

**MISSISSIPPI STATE DEPARTMENT OF HEALTH  
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT  
OCTOBER 30, 2017**

**CON REVIEW: ESRD-ES-0917-012  
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC  
D/B/A FRESENIUS MEDICAL CARE JACKSON  
EXPANSION OF ESRD STATIONS AT EXISTING ESRD FACILITY  
CAPITAL EXPENDITURE: \$27,494.00  
LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI**

**STAFF ANALYSIS**

**PROJECT SUMMARY**

**A. Applicant Information**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson (the "Applicant") is a business corporation. The applicant indicates that Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson is governed by twelve (12) board members.

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**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson operates a thirty-eight (38) stations End Stage Renal Disease (ESRD) facility in Jackson, MS. The applicant states that on May 26, 2016 they received approval to relocate ten (10) stations to its satellite ESRD facility, Fresenius Medicare Care Mid-Mississippi ("Satellite ESRD Facility"). The applicant states that the Satellite is nearing completion and upon its state survey and certification to participate in Medicare the Satellite will begin providing dialysis services. The applicant affirms once the Satellite begins providing services, the authority for ten (10) stations will be reduced at the Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson location.

The applicant states that in order to alleviate some of the stress caused by the removal of the ten (10) stations, the applicant is proposing to add back ten (10) stations after the stations are transferred and operational at the Satellite. The applicant affirms that the approximate construction end date for the Satellite is August 8, 2017.

The applicant received site approval from the Mississippi State Department of Health, Division of Licensure and Certification (Licensure) on August 14, 2017. The applicant states that the proposed project will not require any additional full time equivalents (FTE) personnel.

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson affirms that the total capital expenditure for the proposed project is \$27,494.00. The applicant proposes to fund the project with cash reserves. The

applicant states the money will be obligated within two (2) months of final CON approval.

## II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173 (b) of the Mississippi Code of 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 10 days of the publication of the Staff Analysis. The opportunity to request a hearing expires on November 9, 2017.

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

### A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains policy statements and service specific criteria and standards which the applicant is required to meet before receiving CON authority to expand an existing ESRD facility. This application is in substantial compliance with applicable criteria and standards.

**Policy Statement No. 12 of the 2015 State Health Plan** states that any “Existing ESRD facilities may add ESRD stations without Certificate of Need review, as long as the facility does not add, over a period of two (2) years, more than the greater of four (4) stations or 15% of the facility’s current number of certified stations. The applicant proposes to add ten (10) ESRD stations, which is six (6) more than the exception listed under Policy Statement 12.

#### **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 2015 MSHP* states: “In the event that an existing ESRD facility proposes to add more than the greater of four (4) stations or 15% of the facility’s current number of certified stations within a two-year period, 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 the submission of the CON application. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the expansion of existing ESRD facilities”.

The applicant provided verification to show that Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson has maintained a minimum annual utilization rate of 65% for the 12 months (September 2016 – August 2017) prior to the month of the submission of the CON application.

Based on the ESRD data provided, Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson's utilization is 80.6% for the 12 months referenced above. Thus, the applicant meets the minimum annual utilization rate of 65%.

The proposed project is seeking to expand the facility by ten(10) ESRD stations. Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson states because its request for additional ESRD stations is greater than four (4) and 15% of the applicant's current certified ESRD station number, the applicant filed a CON application.

Also, the applicant states that the utilization is trending upward; therefore, by returning to its original thirty-eight (38) station unit, it can efficiently and effectively meet patient demand.

### **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**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson currently operates thirty-eight (38) 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**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson affirms that the facility will provide, at a minimum, social, dietetic and rehabilitative services. The applicant asserts rehabilitative services will be provided on a referral basis.

### **SHP Criterion 7 - Access to Needed Services**

The applicant affirms that Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson will provide reasonable access to equipment and facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

### **SHP Criterion 8 - Hours of Operation**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson affirms that the normal facility hours of operation are from 7:00 a.m. to 6:00 p.m. and alternate arrangements are made for those patients needing after-hours treatment.

