THE SUPREME COURT OF MISSISSIPPI

NO. 2009-SA-02020

MISSISSIPPI STATE DEPARTMENT OF HEALTH and DVA HEALTHCARE RENAL CARE, INC. — **APPELLANTS**

V.

BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. d/b/a SOUTH MISSISSIPPI KIDNEY CENTER – D'IBERVILLE and BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. d/b/a SOUTH MISSISSIPPI KIDNEY CENTER – BILOXI — **APPELLEES**

APPEAL FROM THE CHANCERY COURT OF HINDS COUNTY, MISSISSIPPI HON. DENISE OWENS, CHANCERY JUDGE

REPLY BRIEF OF APPELLANTS MISSISSIPPI STATE DEPARTMENT OF HEALTH AND DVA HEALTHCARE RENAL CARE, INC.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

ARGUMENT

I. THE DEPARTMENT OF HEALTH CORRECTLY INTERPRETED THE STATE HEALTH PLAN

A. The Department of Health Did Not Apply a Lesser Standard of Need.

In reviewing and analyzing DVA Healthcare Renal Care, Inc.'s ("DVA") Certificate of Need ("CON") application to reestablish its Oceans Springs Dialysis facility following Hurricane Katrina the staff of the Mississippi State Department of Health's Division of Health Planning and Resource Development (the "Staff"), the State Health Officer, and the Administrative Hearing Officer all concluded that the State Health Plan provision at issue, one that requires a showing of 80 percent utilization by certain existing ESRD facilities, does not apply. That provision, again, provides:

> Need Criterion: An applicant proposing the *establishment* of a limited care renal dialysis facility or the relocation of a *portion* of an existing ESRD facility's dialysis stations to another location shall demonstrate, subject to verification by the Mississippi Department of Health, that each individual existing ESRD facility in the proposed ESRD Facility Service Area has . . . maintained a minimum annual utilization rate of eighty (80) percent . . . .

Ex. 20; R.E. 361 (2007 State Health Plan, Ch. 13, Sect. 107.02.01) (emphasis supplied).

"Establishment of an ESRD facility" is a defined term under the State Health Plan, providing that a facility is established: "if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered." Ex. 20; R.E. 359 (State Health Plan, Ch. 13, Sect. 107.01(1)). While it is true that DVA's OSD facility was not operational for more than a year following Hurricane Katrina because of damage to its facility, DVA continued to be a provider of ESRD services to its OSD patients at its undamaged facilities in Pascagoula and Lucedale. Admin. Hrg. 258, 262-63. It is also undisputed that DVA did not relocate a "portion" of an existing facility (which would have the practical effect of establishing another facility). Therefore, DVA's CON application, by the

plain language of the State Health Plan, is not subject to this utilization criterion (the "80 Percent Criterion").

Appellees, subsidiaries of Fresenius Medical Care ("Fresenius"),[1] take issue with the policy behind the Plan as stated by the Department and DVA in their principal brief. Appellees' Br. at 24. Fortunately, this is a subject upon which the parties do not have to speculate:

> **107.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of End Stage Renal Disease (ESRD) Facilities**
>
> > 6. Need Threshold: For planning and CON purposes a need for an *additional ESRD facility* may exist when each individual operational ESRD station within a given ESRD Facility Service Area has maintained an annual utilization rate of 80 percent, i.e. an average of 749 dialyses per station per year.

Ex. 20; R.E. 360 (State Health Plan, Ch. 13, Sect. 107.01 (6)) (italicized emphasis supplied; bolded in original). DVA has not created an additional ESRD facility. After OSD's old building was finally repaired (many moths after the storm), DVA's landlord leased it to a church and retained only a small portion as a medical office. Admin. Hrg. 282-83, 298-99. No part of the building previously occupied by OSD is used an ESRD facility, and DVA has not increased its licensed hemodialysis capacity at its new facility. Admin. Hrg. 549-50.

In interpreting the 80 Percent Criterion when it considered DVA's CON application for OSD, the Department's Staff concluded:

> Although the Ocean Springs Dialysis facility has not offered ESRD services within the past 12 months, it is not considered a new facility in the service area. The former OSD was taken out of service due to circumstances beyond the applicant's control. Also, all facilities within the service area co-existed prior to Hurricane Katrina in 2005; therefore, criteria contained in the State Health Plan for the establishment of an ESRD facility were not given consideration in this staff analysis.

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[1] Both contesting ESRD facilities are operated by Bio-Medical Applications of Mississippi, Inc., a subsidiary of Fresenius Medical Care. Admin. Hrg. 588-90.

Ex. 3; R.E. 254 (OSD Staff Analysis, p. 3).[2] The independent Administrative Hearing Officer agreed with the Staff's conclusion, finding that "the 80 percent need threshold is intended to prevent 'additional' ESRD facilities within 30 miles of existing facilities that already may be underutilized." Ex. 2; R.E. 210 (Hearing Officer's Findings, p. 16) (citing State Health Plan, Ch. 13, Sect. 107.01(6)). The State Health Officer concurred with and adopted the Hearing Officer's findings. Ex. 2; R.E. 245, 248-51.

