

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**

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

ORAL ARGUMENT REQUESTED

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APPELLEES

CERTIFICATE OF INTERESTED PERSONS

The undersigned Counsel of Record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the Justices of the Supreme Court and/or the Judges of the Court of Appeals may evaluate possible disqualification or recusal.

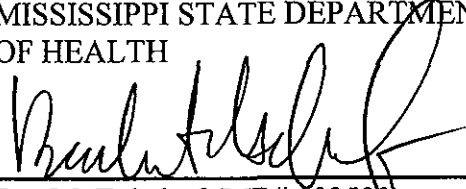
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5. Andy Lowry, Counsel for Appellees
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SO CERTIFIED, this the 21st day of June, 2010.

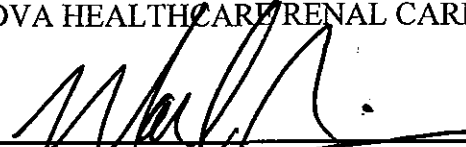
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TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PERSONS	i
TABLE OF AUTHORITIES	i
INTRODUCTION	1
STATEMENT OF ISSUES	2
STATEMENT OF THE CASE.....	3
Course of Proceedings	3
Statement of Facts.....	7
SUMMARY OF ARGUMENT	17
ARGUMENT	18
I. DVA’S REESTABLISHMENT OF ITS DAMAGED OCEAN SPRINGS DIALYSIS FACILITY WAS NOT THE “ESTABLISHMENT” OF A “NEW” ESRD FACILITY WITHIN THE MEANING OF THE STATE HEALTH PLAN	18
a. Standard of Review.....	18
b. The State Health Officer’s Order Was Supported by Substantial Evidence, Was Not Contrary to the Manifest Weight of the Evidence, Was Not In Excess of the Statutory Authority or Jurisdiction of the Department, and Did Not Violate Any Vested Constitutional Rights of Any Party Involved in the Appeal	19
c. The Department’s Identical Treatment of Fresenius’ Post-Katrina CON Application to Relocate One of Its ESRD Facilities Is Substantial Evidence That the Department of Health Did Not Act In an Arbitrary or Capricious Manner	26
II. FRESENIUS IS ESTOPPED FROM ARGUING THAT THE REESTABLISHMENT OF OCEAN SPRINGS DIALYSIS WAS THE ESTABLISHMENT OF A NEW ESRD FACILITY	27
III. THE DEPARTMENT OF HEALTH DID NOT ACT ARBITRARILY OR CAPRICIOUSLY WITH REGARD TO THE EMERGENCY CON LAW	31
a. Fresenius’ Request for a Public Hearing During the Course of Review Was Limited to DVA’s Regular CON Application	31
b. The State Health Officer’s Grant of an Emergency CON To DVA Was Not Subject To Review By the Hearing Officer Or the Chancery Court	32
CONCLUSION.....	34
CERTIFICATE OF SERVICE	37
CERTIFICATE OF FILING.....	38

TABLE OF AUTHORITIES

Cases

<i>Attala County Bd. of Supervisors v. Miss. State Dep't. of Health</i> , 867 So. 2d 1019 (Miss. 2004)	25
<i>Banes v. Thompson</i> , 352, So.2d 812 (Miss. 1977)	30
<i>Biloxi HMA v. Singing River Hosp.</i> , 743 So.2d 979 (Miss. 1999)	23
<i>Buelow v. Glidewell</i> , 757 So. 2d 216 (Miss. 2000)	18
<i>Burks v. Amite County Sch. Dist.</i> , 708 So. 2d 1366, 1370 (Miss. 1998)	26
<i>Coastal Plains, Inc. v. Browning Manuf'g</i> , 179 F.3d 197 (5th Cir. 1999)	30, 31
<i>Dunn v. Miss. State Dep't of Health</i> , 708 So. 2d 67 (Miss. 1998)	18
<i>In re Mun. Boundaries of City of Southaven</i> , 864 So.2d 912 (Miss. 2003)	29
<i>Jackson HMA, Inc. v. Miss. State Dep't of Health</i> , 822 So. 2d 968 (Miss. 2002)	19
<i>King v. Bunton</i> , 2010 WL 1077442	29
<i>Miss. Pub. Serv. Comm'n v. Merchants Truck Line, Inc.</i> , 598 So. 2d 778 (Miss. 1992)	19
<i>Miss. State Dep't of Health v. Baptist Mem'l. Hosp. – DeSoto</i> , 984 So. 2d 967 (Miss. 2008)	passim
<i>Miss. State Dep't of Health v. Natchez Cmty. Hosp.</i> , 743 So. 2d 973 (Miss. 1999)	26
<i>Miss. State Dep't. of Health v. Rush Care, Inc.</i> , 882 So. 2d 205 (Miss. 2004)	24, 35
<i>Miss. State Dep't. of Health v. Southwest Miss. Regional Med. Ctr.</i> , 580 So. 2d 1238 (1991)	35
<i>Miss. State Dep't of Health v. Miss. Baptist Med. Ctr.</i> , 663 So. 2d 563 (Miss. 1995)	18, 19, 23
<i>Oktibbeha County Hosp. v. Miss. State Dep't of Health</i> , 956 So.2d 207 (Miss. 2007)	29, 32
<i>Pub. Employees' Ret. Sys. v. Dishmon</i> , 797 So. 2d 888 (Miss. 2001)	19
<i>Rankin v. American General Finance, Inc.</i> , 912 So.2d 725 (Miss. 2005)	29
<i>Scott v. Gammons</i> , 985 So. 2d 872 (Miss. Ct. App. 2008)	30

<i>St. Dominic – Jackson Mem’l Hosp. v. Miss. State Dep’t of Health</i> , 728 So. 2d 81 (Miss. 1998).....	26
--	----

Statutes and Rules

FY 2007 State Health Plan.....	passim
Miss. Code Ann. § 33-15-11.....	32
Miss. Code Ann. § 41-7-191.....	23
Miss. Code Ann. § 41-7-197.....	32
Miss. Code Ann. § 41-7-201.....	19
Miss. Code Ann. § 41-7-207.....	32
Miss. State Department of Health, CON Review Manual	passim

INTRODUCTION

A specialized healthcare facility is heavily damaged in a hurricane. The owner decides to rebuild the facility further out of harm's way and closer to major evacuation routes. The new facility, while much improved, has the same capacity as the old location and shares its 30-mile service area with the same competitors as before. The old building is repaired and put to a different use. The Department of Health concludes that the rebuilt facility meets all the necessary criteria for a Certificate of Need to be issued. The Department, in interpreting its own rules and regulations, also finds that the Need Criterion contained in the State Health Plan requiring that all competing End Stage Renal Disease facilities located in a particular service area be operating at an 80 percent utilization rate before a new facility can be built in that service area, does not apply to this application. The Department determined that this need criterion had no applicability to the current application because it applies only when a "new" or "additional" health care facility is proposed, and the facility in question will be neither—it will serve as a replacement of an already existing health care facility and the previously existing building will cease to operate as an ESRD Facility.

This describes the essential facts and events of this case. What makes this situation unusual, though, is that it not only describes DVA Healthcare Renal Care, Inc.'s loss and replacement of its Ocean Springs Dialysis facility in the aftermath of Hurricane Katrina, but also Fresenius Medical Care's loss and replacement of its Bay St. Louis ESRD facility. But this is not the happy tale of the recovery of two important ESRD facilities and the restoration of the life-saving hemodialysis services they provide. Instead, it is a story of how Fresenius successfully urged the Mississippi State Department of Health to adopt an interpretation of the State Health Plan that facilitated the relocation and rebuilding of its own facility, but now argues

the Department's identical interpretation of the same provision in DVA's relocation is wrong -- in a transparent effort to eliminate a competing facility.

STATEMENT OF ISSUES

1. Whether the Department of Health's interpretation that the State Health Plan's ESRD Need Criterion applies only when a facility is added to an existing service area, and not when an existing facility relocates to a new address in the same town, is plainly erroneous or so inconsistent with this provision as to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.
2. Whether Fresenius should be barred under the principal of judicial estoppel from challenging the Department of Health's interpretation that the State Health Plan's ESRD Need Criterion does not apply when an existing facility relocates to a new address in the same town, when Fresenius took this same position in its own CON application filed shortly after the DVA application and benefitted from the Department's ruling affirming Fresenius' position.
3. Was the Emergency Certificate of Need issued by the Department of Health to DVA for Ocean Springs Dialysis properly the subject of review by the Chancery Court.

