## MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT NOVEMBER 14, 2016

CON REVIEW: ESRD-ES-0916-022

**BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC.** 

D/B/A BMA OF SOUTHWEST JACKSON

**EXPANSION OF ESRD STATIONS AT EXISTING ESRD FACILITY** 

**CAPITAL EXPENDITURE: \$32,100.00** 

LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI

#### STAFF ANALYSIS

#### PROJECT SUMMARY

#### A. Applicant Information

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson (BMASWJ) is a business corporation. The applicant indicates that Southwest Jackson Dialysis is governed by two Board of Directors and 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

Briefly, Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care- West Hinds County originally received CON (CON R-0877) approval to relocate ten (10) of its thirty-three (33) stations to open its satellite End Stage Renal Disease (ESRD) facility, Fresenius Medical Care West Hinds County on August 28, 2014 and later, received CON approval (CON R-0877 A) on October 29, 2015 to relocate its ESRD facility within the original five (5) miles of the location listed in the CON application approved on August 28, 2014. The applicant states the Satellite ESRD facility anticipates opening in the Fall of 2016.

Now, BMASWJ requests Certificate of Need (CON) authority to expand its existing facility located at 1856 Hospital Drive, Jackson, Mississippi 39204 by ten (10) ESRD stations to allow for additional appointment availability and to better meet the needs of its patients and their schedules. The applicant states there will not be any construction or renovation necessary for the proposed project as the ten stations additional stations can be put in place of the ten stations that will be 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.

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson proposes to fund the project with cash reserves. The applicant includes a capital expenditure summary and consolidated financial statements.

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#### 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 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 Chapter 3, Rule 115 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011;* the applicant has 15 days to submit any additional information to the Department on a negative staff analysis. In accordance with Section 41-7-197 (2) of the Mississippi Code of 1972 Annotated, as amended, once a final recommendation has been made by the Department based on the additional information provided, any affected person may request a public hearing on this project within 10 days of the publication of the final staff analysis.

### 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 establish an ESRD facility or expand an existing ESRD facility. The proposed project is for the expansion of an existing ESRD facility. This application is not 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 proposes to add ten (10) ESRD stations, which is six (6) more than the requirement 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

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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. The applicant states the Department is aware that the West Hinds facility is awaiting its certification survey for the FMC-West Hinds County ESRD Satellite Facility. The applicant also states that the BMASWJ facility will be transferring ten (10) ESRD stations from its host facility (BMASWJ) to its Satellite facility, FMC-West Hinds County. It should also be noted that on November 4, 2016, the Department approved applicants Determination of Reviewability request to add an additional four (4) stations to the approved 10 station Satellite facility, FMC-West Hinds County, bringing the total number of approved stations at that site to 14. The applicant asserts that the transfer will statistically impact the facility and will result in utilization above 65% for BMASWJ.

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

33 stations X 936 treatments per station per year = 30,888 treatments per year for 100 % utilization\*

18,902 (Applicant's treatments for 09/2015-08/2016) 30,888 (Applicant's treatments per year )\*

= 61.19% Utilization Rate

In reviewing the utilization information in the application, staff determined that BMASWJ's utilization rate for the recent twelve months (Sept. 2015 through Aug. 2016) for 33 stations is 61.19%. As a note, the applicant verifies that the transfer of the ten ESRD stations approved for the FMC-West Hinds County ESRD satellite facility has not occurred. Thus, the applicant's utilization is below the required 65% utilization needed to expand its existing ESRD facility (host/main) by ten (10) 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

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson states is has twenty-three (23) ESRD stations and is requesting to add ten (10) ESRD stations to its host/main ESRD facility (BMASWJ); however, the host/main ESRD facility currently has 33 operational hemodialysis ESRD stations. Thus, ten (10) ESRD stations have not been transferred to BMASWJ's CON approved ESRD satellite facility (FMW-West Hinds County).

In addition, BMASWJ was approved on November 4, 2016 to add four (4) additional stations to the existing 10 ESRD station satellite facility (FMW-West Hinds County). Therefore, the applicant is in compliance with this criterion.

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#### 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 BMA of Southwest 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 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

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson 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

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest 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.

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#### 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 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 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 that is applicable to Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson and the University of Mississippi Medical Center.

