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MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT JUNE 9, 2025

CON REVIEW: ESRD-ES-0425-003
BIO-MEDICAL APPLICATIONS OF MISSISSIPPI, INC.
D/B/A FRESENIUS KIDNEY CARE NORTH JACKSON
EXPANSION OF STATIONS AT EXISTING
END STAGE RENAL DISEASE (ESRD) FACILITY

CAPITAL EXPENDITURE: \$1,874,050.88

LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson is a business corporation. The applicant indicates that Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson is governed by one (1) Board of Director and thirteen (13) officers.

The Applicant provided a Certificate from the Secretary of State, verifying that the corporation was issued a Charter/Certificate of Authority on April 4, 2014. 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 Kidney Care North Jackson (Fresenius Kidney Care) is authorized to operate twenty-two (22) End Stage Renal Disease (ESRD) stations located in Jackson, Mississippi. According to the application, due to floor and foundation issues concerning the building that houses the Central Dialysis Unit, on August 20, 2024, the Mississippi State Department of Health (MSDH) approved an Emergency CON request to temporally increase ESRD stations by six (6), totaling twenty-eight (28) stations for Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson. As stated in the FY 2022 Mississippi State Health Plan, Third Edition Emergency CON approval is valid for not more than ninety (90) days. Any recipient of an Emergency CON is required to submit the appropriate CON application to the Department within fifteen (15) calendar days of the effective date of the Emergency CON, addressing the same project for which the Emergency CON was granted. According to the application, the Applicant's failure to submit the appropriate CON application within the fifteen (15) calendar days; resulted in Fresenius Kidney Care having only twenty-two (22) licensed Medicaid ESRD stations, instead of twenty-eight (28) licensed Medicaid ESRD stations.

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson requests Certificate of Need (CON) authority to expand its existing facility located at 5722 I-55 North in Jackson, Mississippi by fifteen (15) ESRD stations, thus bringing the total to thirty-seven (37) ESRD stations. This approval will include the six (6) ESRD stations from the Emergency CON approval with an additional nine (9) ESRD stations for a total of fifteen (15). The Applicant states that the increased utilization will accommodate patients to receive better access to necessary dialysis treatment with the least amount of disruption to patient care. The Applicant states that there will be renovation/construction costs associated with the interior build-out for the additional stations. The Applicant further states

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the space will be built out approximately 3,495 square feet to accommodate the station increase.

The Applicant states that they are an existing freestanding healthcare facility that complies and will continue to comply with state and local building codes, zoning ordinances, and/or appropriate regulatory authority. The Applicant also states they will comply with State statutes and regulations for the protection of the environment, including: 1) approved water supplies; 2) sewage and water disposal; 3) hazardous waste disposal; 4) water pollution control; 5) air pollution control; and 6) radiation control.

The application includes a schematic drawing of Fresenius Kidney Care's proposed ESRD Satellite facility expansion and a letter from The Mississippi State Department of Health, Bureau and Health Facilities, Division of Health Facilities Licensure and Certification approving the site for the proposed project.

The Applicant states Fresenius Kidney Care's final objective is to ensure that the patients in the Jackson metro area will receive the best possible access to life-saving dialysis services with the least amount of disruption to patient care.

The Applicant affirms that the capital expenditure for the project is \$1,874,050.88. The Applicant states Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson proposes to fund the project with cash reserves. The Applicant anticipates the capital expenditure will be obligated upon CON approval. The Applicant anticipates starting on the project upon CON approval though the renovation is anticipated to take almost a year after which the Applicant seeks Medicare certification for the expanded stations.

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 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 ten (10) days of the publication of the Staff Analysis. The staff analysis is due online Monday, June 9, 2025. The opportunity to request a hearing expires on Thursday June 19, 2025.

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

A. Mississippi State Health Plan

The FY 2022 State Health Plan, Third Edition, contains policy statements and service specific criteria and standards which the applicant is required to meet before receiving CON authority to establish facility; however, the proposed project is for the expansion of stations at an existing ESRD facility. This application is in substantial compliance with applicable criteria and standards.

The Plan states Mississippi's health planning and health regulatory activities have the following purposes:

Document the proposed project's compliance with each of the applicable standards. The application must have narrative sections corresponding to each item of the policy statements, and general and/or service specific criteria and

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standards in the current State Health Plan.

