

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

**CON REVIEW: ESRD-NIS-0410-018
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. D/B/A
FRESENIUS MEDICAL CARE – DEKALB
ESTABLISHMENT/CONSTRUCTION OF A SIX-STATION ESRD FACILITY
IN KEMPER COUNTY
CAPITAL EXPENDITURE: \$775,000
LOCATION: DEKALB, KEMPER 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-DeKalb, is a business corporation located at 14365 Highway 16 West in DeKalb, Mississippi. The applicant indicates that BMA of MS, Inc. is governed by 2 directors and 14 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-DeKalb (Fresenius Medical Care-DeKalb) requests Certificate of Need (CON) authority to establish a six- station ESRD facility in Kemper County.

The applicant proposes to lease approximately 5,533 square feet of shelled space from Rush Health Systems at the new John C. Stennis Hospital. The applicant provided a copy of the proposed lease agreement between Rush Health Systems and Fresenius Medical Care-DeKalb. Within this space the applicant proposes to establish a six-station ESRD facility with room for expansion to twelve stations when the patient utilization justifies increasing the number of stations. The applicant states that this will allow the number of available stations to increase with minimal patient disruption.

The applicant's improvements shall include: VCT floor covering throughout most of the facility, carpet in office areas, resinous epoxy floors in wet areas and sealed concrete floor in general storage; walls will be steel stud and drywall construction; walls will be fire rated as required by code; main entrance door will be fully glazed aluminum with handicap operators, interior doors will be wood doors and service doors shall be hollow metal; the hardware package will include automatic operators for the treatment room entry, locksets will be included at those doors that are considered to control patient and employee access; ceilings will typically be acoustical tile, drywall ceilings will be used at rooms that require additional security; HVAC system will be installed to control both temperature

and humidity and provide outside air changes in the building; plumbing will include a complete water system for dialysis and sinks, etc that support clinic operations, electrical systems include a complete lighting package, outlets, etc., electrical system will have an Automatic Transfer Switch to provide a quick connection for a back up generator, also included are intercom and nurse call systems, and a television at each station.

The applicant provided a letter from the architect to verify the estimated cost to complete the project.

The applicant expects to employ 3.6 full-time equivalent employees at a total personnel cost of \$287,642 during the first year of operation.

The total proposed capital expenditure for this project is \$775,000 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 July 6, 2010.

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 criteria and standards which the applicant is required to meet before receiving CON authority to establish a six-station ESRD facility. This application is 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 (RR) 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 two ESRD facilities located in the proposed service area: RCG of Philadelphia which is approximately 26 miles and RCG of Meridian which is

approximately 30 miles from the proposed ESRD facility.

The Mississippi State Department of Health (MSDH) completed a relative risk table using Network 8, Inc. ESRD data to calculate/estimate what counties in Mississippi are in need of an ESRD unit. Pursuant to the *FY 2010 State Health Plan*, calculations produced by MSDH confirmed Kemper County had a relative risk score of 1.5.

Fresenius Medical Care-DeKalb submits that the need for the proposed project is evidenced by the Mississippi State Department of Health's calculation of Kemper County's relative risk score of 1.5. Fresenius Medical Care-DeKalb states that with the relative risk score for Kemper County indicating a need for this project, there should not be any impact on existing facilities. The applicant further states that the relative risk score indicates there are a sufficient number of dialysis patients in the county to support the proposed project.

Of the 29 patients utilized by the MSDH to calculate the relative risk score, the applicant projections for the first, second, and third year of operation are as follows:

- Year One – 19.5 patients
- Year Two – 25.35 patients
- Year Three – 29.25 patients

SHP Criterion 2 - Number of Stations

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

SHP Criterion 3 - Minimum Utilization

The applicant submits that based on Fresenius Medical Care's historical experience, it is anticipated that conservatively each patient will receive 144 treatments a year. The applicant states that while this is not quite 3 treatments a week each year, this conservative approach allows for missed appointments, patients that relocate or change units, patients that miss treatment due to hospitalization and patients on vacation. The following table below gives a comparison of the applicant's projections with the MSDH requirements.

Year	Stations	Applicant's Projections			MSDH Requirements	
		Patients	Treatments	Utilization Rate	Treatments	Utilization Rate
1	6	19.5	2,808	50%	2,808	50%
2	6	25.35	3,650	65%	3,650	65%
3	6	29.25	4,212	75%	4,212	75%

SHP Criterion 4 - Minimum Services

The applicant affirms that the facility will provide social, dietetic, and rehabilitative services.

SHP Criterion 5 - Access to Needed Services

Fresenius Medical Care-DeKalb 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-DeKalb will operate between the hours of 6:00 a.m. to 4:30 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 3% 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 3.6 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, 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, September, 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 DeKalb, Kemper County, Mississippi.

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 Kemper County.

GR Criterion 3 – Availability of Alternatives

The applicant considered the establishment of a larger facility. However, after analyzing the prevalence of patients in Kemper County, the applicant determined that a smaller unit, capable of expansion, would be the most cost effective.

The applicant believes that 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 Kemper County.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$21,338 the first year, \$7,572 the second year, and \$39,062 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 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. 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.

