

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2009**

**CON REVIEW: ESRD-NIS-0909-022
TOTAL RENAL CARE, INC., d/b/a BLUE MOUNTAIN DIALYSIS
ESTABLISHMENT OF A SIX-STATION ESRD FACILITY IN BLUE MOUNTAIN
CAPITAL EXPENDITURE: \$1,039,972
LOCATION: BLUE MOUNTAIN, TIPPAAH COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Total Renal Care, Inc. (TRC) d/b/a Blue Mountain Dialysis ("Blue Mountain") located at 601 Hawaii Street, El Segundo, California, operates as a California corporation and on March 9, 2004, received a certificate of authority from the Office of the Mississippi Secretary of State. Total Renal Care, Inc. continues to maintain its status of good standings with the State of Mississippi. TRC is governed by a nine-member Board of Trustees.

B. Project Description

Total Renal Care, Inc. requests Certificate of Need (CON) authority to establish a six-station End Stage Renal Disease (ESRD) facility in Blue Mountain, Tippah County, Mississippi. TRC is a wholly-owned subsidiary of DaVita, Inc., a provider of renal dialysis service in the United States.

The applicant proposes to construct a 4,984 square foot facility on a proposed site in Blue Mountain, Mississippi. The proposed site is an undeveloped parcel adjacent to 140 N. Guyton Boulevard in Blue Mountain, Mississippi. The Blue Mountain facility will be a state-of-the-art ESRD facility at an estimated cost of \$1,039,972. The applicant proposes that a developer will purchase the land and incur the cost associated with site development and construction of the building shell. This facility will include: patient waiting room, patient preparation area, patient treatment area, laboratory area, staff offices, one lounge for staff members, storage room, water treatment room, and a storage area for waste. The facility will consist of six staff-assisted hemodialysis stations, with one peritoneal dialysis room and a home training room.

The applicant expects to lease this facility from its owner, who will bear all costs for the shell of the building and estimates that construction of the facility will begin within three months of final approval of the CON and that the project will be complete within twelve months after the commencement of construction. The application contains a preliminary cost estimate from C. Robert Cherry, Architect.

The Mississippi State Department of Health, Division of Health Facilities Licensure and Certification, found the site to be acceptable for the stated use on October 2, 2009. The applicant expects to employ 4.8 full-time equivalent employees at a total personnel cost of \$224,220 during the first year of operation.

The applicant anticipates obligation of the capital expenditure on or before June 2010 with an expected completion date on or before June 2011.

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 December 7, 2009.

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

A. State Health Plan (SHP)

The FY 2010 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 in substantial compliance with the policy statement set fourth in the FY 2010 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 score using current ESRD Network 8 data is 1.5 or higher.

An ESRD Facility Service Area is defined as the area within 30 highway miles of an existing or proposed ESRD facility. The applicant submits that currently there are no other ESRD facilities located within 30 highway miles of the proposed Blue Mountain facility; therefore, there are no other facilities within the proposed ESRD Facility Service Area for the Blue Mountain facility.

As of September 1, 2009, the Mississippi State Department of Health has not calculated a relative risk score for Tippah County. Therefore, Need Criterion 1(b) does not apply to the proposed project or this application.

The applicant proposes to establish an ESRD facility in Blue Mountain, Tippah County, Mississippi, comprised of six (6) ESRD stations. The applicant believes that these stations will facilitate patient needs and patient access for Tippah County. According to Network 8 Inc., the incidence of ESRD patients in Tippah County for 2008 was 15, while the prevalence was 36. For the period from January to March 2009 alone, the incidence was 3 ESRD patients in Tippah County. In addition, there were 10 deaths in 2008.

The applicant bases the need for the establishment of an ESRD facility in Blue Mountain, Tippah County, Mississippi, on data published in the latest publication of ESRD Network 8 Inc., data. The applicant states that 64 dialysis patients live within a 20 mile radius of Blue Mountain. During consultation with the proposed Medical Director, they anticipate the following number of patients for the first, second, and third years of operation:

- Year One – 31 patients (48% of 64 patients)
- Year Two – 41 patients (64% of 64 patients)
- Year Three – 51 patients (80% of 64 patients)

SHP Criterion 2 - Number of Stations

The *FY 2010 State Health Plan* establishes a minimum of four ESRD stations that may be approved for establishment of an ESRD facility. The applicant proposes to establish six (6) ESRD stations. The applicant is in compliance with this criterion.

SHP Criterion 3 - Minimum Utilization

The applicant projects to perform 2,823 treatments on 18 patients the first year of operation, for an annual utilization of 50 percent. The table below gives a comparison of the applicant's projections with the MSDH requirements.