**SHP Criterion 9 - Home Training Program**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson affirms that home training program is available for medically eligible patients and that the facility counsels all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.

**SHP Criterion 10 - Indigent/Charity Care**

The applicant affirms that they will provide a reasonable amount of indigent/charity care and that it will continue to provide a reasonable amount of indigent/charity care after the expansion take place.

**SHP Criterion 11 - Facility Staffing**

The applicant included a list of required staff by category, position qualification guidelines (minimum education and experience requirements) and lists a description of the specific duties. The applicant states that Full-Time Equivalents (FTEs) or personnel will not be required for the proposed project nor will the number of FTEs increase.

**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 as listed under SHP Criterion 12.

**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. 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 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. Also, the time frame for the submission of the utilization data shall be established by the Department.

**SHP Criterion 15 - Staff Training**

The applicant asserts that it will provide an ongoing training in dialysis techniques for nurses and technicians at the satellite facility.

**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.

### **SHP Criterion 17 - Affiliation with a Renal Transplant Center**

The applicant affirms that they have an existing Renal Transplant Agreement with University of Mississippi Medical Center, will make their services available for either cadaveric or living related transplants for ESRD patients of the Bio-Medical Application of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson - Jackson, Hinds, MS.

### **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 2015 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 for Jackson/Hinds County area residents.

#### **GR Criterion 3 – Availability of Alternatives**

The applicant asserts that the only feasible alternative was to not file the proposed application for the addition of hemo-dialysis stations; however without the ten (10) station addition, the facility will lose daily treatment time slots. The applicant further suggests that utilization is high and without the ability to add back ten (10) stations, returning to its thirty-eight (38) stations, Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson will be unable to offer its patients the best opportunity to choose convenient time slots to receive necessary dialysis treatment. The applicant affirms that expanding its station's authority was the best option to continue providing dialysis services most effectively and efficiently.

The applicant indicates that because Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson is already prepared to handle the requested station increase, both in terms of space, equipment and staff, it is both efficient and cost effective to add back the requested stations to the facility.

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson states it will operate the same number of stations it did prior to the Satellite's opening. The applicant states that the patients will receive the best quality of care and accessibility to dialysis treatment.

The applicant states that this is not an unnecessary duplication of services as the facility operated at thirty-eight (38) stations prior to the upcoming removal and certification of ten (10) of its stations to the Satellite. The applicant states the proposed project is the most efficient solution to meeting patient demand at the facility after the Satellite's opening. The applicant affirms that the relationship

with Fresenius greatly benefits the existing facility due to Fresenius' integrated delivery and services model.

#### **GR Criterion 4 – Economic Viability**

The applicant provided a three-year projected operating statement and it indicates that the total operating revenue over a projected three year period shows an increase from \$5,416,293 to \$5,828,916. A financial feasibility study is not required for the proposed project. In addition, the statement reflects net incomes for the first three years of operation for the project (see Attachment 1).

The applicant affirms that the proposed project will not increase dialysis costs for the patients or Medicaid. The applicant states the affiliation with the Fresenius network and its integrated delivery system ensures that there will not be negative effect on the healthcare costs associated with this project.

The applicant asserts it has the financial strength to operate at a loss, if necessary.

#### **GR Criterion 5 – Need for Project**

- a. Access by Population Served:** The applicant states that dialysis services exist in the service area at thirty-eight (38) stations. With the decrease in stations after the Satellite's opening; the applicant states that it will reduce the current facility by ten (10) stations. With that reduction, the availability of day slot times for its patients to receive necessary dialysis treatment will be reduced.

The applicant states that the proposed project will improve accessibility for dialysis patients in the area and ensure continuity of care is met. Also, the applicant states that they will continue to provide services to the traditionally underserved groups in particular low-income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly.

