MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT July 31, 2017

CON REVIEW: ESRD-ES-0617-010 BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. D/B/A FRESENIUS MEDICAL CARE – BMA OF SOUTHWEST JACKSON EXPANSION OF STATIONS AT EXISTING ESRD FACILITY CAPITAL EXPENDITURE: \$16,496.76 LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI

STAFF ANALYSIS

PROJECT SUMMARY

A. <u>Applicant Information</u>

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care - BMA of Southwest Jackson (BMASWJ) is a business corporation. The applicant indicates that Southwest Jackson Dialysis is governed by two Board of Directors and ten 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 and is authorized by the Secretary of State to do business in Mississippi.

B. <u>Project Description</u>

BMASWJ is an End State Renal Disease (ESRD) facility that currently operates twenty-seven (27) stations. BMASWJ originally operated thirty-three (33) stations. On August 28, 2011, the applicant received approval for a 10-station satellite ESRD facility, Fresenius Medical Care – West Hinds (CON No R-0877 and CON No R-0877A). Per that CON, the applicant's station authority was reduced by ten (10) stations, to twenty-three (23) stations. Since the Satellite opened in the Fall of 2016, BMASWJ has expanded its station authority by 4 more stations through the Determination of Reviewability process. The Department approved the addition of 2 stations on December 5, 2016 and the addition of another 2 stations on April 6, 2017.

Now, BMASWJ requests Certificate of Need (CON) authority to expand its existing facility located at 1856 Hospital Drive, Jackson, Mississippi 39204 by six (6) ESRD stations, thus brining the applicant back to thirty-three (33) stations and allowing continuing care for its patients. The applicant states there will not be any new construction or renovation necessary for the proposed project as the 6 additional stations can be put in place of the ten stations that were transferred to the satellite facility, FMC-West Hinds.

The applicant states the proposed project will help the applicant efficiently meet the needs of its patients in the area with the least amount of disruptions to patient care.

The total capital expenditure for the proposed project is \$16,496.76. BMASWJ proposes to fund the project with cash reserves. The applicant indicates the capital expenditure will be obligated within one month of final CON approval and

the proposed project will be completed within 3 months from final CON approval.

II. TYPE OF REVIEW REQUIRED

The Department reviews projects for the establishment of an end stage renal disease facility in accordance with Section 41-7-173(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. However, the proposed project is for the expansion of an existing ESRD facility.

In accordance with Section 41-7-197(2) of the Mississippi Code 1972, Annotated, as amended, any affected person may request a public hearing on this project within 10 days of publication of the staff analysis. The opportunity to request a hearing expires on Thursday, August 10, 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, criteria and standards, and service specific criteria and standards, which the applicant is required to meet before receiving CON authority for the expansion of an existing ESRD facility. 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. 12 of the *FY 2015 State Health Plan* states that "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 recently added 4 stations under this Policy Statement and proposes to add six (6) additional ESRD stations, which is six (6) more than the exception listed under Policy Statement 12. Therefore, Policy Statement 12 is not applicable to this project.

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 <u>has maintained a minimum</u> 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 states that because the request for additional stations is greater than four (4) stations or 15% of the applicant's current number of certified stations, the applicant filed the CON application.

Per the *FY 2015 SHP* "Full Utilization" (100 percent) is defined as an average of 936 dialysis treatments per station per year. BMASWJ's application shows that the total number of dialysis treatments from June 2016 through May 2017 is 18,372 and the number of operational, existing ESRD hemo-dialysis stations is 27.

Based on the *FY 2015 MSHP*, the applicant calculated the existing ESRD facility's Utilization Rate as:

27 stations X 936 treatments per station per year = 25,272 treatments per year for 100 % utilization*

<u>18,372 (Applicant's treatments for 06/2016-05/2017)</u> 25,272 (Applicant's treatments per year for 100% utilization)*

= 72.7% Utilization Rate

In reviewing the utilization information in the application, staff noted that for approximately half of the year, applicant was actually operating 33 ESRD stations. However, even if that is taken into consideration in the calculations, applicant's utilization rate would remain above the required 65% utilization needed to expand its existing ESRD facility by 6 ESRD stations.

