

**Division of Health Planning and Resource Development
November 2004**

CON Review: ESRD-NIS-0804-028

Bio-Medical Application of MS, Inc. , dba Fresenius Medical Care Belzoni

Establishment of an Eight (8) Station ESRD Facility

Capital Expenditure: \$426,000

Location: Belzoni, Humphreys County, Mississippi

Staff Analysis

I. Project Summary

A. Applicant Information

According to the applicant, the proposed eight station ESRD facility is incorporated in the name of Bio-Medical Applications (BMA) of Mississippi, Inc. However, the facility will use a "doing business as" (dba) Fresenius Medical Care (FMC) Belzoni. Fresenius Medical Care-North America (FMC) is the parent company of the BMA of Mississippi, Inc. FMC uses the name to distinguish the facility from other FMC facilities and to express its exact location. FMC-North America is owned by Fresenius Medical Care AG, which is the world's largest, integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 1,300,000 individuals worldwide. Through a network of approximately 1,590 dialysis clinics in North America, Europe, Latin America, and Asia-Pacific, Fresenius Medical Care provides dialysis treatment to approximately 122,700 patients around the globe. FMC is also a leading provider of dialysis products such as hemodialysis machines, dialyzers, and related disposable products.

Bio-Medical Applications of Mississippi is a Delaware corporation authorized to do business in Mississippi. The application contains a letter of good standing from the Mississippi Secretary of State.

B. Project Description

The applicant, BMA of Mississippi, Inc., requests Certificate of Need (CON) authority to establish an eight-station ESRD facility in Belzoni, Humphreys County, Mississippi, to better serve the 32 ESRD patients identified by Network 8, Inc. as living there. These stations may serve a dual utilization role as staff assisted hemodialysis and home training.

BMA proposes to lease approximately 3,900 square feet of building space and finance leasehold improvements to make the building suitable for a dialysis facility. The total capital expenditure will be \$426,000. The project proposes to employ 7.25 full-time equivalent staff for a first-year personnel cost of \$358,000. The capital expenditure will be obligated upon CON approval. The project will be completed approximately 180 days from the receipt of the Certificate of Need.

The applicant will be competing with two other applications for the ESRD facility recently approved by the Mississippi State Board of Health to be located in Humphreys County. Other applicants are Diversified Renal Group (DRG), seeking four ESRD stations, and Renal Care Group-Mississippi, requesting six stations.

II. Type of Review Required

This project for the establishment of an end-stage renal disease facility is reviewed in accordance with Section 41-7-173 (h) and 41-7-191 (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, 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 6, 2004.

The Department received three applications competing for the ESRD facility in Humphreys County. These applications were deemed complete on October 1, 2004, and were entered into the October 2004 review cycle as competing applications.

III. **Conformance with the *State Health Plan* and other Adopted Criteria and Standards**

A. *State Health Plan*

The *FY 2005 Mississippi State Health Plan* contains policy statements, service specific criteria, and standards which must be met before an applicant may be granted CON authority to establish an ESRD facility, as set forth below.

State Health Plan Criterion 1 – Need

Pursuant to the revised rules as set forth in the FY 2005 State Health Plan, the ESRD Facility Service Area in question consists solely of Humphreys County, Mississippi. Since there are no ESRD facilities located in this county, there are also no facilities in this service area. There are five other facilities located within thirty-five miles of the proposed location of the Belzoni facility.

According to Network 8, Inc., an end-stage renal disease patient receives an average of three dialysis sessions per week, or an average of 12 per month or 144 dialysis sessions per year. The FY 2005 State Health Plan defines full utilization of an ESRD station as 936 dialyses per year, while optimum utilization is described as 702 dialyses. Network 8, Inc. sets the prevalence of end-stage renal disease for Humphreys County at 32 as of April 30, 2004.

Based on the optimum utilization of 702 dialyses per station per year as contained in the State Health Plan, Humphreys County will need nearly seven ESRD stations to dialyze its 32 end-stage patients.