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

Chapter 8 of the *Mississippi Certificate of Need Review Manual, September 1, 2011, Revision,* addresses general criteria by which all CON applications are reviewed. This application is not in substantial compliance with general review criteria.

#### GR Criterion 1 - State Health Plan

This application is not 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 near Jackson and in Hinds County. 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

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location listed in the CON application approved on August 28, 2014. The applicant proposes to expand by the addition of ten (10) ESRD stations. Therefore, the ten (10) ESRD station expansion of the existing satellite facility will improve the applicant's ability to effectively and efficiently provide high quality ESRD services to residents in and around Hinds County.

#### GR Criterion 3 - Availability of Alternatives

The applicant considered the following alternatives:

- Not expanding its ESRD facility in Hinds County and continuing to service those patients with its existing stations the applicant states that it will be unable to offer its patients the accessibility they need to choose convenient time slots to receive necessary dialysis treatment. Therefore, the applicant feels its only option is to expand the current facility.
- Adding stations at the new Satellite facility; however the applicant is already prepared to handle the requested number of ESRD stations to increase the quantity of ESRD stations at the existing ESRD facility.

The applicant believes that the ten (10) ESRD station expansion at Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson will be the most efficient, effective, and accessible alternative to meet the needs of the patients in Hinds County, Mississippi.

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

Based on the applicant's three-year projections, this project will have a net income of \$3,740,739 the first year, \$3,796,848 the second year, and \$3,853,799 the third year of operation, respectively. A financial feasibly study is not required for the proposed project.

- 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 charges for the services and the profitability of those services will remain the same as before ten (10) of the applicant's stations were transferred to the West Hinds satellite facility after the applicant's facility is expanded.
- b. **Projected Levels of Utilization**: The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 15,900; 18,150 and 20,550 respectively. The applicant asserts the existing ESRD facility (BMASWJ) currently has utilization and has an established patient base in the service area and/or state.

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

The proposed project expansion at the host facility will not increase the cost of dialysis services for patients or Medicaid. Also, the applicant's affiliation with the Fresenius network and its integrated delivery system also helps control healthcare costs.

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

a. Access by Population Served: The applicant states that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population.

Also, BMASWJ affirms that the location of this facility at 1856 Hospital Drive in Jackson, Mississippi and it is central to many of the applicant's patients and caregivers, and it serves over 83% of the remaining applicant's ESRD patients. The applicant states in order to help ensure accessibility to its patients and in order to minimize disruption of patient care, Fresenius reviewed its facility's patient addresses and talked with area patients. Therefore, the applicant calculated a utilization rate for both the Southwest Jackson facility and Satellite ESRD facility. The applicant states that not enough Southwest Jackson patients would transfer to the Satellite to withstand the decrease in stations.

The Satellite project was originally planned to be in placed in 2014 but DaVita contested it. After the issue with DaVita was resolved, the applicant began work on the ten (10) station Satellite facility. The applicant states after work began, soil tests were unacceptable. The applicant filed to relocate the ESRD satellite facility within one (1) mile of the original proposed site; however the Department denied a determination request for the relocation and required a Certificate of Need review. Therefore, the CON for the relocation was not awarded until October 2015. The applicant asserts that the need for additional ERSD stations at the current location is needed.

- **b.** Relocation of Services: The proposed project is not for the relocation of a facility or services
- c. Utilization of Facilities: The FY 2015 MSHP shows that there are seven (7) ESRD facilities in the Hinds County area, which that includes the applicant (BMASWJ). In this case the proposed project is not requesting the need for an additional facility; only the expansion of its existing host/main ESRD facility by ten (10) ESRD stations.
- d. Probable Effect on Existing Facilities in the Area: As previously stated, the applicant affirms that for those diagnosed with ESRD, the expansion of the applicant's facility is vital to the needs of it patients in and around the Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson area. The applicant at the location states that BMASWJ's utilization continues to increase as more patients seek necessary dialysis treatment at the location.
- **e. Community Reaction:** The application contained 13 letters of support for the proposed project from the patients who are serviced at the Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson.

No letters of opposition for the proposed project were received by the Department.

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#### 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%	\$1,356.58
2	2%	\$1.376.92

<sup>\*</sup>Patients without a payor source during a 90 day waiting period are considered medically indigent.

