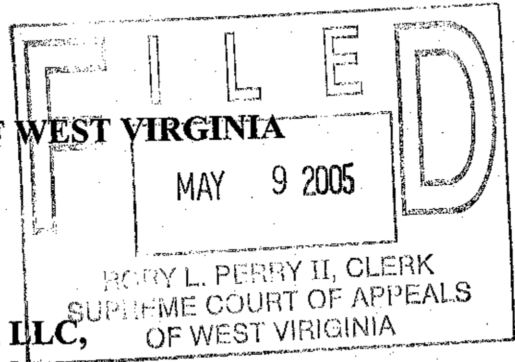

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

Docket No. 32565

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

v.

WEST VIRGINIA HEALTH CARE AUTHORITY,
Appellee,

and

RALEIGH GENERAL HOSPITAL,
Intervenor.

AMICUS CURIAE BRIEF OF THE WEST VIRGINIA HOSPITAL ASSOCIATION

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I. NATURE OF PROCEEDING AND RULING IN LOWER TRIBUNAL

This appeal arises out of a Certificate of Need ("CON") application filed on behalf of Family Medical Imaging, LLC ("FMI") with the West Virginia Health Care Authority ("the Authority") for the acquisition of an ultrasound machine at its offices in Beckley, Raleigh County, West Virginia. This application was considered by the Authority at an administrative hearing conducted on April 16, 2003. The hearing was attended by representatives of both FMI and Raleigh General Hospital ("RGH"). The Authority issued its Decision denying the CON application on October 9, 2003.[1]

FMI appealed the denial of its application to the Office of Judges, the state agency designated to consider administrative appeals from the CON program pursuant to W. Va. Code § 16-2D-10(a). Initially, the Office of Judges dismissed the appeal on technical grounds, but the appeal was later reinstated by the April 14, 2004, Order of the Circuit Court of Raleigh County. Thereafter, the Office of Judges considered the administrative appeal of FMI on the merits, and rendered a Decision affirming the Authority's denial of the application on May 26, 2004.

FMI, along with its owners, Gary L. Poling, D.O. and Scott C. Lostetter, D.O., then appealed the matter to the Circuit Court of Raleigh County. The case was orally argued to the Court, Judge H.L. Kirkpatrick III presiding, on August 17, 2004. After deliberations, the Circuit Court of Raleigh County issued an Order dated September 1, 2004, affirming the prior

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[1] Among other things, a CON application can only be approved if the service proposed therein is found (i) to be needed, and (ii) except in emergency circumstances that pose a threat to public health, consistent with the State Health Plan. See, W. Va. Code § 16-2D-9(b); Princeton Community Hospital v. SHPDA, 174 W. Va. 558, 328 S.E.2d 164 (1985).

Decisions of both the Authority and the Office of Judges. The Appellants' Petition for Appeal to this Court followed.

II. STATEMENT OF INTEREST OF WVHA

The West Virginia Hospital Association ("WVHA") submits this Brief in support of the Decision of the Authority, as affirmed by both the Office of Judges and the Circuit Court of Raleigh County. The WVHA exists as a statewide, not-for-profit organization representing the interests of approximately 73 acute care and specialty hospitals and health systems. The WVHA sponsors numerous advocacy, education, information, and technical assistance programs designed to build a strong and healthy West Virginia. Through these efforts, and through the efforts of its members, the WVHA strives to be a catalyst for positive change in the delivery of health services to all West Virginians.

The WVHA monitors legal developments that may have an impact upon its members, and where necessary, becomes involved as an *amicus curiae* in proceedings of significant import. The instant appeal is such a proceeding. The WVHA is keenly interested in ensuring that West Virginia's CON program is enforced in a manner that establishes a level "playing field" for all participants in the health care system, including the WVHA's members.

One component of that level "playing field" is how the State Health Plan delineates an appropriate service area for a CON application.[2] The methods and standards contained in the State Health Plan for delineating a service area for any given service must be fair and equitable for both the hospital providers of that service, and for all other providers of the same or similar services. That is not to say that those methods and standards must be identical. However, the methods and standards employed by the Authority should not offer undue advantage to one class of competitors over another.