The Department's interpretation of the 80 Percent Criterion does not equate with the imposition of a "lesser standard of need," as Fresenius argues, but only the reasonable interpretation by the agency of its own regulations. Appellees' Br. at 22. As such, the agency's finding should be upheld, "unless it is so plainly erroneous or so inconsistent with either the underlying regulation or statute as to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." *Miss. State Dep't. of Health v. Baptist Mem'l. Hosp. – DeSoto,* 984 So. 2d 967, 981 (¶28) (Miss. 2008) (emphasis supplied) (quoting *Buelow v. Glidewell,* 757 So. 2d 216, 219 (Miss. 2000)).

Fresenius' attempt to characterize the Department's decision as the imposition of a lesser standard of need is based upon its reading of the Supreme Court's decision in *St. Dominic-Jackson Mem'l Hosp. v. Miss. State Dep't of Health*, 728 So.2d 81 (Miss. 1998). Appellees' Br. at 14-15. However, in *St. Dominic* this Court found that there was no

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[2] As shown previously, this finding was almost identical to the one rendered shortly thereafter for Fresenius:

> Although the South Mississippi Kidney Center-Bay St. Louis facility has not offered ESRD services within the past 12 months, it is not considered a new facility in the service area. The former SMKC facility was taken out of service due to circumstances beyond the applicant's control. Also, all facilities within the service area co-existed prior to Hurricane Katrina in 2005; therefore, criteria contained in the State Health Plan for the establishment of an ESRD facility were not given consideration in this staff analysis.

Ex. 78; R.E. 438 (Fresenius Staff Analysis, February 2007, p. 3).

demonstrated need for the hospital beds at issue and that the Department had avoided the issue by labeling the project as a relocation:

> This Court is faced with evidence in the record that new hospitals were not needed and were not even being proposed in Jackson. In this context, we would question a proposal which sought to build what is, for all practical purposes, a new hospital in an affluent part of Jackson under the guise of a "relocation."

St. Dominic, 728 So.2d at 89(¶31). The present situation is quite different.

Unlike the new hospital proposed in *St. Dominic* which merely transferred unused beds at one hospital campus to another, leaving the old campus intact,[3] OSD exists in only a single location. Another important fact that separates the present case from the *St. Dominic* decision is that there is no dispute that the CON applicant in the present case, DVA, sustained its burden to show that its facility satisfied the applicable CON standards. As shown below, both the State Health Officer and the Chancery Court found that DVA's CON application satisfied not only the four General Certificate of Need Policies of the State Health Plan, but also the General Review Criteria of the Department's CON Review Manual.

One of the key findings in *St. Dominic* was that the applicant was attempting to construct a hospital to reach a more economically affluent population. *St. Dominic*, 728 So.2d at 84(¶10). Nothing like that has occurred in the case of OSD; this healthcare facility continues to satisfy the critical needs of traditionally underserved populations, including low income individuals and minorities. Ex. 9 (CON Rev. Man., Ch. 8, Sect. 5.a.); R.E. 337. The Chancery Court found there was a significant need for the OSD project among these groups:

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[3] *St. Dominic*, 728 So.2d at 85(¶13) ("There was no corresponding decrease in services at the main hospital in south Jackson, and, although the North Campus facility lacks an emergency room, the facility is, for all practical purposes, a new hospital.").

> As the SHO [State Health Officer] contends, there is no question that ESRD facilities serve seriously ill patients. In addition, ESRD facilities also serve large minority populations and the elderly. . . . This Court agrees with the SHO's assessment that there is substantial evidence to demonstrate that the population served has significant need for DVA's new healthcare facility.

R. 197; R.E. 13 (Opinion and Order, p. 10).

Frankly, it is difficult to understand just why Fresenius continues to contest DVA's application. Fresenius claimed at the administrative hearing that the reason it had challenged the DVA application was because the company's two closest facilities, located in D'Iberville and Biloxi (and only four miles apart), had been adversely affected by the OSD relocation. Admin. Hrg. 592. As shown in DVA's principal brief, Fresenius' own data does not support this claim. *See* Appellants' Br. at 14-16. Again, Fresenius has not contested these facts or data in its brief.

Instead of challenging what now must be considered established facts, Fresenius argues: "With any luck, this will be the last time this Court has to explain to the Department that the law does not allow the Department to apply a lessened standard of need for a 'relocation' in contradiction of the State Health Plan." Appellees' Br. at 10. This argument is particularly troubling when it is undisputed that Fresenius urged the Department of Health to adopt this very same interpretation of the 80 Percent Criterion in its own CON application filed to relocate its Bay St. Louis ESRD facility to Diamondhead, less than a month after DVA filed its OSD application – another fact not contested by Appellee in its brief. Fresenius, in conformity with the Department's conclusion it now challenges, claimed in its own CON application that the 80 Percent Criterion did not apply because the company already had CON authority to operate its Bay St. Louis facility, and therefore, its application was "not for the establishment or provision

of ESRD services."[4] Ex. 77, p. 11 (emphasis supplied) (response to questions 2-3); R.E. 420; *see also* R.E. 422 (application at p. 13 -same response).

B. The Department of Health Correctly Analyzed the DVA Application Under the Overall Goals of the State Health Plan and the CON Regulations.

