

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 16, 2018**

**CON REVIEW NUMBER: ESRD-ES-1018-012
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC.
D/B/A FRESENIUS MEDICAL CARE MID MISSISSIPPI
EXPANSION OF STATIONS AT EXISTING ESRD FACILITY
CAPITAL EXPENDITURE: \$30,244.06
LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI**

STAFF ANALYSIS

PROJECT SUMMARY

A. Applicant Information

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Mid Mississippi (FMC Mid Mississippi) is a business corporation. The applicant indicates that FMC Mid Mississippi is governed by a two member Board of Directors and has thirteen officers.

The applicant provided a Certificate from the Secretary of State, 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

Fresenius Medical Care Mid Mississippi (FMC Mid Mississippi) operates a fourteen (14) station End Stage Renal Disease (ESRD) facility in Jackson, MS.

Fresenius Medical Care Mid Mississippi requests Certificate of Need (CON) authority to expand its existing facility located at 656 North State Street, Jackson, Mississippi 39202 by eleven (11) stations, thus bringing the total to twenty-five (25) stations. The applicant states that due to an increase in patient volume, the proposed expansion to the existing facility is necessary to provide access to more slot times for patients to receive treatments.

The applicant states that there will be no renovation or construction on this project. The applicant affirms that the facility already has the space and capacity to handle the eleven (11) station increase.

The applicant asserts that the only costs associated with the expansion will result from the dialysis machines and related TV and valve box equipment. The applicant confirms that FMC Mid Mississippi will be responsible for costs associated with the expansion.

The applicant provided a schematic drawing of the proposed ESRD satellite facility. The Mississippi State Department of Health, Division of Health Facilities Licensure and Certification has approved the site for the proposed project.

The applicant anticipates 5.3 additional FTE's (full-time equivalent) at a cost of \$484,463.00 annually as a result of the proposed project. The capital expenditure for the proposed project is \$30,244.06. The application includes a capital expenditure summary and consolidated financial statements for the proposed project. The applicant indicates cash reserves will be used to fund the project.

The applicant anticipates the capital expenditure will be obligated within six (6) months of final CON approval. The applicant states the proposed expansion project will be complete within one (1) year of start date.

II. TYPE OF REVIEW REQUIRED

The Department reviews projects for the establishment of an end stage renal disease facility in accordance with Section 41-7-191, subparagraph (1)(a), and 1(b) of the Mississippi Code 1971, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health. The proposed project is for the expansion of an existing ESRD facility.

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 ten (10) days of the publication of the Staff Analysis. The staff analysis will be posted on Friday, November 16, 2018. The opportunity to request a hearing expires on Thursday, November 26, 2018.

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

A. State Health Plan (SHP)

The *FY 2018 State Health Plan* contains policy statements and service specific criteria and standards which the applicant is required to meet before receiving CON authority to establish a facility; however the proposed project is for the expansion of an existing ESRD facility. This application is in substantial compliance with applicable criteria and standards.

Policy Statement No. 19(c) of the 2018 State Health Plan states "an ESRD facility that has not yet been given a CMS star rating, may add ESRD stations without certificate of need review, as long as the facility does not add, over the period of one (1) year, more than four (4) stations." The Applicant states that the facility has not yet been given a CMS star rating. Because the Applicant does not have a CMS star rating and is requesting to add more than four (4) stations, the Applicant is requesting CON authority to increase its station count from fourteen (14) to twenty-five (25) stations.

The Establishment of an ESRD Facility

SHP Criterion 1- Establishment of New ESRD Facility

State Health Plan Need Criterion 1 is not applicable to the proposed project. The proposed project is for the expansion of an existing ESRD facility.

SHP Criterion 2-Expansion of Existing ESRD Facilities

The FY 2018 MSHP states: “In the event that an existing ESRD facility (that is a satellite facility in operation two years or less), proposes to add more stations than what is outlined in ESRD Policy Statement 9, then the facility must apply for a certificate of need, and shall document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of submission of the CON application. Note: ESRD Policy Statement 3 and Need Criterion 1 do not apply to applications for the expansion of existing ESRD facilities”. The applicant states that FMC Mid Mississippi’s utilization for the past twelve (12) months is 45.8%. The applicant filed its Medicaid application on February 8, 2018 and the application is complete. The applicant anticipates obtaining Medicaid approval at the beginning of 2019. The applicant anticipates an increase over the first eighteen months of an additional forty-three (43) patients, twenty (20) of those within the first two (2) months. This estimation is based on patient growth (thirty-eight (38) additional patients) at Fresenius Medical Care- West Hinds County facility in the eighteen month period following that facility’s Medicaid approval.