The issue of competitive balance is an important one to the WVHA's membership. Hospitals are an essential cog in the health care safety net serving our citizenry. The vast majority of West Virginia hospitals operate emergency rooms to care for the sick and the injured 24 hours per day, 365 days per year. Federal law generally requires hospitals with emergency departments to medically screen each and every person who presents for treatment to an emergency room, and to offer stabilizing treatment and services to all regardless of their ability to pay.[3] Unfortunately, emergency rooms are used by the poor as a medical resource

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[2]The State Health Plan is a document approved by the Governor after preparation by the former Statewide Health Coordinating Council, or after amendment by the former Health Care Planning Council or the current Authority. W. Va. Code § 16-2D-2(ee). Since 1996, full responsibility for amending the State Health Plan has been vested in the Authority. W. Va. Code § 16-2D-5(b). The State Health Plan contains numerous standards that a CON applicant must address in its application. It is commonly required under the State Health Plan for an applicant to identify an appropriate service area in which the need for the proposed service can be assessed. It is undisputed that the provisions of the State Health Plan applicable to the Appellants' application are the Ambulatory Care Center Standards, approved by the Governor on October 5, 1992.

[3]These obligations are imposed upon hospitals by the Federal Emergency Treatment and Active Labor Act codified at 42 U.S.C. § 1395dd.

for more than just true medical emergencies, and this usage contributes to the hundreds of millions of dollars of uncompensated care provided annually by West Virginia hospitals.[4]

What does this have to do with the issue of competitive balance, you ask? Stated simply, hospitals by their very nature must offer a wide array of services. Some of those services are profitable, and some are not. The number of unprofitable hospital services tends to increase when those services are unnecessarily duplicated within the community by other providers who do not have to endure the scrutiny of a fair and equitable CON program. The adverse impact of such a proliferation of services upon hospitals is exacerbated by the fact that these other providers do not bear the cost of a 24-hours per day, 365-days per year operating paradigm, and are under no legal obligation to serve the poor and the indigent. In the end, the safety net of services offered by hospitals can be undermined when the competitive balance is tilted in favor of one class of providers over another.

III. ASSIGNMENT OF ERRORS

The WVHA's interest as an *amicus curiae* in this matter is focused primarily upon the service area standard set forth in the State Health Plan's Ambulatory Care Center Standards. Accordingly, the WVHA will address only the first two (2) of the three (3) assignments of error alleged by the Appellants. Stated properly, they are:

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[4] *2004 Annual Report to the Legislature,* West Virginia Health Care Authority (January 11, 2005).

(1) Whether the Authority applied the service area standard in a manner that was arbitrary, capricious, an abuse of discretion, or otherwise contrary to law; and

(2) Whether the Authority's determination that FMI's service area is too large was clearly wrong in view of the reliable, probative, and substantial evidence on the whole record.

IV. DISCUSSION

Because this case involves an administrative appeal, the applicable standard of review requires some discussion.

A. Standard of Review

The standard of review for an administrative appeal taken under the CON program is set forth at W. Va. Code § 29A-5-4. See, W. Va. Code § 16-2D-10; St. Mary's Hospital v. SHPDA, 178 W. Va. 792, 364 S.E.2d 805 (1987). W. Va. Code § 29A-5-4 provides in relevant part the following:

> (g) The court may affirm the order or decision of the agency or remand the case for further proceedings. It shall reverse, vacate or modify the order or decision of the agency if the substantial rights of the petitioner or petitioners have been prejudiced because the administrative findings, inferences, conclusions, decision or order are:
> (1) In violation of constitutional or statutory provisions; or
> (2) In excess of the statutory authority or jurisdiction of the agency; or
> (3) Made upon lawful procedures; or
> (4) Affected by other error of law; or
> (5) Clearly wrong in view of the reliable, probative and substantial evidence on the whole record; or

(6) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

W. Va. Code § 29A-5-4(g).

While this Court has held that it will review an administrative appeal under W. Va. Code § 29A-5-4(g) *de novo*, it has also repeatedly held that this review is limited to a determination of whether the agency's decision was based on a consideration of relevant factors, and whether there has been a clear error of judgment. HCCRA v. Boone Memorial Hospital, 196 W. Va. 326, 472 S.E.2d 411 (1996); Princeton Community Hospital v. SHPDA, supra. In discussing the deference to be accorded to a predecessor agency of the Authority under the CON program,[5] it was observed that a determination of matters within that agency's area of expertise is entitled to substantial weight. Princeton Community Hospital v. SHPDA, supra, at p. 171. Citing the case of Ethyl Corporation v. EPA, 541 F.2d 1 (D.C. Cir. 1979), cert. denied, 426 U.S. 941, 96 S.Ct. 2663, 49 L.Ed.2d 394 (1976), this Court further stated:

> But that function must be performed with conscientious awareness of its limited nature. The enforced education into the intricacies of the problem before the agency is not designed to enable the court to become a superagency that can supplant the agency's expert decision-maker. To the contrary, the court must give due deference to the agency's ability to rely on its own developed expertise. The immersion in the evidence is designed *solely* to enable to the court to determine whether the agency decision was rational and based on consideration of the relevant factors.

