

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

**CON REVIEW: ESRD-REN-0618-006  
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC. D/B/A FRESENIUS MEDICAL CARE  
TRANSFER OF AN EXPIRED CERTIFICATE OF NEED FOR CON #R-0710  
(CON REVIEW: ESRD-NIS-0905-041)  
ESTABLISHMENT OF SIX (6) STATION ESRD FACILITY IN TALLAHATCHIE COUNTY  
CAPITAL EXPENDITURE: \$254,085  
LOCATION: CHARLESTON, TALLAHATCHIE COUNTY, MISSISSIPPI**

**STAFF ANALYSIS**

**I. PROJECT SUMMARY**

**A. Applicant Information**

Bio-Medical Applications of Mississippi, Inc. ("BMA") d/b/a Fresenius Medical Care is a freestanding business corporation. The applicant indicates that BMA is governed by a two member Board of Directors and has eleven 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 licensed to do business in the State of Mississippi.

**B. Project Background**

The applicant states that Health Care Engineers, LLC ("HCE") obtained CON #R-0710 for the establishment of a six-station End Stage Renal Disease (ESRD) facility in Charleston, Tallahatchie County. The Final Order for the proposed project was approved by the Mississippi State Department of Health on June 29, 2006. The original CON expired approximately 2007, but is shown in the *FY 2015 SHP*. The applicant confirms that the ESRD CON became the property of the estate in the Chapter 11 bankruptcy proceeding, *In Re: Physician and Surgeons Hospital, d/b/a Tri-Lakes Medical Center*, Case No. 07-12967-JDW. The Bankruptcy Court Order approved the sale and transfer of ownership of the ESRD CON to BMA d/b/a Fresenius Medical Care ("Fresenius"), pursuant to a Purchase Agreement in March 2017. The Court further ordered that the Mississippi State Department of Health renew, extend, re-issue and transfer the ESRD CON to the Purchaser (Fresenius) within thirty (30) days of the Department's receipt of a copy of the Final Sale Approval Order.

Because the ESRD CON has been part of the estate in a bankruptcy proceeding, the project to establish a six-station ESRD facility in Tallahatchie County has been held in abeyance. However, the applicant has developed a plan for the development and construction of the ESRD facility in a timely and cost effective manner.

**C. Project Description**

BMA d/b/a Fresenius Medical Care requests the Extension, Renewal, Reissue and Transfer of Certificate of Need (CON) authority to establish an ESRD facility in Charleston, Tallahatchie County. The applicant affirms that the proposed ESRD facility will consist of six (6) staff assisted hemodialysis stations

Currently, Fresenius serves thirty-five (35) ESRD patients who reside in Tallahatchie County or the surrounding areas. Due to the lack of an ESRD facility in Tallahatchie County, these patients are required to travel three (3) days a week to other dialysis facilities in order to receive treatment and care. This creates a burden on patients and their families and results in additional costs for travel and other expenses. The applicant affirms that the residents of Tallahatchie County and the surrounding areas would be better served through the establishment and operation of an ESRD facility in Tallahatchie County. For this reason, Fresenius Medical Care negotiated with HCE for the purchase of the ESRD CON. The Bankruptcy Court approved the sale and transfer of ownership of the ESRD CON to BMA d/b/a Fresenius Medical Care. The court further ordered the Mississippi State Department of Health renew, extend, reissue, and transfer the ESRD CON to the purchaser within thirty (30) days of the Department's receipt of a copy of the final sale approval order.

The applicant affirms that there was and is a continued need for this project. In September of 2005, when the ESRD CON was initially approved, the State Health Plan recognized the need for an ESRD facility in Tallahatchie County. Fresenius currently serves thirty-five (35) ESRD patients who reside in Tallahatchie County. This proves there is an obvious and continuing need for an ESRD facility within Tallahatchie County.

Due to the relocation of the project from its originally approved site, as well as other amendments to the project, Fresenius will file an application for an amendment to the ESRD CON, following its renewal, extension and transfer. The applicant has provided the following timeline for the implementation and completion of the proposed project.