STATEMENT OF THE CASE

Course of Proceedings

Mississippi's State Health Officer granted DVA Healthcare Renal Care, Inc. an Emergency Certificate of Need to reestablish its Ocean Springs Dialysis facility at a different location in Ocean Springs, after its existing building was heavily damaged during Hurricane Katrina. Admin. Hrg. 6; Exs. 2, 32; R.E. 49-52.¹ DVA applied for a regular CON for the new building within 45 days. Ex. 2; R.E. 53-177.² The staff of the Mississippi State Department of Health's Division of Health Planning and Resource Development (the "Staff") recommended approval of DVA's application. Ex. 3; R.E. 252-59 ("Staff Analysis"). The Staff published its findings, including its conclusion that the State Health Plan's 80 percent need threshold to establish a new ESRD facility did not apply because DVA's old building was "taken out of service due to circumstances beyond the applicant's control" and "*all facilities within the service area co-existed prior to Hurricane Katrina in 2005 . . .*" Ex. 3; R.E. 254 (Staff Analysis, p. 3) (emphasis supplied); Admin. Hrg. 8, 151. Bio-Medical Applications of Mississippi, Inc., a subsidiary of Fresenius, requested a Public Hearing During the Course of Review, claiming that its D'Iberville and Biloxi facilities had been adversely affected by the relocation of OSD. Admin. Hrg. 592; Ex. 2; R.E. 178-80 (Ltr. from A. Simpson to S. Dawkins (March 7, 2007)).

¹ Designations to the record of this proceeding are abbreviated in this brief as follow: Transcript of the administrative hearing, referred to in Department of Health regulations as a Public Hearing During Course of Review, held on January 27-29 and February 27, 2009, are designated "Admin. Hrg."; exhibits from the administrative hearing are designated "Ex."; pleadings prepared by the Clerk as part of the Record are designated with an "R"; Appellants' excerpts from the Record are "R.E."; and references to transcripts of proceedings held before the Chancery Court on September 11, 2009, and December 9, 2009, are designated as "Tr."

² The CON Review Manual in effect at the time of the filing of the Emergency CON was introduced into the administrative hearing record as Exhibit 9 (eff. May 13, 2000). The Manual in effect at the time DVA filed its regular CON application for OSD was Exhibit 8. Admin. Hrg. 36-39. Excerpts of both manuals are included within Appellants' Record Excerpts. See R.E. 266-305 (Ex. 8) and R.E. 306-43 (Ex. 9).

Fresenius waited more than 18 months, then finally requested a hearing date. Ex. 2; R.E. 184 (Ltr. from A. Simpson to D. Eicher (September 24, 2008)). The administrative hearing was conducted over four days in early 2009, and the Hearing Officer received both testimony and documentary evidence. At the conclusion, the Hearing Officer found that DVA's application for a regular CON "was in substantial compliance with the State Health Plan . . . , the CON Manual . . . , and the adopted procedures and rules of the Department." Ex. 2; R.E. 193-236 (Hearing Officer's Findings of Fact and Conclusion of Law, p. 2).

The Hearing Officer specifically found that the State Health Plan's 80 percent need threshold was not implicated because the criterion "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 Hearing Office further elaborated on this point by observing that DVA was not proposing an additional facility, but rather the reconstruction of one that coexisted with Fresenius' facilities before the hurricane:

DVA did not construct an *additional* facility in any service area; Ocean Springs Dialysis existed within the D'Iberville and Biloxi service areas prior to Hurricane Katrina. (T. 885-88). Therefore, DVA must obtain a CON to relocate its building, but there is no requirement that DVA satisfy the 80 percent need threshold.

Id., R.E. 210 (emphasis in original).

The State Health Officer issued a Final Order approving DVA's CON application for OSD on June 25, 2009. Ex. 2; R.E. 237, 239, 248-51. Fresenius appealed that order to the Chancery Court of Hinds County. R 1.

The Chancery Court reversed the State Health Officer's order. R. 188; R.E. 4-17. Specifically, the Chancery Court held that the re-opening of OSD in a building within Ocean

Springs, but 4 miles from its old location, created a new “service area,” and because this was a different service area than OSD was in before, a “new ESRD facility” was established:

When DVA moved its location from 12 Marks Road, a new service area was created, even though DVA moved only 4.3 miles away from its prior location. But, when DVA was located at 12 Marks Road, a 30 mile radius certainly existed and could have been sketched out on a map. When DVA moved 4.3 miles away, naturally, the 30 miles radius shifted. DVA’s new location landed in and encompassed an entirely different and distinct 30 miles radius. This Court finds that a new ESRD facility was created.

R. 194, 193; R.E. 10 (Order and Opinion of the Court, p. 7). The Court also found that the re-establishment of OSD was not authorized under the Emergency CON laws and that its continued operation is in violation of law. *Id.* at 200-201; R.E. 16-17.

Despite these findings, the Court found that DVA’s application met the four General Certificate of Need Policies of the State Health Plan:

1. the facility did not result in the unnecessary duplication of health resources;
2. the facility provided a degree of cost containment;
3. it improved the health of Mississippi residents; and
4. the facility increased the accessibility, acceptability, continuity, and quality of health services.

R. 195; R.E. 11 (Opinion and Order, p. 8); *see also* FY 2007 State Health Plan, Ch. 1, Sect. 102. 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). Fresenius did not appeal any of these findings.

The Chancery Court’s original Order did not specifically address what would happen to OSD and its patients while this matter continued in the courts; therefore, DVA and the Department filed a Motion to Clarify and/or Alter and Amend Order and Opinion. R. 202; R.E. 22-25. The movants urged the lower court to allow OSD to remain open pending appeal. Tr. 81, 86. Instead, the Chancery Court ordered OSD to stop treating patients and “close its doors” within ninety (90) days. R. 220; R.E. 20 (Order, p.3).

DVA and the Department of Health filed a timely Notice of Appeal. R. 224; R.E. 26-28. A Motion to Stay Enforcement of Judgment Pending Appeal was granted by the Supreme Court on February 22, 2010.

Statement of Facts

Ocean Springs Dialysis has provided life-saving hemodialysis treatments for patients suffering from End-Stage Renal Disease³ for more than a decade.⁴ OSD is one of three ESRD facilities DVA operates in Mississippi; the other two are located in Lucedale and Pascagoula. Admin. Hrg. 244. South Mississippi Kidney Center (“SMKC”) D’Iberville and SMKC Biloxi are ESRD facilities operated by a subsidiary of Fresenius Medical Care, the world’s largest supplier of renal dialysis services. Admin. Hrg. 588-89. Fresenius operates approximately 50 ESRD facilities in Mississippi and owns all six ESRD facilities in Harrison and Hancock Counties, the two coastal counties adjacent to Jackson County. Admin. Hrg. 589-91. Its Biloxi and D’Iberville facilities - the contestants here - are located within four miles of each other. Admin. Hrg. 807. OSD operated within the facility service areas for Fresenius’ Biloxi and D’Iberville facilities both before and after its relocation. Admin. Hrg. 59, 885.

Until Hurricane Katrina made landfall on August 29, 2005, OSD was located in a two-story townhouse at 12 Marks Road in Ocean Springs. The building was heavily damaged during Hurricane Katrina and thereafter could not be used for dialysis procedures. Admin. Hrg. 244, 247-51, 258. Photographs show that the brick exterior and façade collapsed, and a tarp had to be

³ End-Stage Renal Disease is a condition in which the patient suffers the loss of kidney function to the extent that remaining function is insufficient to support life. FY 2007 Mississippi State Health Plan, Ch. 13, Sect. 106. Dialysis is the process by which either an artificial kidney machine (hemodialysis) or a peritoneal membrane (peritoneal dialysis) is used to remove metabolic waste products from the bloodstream and remove fluids and salts. *Id.* Most ESRD patients who undergo hemodialysis procedures must be treated three times each week, in sessions lasting up to seven hours. Admin. Hrg. 241, 457-58.

⁴ The year that OSD began operations is not clear from the record. However, the first dated Medical Director Agreement for this facility involving the present physician group in the record is dated November 1, 1996, nine years before Katrina. Ex. 2 (Medical Director Agreement). OSD was operated at the time of Hurricane Katrina by Gambro Healthcare Renal Care, Inc. Admin. Hrg. 246. DVA purchased the outstanding stock of a Gambro subsidiary, including the Ocean Springs facility, on or about October 5, 2005. Admin. Hrg. 558, 574.

placed over the roof. Ex. 29; R.E. 364, 365.⁵ This tarp covered a large hole in the ceiling through which one could “see all the way to heaven” from the first floor. Ex. 29; R.E. 366, 371-80; Admin. Hrg. 248-51. Water came through the collapsed wall and the hole in the roof, damaging lighting fixtures and sheet rock in the dialysis treatment room. Admin. Hrg. 249; Ex. 29 (photos); R.E. 364-80. Black mold very soon began to grow on the drywall. Admin. Hrg. 251. The OSD staff put plastic bags over the dialysis machines to protect them from the elements. Ex. 29; R.E. 367; Admin. Hrg. 249.⁶

DVA was forced to treat OSD patients at its Lucedale and Pascagoula locations⁷ until the Ocean Springs facility could reopen. Admin. Hrg. 258, 262-63. The majority of OSD’s patients are often too ill to drive themselves to treatment and must depend on others for transportation; the travel presented a significant hardship for patients, their families, and the DVA doctors and staff. Admin. Hrg. 262, 462-72, 548.