The applicant anticipates achieving 68.7% utilization within the first two months of Medicaid approval. The applicant also utilizes chronic kidney disease (CKD) analysis, incidence data, and prevalence data review in order to project how the patient population will grow over the next three (3) years resulting in a demand for more dialysis treatments. The applicant states that according to the U.S. Department of Health and Human Service’s National Institute of Diabetes and Digestive and Kidney Disease (the Institute), the overall prevalence of CKD in the general population is fourteen (14) percent. The Institute also suggests that the two main causes of CKD are high blood pressure and diabetes. The Department of Health’s Burden of Chronic Diseases in Mississippi reported that the prevalence of diabetes is higher in African Americans than in Caucasians. The applicant states that the African American population makes up 72.5% of the Hinds County population. With a 14% prevalence of CKD in the United States’ general population, Hinds County could anticipate approximately 34,000 residents with some level of CKD. The applicant also states that the national average of diabetes is 9.7%, but in Mississippi it is 12.5%. Therefore, the overall prevalence of CKD in Mississippi, and in Hinds County is likely higher than the national average of 14%. The Institute also reports that ESRD prevalence is 3.7 times greater in African Americans than Caucasians. The ESRD prevalence for Mississippi is 9,272, with the estimate for Hinds County being 756. However, the ESRD prevalence in Hinds County could be higher than the general prevalence rate given the percentage of African Americans in Hinds County (72.5%) compared to the State at 37.8%. In addition, the applicant provides incidence rate data from the United States Renal Data System (USRDS). The applicant affirms that Hinds County demonstrates an incidence rate of 139 residents that will be diagnosed with ESRD in a year. The applicant estimates that by 2020 there will be 162 more ESRD patients in Hinds County. Furthermore, the applicant anticipates achieving 66.7% utilization after three years.

SHP Criterion 3- Need for Establishment of ESRD Satellite Facilities

State Health Plan Need Criterion 3 is not applicable to the proposed project. The proposed project is for the expansion of an existing ESRD facility.

SHP Criterion 4 - Number of Stations

Fresenius Medical Care- Mid Mississippi is an existing ESRD facility and it currently operates fourteen (14) hemodialysis ESRD stations.

SHP Criterion 5 - Minimum Utilization

The proposed project is not requesting to establish a new ESRD facility; thus, Policy Statement Number 10 is not applicable to the CON application.

SHP Criterion 6 - Minimum Services

The applicant affirms that the facility will provide at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.

SHP Criterion 7 - Access to Needed Services

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

SHP Criterion 8 - Hours of Operation

The applicant states that the normal facility hours of operation will be from 6:00 a.m. to 5:00 p.m., six (6) days per week. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

The applicant affirms that a home-training program will be made available, and counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.

The applicant states that Fresenius provides a treatment options program for all pre-ESRD patients. Modality choices, including CAPD, CCPD, and home hemodialysis, are presented by trained staff to patients in a classroom or individual setting.

SHP Criterion 10 - Indigent/Charity Care

The applicant affirms that the propose facility will not have admission policies which adversely affect access to care by indigents, and will provide indigent/charity care. Furthermore, the applicant states that if the applicant determines that a patient does not have insurance coverage, steps will be taken to determine whether viable coverage options exist.

The applicant states it will serve all ESRD patients, including Medicaid and Medicare recipients and approximately 2% indigent/charity care patients.

SHP Criterion 11 - Facility Staffing

The applicant affirms it has the following at its existing facility: registered nurses, licensed practical nurses, patient care and technical/paramedical personnel, social worker, dietician, administrative/management personnel. The applicant

included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D, Section 494.140.

SHP Criterion 13 - 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. The applicant states that FMC Mid Mississippi has established physician relationships in the area so a physician will be available to supplement the services of the medical director if needed.

SHP Criterion 14 - Data Collection

The applicant affirms that it shall record and maintain all required data listed under SHP Criterion 14 and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 15 - Staff Training

The applicant asserts that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility. Specifically, the applicant states that Fresenius and the Applicant will offer comprehensive training program for all direct patient care staff. The allocated training includes didactic and clinical training with qualified preceptors to build clinical skills and includes OSHA and mandatory Fresenius compliance training.