Supra, at p. 171.

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[5]The CON program was formerly administered by the State Health Planning and Development Agency ("SHPDA") until 1983. In 1983, the Authority was empowered with overseeing the CON program. See, W. Va. Code § 16-29B-11.

Similarly, the "arbitrary and capricious" standard under W. Va. Code § 29A-5-4(g) has been held to be deferential to an administrative agency. Hence, an agency's actions are presumed to be valid as long as they are supported by a rational basis. Stewart v. W. Va. Bd. of Exmrs. for Registered Professional Nurses, 197 W. Va. 386, 475 S.E.2d 478 (1996); In re: Queen, 196 W. Va. 442, 473 S.E.2d 483 (1996).

More recently, this Court has noted that an administrative agency's interpretation of a statute or legislative rule is entitled to deference only if the intent of a statute or legislative rule is not clear. HCCRA v. Boone Memorial Hospital, supra, citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). When an agency's decision is based upon a mistaken impression of the legal principles involved, the aforementioned deferential standards have diminished application. However, as discussed hereinbelow, the service area standard at issue in the FMI application does not rise to the level of a statute or legislative rule.

Finally, it is clear under W. Va. Code § 29A-5-4(g) that evidentiary findings made at a contested administrative hearing should not be reversed by a reviewing court unless they are clearly wrong. Stewart v. W. Va. Bd. of Exmrs. for Registered Professional Nurses, supra. The "clearly wrong" standard of review under W. Va. Code § 29A-5-4(g) has also been held to be a deferential one which presumes that an administrative agency's actions are to be upheld as long as they are supported by substantial evidence. Stewart v. W. Va. Bd. of Exmrs. for Registered Professional Nurses, supra; Frymier-Halloran v. Paige, 193 W. Va. 687, 458 S.E.2d 780 (1995). A reviewing court is not free to substitute its own evaluation of the

administrative agency's factual findings under this standard of review, regardless of whether it would have reached a different conclusion upon the same set of facts. Rather, where there are two (2) permissible views of the evidence, the agency's findings of fact must be upheld. Frank's Shoe Store v. W. Va. Human Rights Comm., 179 W. Va. 53, 365 S.E.2d 251 (1986), citing, Anderson v. City of Bessemer City, 470 U.S. 564, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985).

B. Merits of the Service Area Standard

Before discussing the actual merits of the service area standard as applied to the Appellants, it is important for this Court to understand that Dr. Poling and Dr. Lofstetter are not prohibited by the CON laws from purchasing an ultrasound machine and making its services available to their own patients. The Appellants are in fact performing ultrasound procedures upon their own patients as this appeal is being decided. They are able to do so because the private office practice of medicine is statutorily exempted from coverage under the CON program pursuant to W. Va. Code § 16-2D-4(a)(1), so long as that private office practice does not acquire "major medical equipment" or propose to offer one or more health services specified as subject to CON review pursuant to legislative rules adopted by the Authority. The ultrasound machine in question does not constitute "major medical equipment" under the CON law since its cost did not exceed $2,000,000. See, W. Va. Code § 16-2D-2(s).[6]

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[6]The cost of the ultrasound machine was stated to be $174,000.

However, in the legislative rules promulgated by the Authority at W. Va. C.S.R. § 65-17-1, et seq., some nine (9) different services are defined as subject to CON review, even when offered by a private office practice and regardless of the cost associated with their offering. One of these reviewable services is a "diagnostic center," which is defined in relevant part as follows:

> 2.1.c. Any 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; or

W. Va. C.S.R. § 65-17-2.1.c. The Authority determined that Dr. Poling's and Dr. Lofstetter's intent to accept referrals from other physicians for patients needing ultrasound services brought them within the scope of a diagnostic center under the above-quoted language, thereby triggering the CON application and review process. See, Authority Decision at p. 7. The Appellants have not challenged this determination on appeal.