The State Health Plan provision at issue, as stated previously, provides that the "establishment" or relocation of a "portion" of a facility requires the applicant to show that "each individual existing ESRD facility in the proposed ESRD Facility Service Area has . . . maintained a minimum annual utilization rate of eighty (80) percent . . . ." Ex. 20; R.E. 361 (State Health Plan, Ch. 13, Sect. 107.02.01). Fresenius interprets this provision to mean that, in essence, each facility's 30-mile service area is a "bubble" that moves with it. Appellees' Br. at 25. Moving, even *away* from existing facilities, moves the bubble and requires a showing that all existing facilities in the bubble be at an 80 percent utilization rate. *Id.*

What Fresenius fails to explain is how this "bubble" theory makes any sense when the applicant facility and the existing facilities have long existed within the same area of overlapping service areas ("bubbles," if you will) and when the operator of the existing facilities can manipulate facility utilization rates at will. Fresenius' only response is: "Well, yes, that is what the State Health Plan says." Appellees' Br. at 19.

Fresenius' argument ignores the fact that the State Health Plan was written by the Department of Health. *See* Miss. Code Ann. § 41-7-185(g). And while the agency is not allowed to interpret its provisions in an arbitrary or capricious manner, the Department is rightly given the authority to interpret its regulations "to *avoid* arbitrary and capricious results." *Biloxi*

[4] "As the Applicant, prior to Hurricane Katrina, had CON authority to operate 16 ESRD stations in the ESRD Service Area, and as this Application is seeking a CON for an already approved emergency CON, the Application is not for the establishment or provision of ESRD services. Therefore, the State Health Plan's service-specific criteria and policy statements do not apply to the Application." Ex. 77, p. 11 (emphasis supplied) (response to questions 2-3); R.E. 420.

HMA v. Singing River Hosp., 743 So.2d 979, 984(¶29) (Miss. 1999) (emphasis supplied). While Fresenius is free to urge the adoption of its novel bubble theory, the Department's responsibility is to interpret and enforce its regulations in a manner that avoids contrived results and carries out the goals of the CON laws.

The 2007 State Health Plan states that there are four principal policies that underlie the CON process:

- To prevent unnecessary duplication of health resources;
- To provide cost containment;
- To improve the health of Mississippi residents; and
- To increase the accessibility, acceptability, continuity, and quality of health services.

State Health Plan, Ch. 1, Sect. 102. While all of the stated policies are important, cost containment and the prevention of unnecessary duplication of health resources are the primary purposes and shall be given primary emphasis in the Certificate of Need process." *Id.; see also St. Dominic Jackson Mem'l Hosp. v. Miss. State Dep't. of Health*, 954 So. 2d 505, 509(¶ 8) (Miss. 2007).

Don Eicher, the Director of the Office of Health Policy and Planning of the Department of Health, testified that the OSD project satisfies the general goals of the State Health Plan. Admin. Hrg. 58-63. The Administrative Hearing Officer *and* the Chancery Court both agreed. R.E. 11, 231-34. A review of the record confirms they were right in reaching this conclusion.

1. Prevention of Unnecessary Duplication of Health Resources

OSD operated within the facility service areas for Fresenius' Biloxi and D'Iberville facilities both before and after its relocation. Admin. Hrg. 59, 885. The building where OSD was once located is not being used as an ESRD facility, neither has DVA increased its licensed

hemodialysis capacity at its new facility.[5] Admin. Hrg, 549-50. Therefore, the re-establishment and relocation of OSD has not resulted in the "unnecessary duplication" of health resources. State Health Plan, Ch. 1, Sect. 102.

Despite Fresenius' medical director's testimony that it would be a "violation of the healthcare code" and threaten the "integrity of the healthcare system" to allow an ESRD facility to operate four miles from another, Dr. Douglas Lanier had to admit on cross exam that Fresenius' Biloxi and D'Iberville facilities already operate within four miles of each other. Admin. Hrg. 807. In addition, after OSD reopened Fresenius converted its D'Iberville unit from a trailer ("modular unit") to a permanent structure and increased its capacity by 50% (from eight stations to twelve). Admin. Hrg. 616; Ex. 66. Any duplication of ESRD services post-Katrina in this particular area was caused by Fresenius, not DVA.

2. Cost Containment

DVA's construction expert, Mel Ulmer, testified that construction costs for this project were comparable to other ESRD facilities constructed at that time. Admin. Hrg. 357-58. Fresenius produced no expert testimony that DVA could have renovated its damaged Marks Road building for less money. Mr. Ulmer, on the other hand, testified that based on his extensive experience in the renovation and construction of ESRD facilities the cost to fully repair and renovate the Marks Road building would have been comparable to DVA's construction costs for the Ponce DeLeon building.[6] Admin. Hrg. 369, 404.

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[5] A letter from DVA to the Division of Licensure indicates that the Marks Road location was authorized for 20 stations. Ex. 52. The facility administrator testified that the facility was authorized for 16 or more stations at its old location, but was only able to operate 12 because of space limitations. Admin. Hrg. 549-50. The facility currently operates 16 stations. *Id.*

[6] DVA's application indicates that the company's share of construction costs was $700,000. R.E. 160; (DVA CON App. at Table 1); R.E. 257 (Staff Analysis at p. 6). This sum is comparable to the projected cost to renovate the interior of the Marks Road building, estimated by Mr. Ulmer at a range of $110 to $130 per square foot. Admin. Hrg. 369. For a 6,000 square foot building, the total square footage of the Marks Road building, the renovation cost would have been $660,000 to $780,000. Admin. Hrg. 404.