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

State health Plan Need Criterion 4 is not applicable to the proposed project. The applicant currently operated a facility larger than 10 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

BMASWJ 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 BMASWJ 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

BMASWJ affirms that it will operate Monday through Friday between the hours of 9:00 a.m. to 5:00 p.m. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

BMASWJ 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.

SHP Criterion 15 - Staff Training

The applicant asserts that it will provide an ongoing training in dialysis techniques for nurses and technicians at the 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 the University of Alabama at Birmingham, University of Alabama at Birmingham Renal Transplantation Center, University Alabama Health Services, University of Alabama Health Service Foundation P.C. Department of Surgery and Alabama Organ Center. The applicant has the same agreement or a similar agreement with the University of Mississippi Medical Center.

B. <u>General Review (GR) Criteria</u>

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, as discussed above.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to continue to provide high quality, accessible ESRD services for those residents in need of dialysis services in and near Jackson. The applicant received CON approval (CON R-0877) on August 28, 2014 to open its Satellite facility and later, received CON approval (CON R-0877 A) on October 29, 2015 to relocate within the original five (5) miles of the location listed in the CON application approved on August 28, 2014. In order to relieve disruption, the applicant requested and received approval for four (4) stations. However, in order to relieve some of the crowding at the facility and improve the accessibility for patients with limited transportation services, the applicant is filing this application, proposing to expand an additional six stations. The 6 station expansion will return the facility to its station authority prior to the Satellite's opening and will ensure that the applicant's patients continue to receive quality care with the least amount of patient disruption.

GR Criterion 3 – Availability of Alternatives

The applicant considered adding more stations at the Satellite facility; however the cost associated with a satellite expansion would be higher and applicant is already prepared to handle the requested number of ESRD stations to increase the quantity of ESRD stations at the existing ESRD facility.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a total operating revenue of \$4,417,865 the first year, \$5,168,902 the second year, and \$6,047,616 the third year of operation, respectively. A financial feasibly 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 asserts that the proposed project will expand BMASWJ by adding 6 stations and the project will not increase the cost of dialysis services for patients or Medicaid. In addition, the applicant's affiliation with the Fresenius network and its integrated delivery system helps to control the cost of healthcare associated with the proposed project.

GR Criterion 5 – Need for Project

According to BMASWJ, dialysis services will continue to be provided to underserved patients, including low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly.

The applicant affirms that dialysis is not an elective service but is required for patients diagnosed with ESRD. The applicant suggests that the six (6) ESRD station addition should result in the availability of more desirable treatment slot times, which may slightly increase the facility's utilization as patients see more convenient treatment times.

The application contains 13 letters of support regarding the proposed project. The Department did not receive any letters of opposition concerning 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	Medically Indigent *	Total Dollar Amount of Gross Patient Revenue
1	2%	\$2,400
2	2%	\$2,808

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

The applicant confirms that BMASWJ has no existing obligations under any federal regulation requiring provision of uncompensated care, community service, or access by minority/handicapped persons.

The proposed facility will operate from 9:00 a.m. to 5:00 pm, five (5) days per

week. However, alternate times are available by arrangement.

All patients diagnosed with ESRD must receive dialysis services. The expansion of the Applicant's Southwest Jackson facility will ensure that Medicare, Medicaid and medically indigent patients residing in and around Jackson have quality access to care.

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 DaVita Jackson Southwest Dialysis is located 0.7 miles from BMASWJ's existing facility. The applicant states that if BMASWJ does not implement the proposed expansion of the existing ESRD facility the host main facility will continue to face overcrowding issues and the availability of treatment slot options will be limited. The applicant states that the target population is Hinds County and the surrounding areas.

GR Criterion 9 – Availability of Resources

The applicant states that it already has the required staff, which includes registered nurses, nephrologist, and technical/paramedical, administrative/managerial employees at BMASWJ. The applicant asserts it has a satisfactory staffing history.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that all necessary ancillary and support services will be available. There will be no change in costs or charges as a result of this proposed project.

