

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

**CON REVIEW: ESRD-NIS-0908-031
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. D/B/A
FRESENIUS MEDICAL CARE – CALHOUN CITY
ESTABLISHMENT/CONSTRUCTION OF A SIX-STATION ESRD FACILITY
IN CALHOUN CITY
CAPITAL EXPENDITURE: \$462,471
LOCATION: CALHOUN, CALHOUN COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Bio Medical Applications of Mississippi, Incorporated (BMA of MS, Inc.), d/b/a Fresenius Medical Care-Calhoun City, is a business corporation located at 5268 East Raines Road in Memphis, Tennessee. The applicant indicates that BMA of MS, Inc. is governed by a 16 member board of officers. The applicant further states, that as January 1, 2010, Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care of North America, the applicant's parent organization ("Fresenius") is a seven-member Board of Directors and has nine officers.

The applicant provided a Certificate from the Secretary of State dated August 29, 2008, verifying that the corporation was issued a Charter/Certificate of Authority on August 2, 1990. The document indicates that the business is incorporated in the State of Delaware; however, it is authorized by the Secretary of State to do business in Mississippi.

B. Project Description

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care-Calhoun City (FMC-Calhoun City) requests Certificate of Need (CON) authority to establish a six- station ESRD facility in Calhoun City.

The applicant will lease shelled medical office space and renovate it in order to make necessary accommodations to house the six-station ESRD Facility. The proposed projected renovation includes finishing out 3,428 square feet of shell space. The applicant states the proposed project includes: interior studs; dry wall; floor, wall and ceiling finishes; interior doors with hardware; specialty items; casework; complete plumbing; HVAC and electrical systems. The applicant further states that such renovation will comply with all local ordinance and regulations. The location chosen by the applicant is near the center of the population in Calhoun City, and based on Network 8 data demonstrating the zip code of ESRD residents in the County.

The applicant proposes to offer the RightStart program to all new ESRD patients. New ESRD patients will receive weekly face-to-face visits from their RightStart case manager (RSCM) for their first 120 days. The RSCM will coordinate health care needs of new dialysis patients and their families. The applicant suggests

that the RSCM primarily assumes the role of a patient advocate and educator. The RSCM also works with patient family along with facility staff to manage vascular access, adequacy, treatment compliance, anemia management and diabetes control if needed.

The applicant affirms that Fresenius provides dialysis treatment for more than 123,000 patients, performing over 18,452,381 treatments, at more than 1,600 facilities, making it the largest provider of renal services in the nation.

The applicant suggests that the proposed facility will greatly benefit from its association with Fresenius and its integrated delivery and service model. The applicant believes that this association will also bring and ensure quality of care to the residents of Calhoun County.

The total proposed expenditure for this project is \$462,471 that the applicant proposes to finance with cash reserves. The applicant anticipates that the project will commence within 90 days of CON approval and completion within one year.

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 10, 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 *FY 2009 State Health Plan* contains criteria and standards which the applicant is required to meet before receiving CON authority to establish a six-station ESRD facility. This application is not in substantial compliance with applicable criteria and standards.

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. Policy Statements 2, 4, 5, and 6 do not apply to criterion 1(b).

The applicant alleges that Calhoun 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 Calhoun 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 states that the ESRD facility will contain six hemodialysis stations in Calhoun County.

*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 3 - Minimum Utilization

The applicant submits that Network 8 data demonstrated that the prevalence of ESRD patients increased in Calhoun County from 31 in 2005 to 32 in 2006, 38 in 2007 and 39 as of June 30, 2008. 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%

SHP Criterion 4 - Minimum Services

Fresenius Medical Care-Calhoun City affirms that the facility will provide social, dietetic, and rehabilitative services.

SHP Criterion 5 - Access to Needed Services

Fresenius Medical Care-Calhoun City affirms 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 6 - Hours of Operation

Fresenius Medical Care-Calhoun City will operate between the hours of 7:00 a.m. to 6:00 p.m. six days a week. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 7 - Home Training Program

The applicant affirms that patients who would like to participate in the home training program will be counseled on the availability of the home-training program and the requirements to enter the home/self-dialysis program.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirms 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 9 - 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 6.10 full time equivalents will be utilized to operate the ESRD facility.

SHP Criterion 10 - Staffing Qualifications

The applicant asserts that the staff of the facility 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, the applicant affirms that 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 an 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 12 - Data Collection

The applicant affirms that it shall record and maintain the required data and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 13 Staff Training

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

SHP Criterion 14 -Scope of Privileges

The applicant affirms 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.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center within one (1) year after the facility is opened and operating. The applicant provides a copy of the transfer agreement with the University of Mississippi Medical Center. The applicant anticipates this same agreement or a similar agreement will be applicable to the proposed facility.