There is no proof in the record that DVA's construction costs have adversely affected healthcare costs at OSD or in the region. ESRD reimbursement rates, for the most part, are set by Medicare and Medicaid.[7] Admin. Hrg. 243, 285, 413-17, 501-02, 554-55. Fresenius' medical director even went so far as to call ESRD treatment "socialized medicine," because of government price controls. Admin. Hrg. 816. The record shows that the OSD project complies with the State Health Plan's cost containment policy.

3. Improvement of Health of Mississippi Residents and Increase in Accessibility, Adaptability, Continuity and Quality of Health Services

The last two State Health Plan policies are closely related. CON applications must demonstrate to the satisfaction of the State Health Officer that the project will make healthcare more accessible in a way that improves the health of Mississippi residents.

The relocated OSD facility represents a substantial improvement over the old Marks Road structure in terms of space, location, handicapped access, and patient comfort for the individuals it serves. Admin. Hrg. 277-80, 350-52, 495-500. OSD's medical director testified that he believes the new building will improve patient health and assist with continuity of care. Admin. Hrg. 287, 932-33. Highway access is better at the new site. Admin. Hrg. 272, 500. No patients have complained in any way about the new location. Admin. Hrg. 272. By all accounts, DVA's patients are happier with their new surroundings. Admin. Hrg. 932.

Mr. Ulmer testified that the new site was a "definite advantage" in terms of survivability in a future hurricane. Admin. Hrg. 378. Even Fresenius' witnesses, Mr. Sullivan and Dr. Lanier, agreed that this is a legitimate reason to relocate a healthcare facility. Admin. Hrg. 812, 895. Considering the significant disruption of ESRD services along the Mississippi Gulf Coast following Hurricane Katrina, OSD's location should help this facility contribute to the continuity

[7] DVA's most recent figures for OSD show that these payors represent 88% of all reimbursements. Admin. Hrg. 416-17; Ex. 44.

of care for ESRD patients in future disasters. Therefore, the OSD project is in substantial compliance with these State Health Plan policies.

4. Indigent Care

The State Health Plan also requires applicants to provide a "reasonable amount of indigent care." 2007 State Health Plan, Ch. 1, Sect. 102. As shown previously, most ESRD patients qualify for Medicare or Medicaid. Admin. 243, 285, 413-17, 501-502, 554-55. DVA's most recent figures for Ocean Springs Dialysis show that these payors represent 88% of all reimbursements. Admin. 416-17; Ex. 44.

OSD's facility administrator, Yvette Smith, testified that government-payor coverage is so prevalent that she had difficulty remembering if any patient had ever truly been unable to afford dialysis. In her ten years as facility manager for OSD she could only recall two such patients. Admin. Hrg. 501-02, 521-23. Ms. Smith also affirmed that DVA treats all patients regardless of ability to pay: "To the best of my knowledge, we've never turned a patient away for anything." Admin. Hrg. 501. The testimony and evidence introduced at the hearing established that DVA, considering the need at this facility, provides a substantial amount of indigent care.

The Chancery Court also found that DVA's application satisfied the General Review Criteria of the Department's CON Review Manual. R. 196-199; R.E. 12-15 (Opinion and Order, pp. 9-12); *see also* R.E. 298-304 (Certificate of Need Review Manual, Ch. 8, Criteria Used by State Department of Health for Evaluation of Projects). In particular, the Chancery Court found:

1. the new building is a "more effective alternative" to the old location (R.E. 12);
2. the population "has a significant need for DVA's new healthcare facility" (R.E. 13);
3. OSD's facility is an "enhancement to the level of care" in the service area (R.E. 13);
4. "the relocation had no negative effect on the provision of ESRD services in this area" (R.E. 13);

5. "access to and at the facility is better than DVA's old location" (R.E. 14);

6. "impact on existing providers has been and is minimal" (R.E. 14);

7. the new construction maximized cost containment because the facility is "100% accommodating" (R.E. 15); and

8. there was no proof in the record that there was any deficiency in the quality of care at the new facility (R.E. 15).

R. 196-199; R.E. 12-15 (Opinion and Order, pp. 9-12).[8]

The Department's and Chancery Court's conclusion that the general policies of the State Health Plan and the General Review Criteria of the CON Review Manual have been satisfied is supported by substantial evidence, is not contrary to the manifest weight of the evidence, is not in excess of the statutory authority or jurisdiction of the MSDH, and did not violate any vested constitutional rights of any party involved in the appeal.

II. THE DEPARTMENT'S DECISION TO GRANT DVA AN EMERGENCY CON WAS NOT ARBITRARY OR CAPRICIOUS

DVA demonstrated in its principal brief that the Emergency CON granted to DVA by the Department of Health was not properly before the Chancery Court. *See* Appellants' Br. at 31-34. Fresenius' challenge is limited to a determination of whether DVA's "subsequent application" substantially complies with plans, standards, and criteria prescribed for such projects by the governing legislation, by the State Health Plan, and the adopted rules and regulations of the Department. Ex. 8 (CON Review Manual, Ch. 3, Sect. 111.01); R.E. 276.

