

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

**CON REVIEW: ESRD-NIS-0410-016
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. D/B/A
FRESENIUS MEDICAL CARE – CHARLESTON
ESTABLISHMENT/CONSTRUCTION OF A NINE-STATION ESRD FACILITY
IN TALLAHATCHIE COUNTY
CAPITAL EXPENDITURE: \$775,000
LOCATION: CHARLESTON, TALLAHATCHIE COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Bio-Medical Applications of Mississippi, Inc., (BMA of MS, Inc.) d/b/a Fresenius Medical Care-Charleston, is a business corporation located at 603 West Main Street in Charleston, 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-Charleston, requests Certificate of Need (CON) authority to establish a nine-station ESRD facility in Tallahatchie County.

The applicant proposes the facility will consist of 5,533 square feet and will be a lease arrangement. The applicant provided a copy of the lease agreement between Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care-Charleston, and YB Development, LLC. This project would involve new construction of a single story stand-alone structure on a site located at 603 West Main Street in Charleston, Mississippi. Within this space the applicant proposes to establish a nine-station ESRD facility.

The applicant states that the proposed project will consist of the following aspects:

- **Structural:** Footing/Foundation Plan, Column Schedule, Roof Framing, Slab, and Roof Deck Plans, as well as Framing Elevations.
- **Architectural:** Floor, Roof, and Reflected Ceiling Plans, Building Elevators, exterior and Interior Wall Sections, Interior Elevations, Window/Door Alterations, Cabinet and Furniture Plans.
- **Mechanical:** HVAC Floor and Roof Plan, Equipment, Diffusers and Fan Schedule/Details

- **Electrical:** Site, Power, and Electrical Lighting, Low Voltage, Telephone, Data, and Fire Alarm Plans.
- **Plumbing:** Waste Piping, Vent Plan and Isometric, H/C Water Piping, R.O. and Concentrate Piping, Natural Gas, and Combustion Air Plan, Plumbing Riser Diagram, and Plumbing Fixture Schedule and Details.

The applicant states that the proposed site has available electricity, city sewer and water, and is not located in a flood zone. The applicant further asserts that local fire/emergency departments are located within 500 feet of the proposed facility.

The applicant provided a letter from the architect to verify the estimated cost to complete the project. The applicant asserts the estimated cost for the construction including site work, architect fees and contractor fees, is \$775,000 or \$123.80 per square foot. The overall floor plan consists of 5,533 square feet.

The applicant expects to employ 3.6 full-time equivalent employees at a total personnel cost of \$328,614 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 submits that the anticipated date for obligation of the proposed project is October 2010 and the anticipated date of completion is October 2011.

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 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 (RR) using current ESRD Network 8 data is 1.5 or higher. This project is not in substantial compliance as discussed below.

Fresenius Medical Care-Charleston submits that the need for the proposed project is evidenced by the Mississippi State Department of Health's (MSDH) calculation of Tallahatchie County's relative risk score of 1.6. Fresenius Medical Care-Charleston states that with the relative risk score for Tallahatchie 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. The applicant believes the proposed project will fill the unmet need of the Charleston, Tallahatchie County, Mississippi service area.

An ESRD Facility service area is defined as the area within 30 highway miles of an existing or proposed ESRD facility. The applicant states that there are currently no ESRD facilities in Tallahatchie County. The applicant submits that currently the five closest ESRD facilities to the proposed service area are: RCG of Grenada - approximately 36 miles, FMC of Sardis - approximately 38 miles, RCG of Clarksdale - approximately 41 miles, RCG of Greenwood - approximately 46 miles, and RCG of Cleveland - approximately 57 miles from the proposed project.

According to the *FY 2010 State Health Plan* Tallahatchie County's relative risk score is 1.6. However, Healthcare Engineers, LLC, Charleston was issued CON No. R-0710, with an effective date of June 29, 2006, and is currently outstanding. Healthcare Engineers, LLC-Charleston applied for a six-month extension which terminates June 29, 2010. As of June 16, 2010 the ESRD facility is non-operational. Policy Statement 8 states that ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation. Healthcare Engineers, LLC-Charleston proposed ESRD facility is to be located on South Panola Street in Charleston, MS approximately .39 miles from the location of the proposed project.

