

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

**CON REVIEW ESRD-NIS-0905-037
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC.
D/B/A FRESENIUS MEDICAL CARE FLOWOOD
RELOCATION OF 12 ESRD STATIONS FROM HINDS COUNTY TO RANKIN COUNTY
CAPITAL EXPENDITURE: \$646,500
LOCATION: FLOWOOD, RANKIN 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. Fresenius Medical Care Flowood (FMC Flowood) will be a 12-station ESRD facility located in Rankin County.

B. Project Description

BMA-Mississippi requests Certificate of Need (CON) authority to transfer and relocate 12 of 38 hemodialysis stations, the home training department, and administrative offices from FMC Jackson's current location on the north campus of St. Dominic-Jackson Memorial Hospital (St. Dominic) to a new site approximately 2.5 miles away from the current location. The proposed new facility (FMC Flowood) will be located in Flowood, Rankin County, Mississippi, at the southeast corner of Treetops Boulevard and the new Tops Street.

FMC Flowood will occupy approximately 6,000 square feet of a new medical office building being constructed by Central Nephrology Clinic, P.A. The second floor of this new building will be occupied by the medical directors along with a planned access center.

The project will require one Area Clinic Manager, 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 \$540,769 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. The project is expected to be complete approximately 180 days thereafter.

II. TYPE OF REVIEW REQUIRED

Applications for the establishment and relocation of a health care facility or portion thereof are reviewed in accordance with Section 41-7-191, subparagraph (1)(a), (b) and (e) 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 Mississippi 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 or the relocation of a portion of an existing ESRD facility's dialysis stations to another location 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. Although this project will not add new stations to the ESRD Facility Service Area, a new ESRD facility will be established in Rankin County.

BMA Mississippi proposes to transfer/relocate 12 ESRD stations from an existing facility located in Jackson, Hinds County, Mississippi, to a new location in Flowood, Rankin County, Mississippi. Both Hinds County and Rankin County are located within the same ESRD Facility Service Area. An ESRD Facility Service Area is defined as the area within 30 highway miles of an existing or proposed ESRD facility. There are seven (7) ESRD facilities located within the proposed facility's service area (excludes stations operated at University Medical Center Acute and University Hospital & Clinics Transplantation). The facilities and their utilization rates are as follows:

Facility	Distance	Stations	Utilization Rate
FMC Jackson	3.2 miles	38	54%
RCG North Jackson	6.3 miles	40	55%
FMC Rankin County	9.4 miles	12	48%
RCG Terry Road	10.2 miles	35	38%
RCG Brandon	11.6 miles	25	31%
FMC SW Jackson	12.9 miles	24	53%
RCG Southwest Jackson (Renex)	14.5 miles	16	32%

Source: BMA Mississippi application and ESRD Facility Survey, 2005, Mississippi Department of Health.

Based on information presented in the above table, the applicant is not in compliance with the need criterion as stated in the *FY 2006 State Health Plan*.

SHP Criterion 2 - Number of Stations

The State Health Plan establishes a minimum of four (4) ESRD stations for the establishment of a new ESRD facility; therefore, the applicant's proposal to relocate 12 stations is in compliance with this criterion.

SHP Criterion 3 - Minimum Utilization

The applicant projects to perform 6,513 treatments on 46 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	Treatment/ Station	Stations	BMA Projections		MDH Requirements	
				Treatment	Utilization Rate	Treatment	Utilization Rate
1	46	543	12	6,513	57.9%	5,616	50%
2	60	705	12	8,467	73.1%	7,296	65%
3	69	815	12	9,787	88.2%	8,424	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 Flowood 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-hour 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 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 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 Flowood 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 Flowood 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

FMC Flowood 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 agreements 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.

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

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

GR Criterion 2 - Long Range Plan

The applicant submits that FMC-NA provides a ready pipeline to launch new applications in medical technology now being explored in research labs worldwide and its standardized procedures and protocols can be adapted to emerging rural markets.

GR Criterion 3 - Availability of Alternatives

FMC Flowood submits that there is not a less costly or more effective available alternative to the application.

GR Criterion 4 - Economic Viability

The applicant projects earnings before income taxes of \$115,995 the first year, \$258,147 the second year, and \$359,979 the third year. Therefore, the project appears to be economically viable.

The proposed charges per dialysis patient is \$159.00 the first year, \$161.39 the second year, and \$163.80 the third year of operation of this project.

The applicant expects that the projected utilization is consistent with the other providers in the ESRD Service Area. However, none of the existing providers are at the levels of utilization proposed by the applicant.

GR Criterion 5 - Need

The admission policy contained in the application indicates that the policy of the dialysis facility is to admit and to treat all patients referred by physician members of its medical staff without regard to race, creed, color, age, sex, handicap, disability, national origin, or social status.

The applicant estimates that it currently dialyzes approximately 140 patients a month in 12,000+ square feet located on the north campus of St. Dominic. The building which FMC Jackson occupies is jointly owned by St. Dominic (33%) and three of its medical directors (67%). According to the applicant, FMC Jackson was recently notified by St. Dominic that it does not desire to renew the lease beyond two more years. As a result, FMC Jackson requests to relocate 12 of its existing stations to a new site and renovate that portion of the building owned by its medical directors to accommodate the remaining 26 stations.

