

**DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2005**

**CON REVIEW ESRD-NIS-0905-036
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI D/B/A FRESENIUS MEDICAL CARE DESOTO
ESTABLISHMENT OF A 10 STATION ESRD FACILITY IN DESOTO COUNTY
CAPITAL EXPENDITURE: \$539,608
LOCATION: SOUTHAVEN, DESOTO COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Bio-Medical Applications of Mississippi, Inc. (BMA-Mississippi) is a Delaware corporation authorized to do business in the state of Mississippi. It is operated as a subsidiary of Fresenius Medical Care-North America (FMC-NA). The entity has 10 corporate officers.

BMA-Mississippi and FMC-NA currently operate approximately 15 facilities throughout the state, representing approximately 286 stations.

B. Project Description

BMA-Mississippi proposes to establish a new, 10-station end stage renal disease (ESRD) facility in Southaven, DeSoto County, Mississippi, known as Fresenius Medical Care DeSoto (FMC DeSoto). The applicant states that these stations may serve a dual utilization role as staff assisted hemodialysis and home training. BMA-Mississippi proposes to lease approximately 5,000 square feet of building space and finance leasehold improvements to make the building suitable for a dialysis facility. The total proposed capital expenditure of the project is \$539,608.

The project will require three full-time Registered Nurses and five Patient Care Technicians. The applicant projects to hire 11.7 full-time equivalent personnel at an estimated annual cost of \$552,599 the first year.

The proposed site for the project has been zoned for use for medical offices, and has been approved by the MDH Division of Health Facilities Licensure and Certification.

The applicant expects to obligate capital expenditures upon CON approval and expects the project to be complete approximately 180 days thereafter.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Section 41-7-191, subparagraph (1)(a), of the Mississippi Code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi 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 5, 2005.

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

A. State Health Plan (SHP)

The 2006 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.

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 from an existing or proposed ESRD facility. Currently, there is only one provider within the proposed facility's service area - Renal Care Group Southaven (RCG Southaven). For the period July 1, 2004, to June 30, 2005, RCG Southaven reported an average of 106 patients, utilizing from 28 to 40 stations, for an average of 35 stations for the 12-month period. Further, given the number of patients reported by RCG Southaven and the average number of stations, staff estimates the utilization rate of the facility to be as follows:

Average Number of Patients	Average Number of Stations	Average Number of Shifts/Days	Number of Treatments*	Utilization Percentage
106	35	2 shifts/6 days	15,264	46.6

*Note: Total treatments were calculated based on 3 treatments per patient per week, or 12 treatments per month, 144 treatments per year.

In addition, Network 8, Inc. reported an incidence of 44 ESRD patients and a prevalence of 109 patients for DeSoto County for 2004. Based on the number of patients reported by RCG Southaven and the fact that it is the only facility in the area, it appears that all patients are being dialyzed at RCG Southaven. It also appears that there are not enough patients in the service area to justify an addition of 10 ESRD stations. Furthermore, criterion (a) requires 80 percent utilization of existing providers; however, RCG Southaven is averaging only 46.6 percent for the past fiscal year. Therefore, the applicant is not in compliance with this criterion.

SHP Criterion 2 - Number of Stations

The *FY 2006 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 10 ESRD stations. Therefore, the applicant is in compliance with this criterion.

SHP Criterion 3 - Minimum Utilization

The applicant projects to perform 6,840 treatments on 49 patients the first year of operation for an annual utilization of 70 percent. The table below gives a comparison of the applicant's projections with the MDH requirements.

Projected Utilization							
Year	Patients	Treatments per Station	Stations	BMA Projections		MDH Requirements	
				Treatments	Utilization Rate	Treatments	Utilization Rate
1	49	684	10	6,840	73.1	4,680	50%
2	31	720	10	7,200	76.9%	6,084	65%
3	55	763	10	7,632	81.5%	7,020	75%

SHP Criterion 4 - Minimum Services

The applicant affirmed that it will provide, at a minimum, social, dietetic and rehabilitative services. Rehabilitative services shall be provided on a referral basis.

SHP Criterion 5 - Access to Needed Services

FMC DeSoto affirmed 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 the normal facility hours of operation will be from 6:30 a.m. to 6:00 p.m., six days per week. Alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 7 - Home Training Program

The applicant affirmed that a home training program will be made available. Patients are invited to participate in one of the FMC's Kidney Options program classes. This program provides a free patient education community service to any person diagnosed with kidney disease.

SHP Criterion 8 - Indigent/Charity Care

The applicant certified that the proposed facility will not have any admission policies which will adversely affect access to care by indigents, and that it will provide indigent/charity care. The applicant anticipates its percentage of indigent/charity care to be two percent.

The applicant further states that FMC-NA has an Indigent Waiver Program that provides full or partial free care for qualifying patients who lack the means to pay for services.

SHP Criterion 9 - Facility Staffing

The application includes documentation of the proposed facility's staffing by category, including minimum education and experience requirements, specific duties, and full-time equivalents.