Should the Court decide to consider the merits of the Chancery Court's decision related to the Emergency CON it is clear that the State Health Officer's decision in this regard was not arbitrary or capricious and was supported by substantial evidence.

[8] These are the only General Review Criteria Fresenius raised in its appeal to the Chancery Court. *See* R. 41-51.

Admin. Hrg. 456-57. Fresenius' area manager, Jane McDonnell, agreed with Ms. Smith's assessment. Admin. Hrg. 755-56.[9]

Despite the damage to OSD, DVA did everything possible to make sure its patients received the life-saving care they needed. DVA's employees recommended that evacuees stay put if they were able to receive dialysis out of the storm-affected area. Admin. Hrg. 471. They also attempted to place patients at Fresenius facilities in the area. Admin. Hrg. 519-20. DVA shifted its staff to the company's two other two facilities, located in Pascagoula and Lucedale, and offered dialysis to its OSD patients at these locations. Admin. Hrg. 258, 262-63.

Fresenius argues that since there was no proof that any of DVA's patients failed to receive dialysis then there was no emergency. Appellees' Br. at 31. Fortunately, patients do not have to die before the Department can consider a situation deserving of emergency procedures. Instead, all that is required is that "unforeseen or unpredictable events . . . *may* jeopardize the health and/or safety of the patients . . . ." Ex. 8 (CON Rev. Man., Ch. 3, Sect. 111.01 (emphasis supplied)); R.E. 275-76. OSD's patients experienced significant travel issues and long delays in treatment because of the loss of the OSD facility. Admin. Hrg. 464-70. Steve Egger, an employee of the Department's Division of Licensure who was heavily involved in post-Katrina operations, emphatically agreed that the safety of the ESRD population was jeopardized by these conditions post storm: "Yes, sir. Yes, sir, it did. Yes, sir." Admin. Hrg. 657. Even Fresenius'

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[9] Q. Okay. How would you characterize ESRD patients?
A. I would say that they are patients who have been diagnosed with end stage renal disease. And because I believe that there is more offering now as opposed to 20 years ago to — even an age group of patients, we've had patients that are 90 years old or better. Yes, I believe that some patients are sicker because they're older and have more debilitating processes that go along with it, more comorbid conditions that we must deal with.
Q. In any event, wouldn't you agree with me that these are very serious medical conditions? Without the services you provide, they would die?
A. Without the dialysis, yes, they could die.
Admin. Hrg. 755-56.

medical director agreed that travel three times a week for these critically-ill patients could affect their treatment. Admin. Hrg. 813.[10]

Fresenius also argues that there was no emergency a year after the storm because a number of its facilities in Harrison County reopened (in time periods varying from one week to nine months) and had the capacity to treat these patients. Appellees' Br. 31-21. This argument assumes that DVA had the right to tell patients where they would dialyze. As Fresenius' medical director agreed, where patient dialyze is up to them. Admin. Hrg. 814. For those who *chose* to remain DVA's patients there was no DVA facility for them to be treated at except for those located at Lucedale and Pascagoula.

Fresenius' argument is also directly contradicted by a letter sent by a group of Fresenius' medical directors to the Department one year after the storm, on August 25, 2006, to support their own Emergency CON application for the relocation of their damaged Bay St. Louis facility (discussed *infra*). The letter states, in part: "It is a great inconvenience for these patients, and the *Harrison County facilities are now becoming extremely crowded.*" Admin. Hrg. 806; Ex. 69; R.E. 407 (emphasis supplied).[11]

B. OSD did not begin operations until after it received an Emergency CON.

The Chancery Court found that DVA's regular CON was approved "after the new facility opened." R. 199 (Order and Opinion of the Court at 12); R.E. 15. The lower court also

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[10] Q. Do you -- how does transportation figure into the treatment of dialysis patients? Is it a factor at all as to how often or how far they travel to a dialysis center?
A. Transportation can affect the -- the -- the dialysis services.
Q. And that's because these patients are very ill. Wouldn't you agree with me?
A. I agree with you on that.
Q. This is lifesaving care, isn't it?
A. Correct.
Admin. Hrg. 813.

[11] The Court can take judicial notice of the fact that Biloxi and D'Iberville are both located in Harrison County.

determined that DVA "began providing services . . . without obtaining a CON." *Id.* at 13 (R. 200; R.E. 16). Both of these conclusions are incorrect.

DVA's Emergency CON was issued on October 6, 2006. Ex. 7; R.E. 49-52. The administrative record clearly shows that DVA did *not* provide any ESRD services at the new OSD building until *after* the emergency CON was granted and *until* authorized by the Department. Admin. Hrg. 482-87, 527; Exs. 7, 52. DVA began trial dialysis procedures under the supervision of the Department's Division of Licensure. Admin. Hrg. 527; Ex. 52. The Department inspected the facility a number of times during its start-up phase and approved the commencement of operations in November of 2006. Admin. Hrg. 527. The federal agency that oversees Medicare and Medicaid, the Centers for Medicare and Medicaid Services (CMS), formally certified the relocated OSD on December 18, 2006. Admin. Hrg. 487-89; Exs. 53, 54.