**June 2018-** Department of Health approval of renewal, extension and transfer of ESRD CON

**July 2018-** Final Selection of new site for ESRD facility in Tallahatchie County

**July 2018-** Filing of Notice of Intent to apply for amendment to ESRD CON

**July 2018-** Filing of application for amendment to ESRD CON

**July-September 2018-** Department of Health review of application for amendment to ESRD CON

**September 2018-** Relocation of modular building from Belzoni to new site in Tallahatchie County

**October 2018-** Project completion and commencement of operations of ESRD facility. The applicant suggests that BMA will be located in an area likely to attract

patients from Tallahatchie County. The applicant believes that many members of this underserved ESRD community will choose to dialyze in a BMA facility not only because of its geographical convenience but also because of the company's reputation for high quality of care.

The applicant states that Fresenius Medical Care completed construction of a new ESRD facility in Belzoni, Mississippi in May of 2018. This new facility replaces a modular building that was serving that location. The modular building will be relocated to the site of the new ESRD facility in Tallahatchie County, Mississippi. The total proposed capital expenditure for this project is \$254,085. The applicant anticipates that project completion and commencement of operations of the ESRD facility will be in October of 2018.

## II. TYPE OF REVIEW REQUIRED

The original project for the establishment of an end stage renal disease facility was reviewed in accordance with Section 41-7-173 (h), Section 41-7-191, subparagraph (1)(a), and Section 41-7-193 of the Mississippi Code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi Department of Health. The proposed project continues to be in compliance.

As previously notated above, the Court ordered that the Mississippi State Department of Health renew, extend, re-issue and transfer the ESRD CON to the Purchaser (Fresenius) within thirty (30) days of the Department's receipt of a copy of the Final Sale Approval Order.

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 July 26, 2018.

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

### A. State Health Plan (SHP)

The original application was reviewed and found to be in compliance under the *FY 2005 Mississippi State Health Plan*. The *FY 2015 State Health Plan* contains criteria and standards which the applicant is required to meet before receiving CON authority to establish an ESRD facility. This application is in substantial compliance with applicable criteria and standards in regards to the *FY 2015 State Health Plan*.

### B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, (May 13, 2000 as amended)* addresses general criteria by which the original CON application was reviewed. Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised April 9, 2017*, addresses general criteria by which all CON applications are currently reviewed. The applicable criteria are discussed below.

### **GR Criterion 1 – State Health Plan**

The proposed project continues to comply with the 2005 State Health Plan, which was in effect at the time of the submission of the original Application. The proposed project is also in compliance with the overall objectives of the *FY 2015 State Health Plan*. The applicant seeks Certificate of Need authority to establish six (6) hemodialysis stations in Tallahatchie County, Mississippi.

### **GR Criterion 2 – Long Range Plan**

The applicant's long range plan is to provide high quality, easily accessible ESRD services for those residents in need of dialysis services in Tallahatchie County.

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

The applicant states that the only alternative to the implementation of the ESRD CON is to abandon the proposed project. Abandonment of the proposed project would not fulfill the needs of dialysis patients in need of accessible treatment. Because there are no existing ESRD facilities in Tallahatchie County, the applicant suggests that the establishment of a smaller ESRD facility benefits not only the patients but also the system as a whole by providing access and a wider-range of ESRD service providers.

The applicant believes that the establishment of a six-station ESRD facility will be the most efficient, effective and accessible solution to meeting the needs of ESRD patients in Tallahatchie County.

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

- a. **Proposed Charges:** Charges for all services will be compatible with other similar services in the state. Fresenius and its affiliated facilities have extensive experience in the financial operations of ESRD facilities, and the proposed charges will be based on Fresenius' experience.
- b. **Projected Levels of Utilization:** The applicant states that Fresenius has an existing dialysis patient base to support the operation of a six- station ESRD facility. The projected utilization will be consistent with the need level of the service area.
- c. **Project's Financial Feasibility Study:** If the project does not meet projected revenues, Fresenius will be able to cover expenses through cash reserves.

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

- a. **Access by Population Served:** The applicant asserts that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population.
- b. **Relocation of Services:** The applicant plans to request a relocation of the site for the proposed ESRD facility. The site will remain within Tallahatchie county in order to serve the needs of that patient

population.

