

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
AUGUST 2016**

**CON REVIEW: ESRD-NIS-0616-013
RENAL CARE GROUP TUPELO, LLC
D/B/A RCG OF TUPELO
ESTABLISHMENT OF A SATELLITE ESRD FACILITY
CAPITAL EXPENDITURE: \$1,810,566
LOCATION: TUPELO, LEE COUNTY, MISSISSIPPI**

STAFF ANALYSIS

PROJECT SUMMARY

A. Applicant Information

Renal Care Group Tupelo, LLC d/b/a RCG of Tupelo ("RCG Tupelo") is a business corporation and an affiliate of Fresenius Medical Care North America ("Fresenius") located in Memphis, Tennessee. The applicant indicates that RCG Tupelo has two Directors and fourteen officers.

The applicant provided a Certificate from the Secretary of State, verifying that Renal Care Group Tupelo, LLC was issued a Certificate of Authority on November 13, 2001. The document indicates that the business is a Delaware Limited Liability Company authorized by the Secretary of State to do business in Mississippi.

B. Project Description

RCG of Tupelo d/b/a Lee County Dialysis (the "Applicant" or "Satellite") requests Certificate of Need ("CON") authority to establish a ten (10)-station satellite End Stage Renal Disease ("ESRD") facility to be located at 1031 South Madison Street in Tupelo. The proposed satellite location is approximately 2.1 miles from the host facility, RCG of Tupelo, located at 2978 Mattox Street in Tupelo, Mississippi ("the host facility"). The applicant states that the host facility's occupancy rate is 83.4% and the first satellite, RCG of Central New Albany, located in New Albany approximately 29.4 miles from the proposed facility, had an occupancy rate of 62.0% in less than 8 months. The first satellite facility in New Albany helped improve access at both the host facility and RCG Central New Albany; however, the applicant indicates that due to the passage of time from the issuance of CON in June 2012 to completion in Fall 2015, the number of patients seeking dialysis within the City of Tupelo has grown more than originally expected. The creation of the second satellite location is expected to enable the applicant to shift its patients in a way to meet patient needs, staffing needs and physician rounds.

The applicant states that the Satellite facility will be located in the former location of the host facility, which will significantly decrease the cost associated with the proposed facility. The project will entail 8,536 square feet of renovation to accommodate the Satellite facility at an estimate cost of \$148.79 per square foot.

The applicant provided a cost estimate from Bryan Brown & Associates, PLLC (located in Columbus, Mississippi), confirming that the total proposed project budget, is \$1,810,565.90. The applicant indicates cash reserves will be used to fund the project.

The project is estimated to require 12.1 FTE personnel at an annual cost of \$382,653 the first year. The MSDH Division of Fire Safety and Construction approved the site for the project on May 6, 2016.

The applicant anticipates that the construction of the proposed project should begin within six (6) months of final approval and anticipates that the project will be complete within one (1) year of final CON approval.

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) and 1(b) 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 10 days of the publication of the staff analysis. The opportunity to request a hearing expires on September 8, 2016.

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

A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains policy statements and service specific criteria and standards, which the applicant is required to meet before receiving CON authority to establish a ten-station satellite ESRD facility. This application is in substantial compliance with applicable criteria and standards.

Policy Statement No. 14 of the 2015 State Health Plan states “Any existing ESRD facility which reaches a total of 30 ESRD stations, may establish a ten (10) station satellite facility. If a proposed satellite ESRD facility is to be located more than one (1) mile from the existing facility, a Certificate of Need must be obtained by the facility prior to the establishment of the satellite facility”.

According to the *FY 2015 State Health Plan*, RCG Tupelo has 50 certified ESRD stations.

The applicant states that the proposed facility will be located approximately 2.1 miles from the host facility. Therefore, the applicant is requesting CON approval for the establishment of a ten (10) station satellite ESRD facility.