The Plan's General CON Policies include the following:

• To improve the health of Mississippi residents

The Applicant states the expansion of stations at the North Jackson facility will improve the health of Mississippi residents by providing Mississippi residents, and especially those patients around Jackson and Hinds County, with more treatment time slots to receive necessary dialysis services at a more accessible location.

To increase accessibility, acceptability, continuity, and quality of health services

The Applicant states the proposed expansion will improve accessibly to treatment for the patients which will improve their overall health as the increased opportunity to receive treatment will decrease the number of missed appointments. The Applicant further states this project will result in the delivery of more efficient health services.

• To prevent unnecessary duplication of health resources

The Applicant asserts the proposed project will not result in an unnecessary duplication of health services as the expansion will ensure that overcrowding does not occur and that patients continue to receive care with the least amount of disruption to their treatment routines as possible.

To provide cost containment.

The Applicant states Fresenius Kidney Care believes utilizing shelled space to accommodate additional stations achieves cost containment goals rather than creating a costly new unit to support patient care.

<u>Policy Statement Regarding Certificate of Need Application for The Establishment of an End Stage Renal Disease (ESRD) Facility</u>

1. Establishment of New ESRD Facility:

The Applicant states this statement is not applicable. The Application seeks to expand the station count at an *existing* ESRD facility in Jackson by fifteen (15) stations.

2. Type of Review:

The Applicant states that Fresenius Kidney Care acknowledges this statement.

3. ESRD Facility Service Area:

The Applicant states that Fresenius Kidney Care acknowledges this statement. According to the Plan, this Policy Statement does not apply to expansion of stations.

4. <u>Utilization Definitions</u>:

The Applicant states that Fresenius Kidney Care acknowledges this statement.

5. Outstanding CON's:

The Applicant states Fresenius Kidney Care acknowledges this statement.

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6. <u>Utilization Data:</u>

The Applicant states that Fresenius Kidney Care acknowledges this statement.

7. Minimum Expected Utilization:

The Applicant states that Fresenius Kidney Care acknowledges this statement.

8. Minimum Size Facility:

The Applicant states Fresenius Kidney Care acknowledge this statement.

9. Expansion of Existing ESRD Facilities:

The Applicant states that Fresenius Kidney Care acknowledges this statement.

10. Home Dialysis Programs

The Applicant states this statement is not applicable to the proposed project.

11. Establishment of Satellite ESRD Facilities

The Applicant states that this statement is not applicable to the proposed project.

12. Non-Discrimination

The Applicant affirms that neither the facility nor its staff shall have policies or procedures which would exclude patients because of race, color, age, sex, or ethnicity.

13. Indigent/Charity Care:

The Applicant acknowledges this statement and affirms that it will continue to provide a reasonable amount of indigent/charity care.

14. Staffing:

The Applicant affirms to complies with and will continue to comply with staffing requirements.

15. Federal Definitions:

The Applicant acknowledges this statement.

16. Affiliation with a Renal Transplant Center:

The application includes a Transplant Center Program Agreement between The University of Mississippi Medical Center and Fresenius Medical Care- Bio-Medical Application of Mississippi, Inc.

The table below represents the number of patients that the Applicant anticipates it will refer for transplant evaluation. The Applicant can only identify potential candidates and refer for evaluation. The transplant center with its physicians determines if a patient actually is placed on the waitlist for a transplant.

Number of Transplants in the Past Three (3) Years:			I
	Name of Transplant Facility:	UMMC	

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Location of Transplant Facility: Jackson	
Projected number of patients who will be candidates for transplantation during the first three (3) years of operation:	50*

The Establishment of an End Stage Renal Disease (ESRD) Facility

Need Criterion 1: Establishment of New ESRD Facilities

The Applicant states this criterion is not applicable. The Applicant further states their proposed project is to expand stations by fifteen (15), using the station authority at an existing ESRD facility.

Need Criterion 2: For Expansion of Existing ESRD Facilities

a. Expansion of Existing ESRD Facilities – Non-Satellite:

The Applicant acknowledges this statement and affirms Fresenius Kidney Care can project a minimum annual utilization rate of sixty-five percent (65%). The Applicant further state the projected utilization was determined by reviewing current ESRD patients in the area that would benefit from receiving services closer to their residence to decrease transportation times. The Applicant states that they considered that there are approximately twenty (20) patients remaining at affiliated facilities that actually reside closer in proximity to the facility. The Applicant states an additional chair/time availability in closer proximity to existing patients will improve scheduling by the patients and their caregivers and further support the facility's projected utilization.