Network 8, Inc. reported a prevalence of 40 patients for Tallahatchie County for 2008. Based on the prevalence of ESRD patients in Tallahatchie County, it is estimated that the county can support a six-station ESRD facility. As stated above, a CON remains outstanding for Healthcare Engineers, LLC-Charleston for the establishment of a six-station ESRD facility in Tallahatchie County. No new facilities can be approved until the outstanding CON is revoked, rescinded, or until the facility is opened and operating at 80 percent utilization. Therefore, the applicant is not in compliance with this criterion.

SHP Criterion 2 - Number of Stations

The applicant states that the ESRD facility will contain nine hemodialysis stations in Tallahatchie County.

SHP Criterion 3 - Minimum Utilization

		Applicant's Projections			MSDH Requirements	
Year	Stations	Patients	Treatments	Utilization Rate	Treatments	Utilization Rate
1	9	29.25	4,213	50%	4,212	50%
2	9	38	5,475	65%	5,475	65%
3	9	43.88	6,318	75%	6,318	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-Charleston 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-Charleston will operate between the hours of 6:00 a.m. to 4:00 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. 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 states that they have entered into affiliation agreements with renal transplant centers for many of its ESRD facilities, including the University of Alabama at Birmingham, as well as the University of Mississippi Medical Center. Fresenius Medical Care-Charleston affirms that an agreement with respect to renal transplant services will be sought by the applicant and provided to the Mississippi State Department of Health upon receipt.

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 not in compliance with the overall objectives of the *FY 2010 State Health Plan*. The applicant seeks Certificate of Need authority to establish a nine-station ESRD facility in Charleston, Tallahatchie 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 Tallahatchie County.

GR Criterion 3 – Availability of Alternatives

Fresenius Medical Care-Charleston submits that there is no less costly or more effective alternative to the application. No other alternatives were present in the application.

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

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$40,541 the first year, \$891 the second year, and \$30,811 the third year of operation for the proposed project. 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 \$275 per dialysis treatment for the first year, \$279 for the second year, and \$283 for the third year of operation for the proposed project. The applicant projects cost of \$285 per dialysis treatment for the first year, \$279 for the second, and \$278 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 Tallahatchie County's RR is 1.6. The applicant asserts that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population. However, as previously mentioned above Healthcare Engineers, LLC-Charleston has an outstanding CON for the establishment of a six-station ESRD facility in Tallahatchie County. No new facilities can be approved until the outstanding CON is revoked, rescinded, or until the facility is opened and operating at 80 percent utilization. Therefore, the project does not meet the need

requirement as stated in the *2010 State Health Plan*.

- 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, the applicant states that there are currently no ESRD facilities in Tallahatchie County. The applicant submits that currently the five closest ESRD facilities in the proposed service area are: RCG of Grenada - approximately 36 miles, FMC of Sardis – approximately 38 miles, RCG of Clarksdale – approximately 41 miles, RCG of Greenwood – approximately 46 miles, and RCG of Cleveland – approximately 57 miles from the proposed project.

Healthcare Engineers, LLC-Charleston proposed ESRD facility is to be located on South Panola Street in Charleston, MS approximately .39 miles from the location of the proposed project.

- d. Community Reaction:** The application contained 1 letter of support from the Mayor of Charleston, and 19 letters of support from ESRD patients for the proposed project

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	\$3,461 (1%)
2	\$4,482 (1%)

The proposed facility will operate Monday through Saturday from 6:00 a.m. to 4:00 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 Tallahatchie County. Currently residents have to travel to other counties to receive ESRD services. The applicant submits that currently the five closest ESRD facilities in the proposed service area are: RCG of Grenada - approximately 36 miles, FMC of

Sardis – approximately 38 miles, RCG of Clarksdale – approximately 41 miles, RCG of Greenwood – approximately 46 miles, and RCG of Cleveland – approximately 57 miles from the proposed project. One additional provider (Healthcare Engineers, LLC-Charleston) holds a CON to establish a six-station ESRD facility in Tallahatchie County approximately .39 miles away from the proposed project.