SHP Criterion 10 - Staffing Qualifications

The applicant affirmed that the staff of the facility shall, at a minimum, meet all requirements and qualifications as stated in the Medicare Conditions for Coverage of Suppliers of ESRD Services, 42 CFR, Chapter IV, Subpart U.

SHP Criterion 11 - Staffing Time

FMC DeSoto affirmed that when the unit is in operation, at least one (1) RN 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 affirmed that a medical director or a designated physician will be on-site or on call at all times when the facility is in operation.

The applicant further affirmed that when the unit is not in operation the medical director, or designated physician, and an RN will be on-call.

SHP Criterion 12 - Data Collection

FMC DeSoto affirmed that it will record and maintain all utilization data and data regarding services provided to indigent patients and shall make such information available to the MDH as required.

SHP Criterion 13 - Staff Training

The applicant affirmed that it will provide an ongoing program of training for nurses and technicians in dialysis techniques.

SHP Criterion 14 - Scope of Privileges

The applicant affirmed that it 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 affirmed that it will enter into an affiliation agreement with at least one transplantation center upon CON approval in accordance with stated requirements. The application contains an agreement between the applicant and the University of Mississippi Medical Center, Jackson. The applicant also affirmed its understanding and agreement 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 2000*, contains general review criteria which all CON applications must meet. The applicable criteria are discussed below.

GR Criterion 1 – Compliance with the *State Health Plan*

The project is not in compliance with the need criterion stated in the *FY 2006 State Health Plan*.

GR Criterion 2 - Long Range Plan

The applicant indicates that the project is a part of its long range plan for providing ESRD facilities and services.

GR Criterion 3 - Availability of Alternatives

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

GR Criterion 4 - Economic Viability

The applicant projects earnings before income taxes of \$554,482 the first year, \$587,597 the second year, and \$628,739 the third year. However, the only provider of ESRD services in the area had a utilization rate of only 46.6 percent for the 12-month period July 1, 2004 to June 30, 2005. Therefore, staff contends that the project cannot be viable without encroaching on the viability of the existing provider.

The proposed charge per dialysis patient is \$190.57 for the first and second years and \$190.42 during the third year of operation of this project.

The applicant projects utilization of 70 percent for the first year of operation. This projection is approximately 20 percent higher than the actual utilization rate of the current provider in the ESRD Service Area.

GR Criterion 5 - Need

FMC DeSoto asserts that all patients will be served without regard to race, sex, age, physical abilities, or the ability to pay. However, the majority of patients serviced at the proposed facility will be Medicare beneficiaries. Based on the FMC facilities in Mississippi, the applicant anticipates that the facility will serve a minimum of two (2) percent indigent care patients, those who have no insurance coverage and who are unable to pay for treatment.

The applicant believes that there is additional need for ESRD services in the ESRD Facility Service Area. However, RCG-Southaven, the only provider of ESRD services within 30 miles from the proposed facility, had a utilization rate of 46.6 percent for the fiscal year ending June 30, 2005. In addition, Network 8, Inc. reported that there 109 active ESRD patients in DeSoto County in 2004, only 3 patients above the reported number of patients served by RCG-Southaven.

Staff contends that the establishment of 10 additional ESRD stations in DeSoto County would create an unnecessary duplication of a health service.

The application contained six letters of support for the project from physicians in the area.

GR Criterion 6 - Access to Facility/Service

The applicant assures that all patients will have access to the ESRD services. It states that individuals of any age who receive dialysis or renal transplantation for ESRD are eligible for Part A coverage if they file an application and they (1) meet the work requirements for insured status under the Social Security or railroad retirement program, (2) are entitled to monthly Social Security benefits of an annuity under the Railroad Retirement Act, or (3) are the spouses or dependent children of such insured or entitled persons. Medicare-qualified government employees are also eligible for ESRD benefits. FMC DeSoto anticipates that the proposed facility will serve approximately two (2) percent indigent care patients.

The applicant estimates that approximately 88.7 percent of all patients of FMC facilities in Mississippi have Medicare primary coverage.

Further, the applicant submits that while BMA-Mississippi has no community advisory boards, extensive input is received from patients and their families through an annual patient survey and contact with their social workers. The applicant submits that BMA-Mississippi works closely with the National Kidney Foundation of Mississippi to provide public information and community services to help prevent kidney related diseases. In addition, the applicant states that the facility will have a patient representative at Network 8 and the Area Manager will join local civic/business clubs.

GR Criterion 7 - Information Requirement

The applicant affirmed that it will maintain the required information and make it available to the Department within 15 business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

As stated earlier, the only provider of ESRD services in DeSoto County is RCG-Southaven. RCG-Southaven had a utilization rate far less than the 80 percent utilization rate required before an additional provider can be approved.

GR Criterion 9 - Availability of Resources

FMC DeSoto submits that the Area Manager, Area Clinical Manager, Area Chief Technician, Area Education Coordinator, Home Training Coordinator, Social Worker, and Dietitian are currently employed with BMA-Mississippi. BMA-Mississippi has a satisfactory staffing history, and the registered nurses dialysis technicians and equipment technician will be transferred from existing FMC facilities in Mississippi or recruited locally. For any new employees, FMC states that it has an extensive, detailed training program designed and updated with input from personnel in its 1,400 facilities nationwide.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant submits that a division of FMC-NA will handle some of the nephrology support services. FMC-NA is one of the world's largest manufacturers of dialysis supplies and is the

major provider of dialysis laboratory services in the United States. FMC DeSoto states that the company is building its position in the rapidly expanding home care services arena and also in the ancillary testing market.