DVA increased its operational hours for the Lucedale and Pascagoula facilities to meet the increased demand, but conditions remained overcrowded. Admin. Hrg. 263-64, 465-66. Staff members worked very long hours, up to 16 hours per day to try to meet the increased demand. Admin. Hrg. 465-66. Despite these hardships many OSD patients chose to continue their treatments with DVA. Admin. Hrg. 517. Over time, some patients transferred to Fresenius facilities in the area. Admin. Hrg. 264, 470, 519.

⁵ These photographs were supplied to the Department of Health to show the extent of the damage to the old building. Ex. 2; R.E. 37-48 (Ltr. from K. Livingston-Wilson to R. Pittman).

⁶ Due to the extent of the disaster the facility manager, Yvette Smith, recommended to OSD’s patients that they leave the area to be treated, if possible. Admin. Hrg. 471. DVA supplied those who chose to leave with a list of available ESRD facilities in the area in which they planned to relocate. Admin. Hrg. 567. Ms. Smith also contacted Fresenius’ D’Iberville unit, the unit closest to OSD, to attempt to make arrangements for treatment, but was told that they did not have any capacity. Admin. Hrg. 519-20.

⁷ Lucedale is approximately 52 miles from Ocean Springs; the Pascagoula facility is approximately 20. Admin. Hrg. 262-63.

Nearly a month passed before an insurance adjuster even inspected the damage at 12 Marks Road. Ex. 18.⁸ OSD's medical director, Dr. Tracy Pittman, consulted with various DVA employees and decided the better course was to act quickly to relocate the facility within Ocean Springs rather than wait until insurance claims were processed.⁹ Admin. Hrg. 266-68. In October 2005, Dr. Pittman purchased a vacant lot on Ponce DeLeon Drive in Ocean Springs, approximately 4.3 miles northwest of the old facility. Admin. Hrg. 7, 269, 315; Exs. 23, 31, 32.

In August 2006, DVA filed an application for an Emergency CON to reestablish OSD on Ponce DeLeon Drive.¹⁰ Admin. Hrg. 17; Exs. 2, 4; R. E. 29-36, 260. DVA made clear in this filing that land for the new site had already been purchased and construction had begun. Ex. 2; R.E. 35 (Application for Emergency CON, p. 6). The State Health Officer granted the Emergency CON on October 6, 2006. Admin. Hrg. 6; Exs. 2, 3, 7; R.E. 49-52. The facility was completed after the Emergency CON was issued. Ex. 13; R.E. 182-83 (Ltr. from S. Dawkins to T. Kirkland, p. 2 (May 8, 2007)). DVA filed a regular CON application to reestablish OSD on November 20, 2006, within the 45-day regulatory deadline. Ex. 2; R.E. 53-177.

The following month, Fresenius filed its own CON application to rebuild and relocate an ESRD facility damaged by the storm. Ex. 77; R.E. 409-435. The company sought authority to relocate its Bay St. Louis facility to Diamondhead, a town more than 10 miles away.¹¹ *Id.*

Before beginning normal operations, DVA conducted trial dialysis procedures under the supervision of the Department's Division of Licensure. Admin. Hrg. 527. The Department inspected the facility a number of times during its start-up phase, determined it had a valid

⁸ The St. Paul Travelers estimate indicates that the date of inspection was September 25, 2005. Ex. 18.

⁹ More than *five months* passed before the insurer finally delivered an estimate – and then only for repair of the building's "shell." Admin. Hrg. 266; Ex. 18.

¹⁰ Don Eicher testified that the Department received a number of Emergency CON applications more than a year after Hurricane Katrina. Admin. Hrg. 21-22. As discussed *infra*, Fresenius' Hancock County facility was one of those.

¹¹ Fresenius had previously filed an application for and had been granted an Emergency CON for the relocation of this same facility. See Exs. 10, 11; R.E. 344-54.

Emergency CON, and approved commencement of operations. Admin. Hrg. 482-87, 660-62. The federal agency that oversees Medicare and Medicaid, the Centers for Medicare and Medicaid Services (CMS), formally re-certified OSD on December 18, 2006. Admin. Hrg. 487-89; Exs. 53-54.

The new building provided the opportunity to correct inherent structural deficiencies in the old one. The Marks Road clinic was located in a two-story townhouse that was not designed to be an ESRD facility. Admin. Hrg. 351. Both Dr. Pittman and Yvette Smith, the facility manager, testified that the two-story layout made handicapped access difficult, especially for those nursing home patients who were bed-bound. Admin. Hrg. 253, 496-97; Ex. 30. The building's layout forced patients on stretchers to come in through a back door and maneuver through a storage room and around a corner. Admin. Hrg. 497. The Marks Road building had no wheelchair access near the front door, so these patients had to enter at the end of the building. Admin. Hrg. 496. Lack of covered access made entry in the rain difficult. Admin. Hrg. 497. There was insufficient room for a generator to supply emergency power. Admin. Hrg. 253. Limited office space made private conversations with patients nearly impossible. Admin. Hrg. 253, 496. The treatment floor was small and cramped and patients had to dialyze close enough to touch one another. Admin. Hrg. 498. Supply space was limited. Admin. Hrg. 498. The waiting room was very small. Admin. Hrg. 499. These limitations existed despite the fact that the prior operator spent \$111,000 to renovate the facility just four years earlier. Admin. Hrg. 346-47.

The Ponce DeLeon building represents a substantial improvement over the old Marks Road structure in terms of space, location, handicapped access, and patient comfort. Admin. Hrg. 277-80, 350-52, 495-500. It is a modern facility, designed and built to DVA's general specifications to be an ESRD clinic. Admin. Hrg. 350; Ex. 34. The larger building provides

patients more room for treatment. Admin. Hrg. 495. Healthcare workers and their offices are located on the same floor as the treatment area. Admin. Hrg. 495-96. Covered access allows patients easy drive-up and one-story access through an automatic door, even in the rain. Admin. Hrg. 497-99. The waiting room seats up to 20 people, with extra space for wheelchair patients. Admin. Hrg. 499-500. Highway access is better at the new site. Admin. Hrg. 272, 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. By all accounts, DVA's patients are happier with their new surroundings. Admin. Hrg. 932. When asked if the new facility meets the needs of the patients Ms. Smith testified, "They love it." Admin. Hrg. 550.

The facility's manager testified that most of the Ocean Springs patients live to the west of the Marks Road location. Admin. Hrg. 501. As a result, the new location is closer to the patients it serves in that community. Admin. Hrg. 501; *see also* Ex. 32, R.E. 381 (map of locations). In addition, the facility is now closer to those who live west of Ocean Springs, approximately 20% of the patient population at last count. Admin. Hrg. 477, 501; Ex. 49.

Letters of support from two nursing home administrators in Ocean Springs demonstrate the community need for these services. *See* Ex. 2; R.E. 128 (DVA CON App., Ltr. from K. Drake, Adm. of Ocean Springs Nursing Center (Nov. 17, 2006) and R.E. 130 (Ltr. from James Williams, Adm. of Sunplex Subacute Center (Nov. 17, 2006)). The Administrator for one of the nursing homes wrote:

This facility not only supports the relocation and opening of DaVita-Ocean Springs Dialysis Clinic, but our residents are relying on it. Ocean Springs needs a local Dialysis Clinic.

R.E. 130 (Ltr. from James Williams). In addition, the administrator of Ocean Springs Hospital, the hospital adjacent to the Marks Road location, provided a letter of support for the relocation of

OSD. Ex. 2; R.E. 127 (Ltr. from K. Holland, Adm. of Ocean Springs Hospital (Nov. 17, 2006)). Fresenius supplied no letters of opposition to the OSD project.

Testimony at the hearing confirmed that most ESRD patients are either Medicaid or Medicare eligible. Admin. Hrg. 243, 285, 413-17, 501-02, 554-55. These same government payors cover the treatment for most OSD patients. Exs. 43, 44. The elderly and minorities are a significant part of this ESRD patient population. Admin. Hrg. 238, 555. Dr. Pittman testified that the relocated facility will allow these ESRD patients to receive better care. Admin. Hrg. 286. The facility administrator strongly agreed that access was improved by the relocation. Admin. Hrg. 552.

Dr. Pittman also testified that one of the reasons the Ponce DeLeon location was chosen was its proximity to major evacuation routes, including Interstate-10. Admin. Hrg. 268; Ex. 32. The old building was located a significant distance from Interstate-10, requiring travel on Highway 90 east or west before accessing an evacuation route that eventually connects to the interstate. Admin. Hrg. 268, 500.

