to the production of such information as irrelevant.

Finally, once FMI's proposed service area was determined to be overstated, the need methodology was likewise flawed and overstated, as were the financial projections. Since FMI could not establish need or consistency with the State Health Plan, no further analysis of the case needed to take place. It is, however, important to note that there were other flaws in the application which may, if considered, have warranted denial of the CON.

For example, FMI made several assumptions, in its application, which allowed it to project an unmet need in the service area. It assumed both that the lesser number of

ultrasound scans would be performed per day and that the existing ultrasound machines would be operated at 50% of its actual capacity on an annual basis. These assumptions are contrary to information contained in FMI's own application which indicates that the population of the service area is older, as compared to national benchmarks, and thus would reasonably use more diagnostic procedures than the average population. If more diagnostic procedures were required, then it is reasonable to assume that equipment would be used more than half the time and that more than 6 scans per day would be performed.

Additionally, FMI failed to provide for the provision of indigent care. The Authority is required to consider this fact in evaluating a CON application pursuant to W.Va. Code § 16-2D-6(22)(C). Further, the Authority is required to consider the impact that this project will have on existing providers. W.Va. Code § 16-2D-6(6). The fact that FMI failed to establish that it would treat the indigent also impacts existing providers. RGH argued throughout this process that the proposed project would have a negative impact on its facility. For example, if FMI treats only paying clients then those persons without the means to pay for services will either not receive treatment at all or receive treatment for free or at a reduced cost at RGH. This project has the potential to change the payor mix at the hospital by draining paying patients and, thus, poses the potential to both increase the costs of services at RGH and to force RGH to discontinue services that it provides at a loss to offset for the indigent care provided. However, since FMI failed the initial step of justifying its service area, a consideration of these factors was unnecessary.

**B. Family Medical Imaging's assertion that the Authority failed to consider and evaluate the need for the proposed service, based upon the undisputed service area and available equipment, is fundamentally flawed since such a calculation cannot be accurately performed.**

Essentially, FMI argues that the Authority should have taken the two disputed counties, Nicholas and McDowell, out of the calculations and performed the analysis based upon a four county service area. First, the Authority is without power to reform a duly submitted application and substitute a new need methodology for the applicant. See, W.Va. Code 16-2D-9(c). Rather, the Authority simply approves or denies the application as submitted. Second, even if the Authority elected to do so, there is insufficient information in the application to allow it to determine how many ultrasound machines are located in this reduced service area. For example, FMI stated that there are 24 ultrasound machines located in the proposed six county service area, but does not break this number down by location. CON Application, p. 25. Therefore, it is impossible for the Authority to determine how many of these machines are located in the reduced four county service area. This is a fundamental step in the need methodology calculation and since FMI failed to address the location of the existing providers, it is impossible to conduct this calculation accurately. Accordingly, after the size of the service area is reduced, there is inadequate information to support approval of the application.

FMI then argues that although its application did not contain sufficient information to subtract out the existing providers in Nicholas and Summers Counties, there was

testimony from RGH's expert, Ms. Kinneberg, regarding the number of providers in the reduced service area. This is an interesting, but inconsistent, argument since it is FMI's position, on appeal, that her testimony should be stricken in its entirety. Apparently, this argument is only in place when the testimony is adverse to the applicant and not when the testimony is considered to be favorable. In any event, the Authority is without power to approve only part of a CON application. FMI filed an application seeking a CON to provide services in a six county service area, and not a four county service area. The Authority only has power to approve or deny applications, as submitted, and cannot retroactively modify a party's application to conform with testimony to make a project approvable. It is an all or nothing proposition.

At this point in the analysis and without considering the testimony of either expert offered by RGH, FMI has failed to meet its burden to establish an unmet need. Its service area is too large and this will skew, in its favor, all of the need calculations and all of the financial feasibility calculations contained in the application. The application on its face fails to establish an unmet need. Since an unmet need cannot be established, according to this Court's decision in Princeton Community Hospital, the CON should be denied and an analysis of other factors is unnecessary.

Solely for the purposes of rebutting the additional arguments made by FMI, a further analysis justifying why the Authority's Decision should be affirmed is set forth below.