The Applicant states 100% utilization = 936 treatments per station per year. Therefore, for eighteen (18) stations 100% utilization = 16,848 (1/2 year=8,424) and for twenty-two (22) stations 20,592 (1/2 year = 10,296).

65% utilization on eighteen (18) stations at North Jackson is 10,951 treatments (16,848 x 65 = 10,951); for $\frac{1}{2}$ a year = 5,476 (10,951/2 = 5,476)

65% utilization on twenty-two (22) stations at North Jackson is 13,385 treatments (20,592 x 65 = 13,385); for $\frac{1}{2}$ a year = 6,693 (13,385/2 = 6,693)

The Applicant states each patient typically receives treatment 3 times a week, for a total of 156 treatments per year ($3 \times 51=156$).

Number of current patients in 2025 = 77 77 x 156 = 12,012

Number of Patents expected at the end of 2025 = 90 $90 \times 156 = 14,040$

Number	Months	Treatments	Stations
1	24-April	786	18
2	24-May	857	18
3	24-Jun	809	18
4	24-Jul	819	18

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5	24-Aug	852	18	
6	24-Sept	768	18	
Total			4,891	
Utilization Pe	r Plan	58% (4,891 / 8,424)		
7	24-Oct	924	22	
8	24-Nov	907	22	
9	9 24-Dec		22	
10 24-Jan 11 24-Feb 12 25-Mar		858	22	
		841	22	
		914	22	
Utilization Per Plan		52% (%5,355	5 / 10,296)	
Total			5355	

b. Expansion of Existing ESRD Facilities – Satellite:

The Applicant states that that this statement is not applicable. The Applicant is a satellite facility and has been in business for over two (2) years.

Need Criterion 3: For Establishment of ESRD Satellite Facilities

The Applicant states this criterion is not applicable. The Applicant further states Fresenius Kidney Care is not proposing to establish a satellite facility.

Need Criterion 4: Number of Stations

The Applicant states Fresenius Kidney Care is proposing to expand by fifteen (15) stations, bringing its total station authority to thirty-seven (37) stations.

Need Criterion 5: Minimum Utilization

The Applicant affirms Fresenius Kidney Care projected utilization will meet the minimum utilization requirements.

The Applicant included a chart below detailing how they calculated the projected utilization for the expansion project and how they considered the number of patients receiving dialysis treatments and utilization numbers at its North Jackson facility. The Applicant further states the utilization numbers have been increasing over the past eighteen (18) months, with dips due to seasonal changes and business days in the month as shown below.

Month/Year	Treatment Numbers
23-Aug	735
23-Sept	725

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23-Oct	732
23-Nov	745
23-Dec	757
24-Jan	752
24-Feb	765
24-Mar	792
24-Apr	786
24-May	857
24-Jun	809
24-Jul	819
24-Aug	852
24-Sept	768
24-Oct	924
24-Nov	907
24-Dec	911
25-Jan	858
25-Feb	841
25-Mar	914

The Applicant states that in addition to this utilization; the calculation trend increase for this period will be approximately twenty-four percent (24%) to anticipate a growth in treatment/utilization. The Applicant further states that it will also be considered an increase in the number of patients at the facility.

The Applicant states there were fifty (50) patients receiving treatment at the facility in 2023, and there were sixty-five (65) patients receiving treatment at the facility in 2024. The Applicant states currently there are seventy-seven (77) patients at the facility for which it is an increase over fifty percent (50%) for the two and a half (2 ½) year period. The Applicant asserts they anticipate for this number to grow to at least ninety (90) patients by the end of the year given the return of patients to the facility from the displacement last summer and new start patients due to kidney disease. The Applicant submits to verify the reasonableness of this growth is by discussing the growing patient population with supporting nephrologists at Central Nephrology and considering the geographic location and transportation availability in the area. The Applicant further states it has also considered its experience when patients will request to transfer to the expanded facility, if treatment times were available. The Applicant states this will allow the affiliated facilities to aid their patients in finding a chair/time that best meets their and their caregivers' needs regarding scheduling.

The Applicant projects, along with the Facility's general utilization, is in compliance with the Plan, and will reach sixty-five percent (65%) on the thirty-seven (37) total stations within two (2) years of use of the stations. The Applicant further states it is anticipated that the renovation needed to accommodate the stations will take at least nine (9) months. Based on recent experience obtaining approval for station use by payors, including Medicare, the Applicant anticipates it will be at least twelve (12) months from the start of renovation until the stations are ready to be utilized. state during this time, the Applicant anticipates its patient utilization will continue and will exceed its current trajectory based on the reasons set forth in *Exhibit D*. state based on a conservative growth trend, the Applicant will exceed sixty-five percent (65%) utilization as projected below.