DVA's construction expert, Mel Ulmer, was the *only* construction expert to testify at the hearing.¹² Ex. 2; R.E. 215 (Hearing Officer's Findings, p. 21). Mr. Ulmer was the contractor for the repair of a number of ESRD facilities damaged by Hurricane Katrina and was very familiar with the construction challenges that existed in the storm's aftermath. Admin. Hrg. 360-62. He testified, based on his experience, that the cost to rebuild the Marks Road structure to ESRD standards would have been \$110 to \$130 per square foot. Admin. Hrg. 369-70. Therefore, the true cost to rebuild the interior of the Marks Road facility would have been in the range of

¹² Mr. Ulmer's employer, Termac Construction Company, is licensed as a contractor in Mississippi. Admin. Hrg. 345. Mr. Ulmer, by virtue of his employment by Termac, is an authorized contractor. *Id.*

\$660,000 to \$780,000.¹³ This substantial cost would only have restored a facility that already had serious structural limitations, despite a recent and costly renovation.

Mr. Ulmer testified that according to flood insurance rate maps published by the Federal Emergency Management Agency (FEMA) the Marks Road building is located in Zone A-H, a “special flood hazard area.” Admin. Hrg. 372. The new location is designated as Zone X, an area having 1/5 the risk of flooding. Admin. Hrg. 374-75. Mr. Ulmer testified that the new site was a “definite advantage” in terms of survivability in a future hurricane. Admin. Hrg. 378. Even Fresenius’ health planning expert agreed that these would be legitimate reason to relocate the facility:

- Q. Moving this facility further away from the Gulf, would that be also a legitimate reason to relocate this facility?
- A. Sure.
- Q. You heard the testimony of Mr. Ulmer about the improvement in the flood plain. That would also be a legitimate reason?
- A. Sure.

Admin. Hrg. 895.

Annual End Stage Renal Dialysis Utilization Survey Forms submitted to the Department of Health by DVA, before and after Hurricane Katrina, confirm that the relocation has had no negative effect on OSD’s patient access:¹⁴

- FY 2005 56-63 patients
- FY 2006 61-62 patients
- FY 2007 31-54 patients
- FY 2008 51-58 patients

Exs. 47, 48; R.E. 399-400. Although the number of patients dipped in FY 2007 (June 2006 – June 2007), this is understandable considering that the facility was closed from August of 2005

¹³ The Marks Road facility was approximately 6,000 total square feet. Admin. Hrg. 404.

¹⁴ Figures represent lowest and highest reported monthly patient census numbers in each fiscal year. Ex. 48; R.E. 399-400.

through November of 2006. Latest data in the record (FY 2008) confirms that ESRD patient levels for the relocated OSD are approaching pre-storm levels.

Further, the relocation has produced no demonstrable negative effect on traditionally underserved groups. Admin. Hrg. 553-55. If anything, the relocation put the facility closer to the bulk of the patients it serves, a disproportionate number of whom are minorities and/or dependent on Medicare or Medicaid for treatment, in Ocean Springs. Admin. Hrg. 501, 552.

Fresenius' closest facility to OSD is the one located in D'Iberville. Exs. 32, 83; R.E. 381. According to Fresenius' expert, the new location is 3.1 miles closer to the D'Iberville facility than was the Marks Road location. Ex. 83, p. 9. Drive time between the two facilities decreased by only two minutes, from 13 minutes to 11 minutes. Admin. Hrg. 897. The new location is 4.8 miles closer to Fresenius' Biloxi facility. Ex. 83, p. 9. Evidence introduced at the hearing clearly established that there have been no demonstrable adverse effects on either of Fresenius' facilities.¹⁵

DVA introduced into evidence through Fresenius' Regional Vice-President the annual survey forms¹⁶ for Fresenius' D'Iberville and Biloxi facilities for FY 2005 through FY 2008. Admin. Hrg. 606; Exs. 62, 63. Fresenius' own data shows:

- Prior to Hurricane Katrina, D'Iberville reported 15-16 patients each month for the six-month period leading up to the storm, the same numbers it reopened with in January of 2006;
- By December 2006 (the first full month OSD operated in its new location), Fresenius reported 22 patients at D'Iberville;
- Within one year after the relocation (December 2007) D'Iberville's patient number had increased to 30; and

¹⁵ DVA called Jeff McPherson, Regional Vice-President for Fresenius, as an adverse witness at the hearing. Admin. Hrg. 587. Mr. McPherson testified that his company challenged the CON application because its D'Iberville and Biloxi facilities were adversely affected by the OSD relocation. Admin. Hrg. 592. As shown, Fresenius' own data does not support this claim. *See supra* at 14.

¹⁶ ESRD facility operators are required to report to the Department numbers of patients and treatments, by month. Admin. Hrg. 603-04; Exs. 47, 62, 63. These Annual End Stage Renal Dialysis Utilization Survey Forms provide a convenient record of ESRD facility utilization.

- Six months later (June 2008)¹⁷ D'Iberville reported 34 patients, an increase of over 100% from its pre-Katrina (January 2005) levels.¹⁸

Ex. 65. Fresenius' witness confirmed that these figures were not an anomaly and represent substantial growth at Fresenius' D'Iberville facility:

- Q. If you compare that to March of 2006, you actually doubled your patient load since my client moved four (sic) miles closer to your facility –
A. Correct.

Admin. Hrg. 644.

Fresenius' vice-president suggested that the growth in D'Iberville was partially due to the reassignment of some patients from their Biloxi facility.¹⁹ Admin. Hrg. 706. However, if D'Iberville and Biloxi are considered together, a growth trend is still apparent. The combined patient total for both facilities in January 2005 was 84,²⁰ increasing to 101²¹ by June of 2008. Ex. 65. This represents a gain of 20%,²² at a time when OSD reported a census loss of approximately 20%.²³

The number of dialysis treatments reported tells the same story. The number of total treatments for D'Iberville went up 92% between June 2005 and June 2008.²⁴ Admin. Hrg. 697-98; Ex. 64. While the trend for treatments for Biloxi appears to be negative, it is clear that this facility has fared better in the post-Katrina environment than DVA's. Ex. 47. Biloxi experienced a 9% decrease in volume from January 2005 (seven months before the hurricane)

¹⁷ FY 2008 (July 2007 – June 2008) represents the last year for which reported data is available.

¹⁸ $(34 - 15) \div 15 = 1.266$

¹⁹ Fresenius' survey forms show that its Biloxi facility consistently reported numbers in the range of 60-70 patients from 2005 through 2008. Ex. 65. These levels spiked to 79 patients in November and December 2005, when both the D'Iberville and Ocean Springs ESRD facilities were closed. Ex. 65.

²⁰ 15 patients for D'Iberville + 69 for Biloxi = 84 patients. Ex. 65.

²¹ 34 patients for D'Iberville + 67 for Biloxi = 101 patients. Ex. 65.

²² $(101 - 84) \div 84 = .20$ (20%)

²³ OSD reported 65 patients in January of 2005 and 52 patients in June of 2008, for a net loss of 13 patients or 20 percent $((65 - 52) \div 65 = .20$ (-20%)). Ex. 47.

²⁴ The percentage is even higher when considered from January of 2005 through June of 2008. D'Iberville reported 176 treatments in January of 2005 and 380 treatments in June of 2008, for a net gain of 115% $((380 - 176) \div 176 = 1.159)$.

through June 2008 (almost three years after),²⁵ while OSD's loss was 21% over this same period.²⁶ Fresenius' own expert placed the loss in volume at OSD and SMKC Biloxi "[i]n the same ballpark." Admin. Hrg. 904.

The impressive growth of Fresenius' D'Iberville facility is reflected not only in the official data, but also in Fresenius' expansion *after* OSD relocated. In 2007 Fresenius replaced its temporary modular unit in D'Iberville with a permanent facility and increased its hemodialysis units by 50%. Admin. Hrg. 616-17; Ex. 66; R.E. 181.²⁷ Fresenius' own data shows no net loss of Jackson County patients (the county where OSD is located) at the D'Iberville facility in the one year period following OSD's move (constant at 10 patients) and a 50 percent increase (from four to six) in the number of Jackson County patients at SMKC Biloxi.²⁸ Admin. Hrg. 702-04, 729. OSD's facility administrator confirmed that the move to western Ocean Springs (closer to D'Iberville and Biloxi) produced no net gain of patients from west of the city. Admin. Hrg. 475-77, 525-26; Ex. 49.

Dr. Pittman leased the old OSD building to a church, retaining a small portion as his medical office. Admin. Hrg. 282-83, 298-99. No part of the old building is used an ESRD facility, and DVA has not increased its licensed hemodialysis capacity at its new facility.²⁹ Admin. Hrg. 549-50.