Hospitals are not immune from a similar level of scrutiny under the CON laws for ultrasound services. Because ultrasound machines generally cost less than $2,000,000, a hospital can acquire one for use within its own facilities upon hospital patients without triggering CON review as an item of "major medical equipment." See, W. Va. Code § 16-2D-3(b)(9); § 16-2D-2(s). However, if a hospital seeks to establish a free-standing ambulatory health care facility to provide ultrasound procedures for patients to be referred by area physicians, that hospital (like the physicians in the instant appeal) must file a CON application

and undergo review by the Authority. A hospital's development of such an ambulatory health care facility is made reviewable by W. Va. Code § 16-2D-3(b)(l), even when the cost of such a facility does not exceed $2,000,000.

It is clear from the foregoing that both the Legislature and the Authority have attempted to achieve a competitive balance, or as described hereinabove, a level "playing field" between competitors in how the CON laws are applied to the same or similar services. It is that balance which the Appellants seek to disrupt in this appeal.

1. The Authority Did Not Apply the Service Area Standard in a Manner That Was Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Contrary to Law.

The State Health Plan Ambulatory Care Center Standards (hereinafter the "SHP Standards") define five (5) different categories of ambulatory care centers - a community-based primary care center, an urgent care center, an ambulatory surgery center, an outpatient behavioral health facility, and a diagnostic center. See, SHP Standards at Article I, Section B. As stated above, it is undisputed that the Appellants propose the development of a diagnostic center. Since Article III of the SHP Standards contain no facility-specific standards applicable to diagnostic centers, it is likewise undisputed that the General Standards contained at Article II of the SHP Standards apply to the FMI application.

Article II, Section A of the SHP Standards generally require an applicant to delineate a service area for its project, and then to estimate the extent to which the demand or need for the proposed service is being met by existing providers within that service area. In delineating a service area, the General Standards instruct an applicant to do the following:

> The applicant shall delineate the service area by documenting the expected areas around the ambulatory care facility from which the center is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services.

See, SHP Standards at Article II, Section A. This language quite clearly contemplates that an applicant must justify by affirmative proof its proposed service area. The provision makes specific reference to the presentation of either testimony and/or written documentation that is based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services. In other words, a proposed service area must have some quantitative, statistical basis, and cannot be based upon mere anecdotal evidence or supposition.

This was in fact how the Authority interpreted and applied the service area standards to the FMI application. The Authority's original Decision contained the following analysis:

> With regard to the need calculation, the Authority finds that the service area set forth in the application is not reasonable. 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. (Tr. p. 19.) 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 determining an unmet need.

See, Authority's Decision at p. 18. Clearly, the Authority interpreted the service area standard as one which required justification through proof beyond the type of anecdotal testimony offered by FMI. This interpretation of the service area standard was affirmed by both the Decision of the Office of Judges[7] and the Order of the Circuit Court of Raleigh County[8].

The Appellants take issue with the Authority's interpretation and construction of the service area standard. They argue that the need methodology set forth in Article II of the SHP Standards is a general one and not a specific one, and that:

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[7]The Office of Judges stated:

> An applicant is not free to create a service area as expansive as necessary to satisfy the requirements of unmet need but must have a reasonable basis for considering counties as a part of the expected area to be served. To conclude otherwise would defy all logic. While the Standards do not explicitly define a service area for a diagnostic service, the process for determining how the service area is to be established is found in the Standards. An applicant must delineate, through testimony or documentation, the expected areas around the ambulatory care facility from which this center is expected to draw patients. Although correspondence from other healthcare providers was submitted by FMI to show support for the project itself, no evidence was presented to the Authority to explain the logic of the proposed service area.

See, Office of Judge's Decision at p. 8.

[8]The Circuit Court of Raleigh County held:

> . . .the Court observes that there can be no brightline rule to specifically describe an appropriate service area for a diagnostic center, but concedes that the HCA should be allowed some leeway to interpret and apply the State Health Plan. As Judge Hill points out, while the Standards do not explicitly define a service area for a diagnostic center, the process of determining how the service area is to be established may readily be found therein. An applicant must delineate, through testimony or documentation, the expected areas from which the diagnostic center will draw its patients.