**C. Family Medical Imaging failed to establish financial feasibility.**

With respect to financial feasibility, FMI failed to demonstrate that the project was financially feasible. This is established by a simple review of the application. First, FMI's financial feasibility projections are inexorably tied to its flawed need methodology and service area. For this reason, utilization in the form of expected revenue is grossly overstated in the financial pro formas. This fact alone demonstrates that the financial projections are fundamentally flawed and unreliable. In addition, from reviewing the application, it is apparent that a number of expenses were omitted from consideration by FMI. For example, it failed to consider bad debt, contractual write offs and the provision of indigent care in its financial projections. Since the revenues were grossly overstated and the expenses were understated, the financial projections are inherently unreliable and, as such, financial feasibility was not established. In conclusion, once the Authority determined that the need methodology was overstated and flawed, it was not possible for financial feasibility to be established since the two are inextricably intertwined.

**D. The testimony of both Raleigh General Hospital's experts was properly disclosed and admitted into evidence.**

In its petition for appeal, FMI essentially argues that based upon the general and vague motion to exclude evidence that it filed, the entire testimony of RGH's experts, Raymona Kinneberg and Lawrence Pack, should be excluded. However, "[e]vidence is not rendered inadmissible merely because a party contends (with or without justification) that it is inadmissible." F. Cleckley, Handbook on Evidence for West

Virginia Lawyers, § 1-7(C)(1) (4<sup>th</sup> ed. 2000). Rather, “[t]he specific reasons for its inadmissibility must be stated.” Id. at p. 1-89. FMI overlooks the fact that it never specifically asked, in its general motion, for the expert testimony to be excluded from the administrative hearing; and that while it appears to have lodged general objections to the individuals being recognized as experts, it did not, at the outset of either expert’s testimony, object to the experts testifying at the hearing. See, Hearing Transcript at pp. 168, 194, 195. It is well settled law that “[g]eneral objections are not favored under the West Virginia or Federal Rules of Evidence.” Id. citing Hanshaw v. Hanshaw, 180 W.Va. 478, 480, 377 S.E.2d 470, 472 (1988); See, W.Va.R.Evid. 103(a)(1). The “mandate for specificity imposes upon the objecting party the obligation to object with a reasonable degree of precision, which adequately apprises the trial court of the true basis of the objection and clearly state[s] the specific ground now asserted on appeal.” Id. at p. 1-91. In addition, “to preserve an issue for appellate review, a party must articulate it with such sufficient distinctiveness to alert the circuit court to the nature of the claimed defect.” Id. at p. 1-92 citing State ex rel. Cooper v. Caperton, 196 W.Va. 208, 216, 470 S.E.2d 162, 170 (1995).

In its general motion, FMI requested that “all evidence and any testimony arising from said evidence not produced or disclosed by Raleigh General Hospital in response to [a] discovery request” be excluded. The motion, cited in its entirety in the Authority’s statement of facts, did not assert that RGH failed to properly respond to any discovery requests, nor did it indicate that RGH’s expert testimony should be excluded for any reason. Since FMI’s motion did not raise any issues regarding the adequacy of RGH’s discovery responses or RGH’s prehearing filing, the Authority denied, in part, the

motion. Evidence should not be excluded just because a party requests it, rather the requesting party must articulate a basis or reason to exclude such evidence. The Authority did hold that to the extent that RGH attempted to introduce documents that were not previously disclosed, this motion was granted and, in fact, one document was excluded from the hearing because it was not included in RGH's prehearing filing and was not otherwise part of the record<sup>3</sup>.

Now, in its brief, FMI argues that the reason that this general motion to exclude was filed was because RGH improperly responded to discovery. This argument ignores the fact that FMI never articulated this in support of its motion. Had FMI made such an argument in its motion, it would have called the hearing examiner's attention to this issue and given RGH the ability to respond to such an assertion. FMI tries to excuse this neglect by blaming the Authority for the tight time frames in the case. However, it was FMI, not the Authority, that demanded the tight time frames, and neither party objected to going forward under the time frame established. Simply put, FMI is trying to have this Court resolve an evidentiary issue on appeal that it never raised in its motion below. In addition, if FMI truly believed that the Authority had improperly admitted evidence over its objection, logic indicates that FMI would have accepted the

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<sup>3</sup> Lawrence Pack, RGH's financial expert, attempted to introduce a document that was not part of the record and that was not previously disclosed to FMI. FMI apparently believed that it requested the information. RGH asserted that the work product doctrine protected the information from disclosure and FMI argued against the doctrine. Mr. Pack testified that he did not need this piece of evidence to serve as the basis for any of his opinions and he further indicated that he did not need this document to answer any questions about his impressions on this case. See, Hearing Transcript at p. 177. This document was excluded from the hearing and no testimony was based upon this document even when FMI attempted to later question the expert on the contents of the excluded document. See, Hearing Transcript at p. 186.

opportunity to have a new hearing that was offered to both of the parties as a result of a transcription problem.