SHP Criterion 16 -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. The applicant states that their affiliated facilities within the service area have existing relationships with nephrologists in the area who currently treat the applicant's patients and will continue to treat the patients at the proposed facility.

SHP Criterion 17 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center. The application contained a transplant agreement with the University of Mississippi Medical Center.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2017, Revision*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 – State Health Plan

This application is in compliance with the overall objectives of the *FY 2018 State Health Plan*.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, easy access ESRD services for those residents in need of dialysis services near Hinds County.

GR Criterion 3 – Availability of Alternatives

The applicant states the other alternative to expansion would be to not file the proposed request for expansion. However, the applicant affirms that due to high patient demand in the Jackson/Hinds County area, expanding its satellite facility was determined to be the best option. The applicant believes that the expansion of the ESRD stations will be the most efficient and cost effective alternative to meet the needs of the patients in Hinds County.

The applicant states that the proposed eleven (11) ESRD station expansion would not be a duplication of services as the ESRD residents in and around Hinds County need accessibility to the dialysis treatment services provided by the applicant. Furthermore, the Applicant's relationship with Fresenius will greatly benefit the proposed facility. The applicant states that each dialysis patient will benefit from the expertise and experience of the nation's largest dialysis provider and its extensive clinical network.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$683,085 the first year, \$966,778 the second year, and \$1,316,386 the third year of operation, respectively.

- a. **Proposed Charge:** The applicant submits that the proposed project will not increase the cost of dialysis services to patients or Medicaid. The applicant deems that the experience gained by Fresenius in effectively operating other ESRD facilities in the service area and across the state will help ensure that there will not be a negative effect on the cost of health care.
- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 53.2%; 59%; and 66.7%, respectively.
- c. **Project's Financial Feasibility Study:** The applicant asserts it has the financial strength to operate at a loss, if necessary. The Department has determined that a financial feasibility study is not necessary for the proposed project.

GR Criterion 5 – Need for Project

The applicant states that dialysis services will be offered to all ESRD patients, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicant affirms that the proposed project is not for the relocation of a facility or services. This proposed project is not seeking to increase utilization but to increase availability of

treatment times for their ESRD patients. The application contained twenty-three (23) letters of support for the proposed project from patients who are served at FMC Mid Mississippi. No letters of opposition for the proposed project were received by the Department.

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:

FMC Mid Mississippi	Medically Indigent	Gross Patient Revenue
Historical Year 2017	2%	\$49,140
Projected Year 1	2%	\$65,447
Projected Year 2	2%	\$73,924

*Patients without a payor source during a 90-day waiting period are considered medically indigent.

The applicant confirms that FMC West Hinds County is located at 656 North State Street in Jackson, MS. The location is conveniently located near I-55 which makes travel to the facility convenient for patients.

FMC Mid Mississippi affirms that it will operate on Monday through Saturday from 6:00 a.m. to 5:00 p.m. The applicant states alternate times are available by arrangement.

GR Criterion 7 – Information Requirement

The applicant affirms that it will record and maintain all requested information required under GR Criterion 7 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 eleven (11) ESRD facilities located in FMC Mid Mississippi’s Service Area. The applicant affirms that FMC Mid Mississippi is located approximately 27.5 miles or less from each of the nine (9) ESRD facilities.

The applicant suggests that the most significant impact should be on applicant and the applicant’s host facility. The applicant states that affiliated facilities in the area will cooperate to facilitate continuity of care for those patients choosing to receive care at the allocated facility. The applicant insists that failure to implement the proposed project will result in the applicant’s patients continuing to experience overcrowding and limited options to receive necessary dialysis treatment.

GR Criterion 9 – Availability of Resources

The applicant states that FMC Mid Mississippi has the personnel necessary for efficient operation of their facility. The applicant states in the event there is a shortage of staff at the facility, the affiliation with the closest facilities will allow the applicant and these other facilities to supplement and share staff if ever necessary.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that FMC Mid Mississippi and its affiliates will provide the necessary ancillary and support services, including laboratory services, drugs, and any necessary services related to the method in which a patient chooses to receive dialysis services.

GR Criterion 11– Health Professional Training Programs

The applicant asserts that FMC Mid Mississippi cooperates with health professional training programs in the surrounding area.