²⁵ 849 treatments reported in January of 2005, 769 reported in June of 2008, for a net loss of 80 treatments, or 9 percent $((849 - 769) \div 849 = .09422)$. This number may be an anomaly, however. Biloxi reported 901 treatments in May of 2008. Ex. 64.

²⁶ OSD reported 733 treatments in January of 2005, 578 treatments in June of 2008, for a net loss of 155 treatments or 21 % $((733 - 576) \div 733 = .21418)$.

²⁷ An increase in dialysis stations at an existing facility does not require a CON. Admin. Hrg. 639, 901; Ex. 70.

²⁸ Fresenius produced through discovery patient origin data for both facilities for December of 2006 and December of 2007. Ex. 76. This data also showed a growth in the number of Gulfport patients at Biloxi and no change at D'Iberville. Admin. Hrg. 703-04.

²⁹ 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

SUMMARY OF ARGUMENT

After Ocean Springs Dialysis sustained significant damage during Hurricane Katrina, DVA reopened for patient care in a new building a short distance from the unusable facility. The reestablished facility affords greater patient comfort and access, in a safer location. This action does not amount to the “establishment” of a “new” facility under the plain meaning of the State Health Plan. The State Health Officer’s finding that the need criterion in question requires existing ESRD facilities within the given service area to be at a 80 percent utilization level only when “additional” ESRD facilities are contemplated was not arbitrary or capricious.

Fresenius successfully asserted in the CON application for its Bay St. Louis ESRD facility (filed less than a month after DVA’s OSD application) that the 2007 State Health Plan’s ESRD Need Criterion did not apply because the company already had CON authority to operate this facility prior to the hurricane and, therefore, its relocation to Diamondhead was not the establishment of a new facility. In the course of this challenge to DVA’s application Fresenius changed its position, now contending that the criterion applies any time an ESRD facility is moved more than a mile. Fresenius should be precluded from arguing a position here that is contrary to the position from which it received the benefit of relocating its own facility.

In the context of the unique circumstances following Hurricane Katrina the State Health Officer also granted DVA an Emergency CON to authorize the operation of Ocean Springs Dialysis in its new location while its application for a regular CON was pending. The State Health Officer’s authority in this regard is explicitly authorized by statute and Department of Health regulations.

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.*

The Chancery Court did not accord the State Health Officer's interpretation of the State Health Plan's ESRD Need Criterion or the Emergency CON regulations the deference required by statute and established case law precedent. Under the appropriate standard of review, the State Health Officer's decisions must be affirmed as they were not arbitrary, capricious, an abuse of discretion, or otherwise contrary to law.

ARGUMENT

I. DVA'S REESTABLISHMENT OF ITS DAMAGED OCEAN SPRINGS DIALYSIS FACILITY WAS NOT THE "ESTABLISHMENT" OF A "NEW" ESRD FACILITY WITHIN THE MEANING OF THE STATE HEALTH PLAN

a. Standard of Review

On appeal, the Supreme Court conducts a *de novo* review of the Chancellor's action, constrained by the same standard of review under which she operated. *Miss. State Dep't of Health v. Baptist Mem'l. Hosp. – DeSoto*, 984 So. 2d 967, 974-75 (¶12) (Miss. 2008) (citing *Miss. State Dep't of Health v. Miss. Baptist Med. Ctr.*, 663 So. 2d 563, 574 (Miss.1995)). In considering an administrative agency's construction of its own regulations the lower court has a "duty of deference," which should be derived from a "realization that the everyday experience of the administrative agency gives it familiarity with the particularities and nuances of the problems committed to its care which no court can hope to replicate." *Baptist Mem'l. Hosp. – DeSoto*, 984 So. 2d at 975 (¶12) (quoting *Dunn v. Miss. State Dep't of Health*, 708 So. 2d 67, 72 (Miss.1998)). The standard that must be employed in reviewing the agency's interpretation is a familiar one:

This Court has noted that "an agency's interpretation of a regulation it has been authorized to promulgate is entitled to great deference and *must 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.*"

Baptist Mem'l. Hosp. – DeSoto, 984 So. 2d at 981 (¶28) (emphasis supplied) (quoting *Buelow v. Glidewell*, 757 So. 2d 216, 219 (Miss.2000)).

Not only is the agency's interpretation of its own regulations entitled to great deference, but the State Health Officer's final order on a CON application is itself subject to only a limited standard of judicial review, by statute:

The order shall not be vacated or set aside, either in whole or in part, except for errors of law, unless the court finds that the order of the State Department of Health is not supported by substantial evidence, is contrary to the manifest weight of the evidence, is in excess of the statutory authority or jurisdiction of the State Department of Health, or violates any vested constitutional rights of any party involved in the appeal....

Jackson HMA, Inc. v. Miss. State Dep't of Health, 822 So. 2d 968, 970 (Miss. 2002) (quoting Miss. Code Ann. § 41-7-201(2)(f)) (emphasis supplied). A "presumption of validity" attaches to the Department's decision, *Miss. Baptist Med. Ctr.*, 663 So.2d at 579. The Supreme Court and the lower court may not substitute its own judgment for that of the agency which rendered the decision, nor may it re-weigh the facts of the case. *Pub. Employees' Ret. Sys. v. Dishmon*, 797 So. 2d 888, 892 (Miss. 2001) (citing *Miss. Pub. Serv. Comm'n v. Merchants Truck Line, Inc.*, 598 So. 2d 778, 782 (Miss. 1992)).

b. The State Health Officer's Order Was Supported by Substantial Evidence, Was Not Contrary to the Manifest Weight of the Evidence, Was Not In Excess of the Statutory Authority or Jurisdiction of the Department, and Did Not Violate Any Vested Constitutional Rights of Any Party Involved in the Appeal

The Mississippi State Department of Health is the "sole and official agency to administer and supervise all health planning responsibilities for the state, including development and publication of the Mississippi State Health Plan." FY 2007 State Health Plan, Executive Summary, p. XV.³⁰ The State Health Plan "[e]stablishes criteria and standards for health-related

³⁰ Excerpts from the 2007 State Health Plan were used in the administrative hearing. See Ex. 20; R.E. 357-363. A full copy of the plan is available online at the Department of Health's website: http://msdh.ms.gov/msdhsite/_static/19,0,184,419.html (last visited May 6, 2010).

activities which require Certificate of Need review.” *Id.* The provision of the 2007 State Health Plan³¹ at issue 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 (State Health Plan, Ch. 13, Sect. 107.02.01) (emphasis supplied).³²

Pursuant to regular CON procedures, the Department’s Staff analyzed DVA’s application to determine the proper application of the State Health Plan’s Need Criterion. *See* Ex. 8 (CON Review Manual, Ch. 3, Sect. 114, Staff Analysis and Recommendations); R.E. 278-79. The Staff, in their published findings, concluded that a new facility was not created and the 80 percent need threshold did not apply because DVA’s old building was “taken out of service due to circumstances beyond the applicant’s control” and “*all facilities within the service area co-existed prior to Hurricane Katrina in 2005. . . .*” Ex. 3; R.E. 254 (Staff Analysis, p. 3) (emphasis supplied); Admin. Hrg. 8, 151. Don Eicher, Director of the Department’s Office of Health Policy and Planning, testified at the administrative hearing that the Staff “did not consider it to be a new facility. It was already established. And so, therefore, that criterion would not be applicable.” Admin. Hrg. 54-55 (testifying with regard to application of State Health Plan, Ch. 13, Sect. 107.02.01 - Ex. 20; R.E. 361).

After hearing the testimony of witnesses on both sides and considering the evidence, an 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

³¹ The 2007 State Health Plan was the controlling plan at the time DVA’s CON applications were considered. Admin. Hrg. 149.

³² A facility service area is defined as the area within thirty (30) highway miles of an existing or proposed ESRD facility. Ex. 20; R.E. 359 (State Health Plan, Ch. 13, Sect. 107.01(4)).

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 with the entry of a final order on June 25, 2009. Ex. 2; R.E. 245, 248-51.

On appeal, the Chancery Court disagreed with the Staff, the Hearing Officer, and the State Health Officer, and gave the State Health Plan’s 80 percent criterion a directly contrary interpretation. R. 188, 192; R.E. 8-10 (Order and Opinion of the Court, p. 5-7). Adopting Fresenius’ view that the criterion applies any time an ESRD facility moves, the lower court found *DVA* created a new service area when OSD was reestablished 4.3 miles from the damaged facility and, thus, “a new ESRD facility was created.” *Id.*; R.E. 9. The issue for the lower court, however, was not whether it agreed with the Department’s and the Hearing Officer’s interpretation of this criterion. Instead, the Chancery Court should have upheld the agency’s interpretation of its own regulation “unless it [was] 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.” *Baptist Mem’l Hosp. – DeSoto*, 984 So. 2d at 981.