GR Criterion 11– Health Professional Training Programs

BMASWJ asserts the facility presently cooperates and coordinates with area health professional training programs in the surrounding area.

GR Criterion 14– Construction Projects

The applicant is proposing to expand its host/main ERSD facility by six (6) ESRD stations; however the proposed project does not require any construction or renovation.

GR Criterion 16– Quality of Care

The applicant states it has provided quality care. The applicant asserts in order to effectively meet the needs of its increasing patient base the facility needs to expand to accommodate the growth by the approval of six (6) stations for its patients.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage% of Total	
Construction Cost - New	\$0	0%	
Construction Cost - Renovation	\$0	0%	
Capital Improvements	\$ 0	0%	
Total Fixed Equip Cost	\$ 0	0%	
Total Non-Fixed Equip Cost	\$ 0	0%	
Land Cost	\$0	0%	
Site Prep Cost	\$0	0%	
Fees – architectural/engineering	\$0	0%	
Contingency Reserve	\$0	0%	
Capitalized Interest	\$0	0%	
Other*	\$16,497	100%	
Total Proposed Expenditures	\$16,497	100.00%	

*The expense of \$16,497 will be allocated to: TV's and Dialysis chairs.

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

B. <u>Method of Financing</u>

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 BMASWJ provides the following revenue source projections for each payer category listed below.

Payor Mix	Utilization Percentage (%)*	First Year Revenue (\$)		
Medicare	67%	2,958,768		
Medicaid	5.5%	241,878		
Commercial	25.5%	1,126,308		
Self Pay	0%	12,002		
Charity Care	0%	0		
Other	2%	78,909		
Total	100%	\$4,417,865		

* Applicant's percentages were off due to rounding. Staff determined percentages above.

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 Division of Medicaid does not oppose this project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the overall objectives, criteria and standards of the 2015 Mississippi State Health Plan, with regard to the expansion of ESRD facilities; Chapter 8 of the Mississippi Certificate of Need Review Manual, 2017 Revision; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, 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 – BMA of Southwest Jackson for the Expansion of Stations at Existing ESRD Facility.

Attachment 1 Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care - BMA of Southwest Jackson Three-Year Operating Statement with Project (33 ESRD Stations)

	Year 1		Year 2		Year 3	
Revenue						
Inpatient Care Revenue	\$	0	\$	0	\$	0
Outpatient Revenue		4,417,865		5,168,902	-	6,047,616
Gross Patient Revenue	\$	4,417,865	\$	5,168,902	\$	6,047,616
Charity	\$	0	\$	0	\$	0
Deductions from Revenue		0		0		0
Net Patient Care Revenue	\$	4,417,865	\$	5,168,902	\$	6,047,616
Other Operating Revenue	\$	0	\$	0	\$	0
Total Operating Revenue	\$	4,417,865	\$	5,168,902	\$	6,047,616
Operating Expenses						
Salaries	\$	997,054	\$	1,166,553	\$	674,867
Benefits	÷	360,066	Ŧ	421,277	+	492,904
Supplies		903,511		1,057,108		1,236,817
Services		0		0		0
Lease Expenses		63,664		63,664		63,664
Depreciation		111,568		111,568		111,568
Interest		0		0		0
Other		648,770		667,135		780,548
Total Operating Expenses	\$	3,084,632	\$	3,487,305	\$	4,050,367
Net Operating Income	\$	1,333,233	\$	1,681,597	\$	1,997,249
	-	Year Ye		Proposed Year 2	Proposed Year 3	
Inpatient Days		0		0		0
Outpatient Visits		0		0		0
Procedures		21,583		22,784		24,446
Charge per Outpatient Day	\$	0	\$	0	\$	0
Charge per Inpatient Day	\$	0	\$	0	\$	0
Charge per Procedure	\$	205	\$	227	\$	247
Cost per Inpatient Day	\$	0	\$	0	\$ \$	0
Cost per Outpatient Day Cost per Procedure	\$ \$	0 143	\$ \$	<u> </u>	\$ \$	0 166