See, Circuit Court of Raleigh County Order at p. 6.

> . . . there is only one expression of how a service (sic) is to be determined - the area from which the applicant expects to draw patients.

See, Appellant's Brief at p. 15. Appellants further argue that the Authority incorrectly held that:

> . . . FMI was **required** to submit testimony and/or documentation to show FMI would serve a significant percentage of the proposed service area's population. Both ALJ Hill and Judge Kirkpatrick used the term **must** in describing FMI's obligation to justify its proposed service area. This was the wrong standard.

See, Appellant's Brief at p. 18. According to the Appellants, a mere statement of expectation on behalf of FMI was all that was legally required.

Such a construction or interpretation of the service area standard cannot be condoned by this Court. First and foremost, it directly conflicts with the plain language contained in Article II of the SHP Standards cited hereinabove, namely, that:

> The applicant shall delineate the service area **by documenting** the expected areas around the ambulatory care facility from which the center is expected to draw patients. (Emphasis added.)

See, SHP Standards at Article II, Section A. This language expressly requires the applicant to document its expectations. The service area standard then includes provisions describing the nature and extent of documentation that will normally be expected from the applicant. The fact that a specific mathematical formula or calculation is not contained in the Article II General Standards cannot rationally be viewed as absolving the applicant from its burden of proof on the service area issue.

A rejection of the Applicant's proposed construction of the service area standard is very important from a policy standpoint to the WVHA. If applicants are permitted to establish diagnostic centers without having any meaningful burden of proof with respect to their proposed service areas, then a proliferation of centers offering a wide array of outpatient testing and procedures throughout the state would soon follow.[9] That proliferation would lead to an unnecessary duplication of such services, and would undermine the financial viability of those services within the hospital setting. In short, the CON "playing field" would be titled unfairly, and the ability of hospitals to offer such services 24-hours per day, 365-days per year would be jeopardized.

There are other convincing policy reasons to support the Authority's interpretation of the service area standard for diagnostic centers. Currently, West Virginia is not experiencing any significant growth in population. A proliferation of diagnostic centers statewide would only spread the same volume of patients across more facilities. While the Appellants expressed a sincere desire to serve all patients regardless of their ability to pay,[10] not all providers who could potentially benefit from a decision favoring the Appellants will necessarily adhere to the same policy. If more diagnostic centers are approved, and at least

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[9]The services that could potentially be provided in a diagnostic center include laboratory, radiography, ultrasound, general physical examinations, drug testing, nuclear medicine, imaging (e.g. CT scannings), and other procedures that may be reasonably performed in an outpatient setting. See, SHP Standards at Article I, Section B, Paragraph 2(c).

[10]Despite this testimony, the application's financial projections did not demonstrate the impact of indigent care upon net income for the proposed center. This and other failings identified by the Authority led to the conclusion that the applicant failed to prove financial feasibility. See, Authority's Decision at pp. 19-20.

some of them begin skimming the most well-insured patients into their own centers, the ability of West Virginia hospitals to financially support the full range of safety net services (*e.g.*, trauma care, neonatal care, care for the uninsured) needed within our communities would be further impaired.

The Authority's interpretation of the service area standard is consistent with the plain language of the SHP Standards, not to mention common sense. A requirement that an applicant must document its service area with affirmative proof is not arbitrary, capricious, irrational, or an abuse of discretion as alleged by the Appellants. To the contrary, it conforms with one of the most fundamental notions of American jurisprudence - that a party must prove its claims. The fact that an administrative agency like the Authority is entitled to a degree of deference in matters within its area of expertise (like an appropriate service area) further supports the validity of its interpretation of the service area standard. This was in fact the holding in Dep't. of Community Health v. Gwinnett Hospital System, Inc., 586 S.E.2d 762 (Ga. 2003), in which the Georgia Court of Appeals held that the state agency is expert in this very complex field, and that its determination as to a proper service area is entitled to deference.

The Appellants argue that the SHP Standards constitute legislative rules, and that by virtue of their clear intention, no deference is due the Authority's interpretation of the service area standard. See, Appellants' Brief at pp. 13-15. This argument is incorrect for at least a couple of reasons. First, the Authority's interpretation of the service area standard **was consistent** with its plain language and clear intention. Hence, the issue of whether the Authority is due any deference upon appeal is superfluous.