GR Criterion 12– Access by Health Professional Schools

The applicant affirms that the FMC Mid Mississippi cooperates to meet the clinical needs of health professional training programs in the surrounding area.

GR Criterion 13 – Access to Individuals Outside Service Area

The applicant affirms that FMC Mid Mississippi is not proposing to provide access to individuals outside the allocated service area; therefore, Criterion 13 is not applicable.

GR Criterion 14– Construction Projects

The applicant is proposing to expand its ESRD facility by eleven (11) ESRD stations. The proposed project does not require construction to expand the existing ESRD facility; therefore, Criterion 14 is not applicable.

GR Criterion 15 – Competing Applications

The applicant states that FMC Mid Mississippi is not aware of any competing applications.

GR Criterion 16– Quality of Care

The applicant affirms it has provided past quality of care. The applicant states the proposed project expansion will improve accessibility for ESRD patients who must receive dialysis treatment three (3) times per week. The applicant states that the proposed project will enhance the quality of care currently provided at FMC Mid Mississippi by offering more opportunities for dialysis treatment times at its facility.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage% of Total
Construction Cost - New	\$ 0	0.00%
Construction Cost - Renovation	\$ 0	0.00%
Capital Improvements	\$ 0	0.00%
Total Fixed Equip Cost	\$ 11,606	38.37%
Total Non-Fixed Equip Cost	\$ 0	0.00%
Land Cost	\$ 0	0.00%
Site Preparation and improvement	\$	0.00%
Fees (Legal and Accounting)	\$	0.00%
Fees (Architectural/Consultant/etc.)	\$	0.00%
Contingency Reserve	\$	0.00%
Capitalized Interest	\$ 0	0.00%
Other	\$ 18,638	61.63%
Total Proposed Expenditures	\$ 30,244	100.00%

The Department has determined that a financial feasibility study is not necessary for the proposed project.

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves.

C. Effect on Operating Cost

Attachment 1 lists FMC Mid Mississippi projections of expenses, gross revenue, net income 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 review and comment. The Division asserts that no foreseeable increase in allowable costs to Medicaid will result as it relates to the proposed project. The Department of Medicaid does not oppose this project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of a satellite ESRD facility as contained in the *FY 2018 State Health Plan*; the *Mississippi Certificate of Need Review Manual, Revised April 9, 2017*, and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Mid Mississippi, Inc. for the expansion of an existing Satellite End Stage Renal Disease ("ESRD") facility in Hinds County.

Attachment 1

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Mid Mississippi
Expansion of Stations at Existing Satellite ESRD Facility

Three-Year Operating Statement with Project

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	\$ 0	\$ 0	\$ 0
Outpatient Revenue	\$ 3,292,380	\$ 3,696,241	\$ 4,281,191
Gross Patient Revenue	\$ 3,292,380	\$ 3,696,241	\$ 4,281,191
Charity	\$ 0	\$ 0	\$ 0
Deductions from Revenue	\$ 0	\$ 0	\$ 0
Net Patient Care Revenue	\$ 3,292,380	\$ 3,696,241	\$ 4,281,191
Other Operating Revenue	\$ 0	\$ 0	\$ 0
Total Operating Revenue	\$ 3,292,380	\$ 3,696,241	\$ 4,281,191
Operating Expenses			
Salaries	\$ 594,555	\$ 608,800	\$ 623,473
Benefits	180,451	185,094	189,884
Supplies	1,056,334	1,092,758	1,130,551
Services	202,491	210,591	219,014
Lease Expenses	76,848	77,123	77,408
Depreciation	103,268	107,248	111,386
Interest	0	0	0
Other	395,348	447,850	613,089
Total Operating Expenses	\$ 2,609,295	\$ 2,729,463	\$ 2,964,805
Net Operating Income	\$ 683,085	\$ 966,778	\$ 1,316,386
	Proposed Year 1	Proposed Year 2	Proposed Year 3
Inpatient Days	0	0	0
Outpatient Visits	0	0	0
Number of ESRD Procedures	12,450	13,800	15,600
Charge per Outpatient Day	\$ 0	\$ 0	\$ 0
Charge per Inpatient Day	\$ 0	\$ 0	\$ 0
Charge per Procedure	\$ 264	268	\$ 274
Cost per Inpatient Day	\$ 0	\$ 0	\$ 0
Cost per Outpatient Day	\$ 0	\$ 0	\$ 0
Cost per Procedure	\$ 210	\$ 198	\$ 190