The interpretation of this criterion by the Staff, Hearing Officer, and State Health Officer is clearly correct, supported by substantial evidence, and certainly not arbitrary or capricious. The State Board of Health’s policy that underlies the 80 percent requirement plainly states that it applies only to *additional facilities* placed within a given service area:

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)) (emphasis supplied).³³ This policy statement makes clear that in the context of the 80 percent need threshold, “establishment” of an ESRD facility equates with the “addition” of an ESRD facility in a “given service area” – the area presently served by an existing facility.

This makes particular sense in light of one of the principal goals of the State Health Plan: to prevent the unnecessary *duplication* of health resources. FY 2007 State Health Plan Ch. 1, Sect. 102. While it is easy to see how an additional facility constructed within the respective 30-mile service areas of Fresenius’ two facilities might duplicate resources, it is difficult to see how reopening one that was already there could result in any duplication. Even the lower court found that no duplication had occurred with the rebuilding of OSD. R. 195; R.E. 11 (Opinion and Order, p. 8).

In addition, the “Establishment” of an ESRD facility is defined in the State Health Plan as a situation in which 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.” *Id.* at Ch. 13, Sect. 107.01(1) (emphasis supplied); Ex. 20; R.E. 259. While it is true that DVA’s OSD facility was not operational for more than a year because of the 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 until the new building could be put into service. Admin. Hrg. 258, 262-63.

Likewise, the CON laws only consider a reopened facility to be a “*new* health care facility,” requiring a new CON, if it has ceased to operate for a period of sixty (60) months or

³³ Policy statements in the State Health Plan are intended to be “definite course[s] of action selected in light of given conditions to *guide and determine present and future decisions.*” FY 2007 State Health Plan, Sect. C, Glossary, p. 4 (emphasis supplied).

more. Miss. Code Ann. § 41-7-191(m) (emphasis supplied). Therefore, OSD is not a new facility, according to the statutory definition.

The Staff, the Hearing Officer, and the State Health Officer all determined that these unique circumstances did not amount to the establishment of a *new* ESRD facility under the State Health Plan. *See* Ex. 2; R.E. 209 (Hearing Officer's Findings at p.15) (OSD "taken out of service due to circumstances beyond the applicant's control") (quoting Ex. 3, Staff Analysis at p. 3). This conclusion, supported by substantial evidence, was entitled to a "presumption of validity" and "great deference." *Miss. Baptist Med. Ctr.*, 663 So. 2d at 579; *Baptist Mem'l. Hosp. – DeSoto*, 984 So. 2d at 975 (¶12). Instead, it is plain that the lower court simply substituted its judgment for that of the agency, ruling that when the location of OSD was moved it created a new service area which, *ipso facto*, created "a new facility." R. 193; R.E. 9 (Order and Opinion, p. 6).

The Chancery Court's reinterpretation of the State Health Plan here is much like that of the lower court reported in *Biloxi HMA v. Singing River Hosp.*, 743 So.2d 979 (Miss. 1999). In this case the Department of Health had interpreted a State Health Plan provision requiring that "each existing facility" in a planning area be "utilized for a minimum of 600 procedures per operating or procedure room per year" to mean an average, not actual utilization of each individual operating room in the planning area *Id.* at 982(¶19), 983(¶22). The lower court disagreed, finding that it meant that *each* existing facility must meet the 600 procedure threshold. *Id.* at 982(¶20). This court overturned the lower court, reserving to the Department the inherent power to interpret its own guidelines to avoid inconsistent results:

Administrative agencies are vested with certain decision-making powers. Inherent in these powers is the responsibility to consistently interpret guidelines to avoid arbitrary and capricious results.

Id. at 984(¶29).

The Supreme Court has consistently reaffirmed the Department's primary role in the interpretation of need methodology contained in the State Health Plan. For example, the Plan's need criterion at issue in *Miss. State Dep't. of Health v. Rush Care, Inc.*, 882 So. 2d 205 (Miss. 2004) required the showing of 450 examples of clinically appropriate restorative care admissions. *Id.* at 208(¶6). The Department had approved the applicant's CON based upon its showing of the required number of admissions among an appropriate diagnostically related group of patients. *Id.* However, the Chancery Court reversed the Department, accepting the contestant's argument that certain federal guidelines should have also been considered in interpreting the required number. *Id.* at 209(¶10). The Supreme Court reversed, holding that the Chancellor erred "when she substituted her judgment for that of the MDH." *Id.* at 209(¶11). *see also Miss. State Dep't. of Health v. Rush Care, Inc.*, 882 So. 2d 205, 210 (Miss. 2004) (Department's calculation of average length of stay reinstated) ("We have upheld the MDH's findings even where an imperfect analysis is used.").

The Chancery Court's narrow interpretation of the State Health Plan also ignored important evidence introduced in the hearing with regard to how ESRD facilities operate. Utilization is defined in the State Health plan as a function of two factors: number of dialysis treatments and the number of dialysis stations. FY 2007 State Health Plan, Ch. 13, Sect. 107.01(7). The utilization percentage of competing facilities (the 80 percent measure) is not controlled by the Department's CON procedures. ESRD owners can (and do) add dialysis stations without CON approval. Admin. Hrg. 639, 901; Ex. 70; R.E. 408. Fresenius' expert acknowledged that the utilization number is within the operator's control:

- Q. Well, my point – but I don’t mean manipulation in a bad sense. Manipulate it in the sense that it doesn’t require CON approval?
- A. That’s true. Just write a letter.
- Q. So you write a letter, you get the stations. And in the case of D’Iberville, they wrote a letter, they got the stations, and basically drove their utilization number down on paper?
- A. *That’s in effect what happened.*

Admin. Hrg. 901 (emphasis supplied). In fact, after Katrina 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) without seeking a new CON. Admin. Hrg. 616; Ex. 66; R.E. 181. Thus, Fresenius was able to “manipulate” its capacity almost at will. Admin. Hrg. 901. Clearly, *if* its D’Iberville facility is under-utilized it is because Fresenius added 50% more stations *after* DVA reopened Ocean Springs Dialysis.

If the lower court’s interpretation is allowed to prevail, the net effect will be that an ESRD facility will never be able to move as long as another facility within 30 miles keeps its utilization levels below 80% – even if the proposed location is safer and offers greater patient access (as established in the case of OSD’s move). Carried to its logical extreme, the lower court’s ruling would also mean that a facility cannot move 4.3 miles *further* from existing facilities, since that would also be a shift in a service area. Even if the lower court were allowed to interpret this State Health Plan provision *de novo* (which it clearly is not), its interpretation is obviously flawed. *See Attala County Bd. of Supervisors v. Miss. State Dep’t. of Health*, 867 So. 2d 1019, 1023 (¶15) (Miss. 2004) (“Our constitution does not allow for the courts to conduct a *de novo* retrial of matters on appeal from administrative agencies.”). The “everyday experience” of the Department of Health in dealing with ESRD facilities gives it a “familiarity with the particularities and nuances” of this situation that the lower court could not have hoped to replicate. *Baptist Mem’l Hosp. – DeSoto*, 984 So. 2d at 981.

c. The Department's Identical Treatment of Fresenius' Post-Katrina CON Application to Relocate One of Its ESRD Facilities Is Substantial Evidence That the Department of Health Did Not Act In an Arbitrary or Capricious Manner

As Fresenius argued in its own brief filed with the lower court, circumstances related to how other CON applications are handled by the Department can be relevant to a pending application. R. 31 (Br. at 12). Likewise, the Supreme Court in *St. Dominic – Jackson Mem'l Hosp. v. Miss. State Dep't of Health*, 728 So.2d 81 (Miss. 1998) 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. *Id.* at 90(¶32). Therefore, it is entirely appropriate to consider the Department's actions in the context of how it has handled similar situations.

The Department's equal and consistent treatment of Fresenius' and DVA's CON applications shows that the agency did not act arbitrarily or capriciously in the present case and yielded a consistent result. An administrative agency's decision is deemed to be arbitrary “when it is not done according to reason and judgment, but depending on will alone.” *Miss. State Dep't of Health v. Natchez Cmty. Hosp.*, 743 So. 2d 973, 977 (Miss. 1999) (citing *Burks v. Amite County Sch. Dist.*, 708 So. 2d 1366, 1370 (Miss. 1998)). An action is capricious when “done without reason, in a whimsical manner.” *Id.* Clearly, the equal treatment of DVA and Fresenius in the aftermath of Hurricane Katrina and its interpretation of the State Health Plan in the same fashion in both cases is proof of the Department's consistency - not its arbitrariness or capriciousness.