Projected Utilization Blue Mountain Dialysis							
Year	Patients	Treatments per Station	Stations	Blue Mountain Dialysis Projections		MSDH Requirements	
				*Treatments	Utilization Rate	Treatments	Utilization Rate
1	18	471	6	2,823	50%	2,808	50%
2	29	741	6	4,448	79%	3,650	65%
3	36	925	6	5,548	99%	4,212	75%

*Represent procedures that require staff assistance.

SHP Criterion 4 - Minimum Services

The applicant affirmed that, at a minimum, Blue Mountain Dialysis will provide social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.

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 proposes that Blue Mountain Dialysis will operate between the hours of 6:00 a.m. to 6:00 p.m., Monday through Saturday. However, alternate arrangements will be made for those patients needing services beyond the normal hours of operation on an as needed basis.

SHP Criterion 7 - Home Training Program

The applicant affirms that a home training program will be made available to those patients who are medically eligible and receptive to the program. The applicant further affirms that all patients will be counseled on the availability of and eligibility requirements to enter the home/self dialysis program.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirms that the proposed facility will treat all patients regardless of ability to pay and will provide a reasonable amount of indigent care. The applicant states that government-based programs represented approximately 65% of all dialysis and related laboratory services revenue for DaVita and its affiliates in 2008, with commercial payors comprising the rest. ESRD services are generally covered by one or the other. Unreimbursed care, including indigent care, represents 1% or less of revenues. The applicant anticipates that Blue Mountain Dialysis will be consistent with this historical trend.

SHP Criterion 9 - Facility Staffing

The application includes documentation for qualifications and specific duties of the proposed facility's staff. The applicant asserts that they will employ 4.8 FTEs to staff this facility, based upon the expected utilization.

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. When the unit is not in operation, the medical director or a designated physician and a registered nurse will be on call. In addition, a nephrologist will always be available to facilities operated by TRC.

SHP Criterion 12 - Data Collection

TRC affirms that it will 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.

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.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirms that within one year of commencing operation the facility will enter into an affiliation agreement with a transplantation center and that the written agreement will describe the relationship between the transplantation facility and Blue Mountain and the specific services that the transplantation center will provide to patients of the facility.

The applicant also affirms 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 September 1, 2009*, addresses general criteria by which all CON applications are reviewed. The applicable criteria are discussed below.

GR Criterion 1 – State Health Plan

This application is in compliance with the overall objectives of the FY 2010 *State Health Plan*. The applicant seeks Certificate of Need authority to establish a six-station ESRD facility in Blue Mountain, Tippah County, Mississippi.

GR Criterion 2 - Long Range Plan

The applicant states that TRC and its affiliates provide dialysis services for those diagnosed with chronic kidney failure, a condition also known as chronic kidney disease (CKD). The company's parent company, DaVita, Inc., has over 1,500 outpatient dialysis facilities and acute units in over 700 hospitals. DaVita facilities are located in 43 states and the District of Columbia, serving approximately 115,000 patients.

The applicant submits that DaVita is a leading provider of dialysis services in the United States, striving to be the greatest dialysis company ever. They believe this can be accomplished through a shared commitment to their mission and values.

TRC proposes to make ESRD services more accessible to a critically-ill population in the state. TRC employees reviewed ESRD Network 8, Inc. data to identify areas where ESRD patients are forced to travel excessive distances for dialysis treatment. Blue Mountain was identified in this process. If this facility is approved, it will be consistent with the mission and goals of the company.

GR Criterion 3 - Availability of Alternatives

TRC submits that there is no less costly or more effective alternative to the application. No other alternatives were presented in the application.

GR Criterion 4 - Economic Viability

Based on the applicant's three-year projections, this project will suffer a net loss of \$22,506 the first year, but appreciate a net income of \$497,903 the second year, and \$423,487 the third year of operation, respectively. The project appears to be economically viable.

- a. **Proposed Charge:** The applicant projects charges of \$331 per dialysis treatment for the first, \$336 for the second, and \$306 for the third years of operation for the proposed project. The applicant projects cost of \$337, \$244, and \$245 per dialysis treatment for the first three years, respectively, of operation for the proposed project.
- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatment to be performed during the first three years of operation: 3,412; 5,427 and 6,903 respectively. The applicant's projections appear to be overstated, however, given that 100% utilization of six stations will yield only 5,616 treatments.
- c. **Project's Financial Feasibility Study:** The capital expenditure for this project is \$1,039,972; therefore, a feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served:** The applicant asserts that ESRD disproportionately affects minorities, handicapped persons, and other traditionally underserved groups and by placing an ESRD facility closer to these patients, these underserved groups will have increased access to a vital health care service.
- b. **Relocation of Services:** This application does not entail the relocation of services or replacement of a facility that requires CON review.
- c. **Probable Effect on Existing Facilities in the Area:** The applicant submits that there are no other ESRD facilities within the proposed ESRD service area. Additionally, the applicant submits that all ESRD services in areas surrounding Blue Mountain are provided by a single ESRD service provider. Those facilities are Renal Care Group (RCG) of Corinth, RCG of Oxford, RCG of Tupelo, and RCG Holly Springs, which operate a combined total of 101 dialysis stations (See Attachment I).