- b. Relocation of Services:** The proposed project is not for the relocation of a facility or services
- c. Utilization of Facilities:** The applicant states that the proposed project is vital to the needs of its patients in and around the Hinds County area. Also, dialysis is required for patients with ESRD.
- d. Probable Effect on Existing Facilities in the Area:** As previously stated, the applicant affirms this proposed project is not to increase utilization but to provide a better facility with additional time slots for the patients to receive necessary dialysis treatment at Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson.
- e. Community Reaction:** The application contained fourteen (14) letters of support for the proposed project at Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson.

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 historical years 2015, 2016, 2017 and projected years one and two for the proposed project:

<b>Projected Year</b>	<b>Medically Indigent (%)</b>	<b>Medically Indigent (\$)</b>
Historical Year 2015-2016	2%	\$2,398.14
Historical Year 2016-2017	2%	\$3,222.52
Projected Year 1	2%	\$2,896.63
Project Year 2	2%	\$3,013.92

\*ESRD patients qualify for Medicare after 90 days; the numbers that will be reported only represent patients in that 90-day period or sometimes an illegal resident that has no other payor source.

The applicant states that all patients diagnosed with ESRD must receive dialysis services. Furthermore, the applicant states that the facility will ensure that Medicare, Medicaid and medically indigent patients residing in and around Jackson have quality access to care.

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson affirms hours of operation are 7:00 a.m. to 6:00p.m. six (6) days per week. 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 affirms that the most significant impact should be on the applicant and the Satellite. Also, affiliated facilities will cooperate to facilitate continuity of care for those patients choosing to receive at the facility and Satellite facilities.

The applicant states that if the proposed expansion is not approved, daily time slots will be reduced, leaving less options for patients to receive necessary dialysis treatment and result in more missed appointments.

**GR Criterion 9 – Availability of Resources**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson has the personnel necessary for efficient operation of it facility. The applicant affirms it has presence in the area has allowed it to establish relationship with nearby nephrologists who will support the proposed expansion

at Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson.

**GR Criterion 10– Relationship to Ancillary or Support Services**

The applicant affirms that all necessary ancillary and support services will be available. Also, due to the relationship with Fresenius and the surrounding medical community, all ancillary services will be sufficiently available including laboratory services, drugs, and any other necessary services related to the method in, which patients choose to receive dialysis.

**GR Criterion 11– Health Professional Training Programs**

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson asserts the facility presently cooperates and coordinates with area health professional training programs in the surrounding area.

**GR Criterion 12- Access by Health Professional Schools**

The applicant states they will cooperate with the clinical needs of health professional training programs in the area.

**GR Criterion 13 – Access to Individuals Outside Service Area**

The applicant affirms that Bio-Medical Application of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson 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 proposed project is not for construction of a facility.

**GR Criterion 15 – Competing Applications**

The applicant states that Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson is not aware of any competing applications.

**GR Criterion 16– Quality of Care**

The applicant states as previously discussed, this proposed project will add back ten (10) stations, to its original station authority of thirty-eight (38) stations. The applicant states that they will be able to offer its patients the best opportunity to choose convenient time slots to receive necessary dialysis treatment. The applicant states that the proposed expansion will improve accessibility for ESRD patients who must receive dialysis treatment three (3) times per week.



**IV. FINANCIAL FEASIBILITY**

**A. Capital Expenditure Summary**

Cost Item	Estimated Cost	% of the Total
Construction Cost -New	\$0	0.00%
Construction Cost-Renovation	0	0.00%
Capital Improvements, i.e. (minor painting and repairs, refurbishing)	0	0.00%
Total Fixed Equipment Cost	16,050	58.38%
Total Non-Fixed Equipment Cost	11,444	41.62%
Land Cost	0	0.00%
Site Preparation Cost	0	0.00%
Fees (Architectural and Consultant Fees )	0	0.00%
Fees (Legal and Accounting )	0	0.00%
Contingency Reserve	0	0.00%
Capitalized Interest	0	0.00%
Other Cost (Consulting)	0	0.00%
Other Cost	0	0.00%
<b>TOTAL PROPOSED CAPITAL EXPENDITURE</b>	<b>\$27,494</b>	<b>100%</b>

**B. Method of Financing**

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

**C. Effect on Operating Cost**

The applicant's projections of gross revenues for the first, second, and third year of operation, expenses, and net income are shown in Attachment 1. Utilization, cost, and charges are also included in the applicant's Three-Year Projected Operating Statement (see Attachment 1).