BMA Mississippi submits that in addition to the inevitable non-renewal of the lease, the continued growth of the patient census at the current location is creating parking problems. New construction by St. Dominic and the rerouting of the main road on its north campus eliminated approximately 15 percent of FMC Jackson's parking spaces. Also, patient transportation and delivery vans must now back into the parking lot from the new road to drop off patients or deliveries as there is only one way in and out of the facility.

The applicant anticipates that the number of patients in the ESRD Facility Service Area will remain the same since this project will only shift stations from one county to another. As stated earlier, an ESRD Facility Service Area is defined as the area within 30 highway miles from an existing or proposed ESRD facility; therefore, both Hinds and Rankin counties are within the same ESRD Facility Service Area.

As indicated under SHP Criterion 1 – Need, there are seven ESRD facilities located in the proposed ESRD facility service area. None of the seven facilities performed the required 80 percent utilization for the approval of an additional facility. In fact, the two facilities located in Rankin County performed at less than 50 percent utilization for the past 12-month period. In addition, information obtained from Network 8, Inc. indicates that the incidence of ESRD patients in 2004 was 128 for Hinds County and 31 for Rankin County. The prevalence of ESRD patients for the same period was 546 for Hinds County and 97 for Rankin County. Therefore, the relocation of stations from Hinds County to Rankin County will result in the relocation of stations from the area of the greatest need, while creating a duplication of services in an area of lesser need.

The application contained one letter of support for the project.

GR Criterion 6 - Access to Facility/Service

FMC Flowood states 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.

FMC Flowood certified that it will comply with all applicable state and federal licensure, accreditation, and certification standards.

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

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. 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 proposes to 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 Service

FMC Flowood submits that no additional new services will be provided in the ESRD Service Area; therefore, the existing healthcare system should not change as a result of this project.

As stated earlier, there are seven ESRD facilities within the proposed ESRD facility's service area. All facilities operated at less than 80 percent utilization for the most recent 12 month period. Therefore, this project will create a duplication of ESRD services within an area that is not performing at full capacity.

GR Criterion 9 - Availability of Resources

FMC Flowood 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. In addition, the applicant submits that 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. Finally, FMC has an extensive, detailed training program designed and updated with input from personnel in its 1,400 facilities nationwide to accommodate its need for any new employees.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant submits that FMC is one of the world's largest manufacturers of dialysis supplies and is the major provider of dialysis laboratory services in the United States. 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 submits the following in relation to the health professional training programs:

- The establishment of FMC Flowood will enhance the training opportunities available in Rankin County.
- FMC's Clinical Services Department provides professionally developed videos which can be viewed by the patients and their family members, its employees, and all local health care professionals.
- 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.
- 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 Flowood submits that the project will be serviced by a group of highly skilled and qualified nephrologists specially trained for these services. The applicant states that it intends to assure that each recipient of ESRD services receives and the facility provides the highest quality of care and services necessary. It further states that routine inspections by all appropriate federal, state, and local agencies have demonstrated FMC's 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	\$ 490,500	76.0%
Renovation	0	0.0%
Capital Improvements	0	0.0%
Total Fixed Equip Cost	0	0.0%
Total Non-Fixed Equip Cost	156,000	24.0%
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	\$ 646,500	100.0%

The above capital expenditure is for leasehold improvements to approximately 6,000 square feet of leased spaced to accommodate 12 ESRD stations. The cost is estimated to be \$81.75 per square foot. The *Means Construction Data* does not compare leasehold improvement costs for ESRD facilities.

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. 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			
Chronic Revenue	\$1,035,585	\$1,366,454	\$1,603,135
EPO Revenue	430,756	568,383	666,831
Non-EPA Ancillary Revenue	162,828	214,851	252,065
Total Revenue	\$1,629,169	\$2,149,689	\$2,522,031
Expenses			
Personnel	\$ 540,769	\$ 693,015	\$ 807,313
Medical Supplies	133,519	173,574	200,629
EPO	327,127	429,517	501,431
Non-EPO Ancillary	78,157	101,605	117,442
Other Medical	35,822	46,569	53,827
Controllable Administration	65,131	84,670	97,868
Bad Debt	57,021	75,239	88,271
Housekeeping	39,079	50,802	58,721
Rent	108,000	108,000	108,000
Depreciation	68,550	68,550	68,550
Physician Compensation	60,000	60,000	60,000
Total Expenses	\$1,513,175	\$1,891,541	\$2,162,052
Facility EBIT	\$115,995	\$258,148	\$359,979
Facility EBITDA	\$184,545	\$326,698	\$428,529
Utilization Statistics			
Total Patients	42	46	60
Total Treatments	6,513	8,467	9,787
Utilization Rate	57.9%	75.3%	87.1%
Cost per Treatment	\$232.33	\$223.40	\$220.91
Charge per Treatment	\$159.00	\$161.39	\$163.80

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 \$133.90.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of the proposed application for comment. 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/relocation 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 are seven ESRD facilities within 30 highway miles of the proposed facility. None of the seven facilities maintained the required 80 percent utilization rate for the 12 month period prior to the month of submission of BMA Mississippi's application. In addition, Network 8, Inc. data suggests that the greatest need for ESRD services is in Hinds County, not Rankin County.

Consequently, the Division of Planning and Resource Development staff recommends disapproval of the application submitted by BMA Mississippi for the relocation of 12 ESRD stations from Hinds County to Rankin County.