The applicant projects charges of \$295 per dialysis treatment for the first year, \$300 for the second year, and \$304 for the third year of operation. The applicant projects cost of \$303 per dialysis treatment for the first year, \$298 for the second, and \$295 for the third year of operation for the proposed project.

- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 50%, 65%, and 75% respectively.
- c. **Project's Financial Feasibility Study:** The capital expenditure for this project is \$775,000; therefore, a financial feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 – Need for Project

- a. **Access by Population Served:** 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 Kemper County's RR is 1.5. Therefore, the project does meet the need requirement as stated in the *2010 State Health Plan*. The applicant asserts that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population
- b. **Relocation of Services:** This application does not entail the relocation of services or replacement of an ESRD facility.
- c. **Probable Effect on Existing Facilities in the Area:** As previously stated above, the applicant submitted that currently there are two ESRD facilities located in the proposed service area: RCG of Philadelphia which is approximately 26 miles and RCG of Meridian which is approximately 30 miles from the proposed ESRD facility. The applicant further suggests that with the relative risk score for Kemper County indicating a need for this project, there should not be any impact on existing facilities.
- d. **Community Reaction:** The application contained 6 letters of support for the proposed project from the Mayor of DeKalb, nephrologists, clinical directors, and ESRD patients.

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 to be 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	\$28,109 (3%)
2	\$36,312 (3%)

The proposed facility will operate Monday through Saturday from 6:00 a.m. to 4:30 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 Kemper County. Currently residents have to travel to other counties to receive ESRD services. The applicant submits that currently there are two ESRD facilities located in the proposed service area: RCG of Philadelphia which is approximately 26 miles and RCG of Meridian which is approximately 30 miles from the proposed ESRD facility. The applicant states that new transfer/referral/affiliation agreements will be entered into the new local hospital and hospitals in Meridian upon establishment of the ESRD facility.

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

GR Criterion 9 – Availability of Resources

Fresenius Medical Care-DeKalb 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. The applicant asserts that the proposed service area has sufficient nephrologists to support the proposed ESRD facility. Furthermore, the applicant states that prior to the facility opening they will enter into an agreement with Spectra Laboratories, Inc. for lab work.

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

According to the applicant, Fresenius Medical Care-DeKalb plans to cooperate with health professional training programs in the surrounding area.

GR Criterion 16– Quality of Care

The applicant submits that Kemper County does not have an ESRD facility. The applicant believes that this project will establish an ESRD facility in Kemper County to meet the need identified by its relative risk score calculation and allow the residents to receive dialysis closer to home.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	\$501,000	64.65%
Construction Cost - Renovation	\$ 0	0%
Capital Improvements	\$ 0	0%
Total Fixed Equip Cost	\$ 69,000	8.90%
Total Non-Fixed Equip Cost	\$ 48,000	6.19%
Land Cost	\$ 0	0%
Site Prep Cost	\$ 0	0%
Fees - architectural, engineering, etc.	\$ 50,000	6.45%
Fees - legal and accounting	\$ 0	0%
Contingency Reserve	\$ 65,000	8.39%
Capitalized Interest	\$ 0	0%
Other Cost	\$ 42,000	5.42%
Total Proposed Expenditure	\$775,000	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-DeKalb’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 the 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.

The *FY 2010 State Health Plan* states that 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 (RR) using current ESRD Network 8 data is 1.5 or higher.

Fresenius Medical Care-DeKalb affirms that presently there are no ESRD facilities located in Kemper County and that the residents currently travel to other counties to receive ESRD services. According to the *FY 2010 State Health Plan's* calculations, Kemper County has a relative risk score of 1.5, indicating a need for the proposed project.

Therefore, the Division of Health Planning and Resource Development recommends approval of the application submitted by Bio Medical Applications of Mississippi, Incorporated, d/b/a Fresenius Medical Care-DeKalb for the establishment of a six- station ESRD facility in Kemper County.

Attachment I

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

Three-Year Projected Operating Statement

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue			
Outpatient Revenue	\$ 829,841	\$1,094,341	\$1,281,210
Gross Patient Revenue	\$ 829,841	\$1,094,341	\$1,281,210
Charity			
Deductions from Revenue			
Net Patient Care Revenue	\$ 829,841	\$1,094,341	\$1,281,210
Other Operating Revenue			
Total Operating Revenue	\$ 829,841	\$1,094,341	\$1,281,210
Operating Expenses			
Salaries	\$ 224,720	\$297,922	\$ 350,573
Benefits	62,922	83,418	98,160
Supplies	225,946	296,623	345,623
Services			
Lease Expenses	76,330	91,330	91,330
Depreciation	81,475	81,475	81,475
Interest			
Other	<u>179,776</u>	<u>236,001</u>	<u>274,986</u>
Total Operating Expenses	\$ 851,179	\$1,086,769	\$ 274,986
Net Operating Income	\$ 21,338	\$ 7,572	\$ 39,062
	Proposed Year 1	Proposed Year Year 2	Proposed Year 3
Procedures	2,808	3,650	4,212
Charge per outpatient day	\$ 295	\$ 300	\$ 304
Cost per outpatient day	\$ 303	\$ 298	\$ 295