Patients at FKC North Jackson 2023: 50 patients 2024: 65 patients An increase of 30%

Estimated 2025 (based on *Exhibit* D): 90

An increase from current to Estimated year end of 38.5% Estimated end of 2026 with a 34%¹ increase: 121

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Estimated end of 2027 with same increase percentage: 162 Estimated end of 2028 with same increase percentage: 217

The Applicant states traditionally each patient receives three (3) treatments a week, a total of 156 treatments per year, per patient. The Applicant states using the estimated number of patients and projecting the anticipated treatments each will receive allows a comparison to the utilization requirements of the Plan. The Applicant anticipates it will be certified to provide services with additional stations by the end of 2026 and will have a patient population of approximately 111 patients.

100% utilization (per the Plan) = 936 (treatments) x 37 (the number of stations) = 34,632 65% = 22,514.8

First year of operation: 121 patients x 156 anticipated treatments= 18,876

55% utilization (18,876/34,632)

Second year of operation: 162 patients x 156 anticipated treatments= 25,272

73% utilization (25,272/34,632)

Third year of operation: 217 patients x 156 anticipated treatments= 33,852 98% utilization (33,852/34,632)

The Applicant further states Fresenius anticipates a slightly more conservative approach to the growth to ensure the project remained financially viable. The Applicant states they anticipated an, existing utilization higher in Year 1 before using a more conservative ramp up in Years 1 and 2. The Applicant further states by demonstrating that the project remains financially viable with less utilization than that anticipated by the patient growth described above will ensure that the project will succeed financially. In addition, the Applicant states this lower utilization also helps account for the fact that the Applicant cannot exactly predict the certification date for approval for the use of the stations by Medicare. The Applicant provided financial projections and an utilization chart with the application (Exhibit L and Exhibit D of the application).

The Applicant provided the number of procedures/treatments for the prior year of 2024; 9,942; the current year 2025; 2,613 (3 months), and a three-year project completion Year 1; 21,968, Year 2; 22,968, and Year 3; 24,840

Need Criterion 6: Minimum Services

The Applicant affirms that it provides and will continue to provide social, dietic, and rehabilitative services.

Need Criterion 7: Access to Needed Services

The Applicant affirms Fresenius Kidney Care provides and will continue to provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable ESRD patients.

Need Criterion 8: Access to Needed Services

The Applicant affirms Fresenius Kidney care provides and will continue to provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

Need Criterion 9: Home Training Program

The Applicant affirms that it has and will continue to have a home training program available to those patients who are medically eligible and receptive to such a program. The Applicant also affirms that it counsels and will continue to counsel all patients on the availability of and eligibility requirements to

¹ An average of the increases 30% growth for 2024 and 38.5% growth for 2025.

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enter the home/self-dialysis program.

Need Criterion 10: Indigent/Charity Care

The Applicant affirms that it provides and will continue to provide a "reasonable amount" of indigent/charity care.

Need Criterion 11: Facility Staffing

The Applicant provided a more detailed description of the qualifications and specific duties of the staff attached to the application at Exhibit H. See Attachment 2 of this Staff Analysis for a list of physicians and nephrologists.

Registered Nurse: The Applicant proposes employing five (5) FTE registered nurses for the facility. In summary, these nurses are responsible for the support and delivery of the Applicant's policies and procedures; providing direct patient care; performing technical aspects of dialysis procedures; administering medicines; assessing patients' responses to dialysis; and documenting and reporting patient assessment and patient conditions. They are required to have graduated from an accredited school of nursing; hold state licensure; preferably have a minimum of one (1) year medical-surgical nursing experience, hemodialysis experience and intensive care unit experience; and, they must complete training on the theory and practice of hemodialysis and CPR certification.

Aide: The Applicant proposes employing ten (10) FTE aides for the facility.

Dietician: The Applicant proposes employing 1.5 FTEs for dietary services. This person assesses the patient's knowledge of diet and kidney disease and provides education regarding the relationship of diet and kidney disease. The dietician also competes nutritional assessments and calculates diet prescriptions. The dietician must be a registered dietician, hold state licensure, and preferably be board certified in renal nutrition. The dietician must also have one (1) year of work in clinical nutrition as a registered dietitian and preferably have renal experience.