The applicant contends that the relatively small size of Blue Mountain Dialysis facility and its location in a small town/rural setting is not likely to affect ESRD treatment choices for patients located in or near the larger towns in which the existing facilities are located. Furthermore, the applicant states that placing an ESRD facility closer to ESRD patients is an appropriate and efficient use of health care resources that poses no threat to the efficiency of existing facilities.

- d. **Community Reaction:** The application contains 10 letters of support for the proposed project. The Department received one letter of opposition to the project from Renal Care Group, Tupelo, LLC.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, ESRD disproportionately affects traditionally underserved populations, such as minorities and low-income populations. It is the applicant's belief that these underserved populations are expected to comprise a significant portion of Blue Mountain's patient population.

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	\$12,847.95 (1%)
2	\$12,847.95 (1%)

The proposed facility will be available Monday through Saturday 6:00 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 other ESRD facilities located within the proposed ESRD service area or 30 highway miles of the proposed Blue Mountain facility.

The Department received one letter of opposition concerning the proposed project, from Renal Care Group Tupelo, LLC.

GR Criterion 9 - Availability of Resources

The applicant affirms that sufficient personnel and physicians are available to staff the facility. The applicant further affirms that the facility shall provide access to all doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the physicians. Registered Nurses will be recruited from area colleges and universities; Licensed Practical Nurses will be recruited from local community colleges. Social Workers, Dietician Services, and Dialysis

Technicians will be recruited locally by way of local advertisement. An in-house recruiter will be responsible for coordinating staff.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant affirms that all necessary support and ancillary services are available at this location. In addition, electricity, water, sewer, refuse, and janitorial services are available at the proposed site. The facility also has access to laboratory services.

GR Criterion 11 – Health Professional Training Programs

According to the applicant, Blue Mountain Dialysis plans to be available for student tours, lectures, training, and clinical placement opportunities for fellows, residents, and other allied health professionals.

GR Criterion 16 - Quality of Care

The applicant submits that Tippah County does not have an ESRD facility. Thus, having a facility in this region is particularly important for low income persons and other underserved groups that have, historically, had trouble with access to health care services. TRC believes this facility should improve access to all ESRD patients, particularly those who have limited access to transportation or for whom transportation costs are a factor. TRC is committed to the philosophy that optimal care is attained through the application of state-of-the-art technology, continual quality improvement, and patient/family education.

The applicant states that Blue Mountain Dialysis will seek to achieve superior patient outcomes and to provide the best value in patient care.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	-	0.00%
Construction Cost - Renovation	-	0.00%
Capital Improvements	439,450	42.26%
Total Fixed Equip Cost	70,425	6.77%
Total Non-Fixed Equip Cost	455,467	43.80%
Land Cost	-	0.00%
Site Prep Cost	-	0.00%
Fees - architectural, engineering, etc.	42,380	4.08%
Fees - legal and accounting	10,000	0.96%
Contingency Reserve	-	0.00%
Other - Building Expense Escalation	-	0.00%
Capitalized Interest	-	0.00%
Other Cost (other equipment & other escalation contingency)	22,250	2.14%
Total Proposed Expenditures	\$ 1,039,972	100%

B. Method of Financing

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

C. Effect on Operating Cost

Attachment II lists TRC projections for the following: 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

