

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
FEBRUARY 2010**

**CON REVIEW: ESRD-NIS-0908-035
RENAL CARE GROUP TUPELO, LLC
D/B/A FRESENIUS MEDICAL CARE – WATER VALLEY
ESTABLISHMENT/CONSTRUCTION OF A SIX-STATION ESRD FACILITY IN YALOBUSHA COUNTY
CAPITAL EXPENDITURE: \$462,471
LOCATION: WATER VALLEY, YALOBUSHA COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Renal Care Group Tupelo, LLC, d/b/a Fresenius Medical Care – Water Valley, is a joint venture which is majority owned by RCG Mississippi, Inc. and whose parent is Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care of North America (“Fresenius”). The entity is a limited liability company incorporated in the state of Delaware and is authorized to do business in Mississippi. Fresenius, which is governed by a seven-member Board of Directors, owns and operates more than 1,600 ESRD facilities throughout the United States. The entity is a vertically integrated company, offering products and services for the entire dialysis chain. It has developed such programs as UltraCare and RightStart which is accessible for its patients.

B. Project Description

Renal Care Group Tupelo, LLC, d/b/a Fresenius Medical Care – Water Valley, (“FMC-Water Valley”) requests Certificate of Need (CON) authority to establish a six-station End Stage Renal Disease (ESRD) facility in Water Valley, Yalobusha County, Mississippi.

The applicant proposes to lease medical office space and renovate the leased space to house the six-station ESRD facility. According to the applicant, the chosen location is near the center of the population in Water Valley and is easily accessible for those Yalobusha County residents who choose to use the new facility. The proposed renovation includes finishing out 3,428 square feet of shell space for the six-station dialysis unit and related office. The work will include: interior studs; drywall; floor, wall, and ceiling finishes; interior doors with hardware; specialty items; casework; complete plumbing, HVAC, and electrical systems.

The new facility is expected to provide residents in Yalobusha County a more convenient, accessible ESRD facility at which to receive dialysis services. The nearest ESRD facilities to Yalobusha County residents, according to the applicant, are located in Lafayette County – RCG of Oxford (18.5 miles), Grenada County – RCG Grenada (25.1 miles), and Panola County – Fresenius Medical Care of Sardis (26.3 miles). All three facilities are related to the applicant; therefore, it is anticipated that the establishment of a related ESRD facility in Yalobusha County will enable those ESRD patients currently treated at these three facilities to have a near seamless transition to the new facility.

FMC-Water Valley anticipates that the capital expenditure will be obligated within 90 days of CON approval with completion within one year thereafter.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Section 41-7-191, subparagraph (1)(a), of the Mississippi Code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197 (2) of the Mississippi Code of 1972 Annotated, as amended, any affected person may request a public hearing on this project within 20 days of the publication of the staff analysis. The opportunity to request a hearing expires on March 15, 2010.

In addition, CON projects are reviewed under the Plan in effect at the time of receipt. This project was received in September 2008; therefore, it is reviewed under the 2009 State Health Plan.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The 2009 *State Health Plan* contains policy statements and service specific criteria and standards which must be met before an applicant is granted CON authority to establish an ESRD facility, as set forth below.

The applicant is not in substantial compliance with the policy statements and criteria set forth in the *2009 State Health Plan*.

SHP Criterion 1 - Need

An applicant proposing the establishment of a limited care renal dialysis facility shall demonstrate that each individual ESRD facility in the proposed ESRD Facility Service Area has (a) maintained a minimum annual utilization rate of 80 percent or (b) that the location of the proposed ESRD facility is in a county which does not currently have an existing ESRD facility but whose ESRD relative risk (RR) score using current ESRD Network 8 data is 1.5 or higher. Policy Statements 2, 4, 5, and 6 do not apply to criterion 1(b).

The applicant alleges that Yalobusha is a county without an ESRD Facility and meets the relative risk calculation of 1.5 or higher using Network 8 data. The source of the applicant's claim appears to be an unofficial, unverified, and unpublished calculation done by a staff member. The information apparently provided to the applicant had not been verified or approved by the Office Director or the State Health Officer. Network 8 data is necessary for the calculation of the relative risk score and at the time of adoption of the *2009 State Health Plan*, it was assumed that the general public could obtain the information from Network 8 and perform the calculation of the relative risk score. After the Department was approached by an interested party with a complaint about the process, it was discovered that the general public would not have access to the data and information from Network 8. Therefore, the Department maintains that the Plan is defective for the following reasons:

1. The data could not be obtained by the general public;

2. The Plan does not identify the county or counties, if any, that would meet the calculation, as in previously published Plans; and
3. The Plan is not in compliance with the mandate of the Administrative Procedures Act*, as to this specific criterion.