For purposes of rebutting FMI's argument, RGH complied with the Authority's prehearing requirements and properly disclosed a summary of the substance of the expert opinions and it also complied with West Virginia Rules of Civil Procedure. It is necessary to point out that FMI could have deposed both of RGH's experts. Additionally, to the extent that FMI believed that RGH did not properly respond to its discovery requests, the proper remedy for a discovery violation is a motion to compel, which FMI never filed.

With respect to the prehearing filing, the Authority's Notice of Prehearing Conference and Administrative Hearing provided as follows:

The purpose of the prehearing conference is to designate parties to the hearing, to designate the issues for the hearing, resolve any procedural matters, receive any motions, establish the order of proceedings, receive a listing of the witnesses and a **summary** of the direct testimony that will be offered at the hearing, receive a listing of evidence to be offered and copies of any documents to be offered such as reports or analysis prepared by expert witnesses including any financial reports or any other procedural matters. Exhibit 13. (Emphasis added.)

In the Notice of Rescheduled Administrative Hearing and Cancellation of Prehearing Conference, the Authority noted as follows:

The parties are directed to provide to the Authority and to exchange with all affected parties a list of witnesses and a **summary** of direct testimony that will be offered at the hearing as well as all documents that will be offered into evidence on or before April 11, 2003. FAILURE TO PROVIDE these items will result in a refusal to admit the proposed evidence unless good cause for the failure can be demonstrated. Exhibit 16. (Emphasis added.)

In the instant case, RGH, in its prehearing filing submitted on April 11, 2003, disclosed that Raymona Kinneberg and Lawrence Pack were expected to testify at a hearing in this matter. The filing further set forth the following detailed information: "Raymona Kinneberg of Bill J. Crouch and Associates, Inc., an expert in certificate of need matters and health care planning, may testify and offer opinions regarding the need and accessibility of the population to be served, the project's consistency with the State Health Plan and all other aspects of the application." In addition, RGH's filing indicates that "Lawrence A. Pack, of Pack, Hawley, Lambert and Burdette may testify and offer opinions regarding financial issues, project financing and other aspects of the application." A review of the hearing transcript will support findings that Ms. Kinneberg and Mr. Pack testified in conformity with this designation.

FMI did not make an objection to RGH's prehearing filing, which is referenced above. Moreover, according to the plain language of both hearing notices issued in this case, the parties were directed only to submit a **summary** of direct testimony that will be offered at the hearing. In this case, counsel for RGH submitted a summary of each of the expert witness' expected testimony.

Lastly, FMI makes the misguided assertion that the testimony of Lawrence Pack was stricken and then relied upon by the Authority in making its decision. A correct and accurate reading of the transcript confirms that only a document that Mr. Pack sought to introduce was excluded from the record, not his entire testimony. Further, the Authority did not rely on this document to render its decision. In fact, the testimony of both experts was not needed to render a decision in this case, since FMI failed to justify its

overly large service area in its application. At the administrative hearing, FMI did not put on any evidence, but rather rested on its application. Thus, it failed to introduce any additional evidence to rehabilitate its application.

Therefore, the Authority properly ruled upon the evidentiary objection and RGH's expert testimony was properly admitted. However, for the sake of argument, even if all references in the Authority's Decision to the opinion and the testimony of the experts is stricken from the Decision, it should still be affirmed since FMI failed, in its application, to justify approval of this project.

**V. CONCLUSION**

For the reasons presented, the Authority respectfully requests that the Court affirm the Raleigh County Circuit Court Decision dated May 26, 2004 which affirmed the Authority's Decision dated October 9, 2003.

**WEST VIRGINIA HEALTH CARE AUTHORITY**  
**By Counsel,**

Respectfully submitted,

*Cynthia H. Dellinger*

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**CERTIFICATE OF SERVICE**

I, Cynthia H. Dellinger, do hereby certify that on the 6<sup>th</sup> day of May 2005, I caused true and correct copies of the **"Response Brief on Behalf of the West Virginia Health Care Authority"** to which this Certificate is attached, to be transmitted via regular United States mail, postage prepaid, and addressed as follows:

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