

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
OCTOBER 2, 2017**

**CON REVIEW: ESRD-ES-0817-011
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC.
D/B/A FRESENIUS MEDICAL CARE –
SOUTH MISSISSIPPI KIDNEY CENTER – ORANGE GROVE
EXPANSION OF STATIONS AT EXISTING ESRD FACILITY
CAPITAL EXPENDITURE: \$2,273,159.89
LOCATION: GULFPORT, HARRISON COUNTY, MISSISSIPPI**

STAFF ANALYSIS

PROJECT SUMMARY

A. Applicant Information

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Medical Care – South Mississippi Kidney Center – Orange Grove (Orange Grove) is a business corporation. The applicant indicates that Orange Grove 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 and 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 – South Mississippi Kidney Center – Orange Grove is an End Stage Renal Disease (ESRD) facility that currently operates eighteen (18) hemodialysis stations.

Orange Grove requests Certificate of Need (CON) authority to expand its existing facility located at 11531 Old Highway 49, Gulfport, Mississippi 39503 by twelve (12) ESRD stations, thus bringing the applicant to a total of thirty (30) ESRD stations. The applicant states that a contractor will expand the shell of the proposed facility to accommodate the twelve (12) requested stations, while the applicant will incur the costs associated with the interior build-out of the expanded space. The application contained an allocated construction cost estimate from Jennifer Seymour, a registered Architect for the proposed project.

The applicant confirms that the proposed project consists of water treatment equipment, furniture, fixed and non-fixed equipment, television systems, phone systems, and IT equipment.

During the first year of operation the applicant expects to employ 4.0 full-time equivalent employees at a total personnel cost of \$516,119.00. The capital expenditure for the proposed project is \$2,273,159.89. The applicant indicates cash reserves will be used to fund the project. The applicant states the proposed project will assist Orange Grove with efficiently meeting the needs of their patients in the Harrison County area with the least amount of disruptions to patient care.

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

The applicant foresees that the anticipated date for obligation of capital expenditure of the proposed project is within six (6) months of final CON approval and the proposed completion of the proposed project within one (1) year of the 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 41-7-173(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, October 12, 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 proposes to add twelve (12) hemodialysis stations. 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 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, 3, 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. Orange Grove’s application shows that the total number of dialysis treatments from August 2016 through July 2017 is 11,108 and the number of operational, existing ESRD hemo-dialysis stations is 18.

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

18 stations X 936 treatments per station per year = 16,848 treatments per year
for 100 % utilization*

$$\frac{11,108 \text{ (Applicant's treatments for 08/2016-07/2017)}}{16,848 \text{ (Applicant's treatments per year for 100\% utilization)}}^*$$

= 65.93 % Utilization Rate

Based on the utilization data submitted by the applicant, Orange Grove has a utilization rate of 65.9% for the twelve (12) month period notated above (08/2016 - 07/2017).

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

Orange Grove 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 Orange Grove 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 affirms that it will operate Monday, Wednesday and Friday between the hours of 4:30 a.m. to 10:30 p.m. and 4:30 a.m. to 5:30 p.m. on Tuesdays and Thursdays. The applicant asserts that 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 is available for medically eligible patients at North Gulfport Therapies on Highway 49 and that it counsels all patients on the availability requirements to enter the home/self-dialysis program.

SHP Criterion 10 - Indigent/Charity Care

The applicant affirms that Orange Grove currently provides 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 proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties. If the proposed project is CON approved, the applicant affirms that 4.0 full time equivalents will be utilized for the proposed project.

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 Orange Grove currently provides an ongoing training program 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 Orange Grove has an existing Kidney Transplant Affiliation Agreement with the Ochsner Clinic Foundation, which was provided in the application.

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*, as discussed above.

GR Criterion 2 – Long Range Plan

The applicant states that the proposed project expansion is consistent with Orange Grove's long range plan to provide high quality, accessible ESRD services for those residents in need of dialysis services in the Harrison County area. The applicant suggests that the allocated expanded facility will provide a better environment for patient treatment while accommodating growth in patient numbers as more daytime treatment slots will be available with the expansion of stations.

GR Criterion 3 – Availability of Alternatives

The applicant states that the relocation of Orange Grove to a new building was considered however, due to mileage limitations and limited land availability relocation was not a viable option.

The applicant believes that the expansion of the ESRD stations at Orange Grove will be the most efficient, effective, and accessible alternative to meet the needs of the patients in Harrison County.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a total operating revenue of \$4,917,378 the first year, \$5,146,022 the second year, and \$5,394,502 the third year of operation, respectively. 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 asserts that the proposed project will expand Orange Grove by adding twelve (12) 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 Orange Grove, 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 twelve (12) ESRD stations addition will result in the availability of more desirable treatment slot times, which may slightly increase the facility's utilization as patients seek more convenient treatment times.

The application contains 6 letters of support from physicians, various patients and the Mayor of Gulfport, MS 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 historical and projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Orange Grove	Medically Indigent *	Gross Patient Revenue
Historical Year 2016	2%	\$5,367.16
Historical Year 2017	2%	\$5,345.84
Projected Year 1	2%	\$8,197.74
Projected Year 2	2%	\$8,576.10

*The applicant states that patients qualify for Medicare after 90 days, therefore the number reported only represents patients in that 90-day period or a patient without a payor source.

The applicant confirms that Orange Grove is conveniently located off Highway 49 in Gulfport; which makes travel easily accessible for patients.