The Department has made no official and verified calculation prior to the adoption or during the effective dates of the 2007 or 2009 Plans. At this time, the Department cannot obtain the exact data, nor could anyone else, necessary to make the calculation of the relative risk score for the requisite time period of the 2009 Plan. Further, investigation of the prior calculation relied upon by the applicant cannot be verified and in fact, the Department has determined that the calculation was done in error. Specifically, the Department determined that the year 2010 projected population was used in calculating the relative risk scores. This rendered the information inaccurate on its face as the population for 2007 should have been used in the calculation. In addition, current verified calculation of the relative risk score for the county in question, show that the county has a relative risk score of 1.3 which does not meet the threshold requirement of the criterion.

For the reasons stated above, the Department cannot verify that Yalobusha County meets the requirement of the relative risk score of 1.5 or higher and thus the application is not in compliance with this criterion of the Plan.

SHP Criterion 2 – Number of Stations

The applicant proposes that the facility will have six dialysis stations to serve the needs of the ESRD patients of Yalobusha County. Applicant states that the decision for the six stations was based on a consideration of Network 8 data, the Department’s calculation of the relative risk score for the county, and utilization of the other related ESRD facilities in the area.

SHP Criterion 3 - Minimum Utilization

The applicant submits that Network 8 data demonstrated that the prevalence of ESRD patients increased in Yalobusha County from 27 in 2005 to 31 in 2006, and 35 in 2007. Therefore, the applicant projects 24 patients in year 1, 27 patients in year 2, and 32 patients in year 3. Typically, an ESRD patient receives three treatments per week or 156 treatments per year. The following table compares the applicant’s projections with the Department’s requirements:

Year	Stations	Applicant’s Projections			MSDH Requirements	
		Patients	Treatments	Utilization Rate	Treatments	Utilization Rate
1	6	24	3,168	56.4%	2,808	50%
2	6	27	3,672	65.4%	3,650	65%
3	6	32	4,248	75.6%	4,212	75%

*Note: Any Department calculation of the relative risk score and implementation, interpretation, or prescription as a part of the 2009 Plan is thus a “Rule” that requires disclosure under of the Administrative Procedures Act, and had to meet its rulemaking procedure, disclosures, and requirements.

SHP Criterion 4 - Minimum Services

The applicant affirms that it will provide, at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services will be provided on a referral basis. The applicant states that the required minimum services are a part of each patient's Patient Care Plan and are an integral part of the UltraCare program.

SHP Criterion 5 - Access to Needed Services

The applicant affirms that it will provide reasonable access to equipment and facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Criterion 6 - Hours of Operation

The applicant submits that the normal facility hours of operation will be from 7:00 a.m. to 6:00 p.m. six days per week. Alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 7 - Home Training Program

The applicant affirms that a home training program will be made available and it will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program. The Home Training program will be coordinated through the Home Therapies Department located in Tupelo. The applicant states that this Department consists of five trained and experienced Home Therapy RN's who currently oversee approximately 85 home patients located throughout Northeast Mississippi. The applicant submits that Fresenius provides a Treatment Options Program (TOPS) for all pre-ESRD patients. Modality choices, including CAPD, CCPD, and Home Hemodialysis, are presented by trained staff to patients in a classroom or individual setting and even in physician offices.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirms that the proposed facility will have no admission policies which will adversely affect access to care by indigents, and will provide indigent/charity care. The applicant anticipates its percentages of indigent/charity care to be 2%. In addition, the applicant stated that if it determines that a patient does not have or no longer has insurance coverage steps will be taken to determine whether viable coverage options exist.

SHP Criterion 9 - Facility Staffing

The application includes documentation for qualifications and specific duties of the proposed facility's staff.

SHP Criterion 10 - Staffing Qualifications

The applicant asserts that its staff will meet, at a minimum, all requirements and qualifications as stated in the Medicare Conditions for Coverage of Suppliers of ESRD Services.

SHP Criterion 11 - Staffing Time

The applicant affirms that when the unit is in operation, at least one (1) registered nurse will be on duty. There will be a minimum of two persons for each dialysis shift, one of which will be an RN.

The applicant affirms that a medical director or a designated physician will be on-site or on-call at all times when the facility is in operation. The applicant submits that it already has established physician relationships in the area so a physician will be available to supplement the services of the medical director if needed.

SHP Criterion 12 - Data Collection

Fresenius affirms that it shall record and maintain all utilization data and data regarding services provided to indigent patients and shall make this information available to the MSDH as required.