The Department's Division of Licensure certifies that healthcare facilities have met all state requirements, including a valid CON, before beginning operations. Admin. Hrg. 659. An employee of the Division testified that his office inspected OSD and determined it had a valid CON *before* DVA was allowed to begin operations. Admin. Hrg. 660-62.

Therefore, whether DVA should have filed its Emergency CON application sooner became a moot point when operations were approved by the Department. The record clearly shows that DVA did not provide any ESRD services until authorized.

Further, Fresenius' complaints about the continued operation of OSD must be weighed against the fact that it waited over 18 months after it filed its challenge before it finally requested a hearing date. Even after Fresenius demanded that the Department close OSD (in April of 2007), it waited more than a year (September 24, 2008) before attempting to set a hearing. Ex. 2; R.E. 184.

C. Emergency CON regulations allow for the replacement of a facility.

The Chancery Court also found that the Emergency CON statute, Miss. Code Ann. § 41-7-207, only provides for the replacement of "partial" facilities or equipment. R. 200 (Order and Opinion at 13); R.E. 16. However, the final line of this code section clearly contemplates replacement of whole facilities if justified by an emergency: "Expenditures under this section shall be limited to the *replacement of those necessary facilities or equipment*, the loss of which constitutes an emergency." Miss. Code Ann. § 41-7-207 (emphasis supplied).

In addition, the Legislature specifically authorized the Department to promulgate its own rules with regard to certificates of need. Miss. Code Ann. § 41-7-185(c) (Department has power to "[p]rescribe and promulgate such reasonable rules and regulations as may be necessary to the implementation of the purposes of Section 41-7-171, et seq. . . ."); *see also* Miss. Code Ann. § 41-7-173 (b) (definition of CON includes finding proposal complies with statutes "and by rules and regulations promulgated thereunder by the State Department of Health.").

The Department has promulgated its own regulation pertaining to Emergency CONs. The agency's regulation does not limit emergency replacements to partial facilities, instead authorizing the "replacement of or repair to equipment or facility. . . ." Ex. 8 (CON Rev. Man., Ch. 3, Sect. 111.01); R.E. 275.

D. Fresenius' Change of Position - Again.

Fresenius argues: "Neither the statute nor the regulations promulgated under its authority contemplate 'relocation' or replacement of an entire healthcare facility." Appellees' Br. at 29. Fresenius' Vice President confirmed in the hearing that this was his company's position:

> Q. Okay. Are you taking the position that, and you've heard the arguments of your counsel, that the emergency CON law doesn't allow relocations?
>
> A. Correct.

Admin. Hrg. 622.

However, once again, Fresenius' attempt to change its position on an important CON issue to suit its present purposes is on display. The record shows that the company filed an application for an Emergency CON on October 4, 2006 (also more than a year after Katrina), to relocate its hurricane-damaged Bay St. Louis facility to Diamondhead. Ex. 11; R.E. 346. Fresenius' emergency application plainly states: "The Applicant proposes to relocate its 16 End Stage Renal Dialysis ("ESRD") stations from its destroyed facility in Bay St. Louis to Diamondhead." Ex. 11 (Application, p. 3); R.E. 351. Like Fresenius' regular CON application, the contact person listed on the emergency filing is Jeff McPherson. *Id.* at p. 1. When asked about this obvious inconsistency at the OSD hearing, Fresenius' Vice President was forced to admit his company's change of position:

> Q. That as a matter of fact on October 26th, 2006, you filed on behalf of your company, or it was filed on behalf of your company, a request to the Department of Health to relocate under the emergency CON statutes?
>
> A. They filed that in my behalf.

Admin. Hrg. 622.

Fresenius should be prevented from taking the position that the Emergency CON laws do not allow the Department to approve a relocation - only now to change its position "when it becomes more convenient or profitable" to do so. *Scott v. Gammons*, 985 So. 2d 872, 877(¶18) (Miss. Ct. App. 2008). As it did with DVA's emergency filing, the Department of Health approved Fresenius' emergency application. Ex. 10; R.E. 344.

Neither the emergency replacement statute nor the Department's regulations specify whether a replaced facility can be relocated. In the absence of clear statutory direction the agency's reasonable interpretation of its own rules is entitled to "great deference" and courts must not substitute their judgment for the agency's unless the latter's interpretation is arbitrary or unreasonable. *Elec. Data Sys. Corp. v. Miss. Div. of Medicaid,* 853 So. 2d 1192, 1202 (Miss.

2003). Further, the Department's consistent application of the emergency replacement laws, allowing both Fresenius and DVA to relocate their damaged ESRD facilities, is further proof that its actions were not arbitrary or capricious.

III. THE DEPARTMENT HAS THE AUTHORITY AND DISCRETION TO ENFORCE THE CON LAWS TO ACHIEVE THE OVERALL POLICIES OF THE STATE HEALTH PLAN

Fresenius contends that DVA did not have the authority to begin construction of the new OSD building before obtaining a certificate of need.[12] [13] Appellees' Br. at 32. As shown previously, the OSD facility did not provide any ESRD services until *after* the emergency CON was granted and *until* authorized by the Department. Admin. Hrg. 482-87, 527, 660-62; Exs. 7, 52.