SHP Criterion 3- Need

Need Criterion for Establishment of ESRD Satellite Facilities: In order for a 30 station ESRD facility to be approved for the establishment of a ten (10) station

satellite facility through the transfer and relocation of existing stations within a five mile radius or less from the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility. If the proposed satellite facility will be established at a location between a five and twenty-five mile radius of the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility; and (d) demonstrate that the proposed satellite facility's location is not within 30 miles of an existing facility without obtaining the existing facility's written support. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the establishment of satellite ESRD facilities. An ESRD satellite facility established under this Need Criterion 3 shall not be used or considered for purposes of establishing or determining an ESRD Facility Service Area.

(a) Document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application.

The applicant indicates that RCG Tupelo is currently experiencing 83.4% utilization of its 50 stations, which includes four (4) stations under CON R-0903.

The application contained utilization for the period June 2015 to May 2016. The applicant indicates that during this period the facility operated an average of 48 stations and performed 36,947 procedures. The applicant noted that 10 stations were removed from RCG of Tupelo to establish RCG of Central New Albany per CON R-0854; a determination of reviewability added back 6 stations, resulting in 46 ESRD stations at RCG of Tupelo; CON R-0903 was issued March 4, 2016 approving the expansion by 4 stations, returning RCG of Tupelo to 50 certified ESRD stations.

(b) Justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility.

The applicant submits that the satellite facility will provide ESRD patients an additional access point for dialysis services, which will help reduce the crowding issues experienced at the nearby facilities and the host facility, provide improved patient care and enable patients to have flexibility with their appointment times.

(c) Document that it is more cost effective to establish a satellite facility than to expand the existing facility.

The applicant asserts that additional construction would have to be undertaken in order to expand the existing facility, which will result in additional cost. The host facility's previously vacated building is still available and is appropriate for a smaller satellite facility. In addition, the applicant states that the cost of reconfiguring this existing building is significantly lower than the cost for construction and/or renovating a new building.

(d) Demonstrate that the proposed satellite facility's location is not within thirty miles of an existing facility without obtaining the existing facility's written support.

The applicant submits that the proposed satellite is located approximately 2.1 miles from the host facility and 29.0 miles from the host facility's first satellite. Both facilities support the establishment of the proposed second satellite.

SHP Criterion 4 - Number of Stations

The applicant affirms that the satellite ESRD facility will contain 10 hemodialysis stations. Therefore, the applicant is in compliance with this criterion.

SHP Criterion 5 - Minimum Utilization

The applicant projects 33 patients in year one, 43 patients in year two, and 49 patients in year three for the proposed 10-station satellite ESRD facility. Typically, an ESRD patient receives three (3) treatments per week or 156 treatments per year. The applicant determined a lower number of treatments per patient could result in a more accurate estimate, due to missed appointments. Therefore, the applicant estimated each patient would receive 144 treatments per year. The following tables compare the applicant's projections with the Department's requirements:

		Applicant's Projections		
Year	Stations	Patients	Treatments	Utilization Rate
1	10	33	4,752	50.7%
2	10	43	6,192	66.2%
3	10	49	7,056	75.4%

Based on MSDH's utilization requirements in the *FY 2015 MSHP* and numbers provided by applicant, staff determined the number of treatments for the first through third year of operation could be as follows (based on 156 treatments per patient):

		MSDH Projections		
Year	Stations	Patients	Treatments	Utilization Rate
1	10	33	4,680	50 %
2	10	43	6,084	65 %
3	10	49	6,084	65 %

SHP Criterion 6 - Minimum Services

The applicant affirmed that the facility will provide social, dietetic, and rehabilitative services. The applicant further states that these services are a part of each patient's care plan and are an integral part of Lee County Dialysis' services.