SHP Criterion 13 - Staff Training

The applicant affirms that it will provide an ongoing program of training for nurses and technicians in dialysis techniques. Specifically, the applicant states that Fresenius will offer a comprehensive training program for all direct patient care staff. The training includes didactic and clinical training with qualified preceptors to build clinical skills. The program is taught by Certified Nephrology Nurses over a four-week period with structured learning activities to activate adult learning. An outline of the training module is included in the application.

SHP Criterion 14 - Scope of Privileges

The applicant affirms that the proposed facility shall provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility. The applicant submits that Fresenius has existing relationships with nephrologists in the area who currently treat the applicant's patients and will continue to treat the patients at the proposed facility.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirms that it presently has and will maintain its affiliation agreements with University of Mississippi Medical Center, University of Alabama at Birmingham and the Mid-South Transplant Foundation, Inc.

The applicant further affirms that it understands and agrees that failure to comply with this criterion may after due process result in revocation of the CON.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, revised February 2008*, addresses general criteria by which all CON applications are reviewed. The applicable criteria are discussed below.

GR Criterion 1 – State Health Plan

This application was submitted for compliance with Need Criterion 1(b) of the FY 2009 *State Health Plan*. Need Criterion 1(b) provides that counties without an ESRD facility may qualify for a facility if its RR score using current Network 8, Inc. data is 1.5 or higher. Current verified calculation of the relative risk score for Yalobusha County shows that the county has a relative risk score of 1.3, which does not meet the threshold requirement of the criterion. Therefore, the application is not consistent with the 2009 State Health Plan.

GR Criterion 2 - Long Range Plan

The applicant submits that Fresenius' long range plan is to provide high quality, easy to access ESRD services for those residents in need of dialysis services in Yalobusha County. These objectives, according to the applicant, tie into the applicant's mission statement: to improve the quality of life of every patient, every treatment, through UltraCare.

GR Criterion 3 - Availability of Alternatives

The applicant states that it considered not establishing a facility in the county and continuing to service those patients through its existing facilities. However, given the continued growth in ESRD, the applicant determined it should establish a new facility to serve the county whose relative risk score had increased to meet the Department's determination of need.

The applicant further considered establishing both a larger and smaller facility; however, it determined that based on current utilization at other facilities in the service area and Network 8 data, that a smaller facility would not adequately meet the needs of the residents of the county and a larger facility would cause more healthcare dollars to be spent than was necessary to efficiently serve the ESRD population in the area.

The applicant believes that its relationship with Fresenius will greatly benefit the proposed facility due to Fresenius' integrated delivery and service model. This association, according to the applicant, will also bring and ensure quality care to the residents of Yalobusha County. The applicant submits that each dialysis patient will benefit from the expertise and experience of the nation's largest dialysis provider and its extensive clinical network.

GR Criterion 4 - Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$16,357 the first year, \$37,886 the second year, and \$60,735 the third year of operation. The project appears to be economically viable.

The applicant submits that the ESRD reimbursement environment and the patient population of any area are ever changing; however, the applicant has the financial strength to operate the facility at a loss, if necessary.

- a. **Proposed Charge:** The applicant submits that the proposed project will not increase the cost of dialysis services to patients or Medicaid. It believes that the

experience gained in effectively operating other ESRD facilities in the service area and across the state will help ensure that there will not be a negative effect on the cost of health care as it is associated with the project. The applicant also believes that the charge for the services is comparable to other ESRD facilities' charges because Medicare sets in advance a composite rate per treatment for each geographic area.

- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 56.4%; 65.4%; and 75.6% respectively.

GR Criterion 5 - Need for the Project

This application was submitted under SHP Need Criterion 1(b) which indicates that an ESRD facility may be needed in a county that does not currently have an ESRD facility and whose RR is 1.5 or higher. The applicant submits that Yalobusha County's RR is 1.52. However, further calculation of the RR indicates a score of 1.3 for Yalobusha County. Therefore, the project does not meet the need requirement as stated in the *2009 State Health Plan*. Furthermore, staff maintains that the project is an unnecessary duplication of a health service since there are three other ESRD facilities located within a 30-mile radius of the proposed facility. All three facilities indicate utilization below 80%.

GR Criterion 6 - Access to the Facility or Service

The applicant indicates that all residents of the health planning service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly have access to the services of the existing facility and will have access to the proposed facility.

The applicant anticipates that approximately 2% of its gross patient revenue will be required to provide care to charity/medically indigent patients. It states that all patients not otherwise covered by insurance qualify for Medicare/Medicaid after an initial 90-day waiting period. Therefore, indigent/charity care provided is calculated by estimating the percentage of patients who will be subject to the 90-day qualification period.