II. FRESenius IS ESTOPPED FROM ARGUING THAT THE REESTABLISHMENT OF OCEAN SPRINGS DIALYSIS WAS THE ESTABLISHMENT OF A NEW ESRD FACILITY

By the time that Fresenius challenged DVA's CON application it was very familiar with the Department of Health's interpretation of the 80 percent Need Criterion. That is because Fresenius had filed CON applications for both emergency and permanent CONs to relocate its hurricane-damaged Bay St. Louis facility to Diamondhead, more than 10 miles from the previous location, within days of DVA's OSD applications.³⁴ Admin. Hrg. 622-37; Exs. 11, 77; R.E. 409-435. Like DVA, Fresenius took the position in its regular CON application (filed less than a month after DVA's application) that the 80 percent need threshold did not apply because the company already had CON authority to operate its Bay St. Louis facility:

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. 422.³⁵

The Department's Staff agreed that the 80 percent Need Criterion did not apply to the relocation of Fresenius's damaged facility:

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

³⁴ The old Fresenius facility was located 2.5 miles from the Gulf of Mexico while the new one was constructed in the Diamondhead community, 14 miles away. Ex. 77; R.E. 413 (CON App. at p.6).

³⁵ Fresenius objected to any consideration of its own post-Katrina CON applications in the hearing on the grounds of relevance. Admin. Hrg. 44. The Hearing Officer sustained the objection and refused to consider this evidence (even threatening at one point to leave the room during DVA's proffer). Admin. Hrg. 49, 620-21, 718-19.

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). The Staff's published analysis on this point is virtually identical to the one for OSD, rendered one month earlier.³⁶ Based on this Staff Analysis, the State Health Officer granted Fresenius a CON for this facility without requiring that it satisfy the 80 percent standard. Ex. 79.

One month after it received its favorable Staff Analysis, Fresenius filed a challenge to the OSD application. R.E. 179 (Request for Public Hearing During the Course of Review). At the administrative hearing Fresenius took a position directly contrary to the one by which it obtained its own CON. Fresenius argued through its Regional Vice President (the same individual who submitted the Diamondhead application)³⁷ that it had *always* been his company's position that any time an ESRD facility was moved more than one mile the 80 percent rule applied:

- Q. And is it your company's contention that DVA had to satisfy that 80 percent criteria?
- A. That's my interpretation of it, but the state -- the state has to interpret that themselves.
- Q. Okay. But that's your position?
- A. *Yes. 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. You can move within one mile, but not outside of one mile.*

Admin. Hrg. 710 (emphasis supplied).

Fresenius attempted to buttress this testimony with that of an expert witness who, like Fresenius' Vice President, now also contended that moving an ESRD facility created a "new

³⁶ "Although the OSD 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 in the State Health Plan for the establishment of an ESRD facility were not given consideration in this staff analysis."

Ex. 3 (OSD Staff Analysis, January 2007, p.3); R.E. 252-59.

³⁷ See Ex. 77, p.2; R.E. 409 (Fresenius' Diamondhead CON application).

service area, and you have to make a new need determination.” Admin. Hrg. 842. The expert even produced a handout, laying out the new Fresenius line on the 80 percent threshold:

- Ocean Springs Dialysis failed to demonstrate its consistency with this criterion in its application for the permanent relocation of its facility.
- The Department cited this criterion in the Staff Analysis, but stated: “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.”
- *There are no exceptions set forth in the State Health Plan to this need criterion.*
- A review of historical utilization data demonstrates that not all providers in the Ocean Springs Dialysis’ service area were at 80% utilization.
- The Ocean Springs Dialysis CON application fails to meet the need criterion in the State Health Plan.

Ex. 83, p. 7 (Exhibit prepared by Daniel Sullivan) (emphasis supplied). After benefitting from the Department’s finding that the relocation of an ESRD facility damaged by Hurricane Katrina did not constitute the “establishment” of an ESRD facility, Fresenius now argued the complete opposite, that the criterion applied and there were “no exceptions.” *Id.*

The Department and DVA argued to the Chancery Court that the principal of judicial estoppel should be applied to prevent Fresenius from benefitting from this tactic. Tr. 41-42. The Chancery Court did not even acknowledge the argument in its Opinion and Order. The application of the doctrine represents a question of law, which is subject to a de novo review by this court. *Oktibbeha County Hosp. v. Miss. State Dep’t of Health*, 956 So.2d 207, 208-209(¶5) (Miss. 2007).

As this court has stated, “We apply the doctrine of judicial estoppel where ‘there is multiple litigation between the same parties and one party knowingly asserts a position inconsistent with the position in the prior litigation.’ ” *Rankin v. American General Finance, Inc.*, 912 So.2d 725, 728(¶10) (Miss. 2005) (quoting *In re Mun. Boundaries of City of Southaven*, 864 So.2d 912, 918(¶ 17) (Miss. 2003)); *see also King v. Bunton*, 2010 WL 1077442, *2(¶12) (“Judicial estoppel normally arises from the taking of a position by a party that is inconsistent

with a position previously asserted.”) (quoting *Banes v. Thompson*, 352, So.2d 812, 815 (Miss. 1977)).

The doctrine’s purpose is “to protect the integrity of the judicial process”, by “prevent[ing] parties from playing fast and loose with the courts to suit the exigencies of self interest.” *Coastal Plains, Inc. v. Browning Manuf’g*, 179 F.3d 197, 205 (5th Cir. 1999) (internal quotation marks, parentheses, and citation omitted). A party can be estopped from taking one position, benefiting from it, “and then, when it becomes more convenient or profitable, retreating from that position later in the litigation.” *Scott v. Gammons*, 985 So. 2d 872, 877(¶18) (Miss. Ct. App. 2008).

The plaintiffs in *Scott v. Gammons* received settlements and executed releases based upon their claim that one of two occupants of a vehicle that collided with their car (Conway) was at fault. *Scott*, 985 So.2d at 873(¶1). They then filed suit against the second occupant of the other vehicle (Gammons), now claiming that she was at fault. *Id.* at 873(¶2). The second claim was dismissed by the trial court, and on appeal Plaintiffs argued that the doctrine of judicial estoppel did not apply since the earlier position was asserted in a different proceeding. *Id.* at 877(¶17). The Court of Appeals disagreed, holding that the change in position does not have to take place within the scope of the same litigation, as long as there is sufficient identity of issues and parties. *Id.* at 877(¶18).

There is a clear identity of the parties and issues in the present case. Fresenius and the Department of Health are important participants in both the Bay St. Louis CON filing and the present CON proceeding. Fresenius took the position in its own CON application for an ESRD facility damaged by Hurricane Katrina that since it operated the facility pre-storm and had already obtained an Emergency CON, the State Health Plan’s ESRD need criterion did not apply - even if the facility were moved 10 miles and to a different town. Ex. 77, p. 11; R.E. 420.

However, when challenging the OSD application it claimed that moving a dialysis facility creates a new “Service Area” which, in turn, “constitutes the establishment of a new dialysis facility” and requires the ESRD criteria, including the 80 percent threshold, to be met. R. 32-37 (Br. at 13, 13-18).

Fresenius must not be allowed to play “fast and loose” with the courts, the Department, or the State Health Plan in this manner. *Coastal Plains, Inc.* 179 F.3d at 205. Fresenius should be estopped from taking a position, benefitting from it, and now taking the opposite view only after it has become (potentially) more profitable to do so.

III. THE DEPARTMENT OF HEALTH DID NOT ACT ARBITRARILY OR CAPRICIOUSLY WITH REGARD TO THE EMERGENCY CON LAW

a. Fresenius’ Request for a Public Hearing During the Course of Review Was Limited to DVA’s Regular CON Application

DVA filed an application for an Emergency CON on August 7, 2006, to re-establish and relocate Ocean Springs Dialysis at the Ponce DeLeon location. Admin. Hrg. 17; Ex. 2; R.E. 29-36. The Department of Health posted a notice of this filing on its website the next week. Ex. 4; R.E. 260. The Department’s Staff published a Staff Report in October 2006, recommending approval of DVA’s application, number ESRD-ERE-0806-001, and published this recommendation on its website. Exs. 2, 6; R.E. 264. The State Health Officer then granted an Emergency CON on October 6, 2006, to DVA for the relocation, terming his decision a “Final Order.” Exs. 2, 7; R.E. 49-52. (Ltr. from B. Amy to K. Livingston-Wilson (Oct. 6, 2006));

After the publication of the Department’s Staff Analysis for OSD’s regular CON application, Fresenius requested an administrative hearing. Ex. 2; R.E. 178-80 (Request for Public Hearing During the Course of Review, ¶ 10 (March 7, 2007)). The request plainly incorporates only the CON Review number for DVA’s regular application, ESRD-NIS-1106-033, “on the above-styled Application”

DVA moved to limit the testimony and evidence at the administrative hearing to DVA's regular CON application. Ex. 2; R.E. 186-92 (Applicant's Motion In Limine (Jan. 14, 2009)). The Hearing Officer overruled DVA's objection, eventually opining that the Emergency CON should not have been granted. Ex. 2; R.E. 198-208 (Hearing Officer's Findings, pp. 5-14).