Fresenius accuses DVA of attempting to purposefully circumvent the CON laws. In using language that surely approaches the limits of that allowed by M.R.A.P. 28(k), Fresenius even goes so far as to criticize the Supreme Court's stay that currently allows OSD to remain

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[12] Miss. Code Ann. § 41-7-191(1) provides that no one may engage in the following activities without obtaining a certificate of need: (a) The construction, development or other establishment of a new health care facility . . .; (b) The relocation of a health care facility or portion thereof, or major medical equipment, unless such relocation of a health care facility or portion thereof, or major medical equipment, which does not involve a capital expenditure by or on behalf of a health care facility, is within five thousand two hundred eighty (5,280) feet from the main entrance of the health care facility . . .; (e) The relocation of one or more health services from one physical facility or site to another physical facility or site, unless such relocation, which does not involve a capital expenditure by or on behalf of a health care facility, (i) is to a physical facility or site within five thousand two hundred eighty (5,280) feet from the main entrance of the health care facility where the health care service is located . . . ; (j) Any capital expenditure or deferred capital expenditure by or on behalf of a health care facility not covered by paragraphs (a) through (h) . . . . *See also* Ex. 8 (CON Review Manual, Ch. 2). "Relocation" is not defined in the State Health Plan or in statute. *St. Dominic,* 728 So.2d at 84(¶12).

[13] Fresenius' broad interpretation of the CON laws to strictly prohibit "*any* financial arrangement" belies the fact that it entered into a lease for the new location for its Diamondhead ESRD facility in August of 2006, some two months before it even applied for an Emergency CON to relocate its damaged Bay St. Louis facility. R. 56 (emphasis in original); Ex. 67. Fresenius' Vice President attempted to qualify the significance of this fact by contending that his lease did not "start" until a CON was awarded. Admin. Hrg. 626. Even if true, an executed lease, by any stretch of the imagination, would still be a "financial arrangement."

open,[14] which it contends allows DVA "to get away with it." Appellees' Br. at 24.

It is abundantly clear from the record in this case that the Department of Health attempted to give reasonable interpretations to the applicable CON regulations and statutes in a very difficult and challenging situation. There is no dispute that the conditions faced by the Department of Health and all those adversely affected by Hurricane Katrina were extreme and called for the State Health Officer to carry out his duties in a manner that gave reasonable effect to the CON laws, while also allowing critical healthcare facilities on the Mississippi Gulf Coast to be rebuilt as soon as possible. Fresenius, DVA, and more importantly - their patients, benefitted from the Department's efforts to restore the existing ESRD facilities on the Coast as quickly as possible. Fresenius cannot point to the slightest trace of evidence that would support its blustery accusation that DVA had any ulterior motives in taking the actions it took with regard to OSD.

Fresenius argues that DVA used Hurricane Katrina as a "convenient excuse" to utilize the Emergency CON regulations. Appellees' Br. at 28. Considering the fact that Fresenius interpreted not only the emergency regulations, but also the regular CON standards in the same manner as the Department of Health and DVA, it is abundantly clear that it is Fresenius who is attempting to use the unfortunate effects of a devastating hurricane as a convenient excuse to attempt to enhance its competitive position.

Whether DVA violated the applicable CON regulations or statutes by beginning construction before receiving formal approval from the Department is a subject entirely within the jurisdiction of the Department of Health to resolve. Miss. Code Ann. § 41-7-209 gives the State Health Officer the exclusive authority to determine whether CON laws have been

[14] The Supreme Court entered an Order on February 22, 2010, granting DVA's Motion to Stay Pending Appeal.

violated.[15] Unlike the regular CON laws, this statute contains no right of challenge by an affected party, no public hearing, and no review by a hearing officer. *Id.* Therefore, whether DVA should have obtained a CON at an earlier stage is a regulatory matter left to the sound discretion of the State Health Officer, subject to review by this Court under the abuse of discretion standard, previously cited.

IV. FRESENIUS' CHANGES OF POSITION ARE ENTIRELY RELEVANT

Before addressing Fresenius' last argument it is important to note that it has not contested two very important facts: (1) Fresenius filed a sworn Emergency CON application to relocate an entire ESRD facility on the Gulf Coast more than a year after Hurricane Katrina – and was awarded an Emergency CON; and (2) Fresenius filed a sworn CON application in which it claimed that the 80 Percent Criterion did not apply – and was awarded a permanent CON on that basis.

Fresenius contends that the doctrine of judicial estoppel is not applicable in this case because it does not apply to positions taken in regard to interpretations of law. Appellees' Br. at 39. First, it must be noted that both of Fresnius' CON applications were sworn documents. *See* Exs. 11 (Fresenius Emergency CON), 77 (Permanent CON Application). The permanent CON application containing Fresenius' statement that the 80 Percent Criterion does not apply - even when moving 14 miles to another town - was submitted by the same company officer who testified in DVA's CON hearing that it had always been his company's position that the 80 Percent Criterion applied when moving

[15] "Any person or entity violating the provisions of *Sections 41-7-171 through 41-7-209, or regulations promulgated thereunder, by not obtaining a certificate of need,* by deviating from the provisions of a certificate of need, or by refusing or failing to cooperate with the State Department of Health in its exercise or execution of its functions, responsibilities and powers shall be subject to the following . . . ." Miss. Code Ann. § 41-7-209(1) (emphasis supplied).

an ESRD facility.[16] Ex. 77, p. 11 (response to questions 2-3); R.E. 420; Admin. Hrg. 710 ("The position I've always worked off of as within -- every unit in a service area has to be 80 percent utilized before a new dialysis facility can be established.").[17]

Second, it is not true that the doctrine of judicial estoppel applies only to assertions of fact. As this Court has stated:

> Judicial estoppel is a doctrine of law applied by a trial court to a situation where a party asserts one *position* in a prior action or pleading but then seeks to take a contrary *position* to the detriment of the party opposite. As we have stated: [T]he doctrine 'is based on expedition of litigation between the same parties by requiring orderliness and regularity in pleadings.'