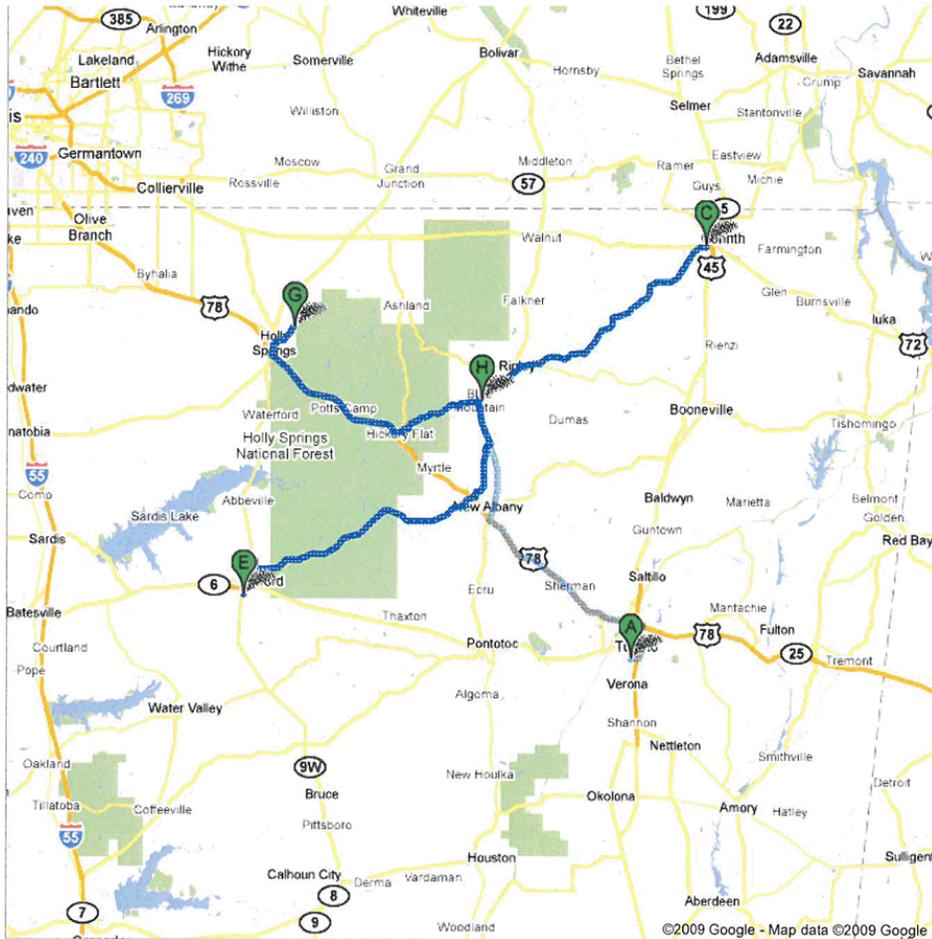
The Division of Medicaid was provided a copy of this application for review and comment; however, the department received no response, as of the date of this staff analysis.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with criteria and standards for establishment of end stage renal disease facilities as contained in the *FY 2010 State Health Plan*; the *Mississippi Certificate of Need Review Manual, revised September 2009*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of the application submitted by Total Renal Care Inc. d/b/a Blue Mountain Dialysis for the establishment of a 6-station ESRD facility in blue Mountain, Tippah County, Mississippi.

ATTACHMENT I
ESRD Facilities Site Map



(H) 140 N. Guyton Boulevard
 Blue Mountain, MS
 (adjacent to proposed site)

	Current ESRD Facility	Address	Distance from proposed site
A	RCG of Tupelo	1031 S. Madison Street (Tupelo, MS)	42.7 miles
C	RCG of Corinth	810 Alcorn Drive (Corinth, MS)	35.7 miles
E	RCG of Oxford	1760 Barron Street (Oxford, MS)	57.5 miles
G	RCG of Holly Springs	1325 Highway 4 East (Holly Springs, MS)	34.0 miles

ATTACHMENT II

Total Renal Care Inc., d/b/a Blue Mountain Three-Year Operating Statement			
	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient			
Outpatient	\$ 1,127,690.00	\$ 1,823,313.00	\$ 2,114,847.00
Total Gross Patient Revenue	<u>\$ 1,127,690.00</u>	<u>\$ 1,823,313.00</u>	<u>\$ 2,114,847.00</u>
Charity Care	\$ -	\$ -	\$ -
Deductions	-0-	-0-	-0-
Net Patient Revenue	\$ 1,127,690.00	\$ 1,823,313.00	\$ 2,114,847.00
Other Operating Revenue	-0-	-0-	-0-
Total Operating Revenue	<u>\$ 1,127,690.00</u>	<u>\$ 1,823,313.00</u>	<u>\$ 2,114,847.00</u>
Expenses			
Salaries	\$ 224,220.00	\$ 260,116.00	\$ 354,723.00
Benefits	\$ 87,446.00	\$ 101,445.00	\$ 138,342.00
Services	\$ -	\$ -	\$ -
Supplies	\$ 296,375.00	\$ 490,892.00	\$ 638,721.00
Lease	\$ 99,680.00	\$ 102,670.00	\$ 105,751.00
Depreciation	\$ 95,498.00	\$ 99,805.00	\$ 104,448.00
Other	\$ 346,977.00	\$ 270,482.00	\$ 349,375.00
Total Expenses	<u>\$ 1,150,196.00</u>	<u>\$ 1,325,410.00</u>	<u>\$ 1,691,360.00</u>
Net Income (Loss)	<u>\$ (22,506.00)</u>	<u>\$ 497,903.00</u>	<u>\$ 423,487.00</u>
Utilization Rate (percent)	50	79	99
*Total treatments	3,412	5,427	6,903
Patients	18	29	36
Charge Per Treatment	\$ 330.51	\$ 335.97	\$ 306.37
Cost Per Treatment	\$ 337.11	\$ 244.23	\$ 245.02

NOTE: * Includes treatments for home hemodialysis and peritoneal dialysis.