Number of dialyses per patient/year = 144
Number of dialyses for 32 patients $144 \times 32 = 4,608$
Optimum dialyses per station = 702 dialysis per year
Number of stations needed to dialyze 32 patients $4,608/702 = 6.56$ dialysis stations

The prevalence of end-stage renal disease in Humphreys County has gradually decreased from 54 patients in 2000, to 40 in 2003, and as of April 30, 2004, the prevalence of kidney disease had dropped to 32. This trend indicates a correspondent decrease in the number of ESRD stations needed by Humphreys County. This application, requesting eight stations, is not the most appropriate application to adequately satisfy the renal dialysis needs of the kidney patients of Humphreys County. The table below indicates this falling kidney disease prevalence.

**ESRD Incidence and Prevalence
 for Humphreys County
 1999-2004**

Year	Incidence	Prevalence
1999	9	50
2000	7	54
2001	2	52
2002	4	43
2003	6	40
2004 (as of April 30)	n/a	32

Source: Network 8, Inc., Jackson, Mississippi

State Health Plan Criterion 2 – Minimum Number of Stations

The *FY 2005 Mississippi State Health Plan* establishes the minimum number of ESRD stations that can be approved per ESRD facility at four. The applicant, requesting eight, is in compliance with this criterion.

State Health Plan Criterion 3 – Minimum Expected Utilization

The *FY 2005 Mississippi State Health Plan* implies that a proposed ESRD facility must accurately project a minimum utilization of 50, 65, and 75 percent during the first, second, and third years, respectively.

BMA estimates that the facility will serve 32, 35, and 40 patients during the first, second, and third year, respectively, at a projected utilization rate of 62.5 percent, 72.1 percent and 81.7 percent for those years of operation as indicated below.

Projected Utilization For BMA-Belzoni			
	Year 1	Year 2	Year 3
Estimated Beginning Patient Population	32	35	40
Estimated New Patients During the Year	9	10	11
Less: Patients Home Trained	(1)	0	0
Less: Estimated Mortality Among Patients	(4)	(5)	(6)
Less: Estimated Transplantation Patients	<u>(1)</u>	<u>0</u>	<u>0</u>
Total Patient Loss	<u>(6)</u>	<u>(5)</u>	<u>(6)</u>
Total Patients at End of Year	<u>35</u>	<u>40</u>	<u>45</u>
Total Treatments at End of Year*	4,620	5,280	5,940
Percent Utilization**	61.7	70.5	79.3

* Based on an average of 11 treatments per month per patient. The applicant estimated

total treatments of 4,680, 5,400, and 6,120 for years one, two, and three, respectively.
** Based on full utilization at 936 dialysis treatments per station per year or 7,488 total treatments.

State Health Plan Criterion 4 – Minimum Services

The applicant affirms that the staff members of the facility will provide social and dietetic services. Vocational and physical rehabilitative will be handled by the social worker through referral agencies. Mississippi Vocational Rehab is the primary agency used for vocational rehabilitation and numerous home health agencies are used for physical rehabilitation.

State Health Plan Criterion 5 – Access to Needed Services

The applicant affirms that it will provide reasonable access to equipment/facilities for such needs as vascular access and transfusion required by stable maintenance dialysis patients.

State Health Plan Criterion 6 – Hours of Operation

The applicant states that the normal facility hours of operation will be from 6:30 a.m. to 6:00 p.m., six days per week. Arrangements will be made for those patients needing after-hours treatments.

State Health Plan Criterion 7 – Home Training Program

The applicant affirms that a home training program will be made available through the FMC Jackson facility.

State Health Plan Criterion 8 – Indigent /Charity Care

The applicant affirms that the proposed facility will not have any admission policies which will adversely affect access to care by indigents. Presently, approximately ten percent of the patients being treated by the FMC facilities in central Mississippi do not have secondary insurance coverage to pay the 20 percent not covered by Medicare. If the facility identifies that a patient does not have insurance coverage, steps will be taken to determine whether viable coverage options exist. Where no options exist, FMC has an Indigent Waiver Program that provides full or partial free care for qualifying patients who lack the means to pay for services, according to the applicant.

State Health Plan 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.