GR Criterion 11 – Health Professional Training Programs

The applicant believes that the establishment of FMC Desoto will enhance the training opportunities available in the county. FMC DeSoto states that internal services provided by the facility’s clinical, technical, social services, and dietary departments are open to the public; the medical director will consult with local physicians and give lectures at local hospitals, and local nursing programs will be allowed to send students to observe dialysis procedures as part of their clinical rotation.

GR Criterion 16 - Quality of Care

FMC Desoto submits that the project will be serviced by a group of highly skilled and qualified nephrologists specially trained for these services. The applicant further contends that routine inspections by all appropriate federal, state, and local agencies have demonstrated BMA-Mississippi’s compliance with all licensure, certification, and accreditation standards.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	\$ 408,750	75.7%
Renovation	0	0.0%
Capital Improvements	130,858	24.3%
Total Fixed Equip Cost	0	0.0%
Total Non-Fixed Equip Cost	0	0.0%
Land Cost	0	0.0%
Site Prep Cost	0	0.0%
Fees	0	0.0%
Contingency Reserve	0	0.0%
Capitalized Interest	0	0.0%
Other Cost - Testing Services	0	0.0%
Total Proposed Expenditures	\$ 539,608	100.0%

B. Method of Financing

The applicant proposes that the project will be financed from the parent company’s (FMC-NA) internal funds. Internal funds will cover the leasehold improvements, the purchase of equipment and supplies, rental payments for the building, and other similar start-up expenses. The financial statements contained in the application indicate that the applicant has the ability to undertake this project.

C. Effect on Operating Cost

The applicant projects the following expenses, utilization, and results from operation for the first three years following completion of this project:

Three-year Projected Operating Statement

Item	Year 1	Year 2	Year 3
Revenue			
Clinical Revenue	\$1,303,499	\$1,372,104	\$1,454,430
EPO Revenue	615,190	647,568	686,422
Ancillary Revenue	171,205	180,216	191,029
Total Revenue	\$2,089,894	\$2,199,888	\$2,331,881
Expenses			
Personnel	\$ 552,599	\$ 583,723	\$ 620,561
Medical Supplies	140,220	147,600	156,456
Ancillary Cost (w/o Acute)	94,871	99,864	105,856
EPO Cost (w/o Acute)	337,691	355,464	376,792
Other Med-No Equip Leasing (w/o Acute)	33,516	35,633	38,148
Other Med- Equip. Leasing (w/o Acute)	32,042	32,042	32,042
Housekeeping (w/o Acute)	37,661	61,303	65,631
Adm Exclude Regional & BU Allocation	26,129	27,779	29,740
Bad Debt (w/o Acute)	62,419	65,704	69,646
Depr/Amort (with Acute)	57,232	57,232	57,232
Property/Insurance (with Acute)	2,632	2,711	2,792
Rent (with Acute)	80,000	72,100	74,263
Total Expenses	\$1,467,012	\$1,541,155	\$1,629,161
Less Phycom & Allocation	\$ 68,400	\$ 71,136	\$ 73,981
Earnings Before Income Taxes	\$ 554,482	\$ 587,597	\$ 628,739
Utilization Statistics			
Total Patients	49	51	55
Total Treatments	6,840	7,200	7,632
Utilization Rate	79.0%	71.9%	76.1%
Cost per Treatment	\$214.48	\$214.05	\$213.46
Charge per Treatment	\$190.57	\$190.57	\$190.42

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.

According to the applicant, the Medicare composite rate per treatment for this geographic area is \$137.11.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of the proposed application for comment. Outpatient services are paid as outlined in the Medicaid State Plan. The Division of Medicaid took no position on this project.

IV. 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 2006 State Health Plan*; the *Mississippi Certificate of Need Review Manual, revised 2000*; and all adopted rules, procedures, and plans of the Mississippi Department of Health. Specifically, the project does not comply with SHP Criterion 1 and GR Criterion 5 – Need. Policy Statement 5 of the *FY 2006 State Health Plan* states: “A CON application for the establishment of an ESRD facility shall be considered for approval only when each individual facility within an applicant’s proposed ESRD Facility Service Area has maintained, at a minimum, an annual or prorated utilization rate of 80 percent as verified by the MDH. The 12 months prior to the month of submission of the CON application shall be used to determine utilization.” Staff found that there is only one ESRD facility within 30 highway miles of the proposed facility. That facility had a utilization rate of 46.6 percent, less than the required 80 percent. Given the low utilization rate of the existing provider, staff questions the viability of the applicant’s proposal and contends that the proposal, if approved, will be an unnecessary duplication of a health service.

Consequently, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by BMA-Mississippi for the establishment of a 10-station ESRD facility in DeSoto County.