SHP Criterion 7 - Access to Needed Services

Renal Care Group Tupelo, LLC affirmed that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Criterion 8 - Hours of Operation

Lee County Dialysis will operate six days per week between the hours of 6:00 a.m. to 5:00 p.m. The applicant affirmed that alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

The applicant affirmed that a home-training program will be made available at the host facility and it will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program. Fresenius provides a treatment-options program for all pre-ESRD patients. The applicant states that 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 10 - Indigent/Charity Care

The applicant affirmed that they will provide a reasonable amount of indigent/charity care and serve approximately 2% indigent/charity care patients. The applicant states it will serve all ESRD patients, including Medicaid and Medicare recipients.

SHP Criterion 11 - Facility Staffing

The applicant included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties. If the proposed project is CON approved, the applicant affirms that 12.1 full time equivalents will be utilized to operate the satellite ESRD facility.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 C.F.R., Subpart D, Section 494.140 as listed under this Criterion.

SHP Criterion 13 - Staffing Time

The applicant affirmed that when the unit is in operation, at least one (1) R.N. will be on duty and at least two (2) persons will be present for each dialysis shift, one of which will be a R.N. In addition, the applicant affirms that the medical director or a designated physician will be on site or on call at all times when the unit is in operation. When the ESRD facility is not in operation, the applicant states that the medical director or a designated physician and one R.N. will be on call.

SHP Criterion 14 - Data Collection

The applicant affirmed that it shall record and maintain all required data listed under SHP Criterion 14 and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 15 - Staff Training

The applicant affirmed that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility. Furthermore, the applicant

states that specifically Fresenius and the applicant 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 as well as OSHA and mandatory Fresenius compliance training.

SHP Criterion 16 -Scope of Privileges

The applicant affirmed that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the proposed governing body of the facility. The applicant states that their affiliated facilities within the service area have 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 17 - Affiliation with a Renal Transplant Center

The applicant affirmed that they will enter into an affiliation agreement with at least one transplant center within one (1) year after the facility is opened and operating. The applicant understands and agreed 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, September 1, 2011, Revision*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 – State Health Plan

This application is in compliance with the *FY 2015 State Health Plan*.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, easy to access ESRD services for those Mississippi residents in need of dialysis services in and near Lee County. The applicant states that the proposed facility will offer a calmer, less congested environment for the patients. The applicant further states that prior to submitting this application, Fresenius discussed the growing utilization at the host facility and satellite and determined that better overall care could be provided to its patients if a second satellite facility was established in Tupelo. In addition, the Satellite will offer greater accessibility for Lee County residents to receive necessary dialysis services at more convenient times.

GR Criterion 3 – Availability of Alternatives

The applicant stated that they considered not establishing a satellite facility in Tupelo and continuing to service those patients through its existing facility. The applicant states that for reasons stated above, expansion at the host facility is not the best option. The application further indicates that the creation of the satellite facility is more efficient and cost effective for solving crowding and flexibility issues than other alternatives such as creating a newly constructed satellite or expanding the host facility.

The applicant believes that the establishment of a ten-station satellite ESRD facility in Tupelo will most efficiently and effectively meet the needs of the patients traveling within and to Lee County for dialysis services.

Renal Care Group Tupelo, LLC states that its relationship with Fresenius will greatly benefit the proposed facility due to Fresenius' integrated delivery and service model.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net loss of \$38,375 the first year. The application shows that the net income for year two and three of operation will be \$103,482 and \$205,048, respectively.

- a. **Proposed Charge:** The applicant submits that the charges for the proposed facility will be substantially the same as the applicant's affiliates in the metro area.
- b. **Projected Levels of Utilization:** The applicant states that the projected utilization was determined by reviewing the current ESRD patients receiving treatment at the host facility. ESRD patients receive an average of three (3) treatments per week. The applicant projects utilization of 50.7%, 66.1%, and 75.38% in Years 1 – 3, respectively.