Social Worker: The Applicant proposes employing 1.75 FTEs for social service. This social worker provides psychosocial services to patients. The social worker also provides information and assists the facility and patients with referral to community resources to facilitate optimal treatment outcomes. This person must have a master's degree in social work with a concentration in clinical practice from a school accredited by the Council on Social Work Education and be certified/licensed by the state. Preferably, the person will also have experience with renal patients or other physically ill people.

Administrative/Management: The Applicant proposes employing .4 FTEs that are administrative/management staff. The Applicant further states that these people are responsible for running the facility, leading the staff, managing all aspects of customer service and quality patient care, financial management and marketing. Advanced education is preferred but this position must be filled by a person with an RN degree with twelve (12) months experience in clinical nursing and a minimum of six (6) months nursing experience with chronic or acute dialysis patients.

Need Criterion 12: Staffing Qualifications

The Applicant confirms the staff will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D § 494.140.

Need Criterion 13: Staffing Time:

- a. The Applicant affirms when the unit is in operation, at least one (1) RN is on duty. The Applicant further states thee will be a minimum of two (2) people for each dialysis shift, one (1) of which will be an RN.
- b. The Applicant affirms a medical director, or a designated physician will always be on-site or on-call when the unit is in operation. The Applicant further states they have already established physician relationships in the area so a physician will be available to supplement the services of the medical director if needed.

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c. The Applicant affirms when the unit is not in operation the medical director or designated physician and an RN will be on call.

Need Criterion 14 - Data Collection:

The Applicant states that it records and maintains and will continue to record and maintain at a minimum, the aforementioned utilization data and data regarding services to indigent patients and shall make such information available to the Mississippi State Department of Health as required.

Need Criterion 15 - Staff Training:

The Applicant affirms they will provide and continue to provide an ongoing program of training in dialysis techniques for nurses and technicians at the facility. The Applicant states specifically Fresenius, and the Applicant offers a comprehensive training program for all direct patient care staff. The Applicant further states the training includes didactic and clinical training with qualified preceptors to build clinical skills and includes OSHA and mandatory Fresenius compliance training.

Need Criterion 16 - Scope of Privileges:

The Applicant affirms the facility shall provide access to Doctor of Medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility. The Applicant further states Fresenius Kidney Care has existing relationships with nephrologists in the service area, who currently treat the Applicant's patients, and will continue to treat the patients at the facility.

Need Criterion 17 - Affiliation with a Renal Transplant Center

The Applicant affirms as an existing provider of ESRD services, it has an existing affiliation agreement with a transplant center. The Transplant agreement was provided with the application (Exhibit G).

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, November 11, 2023, Revision*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

Need Criterion 1 – State Health Plan

The Applicant acknowledges an understanding that the project will be reviewed for consistency with the State Health Plan in effect at the time of submission. The Applicant further states the responses to the Plan criteria and standards demonstrate consistency with the Plan in effect at the time of submission, in compliance with General Review Criteria.

Need Criterion 2 – Long Range Plan:

The Applicant states Fresenius Kidney Care's long-range plan is to provide its patients with the best quality of care and improve their overall health by offering desirable time slots for treatment at a convenient time and place. The Applicant states dialysis treatment is typically required three (3) times a week. The Applicant further states it is vital that Fresenius offer enough time slots for treatment, so that its patients can receive treatment and improve their overall health and quality of life. The Applicant states Fresenius Kidney Care has determined expanding the station authority at its North Jackson location would be the best possible route for providing continuity of care.

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Need Criterion 3 - Availability of Alternatives:

a. Advantages and Disadvantages of Alternatives:

The Applicant states they discussed not moving forward with the Fifteen (15) station expansion request, but it would not address the continued increased utilization it is experiencing. The Applicant further states they have seen a steady increase in utilization over the past year and anticipates increased patient use. The Applicant states to ensure that patients continue to receive quality access to care, the increase in the station authority at the Applicant is needed. Therefore, the Applicant states, Fresenius Kidney Care chose to move forward with the fifteen (15)-station expansion request.

b. New Construction Projects:

The Applicant states this statement is not applicable to the proposed project.

c. Beneficial Effects to the Health Care System:

The Applicant states the proposed fifteen (15) station expansion will effectively and efficiently meet the needs of dialysis patients in the area by allowing patients to continue to receive life-saving treatment with the least amount of disruption to patient care.