b. The State Health Officer's Grant of an Emergency CON To DVA Was Not Subject To Review By the Hearing Officer Or the Chancery Court

Don Eicher, a Department Director, testified that Emergency CONs are not subject to review through the regular administrative hearing process.³⁸ Admin. Hrg. 17. As he noted, this special type of CON is specifically exempted by the Legislature from the normal CON review processes:

Notwithstanding any other provisions of Sections 41-7-171 to 41-7-209, when the need for any emergency replacement occurs, *the certificate of need review process may be expedited by promulgation of administrative procedures for expenditures necessary to alleviate an emergency condition. . . .*

Miss. Code Ann. § 41-7-207 (emphasis supplied).³⁹ Among the provisions that do not apply is a right to an administrative hearing for an affected party (Miss. Code Ann. § 41-7-197). *Id.*

In conformity with the emergency statute, the Department's regulation providing for Emergency CONs does not provide for the right to a Public Hearing During the Course of Review. The CON Review Manual simply states that the State Health Officer, after considering

³⁸ Mr. Eicher also testified that the Department received applications for emergency CONs more than a year after Hurricane Katrina. Admin. Hrg. 22. Evidence relating to Fresenius' Emergency CON application for its Bay St. Louis facility and its timing was excluded from evidence by the Hearing Officer. Admin. Hrg. 44-50. DVA proffered testimony and evidence on this point. Admin. Hrg. 51-53. Fresenius' application was also for the relocation of an entire facility, more than one year after Katrina. *See* Exs. 10 and 11; R.E. 344-54.

³⁹ Emergency CONs are not the only type of certificate of need for which the legislature has allowed the normal CON hearing process to be suspended. *See, e.g., Oktibbeha County Hosp.*, 956 So. 2d 207 (no right of hearing for grant of CON for MRI pursuant to Miss. Code Ann. § 41-7-191(16)). In addition, other officers of the executive branch have the authority to suspend agency regulations in time of emergency. *See, e.g.,* Miss. Code Ann. § 33-15-11 (empowers Governor to suspend regulatory statutes prescribing conduct of state business); § 33-15-11(c)(4) (authorizes Governor to exercise powers as necessary to promote and secure safety and protection of civilian population); § 33-15-11(b)(9) (Governor can delegate emergency powers).

an emergency application and any documentation submitted, “shall grant or deny the emergency Certificate of Need application.” Ex. 9; R.E. 315 (CON Rev. Man., Ch. 3, p. 30). Consistent with this procedure and statutory authority, the Department has included Emergency CONs within the category of “Administrative Decisions” that can be made by the Health Officer without affording the public notice or a hearing during the course of review:

The State Health Officer may approve emergency CON’s . . . without providing notice to affected persons or the public or providing an opportunity for a hearing during the course of review.

Id. at Ch. 5, p. 48; *see also* Ex. 8; R.E.294 (CON Rev. Manual, Ch. 5, Sect. 103.01). Further, under the Department’s regulations the Hearing Officer’s authority extends only to the review of an analysis of a CON project by the Department’s Staff, called a “staff analysis,” and does not include the review of actual CONs issued by the State Health Officer, emergency or otherwise. Ex. 9; R.E. 320 (CON Rev. Manual, Ch. 4, p. 35); *see also* Ex. 8; R.E. 281 (CON Rev. Manual, Ch. 4, Sect. 100).

On appeal, the Chancery Court found that the Emergency CON “should have never been approved.” R. 199; R.E. 15 (Order and Opinion at 12). However, this issue was never properly before the Chancery Court. The Staff Analysis, the State Health Officer’s order, and the CON itself all reflect the application number for DVA’s regular CON application only, “ESRD-NIS-1106-033.” Ex. 2; R.E. 248-511 (State Health Officer); Ex. 3; R.E. 252-59 (Staff Analysis). As noted previously, it was this order on which Fresenius requested an administrative hearing, not the Emergency CON (number ESRD-ERE-0806-001). R.E.178-80. Therefore, despite the opening of the Hearing Officer and the Chancery Court, the Emergency CON granted to DVA was not properly subject to their review or consideration on appeal.

This does not mean, however, that Fresenius is without a right of redress. The Emergency CON regulation requires the applicant to file a regular CON application “within 45

days of the effective date” of the Emergency CON and specifies that “normal CON procedures are applicable to any *subsequent application*. . . .” Ex. 8; R.E. 275 (CON Rev. Man., Ch. 3, Sect. 111.01) (emphasis supplied).⁴⁰ DVA filed its application for a regular CON within 45 days of the grant of an Emergency CON. Admin. Hrg. 67-68; Exs. 2, 13. Therefore, while Fresenius has no right to challenge DVA’s Emergency CON through the administrative hearing process, it preserved its right to have the Chancery Court determine whether the State Health Officer’s decision to issue a regular CON to DVA was arbitrary and capricious and not based on substantial evidence.

CONCLUSION

The deference due a governmental agency’s interpretation of its own regulations is derived from a “realization that the everyday experience of the administrative agency gives it familiarity with the particularities and nuances of the problems committed to its care which no court can hope to replicate.” *Baptist Mem’l. Hosp. – DeSoto*, 984 So.2d at 975 (¶12). Unfortunately, the Chancery Court’s order to close Ocean Springs Dialysis bears little trace of this deference, nor any recognition of the problems encountered by DVA and the Department of Health in the aftermath of Hurricane Katrina.

The State Health Plan provision at issue, the 80 percent need threshold, clearly equates the “establishment” of an ESRD facility with an “additional” facility in a “given service area.” Ex. 20; R.E. 360-61 (State Health Plan, Ch. 13, Sect. 107.02.01 and Ch. 13, Sect. 107.01(6)). An additional ESRD facility was not established within the respective 30 highway mile service areas of Fresenius’ D’Iberville or Biloxi facilities when Ocean Springs Dialysis moved two minutes

⁴⁰ The emergency CON regulation provides, in part: “Emergency CONs shall be valid for not more than 90 days. Consequently, any recipient of an emergency CON is required to submit the appropriate CON application to the Department within 45 days of the effective date of the emergency CON, addressing the same project for which the emergency CON was granted. Normal CON procedures are applicable to any *subsequent application* submitted by a recipient of an emergency CON with reference to the same project.” Ex. 8; R.E. 276 (CON Rev. Manual, Ch. 3, Sect. 111.01) (emphasis supplied).

away, to Ponce DeLeon Drive. Further, the lower court should never have allowed Fresenius to challenge the Department's interpretation of this provision, after the company had previously urged the same interpretation and benefitted from it when it was allowed to rebuild and relocate its Bay St. Louis facility to a different town without having to satisfy the 80 percent threshold.

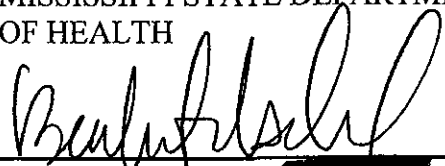
The Chancery Court, in a matter of first impression, substituted its own interpretation of the State Health Plan provision at issue for that of the state agency that formulated it and administers it. This Court has repeatedly cautioned against such. *See, e.g., Southwest Miss. Regional Med. Ctr.*, 580 So. 2d at 1241-42; *see also Rush Care, Inc.*, 882 So. 2d at 210. When considered in the context of the standard of review that should have been employed and the facts of this unique case, 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 Department.

THIS the 28th day of June, 2010.

Respectfully submitted,


MISSISSIPPI STATE DEPARTMENT
OF HEALTH

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CERTIFICATE OF SERVICE

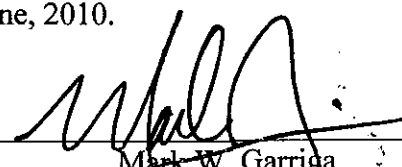
I, Mark W. Garriga, do hereby certify that a true and correct copy of the above and foregoing Brief of Appellants was this day served by U. S. Mail, first class, postage pre-paid, upon the following:

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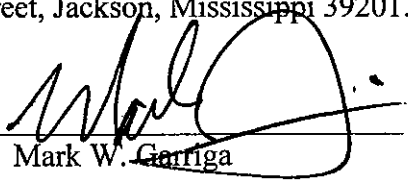
SO CERTIFIED, this the 28th day of June, 2010.



Mark W. Garriga

CERTIFICATE OF FILING

I, Mark W. Garriga, certify that I have had hand-delivered the original and three copies of the Brief of Appellants Mississippi State Department of Health and DVA Healthcare Renal Care, Inc. and an electronic diskette containing same on June ^{24th}~~26th~~, 2010, addressed to Ms. Kathy Gillis, Clerk, Supreme Court of Mississippi, 450 High Street, Jackson, Mississippi 39201.



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