GR Criterion 5 – Need for Project

- a. **Access by Population Served:** The applicant states that dialysis services are provided and will continue to be provided to the traditionally underserved population.
- b. **Relocation of Services:** The application does not propose the relocation of facility or service.
- c. **Current and Projected Utilization of Like Facilities:** The applicant submits that dialysis is not an elective service but one that is required for patients with ESRD. Thus, the proposed project does not seek to add a facility to increase utilization but to provide dialysis patients with another access point in Tupelo.
- d. **Probable Effect on Existing Facilities in the Area:** The applicant believes that the establishment of the satellite facility will slightly decrease the utilization at other surrounding, affiliated facilities as those Fresenius dialysis patients in the Lee County area will seek services at the satellite facility since it will be more accessible for certain patients and not as crowded.
- e. **Community Reaction:** The application contained five letters of support for the proposed project.

No letters of opposition for the proposed project were received.

GR Criterion 6 – Access to the Facility or Service

According to the applicant, all patients of the ESRD service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic

minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

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	\$4,102.76 (2%)
2	\$5,391.94 (2%)

The applicant confirmed that it has no existing obligations under any federal regulation requiring provision of uncompensated care, community service, or access by minority/handicapped persons.

The proposed facility will operate six days a week from 6:00 a.m. to 5:00 p.m. In addition, the applicant states that alternate times will be available by arrangement, and Medicaid recipients can receive transportation assistance for travel to dialysis appointments.

GR Criterion 7 – Information Requirement

The applicant affirmed that it will record and maintain all requested information required under GR Criterion 7 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

The applicant states that the target population accesses dialysis treatment services at the Applicant's facility (RCG of Tupelo) and the Applicant's first satellite facility (RCG of Central New Albany).

The applicant asserts that if the proposed satellite facility is not established, current and future ESRD patients residing in the area will continue to travel three times a week to the host facility or other locations to receive necessary dialysis services; however this would not address the congestion issues and availability of day chairs.

The application contains copies of renal transplantation agreements between Renal Care Group Tupelo, LLC and The University of Alabama and the University of Mississippi Medical Center, and a support agreement with North Mississippi Medical Center.

GR Criterion 9 – Availability of Resources

The applicant states that its affiliates have successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of their current facilities. The applicant proposes to use the same method. Furthermore, the applicant states, that in the event of a shortage of staff at the new facility, the affiliation with the closest facility, will allow the applicant and the other facilities to supplement and share. The applicant affirms that due to its existing presence in the metro area, it has established relationships with nearby nephrologists who will support the proposed facility.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirmed that all necessary ancillary or support services will be available due to its relationship with both Fresenius and the surrounding medical community.

GR Criterion 11– Health Professional Training Programs

The Applicant asserts that the facility will cooperate with health professional training programs in the surrounding area.

GR Criterion 14– Construction Projects

This project does not propose new construction; rather it involves the renovation of an existing building.

GR Criterion 16– Quality of Care

The applicant states that their relationship with Fresenius will greatly benefit the proposed facility due to Fresenius’ integrated delivery and service model. The applicant suggests this affiliation will help guarantee quality of care through delivery of health services, staff training and expectations.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage% of Total
Construction Cost - New	\$ 0	0%
Construction Cost - Renovation	\$1,067,000	58.93%
Capital Improvements	\$ 0	0%
Total Fixed Equip Cost	\$ 403,129	22.27%
Total Non-Fixed Equip Cost	\$ 137,707	7.61%
Land Cost	\$ 0	0%
Site Prep Cost	\$ 0	0%
Fees – architectural/engineering	\$ 96,030	5.30%
Contingency Reserve	\$ 106,700	5.89%
Capitalized Interest	\$ 0	0%
Other (equipment contingency)	\$ 0	0%
Total Proposed Expenditures	\$1,810,566	100.00%

The applicant will renovate and update the interior shell of the building which formerly held the host facility. Approximately 8,536 square feet will be renovated at an estimated cost of \$148.75 per square foot (excluding equipment and \$195.98 including equipment). See Attachment 2 for the computation of the cost per square foot. The *RS Means Construction Cost Data, 2015 Edition* does not compare cost of ESRD facilities or renovation projects.