The following table shows the projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$833.18
2	\$965.74

The proposed facility will be available Monday through Saturday 7:00 a.m. to 6:00 p.m.

GR Criterion 7 - Information Requirement

The applicant affirms that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 - Relationship to Existing Health Care System

As previously stated, there are no ESRD facilities in Yalobusha County. Currently residents travel to other related facilities in Grenada, Sardis, and Oxford. The applicant submits that all of these facilities serve the same population, and will cooperate to transfer any patients from the other facilities to the Water Valley facility for the patient's continuity of care.

GR Criterion 9 - Availability of Resources

The applicant submits that ESRD facilities affiliated with the applicant have successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of their current facilities. It further submits that the surrounding area has sufficient nephrologists to support the proposed facility.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant affirms that it will provide all necessary support and ancillary services. Also, due to its relationship with both Fresenius and the surrounding medical community, the applicant states that all ancillary services will be sufficiently available including laboratory services, drugs and any necessary services related to the method in which a patient chooses to receive dialysis services.

GR Criterion 11 – Health Professional Training Programs

The applicant submits that it will cooperate with health professional training programs in the surrounding area.

GR Criterion 16 - Quality of Care

As stated earlier, Fresenius, the parent company, owns and operates more than 1,600 ESRD facilities throughout the United States. Fresenius is a vertically integrated company, offering products and services for the entire dialysis chain. It has developed such programs as UltraCare and RightStart which will be accessible for its patients.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	\$	0.00%
Construction Cost - Renovation	325,660	70.42%
Capital Improvements	-	0.00%
Total Fixed Equip Cost	-	0.00%
Total Non-Fixed Equip Cost	107,705	23.29%
Land Cost		0.00%
Site Prep Cost	-	0.00%
Other - Site Expense Excavation	-	0.00%
Fees - architectural, engineering, etc.	29,106	6.29%
Fees - legal and accounting	-	0.00%
Contingency Reserve		0.00%
Other - HUD and banking fees	-	0.00%
Capitalized Interest	-	0.00%
Other Cost	-	0.00%
Total Proposed Expenditures	\$ 462,471	100%

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves.

C. Effect on Operating Cost

Attachment 1 lists Fresenius Medical Care-Water Valley's projections of expenses, revenues, and utilization for the first three years of operation.

D. Cost to Medicaid/Medicare

ESRD treatment is a Medicare entitlement. As such, the Medicare program will absorb a majority of the costs associated with this project. The cost to the Medicaid program will be negligible.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; however, the department received no response, as of the date of this staff analysis.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with criteria and standards for establishment of end stage renal disease facilities as contained in the *FY 2009 State Health Plan*; the *Mississippi*

Certificate of Need Review Manual, revised February 2008; and all adopted rules, procedures, and plans of the Mississippi State Department of Health. Specifically, the Department could not verify the data relied upon by the applicant for calculation of relative risk score of 1.52. Further, current verified calculation of the relative risk score for Yalobusha County show that the county has a relative risk score 1.3, less than the required score of 1.5 as indicated in the *2009 State Health Plan* for approval of an ESRD facility in a county without an ESRD facility.

Therefore, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by Renal Care Group Tupelo d/b/a Fresenius Medical Care – Water Valley for the establishment of a six-station ESRD facility in Yalobusha County, Mississippi.

ATTACHMENT 1

Fresenius Medical Care – Water Valley Three-Year Operating Statement			
	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient			
Outpatient	\$833,183	\$965,736	1,117,223
Total Gross Patient Revenue	\$ 833,183	\$ 965,736	\$ 1,117,223
Charity Care			
Deductions	-	-	-
	-	-	-
Net Patient Revenue	\$ -	\$ -	\$ -
Other Operating Revenue	\$ 833,183	\$ 965,736	\$ 1,117,223
Total Operating Revenue	\$ 833,183	\$ 965,736	\$ 1,117,223
Expenses			
Salaries	\$230,374	\$263,809	\$303,197
Benefits	49,300	56,500	64,900
Services	272,068	315,351	364,818
Supplies	-	0	0
Lease	54,455	54,455	54,455
Depreciation	52,500	52,500	52,500
Other	-		0
Total Expenses	158,129	185,235	216,618
	\$ 816,826	\$927,850	\$1,056,488
Net Income (Loss)	\$16,357	\$37,886	\$60,735
Utilization Rate (percent)			
Total treatments	3,168	3,672	4,248
Patients	24	27	32
Charge Per Treatment	\$263	\$263	\$263
Cost Per Treatment	\$258	\$253	\$249