**D. Cost to Medicaid/Medicare**

In the application Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson provides the following revenue source projections for each payer category listed below.

<b>Bio-Medical Application of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson</b>		
<b>Payor</b>	<b>Utilization Percentage</b>	<b>First Year Revenue</b>
<b>Medicaid</b>	4.00%	\$320,364.00
<b>Medicare</b>	72.00%	\$5,500,027.00
<b>Self Pay</b>	0.00%	\$5,352.00
<b>Commercial</b>	22.00%	\$1,703,595.00
<b>Charity</b>	0.00%	\$0.00
<b>Other</b>	2.00%	\$144,831.00
<b>Total</b>	<b>100%</b>	<b><u>\$7,674,168.00</u></b>

**V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided a copy of this application for review and comment. As of this date, the Division has not provided any comments on the proposed 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 2015 State Health Plan*; the *Certificate of Need Review Manual, Revision 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 Jackson for expansion of ESRD stations by ten (10) at its existing facility.

**Attachment 1**  
**Bio-Medical Application of Mississippi, Inc. d/b/a Fresenius Medical Care Jackson**  
**Three-Year Operating Statement with Project Only**

	Year 1	Year 2	Year 3
<b>Revenue</b>			
Inpatient Care Revenue	\$ 0	\$ 0	\$ 0
Outpatient Revenue	7,674,168	7,998,396	8,330,010
<b>Gross Patient Revenue</b>	<b>\$ 7,674,168</b>	<b>\$ 7,998,396</b>	<b>\$ 8,330,010</b>
Charity	\$ 0	\$ 0	\$ 0
Deductions from Revenue	0	0	0
<b>Net Patient Care Revenue</b>	<b>\$ 7,674,168</b>	<b>\$ 7,998,396</b>	<b>\$ 8,330,010</b>
Other Operating Revenue	\$ 0	\$ 0	\$ 0
<b>Total Operating Revenue</b>	<b>\$ 7,674,168</b>	<b>\$ 7,998,396</b>	<b>\$ 8,330,010</b>
<b>Operating Expenses</b>			
Salaries	\$ 1,736,043	\$ 1,817,055	\$ 1,900,543
Benefits	677,057	708,652	741,212
Supplies	1,234,447	1,279,517	1,325,341
Services	0	0	0
Lease Expenses	287,550	287,130	287,550
Depreciation	217,130	217,130	217,130
Interest	0	0	0
Other	1,264,066	1,310,218	1,357,140
<b>Total Operating Expenses</b>	<b>\$ 5,416,293</b>	<b>\$ 5,620,122</b>	<b>\$ 5,828,916</b>
<b>Net Operating Income</b>	<b>\$ 2,257,875</b>	<b>\$ 2,378,274</b>	<b>\$ 2,501,094</b>
	<b>Proposed Year 1</b>	<b>Proposed Year 2</b>	<b>Proposed Year 3</b>
Inpatient Days	0	0	0
Outpatient Visits	0	0	0
Procedures	26,030	26,715	27,400
Charge per Outpatient Day	\$ 0	\$ 0	\$ 0
Charge per Inpatient Day	\$ 0	\$ 0	\$ 0
Charge per Procedure	\$ 295	\$ 299	\$ 304
Cost per Inpatient Day	\$ 0	\$ 0	\$ 0
Cost per Outpatient Day	\$ 0	\$ 0	\$ 0
Cost per Procedure	\$ 208	\$ 210	\$ 213