Second, the SHP Standards do not constitute a legislative rule[11] as contended by the Appellants. This is because the SHP Standards were not promulgated by the Authority pursuant to Chapter 29A of the W. Va. Code, nor were they promulgated by specific authorization of the Legislature, all as required by W. Va. Code § 29A-1-2(d). Rather, the Legislature has by statute historically placed the authorship of that document into the hands of a succession of state agencies, including most recently the Authority, with a specific and unique set of procedures for notice, comment, and gubernatorial approval.[12] See, W. Va. Code

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[11]A legislative rule is defined as follows:

> (d) "Legislative rule" means every rule, as defined in subsection (i) of this section, proposed or promulgated by an agency pursuant to this chapter. Legislative rule includes every rule which, when promulgated after or pursuant to authorization of the legislature, has (1) the force of law, or (2) supplies a basis for the imposition of civil or criminal liability, or (3) grants or denies a specific benefit. Every rule which, when effective, is determinative on any issue affecting private rights, privileges, or interests is a legislative rule. Unless lawfully promulgated as an emergency rule, a legislative rule is only a proposal by the agency and has no legal force or effect until promulgated by specific authorization of the legislature. Except where otherwise specifically provided in this code, legislative rule does not include (A) findings or determinations of fact made or reported by an agency, including any such findings and determinations as are required to be made by any agency as a condition precedent to proposal of a rule to the legislature; (B) declaratory rulings issued by an agency pursuant to the provisions of section one [§ 29A-4-1], article four of this chapter; (C) orders, as defined in subdivision (e) of this section; or (D) executive orders or proclamations by the governor issued solely in the exercise of executive power, including executive orders issued in the event of a public disaster or emergency.

[12]This Court has never squarely addressed the degree of deference that is due the Authority in its interpretation of the SHP Standards. While this Court need not reach this issue in the instant appeal in order to affirm the Authority's interpretation of the plain language found in the service area standard, it is at least

(continued...)

§ 16-2D-5. This legislatively-mandated procedure for adopting and amending the State Health Plan is outside the scope of the rulemaking procedures found in Chapter 29.

Finally, the Appellants allege that the Authority acted improperly in holding them to the same service area standard applicable to hospitals. This standard, known as the 25/10 acute care study area,[13] is not a part of the General Standards contained in Article II of the SHP Standards, and could not have been applied to FMI without first amending those Standards according to the Appellants. See, Appellants' Brief at pp. 8-11. The WVHA agrees that it would have been improper for the Authority to impose the 25-10 acute care study area upon the Appellants, while not allowing them to adopt some other method of proof under Article II. The SHP Standards in Article II do not reference or incorporate the 25/10 acute care study area. The WVHA believes that the language contained therein is general enough to possibly allow use by an applicant of this particular methodology, but it certainly does not mandate it. An applicant is free to devise another means of delineating a service area for its diagnostic center, as long as it offers appropriate documentation.

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[12](...continued)
instructive to note that this Court appeared to apply a limited and deferential standard of review to the SHPDA's construction of the State Health Plan in Princeton v. Community Health v. SHPDA, supra at pp. 171-174.

[13]For acute care beds and services, the study area is the county of proposal and any adjacent county significantly impacted. A significantly impacted county is defined as: (i) a county wherein at least 25% of the residents rely on or will rely on the acute care services in the county of proposal; or (ii) a county which generates or will generate at least 10% of the patient load in the county of proposal. Princeton Community Hospital v. SHPDA, supra at p. 172.

Contrary to the assertions of the Appellant, it was **not** the holding of the Authority or the Office of Judges or the Circuit Court of Raleigh County that FMI had to rely upon the 25/10 acute care study area in its application. Their rulings were all based upon the lack of documentation offered by FMI to justify **any** service area. The service area standard applicable to FMI, albeit general, required at least some documentation or proof. The Authority merely used the 25/10 acute care study area as an example of a projection that is generally relied upon by professionals engaged in health planning or the development of health services. The fact that the 25/10 acute care study area for Raleigh County is much smaller than FMI's proposed six (6) county service area only reinforced the agency's conclusion that the FMI's service area lacked factual support.