State Health Plan Criterion 10 – Staffing Qualifications

The applicant affirms that the staff of the proposed facility shall, at minimum, meet all requirements and qualifications as stated in 42 CFR, Chapter IV, Subpart U.

State Health Plan Criterion 11 – Staffing Time

BMA-Belzoni affirms that when the facility is in operation, at least one Registered Nurse will be on duty. There shall be a minimum of two persons for each dialysis shift (one of which will

be a RN). The proposed facility's Medical Director or designated physician shall be on-site or on-call at all times when the facility is in operation. The applicant further states that at all times when the facility is not in operation, the Medical Director or designated physician and a Registered Nurse shall be on-call.

State Health Plan Criterion 12 – Data Collection

The applicant affirms that utilization data will be recorded and made available as required by the Department.

State Health Plan Criterion 13 – Staff Training

BMA-Belzoni will provide an on-going program of training and dialysis techniques for nurses and technicians at the facility. The applicant also affirms that in-service training sessions will be held at least monthly.

State Health Plan Criterion 14 – Scope of Privileges

The applicant affirms 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.

State Health Plan Criterion 15 – Affiliation with a Renal Transplant Center

The applicant affirmed that it shall, within one year of commencing operation of the facility, enter into an affiliation agreement with a transplantation center. The written agreement shall describe the relationship between the transplantation facility and the ESRD facility and the specific services that the transplantation center will provide to the patients of the ESRD facility. The agreement will comply with all requirements of this criterion. The application contains such a proposed agreement between the applicant and University of Mississippi Medical Center and the applicant and the University of Alabama.

B. General Review Criterion

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, revision 2000, contains general review criteria which all Certificate of Need applications must meet.

General Review Criterion 3 – Availability of Alternatives

The applicant states that there is no less costly or more effective available alternative to their application. Being a part of the largest provider of kidney dialysis services in the world, FMC Belzoni will take advantage of FMC's purchasing power. Medical supplies, equipment pharmacy items, medical waste disposal, and lab services will be purchased through national contracts at a much lower cost to the facility. In addition, FMC Belzoni will operate more efficiently and effectively due to staffing hierarchy of the company. National and regional staff will assist the clinical, technical, and financial operations of the facility. Locally, the patients and employees in the facility will benefit from the expertise and support of the Area Manager, Area Clinic Manager, Area Chief Technician, and Area Education Coordinator.

General Review Criterion 4 – Economic Viability

The applicant expects the immediate and long-term financial feasibility of the project to be excellent. The net income is projected to be \$11,544, \$46,260, and \$72,733 during the first, second, and third years of operation, respectively.

General Review Criterion 6 – Access to Facility/Services

The applicant affirms that BMA of Mississippi does not discriminate against the poor, the handicapped, women, the elderly, or members of racial and ethnic minorities with regard to the delivery of health care services. Patients are provided health care services without regard to physical conditions, age, or ethnic background.

General Review Criterion 7 – Information Requirement

BMA-Belzoni affirmed that it will maintain the required information and make it available to the Department within 15 days of request.

General Review Criterion 8 – Relationship to Existing Health Care Services

The applicant states that the establishment of an ESRD facility in Humphreys County will be beneficial to the existing health care delivery system.

A letter of opposition to this project was submitted by RCG, Inc.

General Review Criterion 15 - Competing Applications

Applicants competing for the ESRD stations for Humphreys County are as follows:

Diversified Renal Group for four stations,
Renal Care Group of Mississippi for six stations, and
Bio-Medical Applications of Mississippi for eight stations.

Each application was adjudged to be complete on October 1, 2004, and entered into the October review cycle as competing applications. Comparison among the three indicates the following:

Number of Stations Needed

Network 8, Inc. has determined that as of April 30, 2004, 32 chronic kidney failure patients resided in Humphreys County. This number of patients will require six stations to maintain an optimally operated renal dialysis facility. Renal Care Group is requesting six stations, the desired number for Humphreys County patients. The four requested by Diversified Renal Group is inadequately low, and the eight requested by Bio-Medical would generate excess capacity.