The applicant affirms that it will operate Monday, Wednesday and Friday between the hours of 4:30 a.m. to 10:30 p.m. and 4:30 a.m. to 5:30 p.m. on Tuesdays and Thursdays. The applicant asserts that alternate arrangements will be made for those patients needing after-hours treatments.

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 fifteen (15) business days of request.

GR Criterion 8 – Relationship to Existing Health Care System

The *FY 2015 State Health Plan* defines a "Service Area" as the area within a thirty (30) mile radius of an existing or proposed ESRD Facility. The applicant states there are five (5) ESRD facilities located in Orange Grove's Service Area: FMC-South Mississippi Kidney Centers of Biloxi, FMC-Diamondhead, FMC-North Gulfport, FMC-D'Iberville and Davita Ocean Springs. The applicant submits that the target population served by Orange Grove should remain substantially the same.

The applicant states that while patients continue to receive life-saving dialysis treatments at the facility, they will also continue to deal with the effects of overcrowding on treatment times. The applicant believes that if the proposed expansion is not allowed, daily time slots will be limited resulting in fewer options for patients to receive treatment and more missed appointments; which does not promote the continuity of care.

GR Criterion 9 – Availability of Resources

The applicant submits that it currently has the following required personnel for the proposed project: registered nurses, nephrologists, technical/paramedical, administrative/managerial employees at its existing facility. The applicant states that in the event there is a shortage of staff, their affiliation with other ESRD facilities in the area will allow them to supplement and share personnel from other affiliated facilities when necessary. The applicant asserts it has a satisfactory staffing history.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that it currently has all necessary support and ancillary services for Orange Grove. The applicant states there will be no change in costs or charges as a result of this proposed project.

GR Criterion 11– Health Professional Training Programs

Orange Grove asserts the facility will cooperate with area health professional training programs in the surrounding area.

GR Criterion 14– Construction Projects

The applicant states that a selected contractor will expand the shell of the proposed facility to accommodate the twelve (12) requested stations, while the applicant will incur the costs associated with the interior build-out of the expanded space. The application contained an estimate from Jennifer Seymour, a registered Architect, with the projected construction cost associated with the proposed project.

The applicant asserts that the proposed interior build-out will include 4,113 square feet and the shell expansion will include 4,113 square feet. The applicant states that the construction/renovation will comply with all ordinances and regulations in regards to the proposed project.

The Mississippi State Department of Health, Division of Health Facilities Licensure and Certification has approved the site for the proposed project.

GR Criterion 16– Quality of 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 twelve (12) ESRD stations. The applicant asserts that the proposed project will improve accessibility and enhance the quality of care currently given at the existing facility.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost (\$)	Percentage% of Total
Construction Cost - New	\$ 843,165	37.09%
Construction Cost - Renovation	748,566	32.93%
Capital Improvements	0	0%
Total Fixed Equip Cost	260,000	11.44%
Total Non-Fixed Equip Cost	8,000	0.35%
Land Cost	0	0.00%
Fees – architectural/engineering	143,255	6.30%
Contingency Reserve	159,173	7.00%
Capitalized Interest	0	0.00%
Other	111,000	4.89%
Total Proposed Expenditures	\$2,273,159	100.00%

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 Orange Grove provides the following revenue source projections for each payer category listed below (with project):

Payor Mix	First Year Revenue (\$)	Utilization Percentage (%)*
Medicare	\$ 3,079,062	63%
Medicaid	463,278	9%
Commercial	934,790	19%
Self Pay	30,361	1%
Charity Care	0	0%
Other	409,887	8%
Total	\$4,917,378	100%

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; however, the Division of Medicaid has not provided a comment on the proposed project as of the date of this staff analysis.

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 –South Mississippi Kidney Center – Orange Grove for the expansion of twelve (12) End Stage Renal Disease (ESRD) stations.

Attachment 1
 Bio-Medical Applications of Mississippi, Inc.
 d/b/a Fresenius Medical Care – South Mississippi Kidney Center – Orange Grove
 (Orange Grove)
Three-Year Operating Statement (with Project)

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	\$ 0	\$ 0	\$ 0
Outpatient Revenue	4,917,378	5,146,022	5,394,502
Gross Patient Revenue	\$ 4,917,378	\$ 5,146,022	\$ 5,394,502
Charity	\$ 0	\$ 0	\$ 0
Deductions from Revenue	0		
Net Patient Care Revenue	\$ 4,917,378	5,146,022	5,394,502
Other Operating Revenue	\$ 0	\$ 0	\$ 0
Total Operating Revenue	\$ 4,917,378	\$ 5,146,022	\$ 5,394,502
Operating Expenses			
Salaries	\$ 1,109,064	\$ 1,166,476	\$ 1,228,585
Benefits	410,354	431,596	454,577
Supplies	976,882	1,017,401	1,061,111
Services	0	0	0
Lease Expenses	244,600	244,600	244,600
Depreciation	312,054	312,054	312,054
Interest	0	0	0
Other	934,627	973,394	1,015,212
Total Operating Expenses	\$ 3,987,581	\$ 4,145,521	\$ 4,316,139
Net Operating Income (Loss)	\$ 929,797	\$ 1,000,501	\$ 1,078,363
Inpatient Days			
Outpatient Visits	624	626	626
Procedures	17,154	17,690	18,266
Charge per Outpatient Day	\$ 7,880	\$ 8,220	\$ 8,617
Charge per Inpatient Day	0	0	0
Charge per Procedure	\$ 287	\$ 291	\$ 295
Cost per Inpatient Day	0	0	0
Cost per Outpatient Day	\$ 6,390	\$ 6,622	\$ 6,895
Cost per Procedure	\$ 232	\$ 234	\$ 236