- c. **Probable Effect on Existing Facilities in the Area:** As previously stated above, the applicant submits that currently there are no ESRD facilities located in the proposed service area.
- d. **Community Reaction:** The applicant states that letters of comment are being compiled and will be submitted. However, no letters were received by MSDH prior to July 16, 2018.

**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 projected percentage of gross patient revenue (GPR) of health care provided to medically indigent care patients for the two years following completion of the proposed project:

**Medically Indigent Care Patients  
Gross Patient Revenue**

	<b>Medically Indigent</b>	<b>Charity Care</b>
Projected Year 1	2.5%	2.5%
Projected Year 2	2.5%	2.5%

The applicant states that BMA hours of operation will be Monday – Saturday from 6:00 a.m. to 5:00 p.m. The applicant is currently evaluating a new site for the proposed ESRD facility. The applicant affirms that one of the most important factors in the site selection process is geographic accessibility.

**GR Criterion 7 – Information Requirement**

The applicant affirms that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within fifteen (15) days of request.

**GR Criterion 8 – Relationship to Existing Health care System**

The applicant states that there are no ESRD facilities in Tallahatchie County. Fresenius currently serves thirty-five (35) dialysis patients who reside in Tallahatchie County. Currently residents have to travel to other counties to receive ESRD services. The proposed project will complement the services of existing dialysis providers by establishing another ESRD facility in a medically underserved area. The applicant affirms that prior to commencing operation of the facility they will enter into transfer and affiliation agreements with a variety of providers and institutions, including hospitals, renal transplant centers, and others.

The applicant believes that failure to implement this project will restrict access to the growing ESRD patient population in Tallahatchie County.

**GR Criterion 9 – Availability of Resources**

The applicant affirms that Dr. Allison R. White, a board certified nephrologist, will serve as medical director for the proposed facility. The applicant states that it will enter into contracts for clinically-related services as needed. Fresenius and its affiliates currently operate sixty-four (64) facilities throughout Mississippi. All of these facilities are Medicare and Medicaid certified and comply with all regulations governing operations and staffing.

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

The applicant affirms that all necessary ancillary or support services will be available.

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

According to the applicant, Fresenius will coordinate with the health professional schools in the area to provide training for student health professionals.

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

Fresenius works with health professional programs in order to meet the clinical needs of health professionals.

**GR Criterion 16– Quality of Care**

The applicant asserts that Fresenius and its affiliates provide high quality dialysis services and all facilities are certified for participation in Medicare and Medicaid.

Tallahatchie County currently does not have an ESRD facility. The applicant believes that approval of this project will enable dialysis patients to receive treatment closer to home.

**IV. FINANCIAL FEASIBILITY**

**A. Capital Expenditure Summary**

The proposed project does not have a capital expenditure summary. The applicant states the capital expenditure for the proposed project is \$254,085. The Capital Expenditure fee associated with the proposed project's transfer of an expired CON is the calculation of one-half of the original CON assessment.

**B. Cost to Medicaid/Medicare**

The applicant’s projections of gross patient revenue percentages to Medicaid and Medicare payor sources for the first year of operation is presented below:

<b>Payor Mix</b>	<b>Utilization Percentage (%)</b>
<b>Medicare</b>	90.00
<b>Medicaid</b>	5.00
<b>Commercial</b>	2.50
<b>Other</b>	2.50
<b>Total</b>	<b>100.00%</b>

**C. Effect on Operating Cost**

The proposed project does not have any operating cost.

**V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided a copy of this application. The Division of Medicaid had not responded on this proposal as of this staff analysis.

**VI. CONCLUSION AND RECOMMENDATION**

This project is in substantial compliance with criteria and standards for establishment of end stage renal disease facilities as contained in the *FY 2015 State Health Plan*; the *Mississippi Certificate of Need Review Manual, April 9, 2017*,; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Bio-Medical Applications of Mississippi d/b/a Fresenius Medical Care for the establishment of a six- station ESRD facility in Tallahatchie County.