The applicant confirms that Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson 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 Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jacksons 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**

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson 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 ten (10) 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 ten (10) 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*	\$11,000	34.27%	
Land Cost	\$0	0%	
Site Prep Cost	\$0	0%	
Fees – architectural/engineering	\$0	0%	
Contingency Reserve	\$0	0%	
Capitalized Interest	\$0	0%	
Other	\$21,000	64.42%	
Total Proposed Expenditures	\$32,100	99.00 or 100.00%	

<sup>\*</sup>The expenses of 11,000.00 will allocated to: TV's, TV arms, TV mounts, electrical, valve boxes, Dialysis chairs and Dialysis machines.

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

#### 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 BMA of Southwest of Jackson provides the following revenue source projections for each payer category listed below.

Bio-Medical Applications of d/b/a BMA of Southwest Jackson							
Payor	Utilization Percentage	First Year Revenue					
Medicaid	5.00%	\$204,740.00					
Medicare	67.00%	\$2,505,254.00					
Self Pay	0.00%	\$10,210.00					
Commercial	25.00%	\$953,708.00					
Charity	0.00%	\$0.00					
Other	2.00%	\$66,827.00					
Total	99%	<u>\$3,740,739.</u> 00					

#### 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 not 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 Mississippi Certificate of Need Review Manual, Revised September 1, 2011; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends disapproval of the application submitted by Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest of Jackson for the expansion of ESRD stations at its existing facility due to the following reason:

Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest of Jackson is an existing ESRD facility and complied with **SHP Criterion 2 - Expansion of Existing ESRD Facilities** by filing a CON application because it 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; however, BMASWJ does not meet the minimum annual

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<u>utilization rate of 65% for the 12 months prior to the month of the submission of the CON application.</u>

In this case, Bio-Medical Applications of Mississippi, Inc. d/b/a BMA of Southwest Jackson states is has twenty-three (23) ESRD stations and is requesting to add ten (10) ESRD stations to its host/main ESRD facility (BMASWJ); however, the host/main ESRD facility <u>currently</u> has <u>33 operational</u> hemodialysis ESRD stations.

Since the transfer of the ten (10) ESRD stations approved for the FMC-West Hinds County ESRD satellite facility has not occurred, the applicant's utilization reported in the CON application is below the required 65% utilization needed to expand its existing ESRD facility (host/main) by ten (10) ESRD stations. Thus, the applicant is not in compliance with this criterion.

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# Attachment 1 Bio-Medical Applications of Mississippi, Inc. d/b/a 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	T	3,740,739	,	3,796,848		3,853,799
Gross Patient Revenue	\$	3,740,739	\$	3,796,848	\$	3,853,799
Charity	\$	0	\$	0	\$	0
Deductions from Revenue		0		0		0
Net Patient Care Revenue	\$	3,740,739	\$	3,796,848	\$	3,853,799
Other Operating Revenue	\$	0	\$	0	\$	0
Total Operating Revenue	\$	3,740,739	\$	3,796,848	\$	3,853,799
Operating Expenses						
Salaries	\$	844,220	\$	856,883	\$	882,589
Benefits	<u> </u>	321,689		326,514		331,411
Supplies		765,016		776,491		788,138
Services		0		0		0
Lease Expenses		59,156		59,156		59,156
Depreciation		136,361		136,361		136,361
Interest		. 0		0		0
Other		482,799		490,040		497,390
Total Operating Expenses	\$	2,609,241	\$	2,645,445	\$	2,695,045
Net Operating Income	\$	1,131,498	\$	1,151,403	\$	1,158,754
	ı	Proposed Proposed Year Year 2		Proposed Year 3		
Inpatient Days		0		0		0
Outpatient Visits		0		0		0
Procedures		15,900		18,150		20,550
Charge per Outpatient Day	\$	0	\$	0	\$	0
Charge per Inpatient Day	\$	0	\$	0	\$	0
Charge per Procedure	\$	235	\$	209	\$	188
Cost per Inpatient Day	\$	0	\$	0	\$	0
Cost per Outpatient Day	\$	0	\$	0	\$	0
Cost per Procedure	\$	164	\$	146	\$	131