It is not the position of the WVHA that the 25/10 acute care study area should be applied to all applicants seeking to develop diagnostic centers under the SHP Standards. Nor is it the position of the WVHA that a non-hospital applicant can never justify a study area that is larger than one defined by the 25/10 acute care study area. It may in fact be possible that, given the right circumstances and proper proof, an applicant for a diagnostic center could document a proposed service area that exceeds the 25/10 acute care study area for the same county of proposal. Rather, it is the WVHA's position that a standard based solely upon expectation or anecdotal evidence is not a standard at all. Even a general service area standard requires some threshold of proof from an applicant. Otherwise, the CON program falls out of balance, and its primary purpose is subverted. The WVHA respectfully submits that if we

are to have a CON program in West Virginia, it must be one that is administered with some modicum of substance for all applicants proposing the same or similar services.

2. The Authority's Determination That FMI's Service Area is Too Large Was Not Clearly Wrong in View of the Reliable, Probative, and Substantial Evidence on the Whole Record.

It has already been established that FMI stated its expectation to serve a large, six (6) county service area in its CON application. The size of a service area can be crucial, because it ultimately affects the determination of unmet need by impacting both the total population to be served, and the level of existing services. It generally behooves an applicant to include as many "underserved" counties as possible in order to boost the level of unmet need for its project. However, this desire by an applicant must be tempered with the need for rational health planning. If there is no reasonable, realistic expectation that a substantial number of persons will be served by an applicant in any given county, then an applicant should not be permitted to include it as part of its service area. A "gerrymandered" service area will only lead to an unnecessary duplication of services.

After stating its expectation to serve six (6) counties, FMI did nothing to document the reasonableness of that expectation. No statistical breakdown of the residences of either Dr. Poling's or Dr. Lofstetter's patients was offered. In fact, the Appellants refused to provide this data in response to discovery requests from Raleigh General Hospital. See, Exhibit 23. Upon cross-examination at the administrative hearing, Dr. Poling testified that he currently serves two (2) families from McDowell County, and "several" from Nicholas

County. See, Exhibit 31 at p. 19. However, it is clear from Dr. Poling's testimony that the vast majority of his patients reside in Raleigh and Fayette Counties:

> Q. How many of those patients are from Raleigh County?
>
> A. A ton.
>
> Q. The overwhelming majority of your patients are local patients?
>
> A. Well, I consider Raleigh County and Fayette County would be the two biggest areas.

See, Exhibit 31 at pp. 19-20. This type of anecdotal testimony is hardly substantial evidence of a six (6) county service area.

The applicant did file letters of support from six (6) different physicians. However, five (5) of those maintain practices in Beckley, and the sixth maintains a practice in Kanawha County, which is outside the proposed service area. See, Exhibits 7 and 23. Beyond this, the applicant offered no documentation of its proposed service area. Specifically, the record is devoid of any regional or national data showing how far patients can be expected to migrate for ultrasound services. It likewise lacks any projections or statistics that can generally be relied upon by health planning professionals. The Authority readily recognized this factual insufficiency in its Decision. The only logical conclusion to be drawn is that the Authority's finding in this regard was not clearly wrong in view of the reliable, probative, and substantial evidence on the whole record.

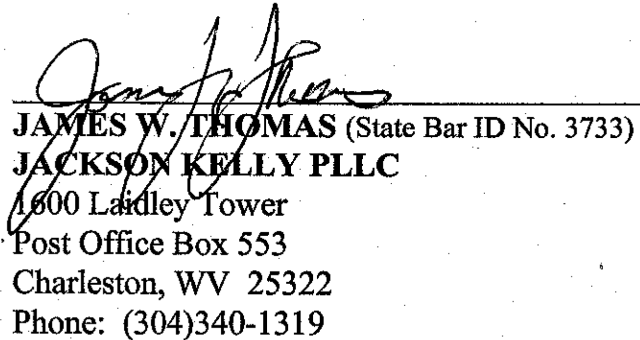
V. REQUESTED RELIEF

Based upon the foregoing discussion, the WVHA requests that this Honorable Court affirm the Decisions of the Authority and the Office of Judges, as well as the Order of the Circuit Court of Raleigh County.

Respectfully submitted this 9th day of May, 2005.

WEST VIRGINIA HOSPITAL ASSOCIATION

By Counsel



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CERTIFICATE OF SERVICE

I, James W. Thomas, counsel for the West Virginia Hospital Association, do hereby certify that a true and exact copy of the "*Amicus Curiae* Brief of the West Virginia Hospital Association" has been served by United States mail, postage pre-paid, this 9th day of May, 2005, to the following:

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