B. General Review (GR) Criteria

Chapter 8 of the Mississippi Certificate of Need Review Manual, 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

Calhoun 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's long range plan is to provide high quality, easily accessible ESRD services for those residents in need of dialysis services in Calhoun County. The applicant states that these objectives tie into their mission statement - to improve the quality of life of every patient and every treatment. The applicant believes that by providing comprehensive dialysis services and the highest quality of products and equipment, Fresenius will be able to deliver the best possible care for its patients and County residents.

GR Criterion 3 – Availability of Alternatives

The applicant considered the following alternatives:

- Not establishing an ESRD Facility in Calhoun County and continuing to service those patients through existing facilities – however; given the continued growth in ESRD, the applicant determined that it should serve Calhoun County whose relative risk score had increased, to meet the Department's determination of need.
- The establishment of both a larger and a smaller facility – however; the applicant was determined based on current utilization at similar facilities in the Service Area and Network 8 data, a smaller facility would not adequately meet the needs of the residents, and a larger facility would result in more healthcare dollars to be spent than necessary to efficiently serve the ESRD population in the area.

The applicant believes the establishment of a six-station ESRD facility will be the most efficient, effective, and accessible alternative to meet the needs of ESRD patients in the Calhoun County.

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, respectively. The project appears to be economically viable.

The applicant submits that the ESRD reimbursement environment and the patient population of the 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 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 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 Calhoun County's RR is 1.5. However, further calculation of the RR indicates a score of 1.3 for Calhoun 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 is one other ESRD facility located within a 30-mile radius of the proposed facility and this facility indicates utilization below 80%.

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	\$833.18 (2%)
2	\$965.74 (2%)

The proposed facility will operate Monday through Saturday from 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

The applicant states that there are no ESRD facilities in Calhoun County. Currently residents travel to other counties to receive ESRD services. The applicant's related facility, Fresenius Medical Care of Eupora is the only ESRD facility within the Service Area, approximately 25 miles from the proposed facility. These two facilities will in essence serve the same population and will cooperate to transfer any patients from the Eupora facility to Calhoun City facility for the patient's continuity of care.

The applicant believes that failure to implement this project will restrict access to the growing ESRD patient population in Calhoun County.

GR Criterion 9 – Availability of Resources

The applicant states that ESRD facilities 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 next closest facility, will allow the applicant and the Eupora facility to supplement and share staff if ever necessary. The applicant affirms that due to its existing presence in the Service Area, relationships with nearby nephrologists have been established.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that all necessary ancillary or support services will be available.

GR Criterion 11– Health Professional Training Programs

Bio Medical Applications of Mississippi, Incorporated (BMA of MS, Inc.) d/b/a Fresenius Medical Care-Calhoun City asserts the facility will coordinate with area health professional schools to have access to the services for training purposes.

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	% of Total
Construction Cost - New	\$ 0	0.00%
Construction Cost - Renovation	325,660	70.42%
Capital Improvements	0	0.00%
Total Fixed Equip Cost	0	0.00%
Total Non-Fixed Equip Cost	107,705	23.29%
Land Cost	0	0.00%
Site Prep Cost	0	0.00%
Fees - architectural, engineering, etc.	29,106	6.29%
Fees - legal and accounting	0	0.00%
Contingency Reserve	0	0.00%
Capitalized Interest	0	0.00%
Other Cost	0	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-Calhoun City'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 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 1.5. Further, current verified calculation of the relative risk score for Calhoun County show that the county has a relative risk score 1.3, less that 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 Bio Medical Applications of Mississippi, Incorporated, d/b/a Fresenius Medical Care-Calhoun City for the establishment of a six-station ESRD facility in Calhoun City.

**Bio Medical Applications of Mississippi, Incorporated
 d/b/a Fresenius Medical Care-Calhoun City**

**Three-Year Operating Statement
 Attachment I**

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	\$ 833,183	\$ 965,736	\$1,117,223
Outpatient Revenue			
Gross Patient Revenue	833,183	965,736	1,117,223
Charity			
Deductions from Revenue			
Net Patient Care Revenue	833,183	965,736	1,117,223
Other Operating Revenue			
Total Operating Revenue	\$ 833,183	\$ 965,736	\$1,117,223
Operating Expenses			
Salaries	\$ 230,374	\$ 263,809	\$ 303,197
Benefits	49,300	56,500	64,900
Supplies	272,068	315,351	364,818
Services			
Lease Expenses	54,455	54,455	54,455
Depreciation	52,500	52,500	52,500
Interest			
Other	158,129	185,235	216,618
Total Operating Expenses	\$ 816,826	\$ 927,850	\$1,056,488
Net Operating Income	\$ 16,357	\$ 37,886	\$ 60,735
	Proposed Year 1	Proposed Year 2	Proposed Year 3
Outpatient days	313	313	313
Charge per outpatient day	2,662	3,085	3,569
Cost per outpatient day	2,610	2,964	3,375