The applicant states that a transfer agreement between Fresenius Medical Care-Charleston and Tallahatchie General Hospital will be established upon completion of the proposed project. The application contained a draft copy of the proposed transfer agreement between the two parties.

The applicant believes that failure to implement this project will severely disrupt the care of dialysis patients in the area, resulting in adverse impact on the health care system and service delivery of dialysis treatment in the community. The applicant further states that accessible renal dialysis services are crucial to the health care delivery system and the care of these patients.

GR Criterion 9 – Availability of Resources

Fresenius Medical Care-Charleston asserts that their affiliated companies have operated ESRD facilities throughout the state of Mississippi for many years, and their staffing history has been proven to be exemplary. The applicant further suggests that they will utilize their current resources and contacts within the state to staff the proposed facility. The applicant affirms that physician resources are available for the proper implementation of the proposed project.

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-Charleston plans to cooperate with health professional training programs in the surrounding area.

GR Criterion 16– Quality of Care

Fresenius Medical Care-Charleston states that the applicant and its affiliated companies have provided high quality dialysis services in ESRD facilities throughout the state of Mississippi for many years. The applicant believes that this evidences both the operational experience of the applicant, and the high quality care to be offered at the proposed facility.

The applicant states that providing renal dialysis services in the Tallahatchie County service area is not only essential to the provision of quality care, but also to the accessibility of that care for patients seeking these services. Accessibility to quality of care is a significant factor in providing appropriate health care services to ESRD patients.

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-Charleston’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 not 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. Specifically, the project does not comply with SHP Criterion 1 and GR Criterion 5 – Need.

The *FY 2010 State Health Plan* Criterion 1(a) 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 maintained a minimum annual utilization rate of 80 percent. Healthcare Engineers, LLC, Charleston was issued CON No. R-0710, with an effective date of June 29, 2006, and is currently

outstanding. As of June 16, 2010 the ESRD facility is non-operational. Policy Statement 8 states that ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation. No new facilities can be approved until the outstanding CON is revoked, rescinded, or until the facility is opened and operating at 80 percent utilization. Therefore, the applicant is not in compliance with this criterion.

SHP Criterion 1 (b) states that if 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 can qualify for an ESRD facility. However, as previously mentioned above, a CON remains outstanding for Healthcare Engineers, LLC-Charleston for the establishment of a six-station ESRD facility in Tallahatchie County. Therefore, the applicant cannot qualify for the exclusion under this criterion. Given the outstanding CON, the 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 Bio Medical Applications of Mississippi, Incorporated, d/b/a Fresenius Medical Care-Charleston for the establishment of a nine-station ESRD facility in Tallahatchie County.

Attachment I

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

Three-Year Projected Operating Statement

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue			
Outpatient Revenue	\$1,158,498	\$1,528,119	\$1,789,694
Gross Patient Revenue	\$1,158,498	\$1,528,119	\$1,789,694
Charity			
Deductions from Revenue			
Net Patient Care Revenue	\$1,158,498	\$1,528,119	\$1,789,694
Other Operating Revenue			
Total Operating Revenue	\$1,158,498	\$1,528,119	\$1,789,694
Operating Expenses			
Salaries	\$ 328,614	\$ 435,591	\$ 512,713
Benefits	\$ 92,012	\$ 121,965	\$ 143,560
Supplies	\$ 355,999	\$ 467,264	\$ 544,602
Services	\$ 0	\$ 0	\$ 0
Lease Expenses	\$ 85,000	\$ 85,000	\$ 85,000
Depreciation	\$ 81,475	\$ 81,475	\$ 81,475
Interest	\$ 0	\$ 0	\$ 0
Other	\$ 255,940	\$ 335,932	\$ 391,533
Total Operating Expenses	\$1,199,039	\$1,527,228	\$1,758,883
Net Operating Income	\$ 40,541	\$ 891	\$ 30,811
	Proposed	Proposed	Proposed
	Year 1	Year 2	Year 3
Procedures	4,213	5,475	6,318
Charge per outpatient day	\$ 275	\$ 279	\$ 283
Cost per outpatient day	\$ 285	\$ 279	\$ 278