Present ESRD Provider for Humphreys County Patients

Twenty-five of Humphreys County's renal patients are currently being dialyzed in renal dialysis facilities operated by Renal Care Group in their Indianola and Lexington facilities. The transfer of these patients to another provider would require a likely switch of nephrologist, social worker, dietician, staff nurses, and support staff; professionals with whom these patients have probably established a close working therapeutic relationship. DRG does not operate a dialysis facility in the area. Fresenius' nearest facility is located in Yazoo City. The transfer of the majority of Humphreys County patients to a facility in Humphreys County would probably be less traumatic to the patients if their present kidney care providers remained the same, particularly their nephrologist, social worker, and dietician.

General Review Criterion 16 – Quality of Care

The applicant states that the proposed facility will be part of the world's largest renal dialysis service company.

IV. Financial Feasibility

A. Capital Expenditure Summary

New Construction Cost	\$ 306,000
Renovation Cost	0
Capital Improvement Cost	0
Non-Fixed Equipment Cost	120,000
Fixed Equipment Cost	0
Land Cost	0
Site Preparation Cost	0
Fees (Contractual, legal, etc.)	0
Contingency Reserve Cost	0
Other Cost (Specify)	_____0
Total Proposed Capital Expenditure	<u>\$ 426,000</u>

B. Method of Financing

The applicant affirms that the BMA-Belzoni project will be financed through parent company's internal funds.

C. Effect on Operating Cost

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

RMA-Belzoni Three Year Projected Operating Statement			
<u>Expenses</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>
Salaries, Wages, and Benefits	\$ 359,429	\$ 400,284	\$ 451,121
Ancillary Cost	83,772	97,627	111,750
EPO Cost	295,402	344,256	394,059
Other Medical Leasing	14,087	16,417	18,791
Other Medical Equipment Leasing	15,474	15,474	15,474
Housekeeping	25,553	29,779	34,087
Administrative Expense	64,912	75,647	86,591
Bad Dept Allowance	31,270	36,441	41,713
Depreciation	36,473	36,473	36,473
Property Insurance	1,963	2,022	2,083
Rent	31,408	32,350	33,321
Supplies and Misc. Expense	<u>95,940</u>	<u>110,700</u>	<u>125,460</u>
Total Expenses	<u>\$ 1,055,683</u>	<u>\$ 1,197,470</u>	<u>\$ 1,350,923</u>
<u>Revenue</u>			
Total Revenue	\$ 1,067,227	\$ 1,243,730	\$ 1,423,656
Net Income	<u>\$ 11,544</u>	<u>\$ 46,260</u>	<u>\$ 72,733</u>
Treatments	4,620	5,280	5,940
Cost Per Treatment*	\$ 229.50	\$ 221.38	\$ 227.43
Charge Per Treatment*	\$ 231.00	\$ 226.79	\$ 239.67
Net Income per Treatment	\$ 2.50	\$ 8.76	\$ 12.24

* Staff Calculations

D. Cost to Medicare/Medicaid

ESRD treatment is a Medicare entitlement program. 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 the proposed application, and does not oppose the project.

VI. Conclusion and Recommendation

This project is in substantial compliance with criteria and standards for the establishment of end-stage renal disease facilities, as contained in the FY2005 State Health Plan; the *Mississippi Certificate of Need Review Manual*, revised 2000; and adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Department received three competing applications, all requesting Certificate of Need authority to establish ESRD services in Humphreys County. The three applications were deemed complete on October 1, 2004, and entered into the October Review Cycle.

All projects were found to be in substantial compliance with the ESRD Certificate of Need criterion. However, with competing applications, the Department must determine which applicant, if any, is the most appropriate applicant for providing the proposed services. Staff has determined that the application submitted on behalf of Renal Care Group Mississippi, Inc., dba, RCG-Belzoni to be the most appropriate application for providing ESRD dialysis services in Humphreys County. Since only one application can be approved for Humphreys County, the Division of Health Planning and Resource Development recommends the disapproval of the application submitted on behalf of Bio-Medical Applications of Mississippi, Inc., dba Fresenius Medical Care Belzoni.