City of Horn Lake v. City of Southaven, 864 So.2d 912, 918-919 (¶17) (Miss. 2004) (emphasis supplied) (citations omitted).

The Administrative Hearing Officer's admonition relied upon by Fresenius, to not offer evidence from "pending or yet to be offered" applications that are "not relevant," obviously has no application here. Appellees' Br. at 37 (citing CON Rev. Manual at 45). Neither Fresenius application was pending at the time of the DVA hearing. R.E. 344, 436 (both staff analyses were rendered in 2006 and not challenged). And neither can there be any doubt that the Fresenius applications are relevant. Both DVA's and Fresenius' CON applications were filed near in time, in the aftermath of Katrina, for the same type of healthcare facilities, to be constructed within a few miles of each other.

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[16] "As the Applicant, prior to Hurricane Katrina, had CON authority to operate 16 ESRD stations in the ESRD Service Area, and as this Application is seeking a CON for an already approved emergency CON, the Application is not for the establishment or provision of ESRD services. Therefore, the State Health Plan's service-specific criteria and policy statements do not apply to the Application." Ex. 77, p. 11 (emphasis supplied) (response to questions 2-3); R.E. 420; see also application at p. 13 (same response); R.E. 422.

[17] The old Fresenius facility was located in Bay St. Louis while the new one was constructed in the Diamondhead community, 14 miles away. Ex. 77; R.E. 413 (CON App. at p.6). Apparently the ESRD "bubble" theory espoused by Fresenius is of recent origin. Appellees' Br. at 25.

As Fresenius acknowledges in its own brief, circumstances related to how other CON applications are handled by the Department can certainly be relevant in CON contests. *See* Appellees' Br. at 14 (arguing the present case is similar to *St. Dominic* decision). In fact, in the case relied on by Fresenius this Court stated that it considered the testimony of an officer of the Department, with regard to another CON matter decided four years earlier, to be "particularly enlightening" with regard to the CON matter at hand. *St. Dominic – Jackson Mem'l Hosp.*, 728 So. 2d at 90(¶32) (emphasis supplied).

CONCLUSION

DVA's reconstruction of Ocean Springs Dialysis satisfies the General Policies of the State Health Plan and the General Review Criteria of the Department of Health's CON Review Manual. The reestablishment of a much improved facility in a safer and more accessible location is the kind of CON project the State Health Plan and the CON laws were designed to encourage.

It is also clear that the policy behind the State Health Plan's ESRD Need Methodology, requiring a showing that all facilities within a 30 mile area are at an 80 percent utilization rate, is to prevent additional facilities from being established too close to existing underutilized units. The reasonableness of the Department's interpretation of this provision, as expressed in the Staff Analysis for Ocean Springs Dialysis published almost four years ago, is still apparent:

> Although the Ocean Springs Dialysis facility has not offered ESRD services within the past 12 months, it is not considered a new facility in the service area. The former OSD facility was taken out of service due to circumstances beyond the applicant's control. Also, all facilities within the service area co-existed prior to Hurricane Katrina in 2005; therefore, criteria contained within the State Health Plan for the establishment of an ESRD facility were not given consideration in this staff analysis.

Ex. 3 (Staff Analysis, p. 3); R.E. 254. It is clear that the Department of Health's grant of a CON to DVA for Ocean Springs Dialysis was supported by substantial evidence, was not contrary to

the manifest weight of the evidence, and was not in excess of the statutory authority or jurisdiction of the Mississippi State Department of Health.

THIS the 17th day of November, 2010.

Respectfully submitted,

MISSISSIPPI STATE DEPARTMENT
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CERTIFICATE OF SERVICE

I, Mark W. Garriga, do hereby certify that a true and correct copy of the above and foregoing Reply Brief of Appellants was this day served by U. S. Mail, first class, postage pre-paid, upon the following:

The Honorable Denise Owens
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SO CERTIFIED, this the 17th day of November, 2010.

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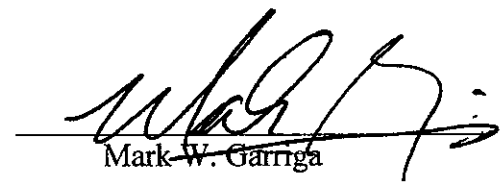
CERTIFICATE OF FILING

I, Mark W. Garriga, certify that I have had hand-delivered the original and three copies of the Reply Brief of Appellants Mississippi State Department of Health and DVA Healthcare Renal Care, Inc. and an electronic diskette containing same on November 17, 2010, addressed to Ms. Kathy Gillis, Clerk, Supreme Court of Mississippi, 450 High Street, Jackson, Mississippi 39201.



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