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves. The applicant submitted documentation that it has sufficient cash to fund this project.

C. Effect on Operating Cost

Attachment 1 lists the Applicant's projections of expenses, gross revenue, net income 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. The Division of Medicaid states that the agency does not foresee any increase in allowable costs to Medicaid as it relates to the proposed project. Thus, the Division of Medical does not oppose the proposed project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of a satellite ESRD facility as contained in the *FY 2015 State Health Plan*; the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Renal Care Group Tupelo, LLC d/b/a RCG of Tupelo d/b/a Lee County Dialysis for the establishment of a ten (10) station, satellite End Stage Renal Disease ("ESRD") facility in Tupelo, Mississippi.

Attachment 1

**RCG of Tupelo d/b/a Lee County Dialysis
 Establishment of a Satellite ESRD Facility**

Three-Year Operating Statement – Project Only

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	\$ 0	\$ 0	\$ 0
Outpatient Revenue	1,263,888	1,666,475	1,952,274
Gross Patient Revenue	\$ 1,263,888	\$ 1,666,475	\$ 1,952,274
Charity	\$ 0	\$ 0	\$ 0
Deductions from Revenue	0	0	0
Net Patient Care Revenue	\$ 1,263,888	\$ 1,666,475	\$ 1,952,274
Other Operating Revenue	\$ 0	\$ 0	\$ 0
Total Operating Revenue	\$ 1,263,888	\$ 1,666,475	\$ 1,952,274
Operating Expenses			
Salaries	\$ 273,324	\$ 362,350	\$ 426,458
Benefits	109,329	144,940	170,583
Supplies	233,395	306,382	357,053
Services	0	0	0
Lease Expenses	289,839	289,839	289,839
Depreciation	194,577	194,577	194,577
Interest	0	0	0
Other	201,799	264,905	308,716
Total Operating Expenses	\$ 1,302,263	\$ 1,562,993	\$ 1,747,226
Net Operating Income	\$ (38,375)	\$ 103,482	\$ 205,048
	Proposed Year 1	Proposed Year 2	Proposed Year 3
Inpatient Days	0	0	0
Outpatient Visits	0	0	0
Number of ESRD Procedures	4,752	6,192	7,056
Charge per Outpatient Day	\$ 0	\$ 0	\$ 0
Charge per Inpatient Day	\$ 0	\$ 0	\$ 0
Charge per Procedure	\$ 266	\$ 269	\$ 277
Cost per Inpatient Day	\$ 0	\$ 0	\$ 0
Cost per Outpatient Day	\$ 0	\$ 0	\$ 0
Cost per Procedure	\$ 274	\$ 252	\$ 248

Attachment 2

**Fresenius Medical Care-Mid Mississippi
 Establishment of a Satellite ESRD Facility**

Computation of Construction and Renovation Cost

	Cost Component	Total	New Construction	Renovation
A	New Construction Cost	\$0	\$0	
B	Renovation Cost	\$1,067,000		\$1,067,000
C	Total Fixed Equipment Cost	\$403,129	\$0	\$403,129
	Total Non-Fixed Equipment Cost	\$137,707		
	Land Cost	\$0	\$0	
D	Site Preparation Cost	\$0	\$0	
E	<i>Fees (Architectural, Consultant, etc.)</i>	\$96,030	\$0	\$96,030
F	<i>Contingency Reserve</i>	\$106,700	\$0	\$106,700
G	<i>Capitalized Interest</i>	\$0	\$0	\$0
	<i>Other</i>	\$0	\$0	
	Total Proposed Capital Expenditure	\$1,810,566	\$0	\$1,672,859
	Square Footage	8,536		8,536
	<i>Allocation Percent</i>			100.00%
	Costs Less Land, Non-Fixed Eqt., Other	\$1,672,859	\$0	\$1,672,859
	Cost Per Square Foot	\$195.98	\$0.00	\$195.98

Source: Mississippi Certificate of Need Review Manual, Revised September 1, 2011