d. Effective and Less Costly Alternatives:

i. Unnecessary Duplication of Services

The Applicant states the proposed expansion is not an unnecessary duplication of services due to the increased utilization at the facility. The Applicant further state patients in the metro area are in need of life-saving dialysis treatment and ensuring they will have appropriate access to care is essential to their overall health.

ii. Efficient Solution:

The Applicant states the proposed expansion will increase the availability of appointment times, allowing patients to receive optimal care with the least amount of disruption to patient care.

e. Improvement and Innovations:

The Applicant states its relationship with Fresenius greatly benefits the proposed expansion due to Fresenius' integrated delivery and service model. The Applicant states this association will also ensure quality of care to the residents of Jackson, Hinds County, and the surrounding area. The Applicant further states that each dialysis patient will benefit from the expertise and experience of the nation's largest dialysis provider and its extensive clinical network. The Applicant submits this affiliation also helps provide and promote the delivery of health care services in a cost- effective manner.

f. Relevancy:

The Applicant states they have experienced an increase in utilization over the past year and anticipates increased patient use. The Applicant submits, to ensure patients continue to receive quality access to care, the increase in station authority at the Applicant is needed. The Applicant further states, patients in the metro area are in need of life saving dialysis treatment. The Applicant asserts the proposed expansion will increase the availability of appointment times, and thus, effectively and efficiently meet the needs of dialysis patients to continue to receive life-saving treatment. The Applicant states Fresenius Kidney Care anticipates that

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approximately twenty-five (25) new patients start each year, and this trend is expected to increase. The Applicant states the relationship with Fresenius greatly benefits the proposed expansion due to Fresenius' integrated delivery and service model. The Applicant further states this association helps support quality of care to Jackson area residents.

Need Criterion 4 – Economic Viability:

- a. The Applicant states the charges are expected to remain substantially the same.
- b. The Applicant states the projected utilization was determined by reviewing current ESRD patients at the facility and patients in the area that would benefit from receiving services closer to their residence to decrease transportation times.
- c. The Applicant states this statement is not applicable to this project.
- d. The Applicant states this statement is not applicable to this project.
- e. The Applicant states the ESRD reimbursement environment, and the patient population of any area are ever- changing; however, the Applicant states they have the financial strength to operate the facility at a loss, if necessary.
- f. The Applicant states the project will not increase the cost of dialysis services to patients or Medicaid. The Applicant further states the experience gained by Fresenius Kidney Care in effectively operating other ESRD facilities in the service area and across the State will help ensure that there will not be a negative effect on the cost of healthcare as it is associated with this project. The Applicant asserts its affiliation with the Fresenius Kidney Care's network and its integrated delivery system also helps to control healthcare costs.

Need Criterion 5 – Need for Project:

- a. The Applicant states, dialysis services are provided and will continue to be provided to these traditionally underserved groups, including low-income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly.
- b. The Applicant states this statement is not applicable to this project.
 - **I.** The Applicant states this statement is not applicable to this project.
 - II. The Applicant states this statement is not applicable to this project.
- c. The Applicant states that dialysis is not an elective service, but a service required for ESRD patients. The Applicant states that they propose to serve the facility's current and projected patients. The Applicant further states Fresenius utilization justifies and supports the need for the expansion of stations to ensure access for services now and into the future. The Applicant states the affiliated facilities will work to assist patients in receiving required dialysis in an available location that aligns with their time and transportation needs. The Applicant submits the expansion will help improve accessibility for dialysis patients as many patients are dependent on caregivers and transportation services to come to an ESRD facility to receive dialysis. The Applicant anticipates the expanded stations will primarily serve its patient population, including those currently receiving care at affiliated facilities and under the care of its supporting nephrologists. The Applicant further

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states the expansion will allow patients to receive additional access to life-saving treatment.

- d. The Applicant states Fresenius Kidney Care believes that the expansion of stations at the existing ESRD facility will not impact the utilization at other surrounding affiliated facilities. The Applicant further states the expansion will allow patients to receive additional access to life-saving treatment.
- e. The application included eight (8) support letters from Fresenius Kidney Care of North Jackson (Exhibit I).

The Department also received a letter in opposition for the proposed project on behalf of DaVita Kidney Care ("DaVita"). DaVita argues that the proposed project does not substantially comply with the FY 2022 State Health Plan, Third Edition or the Certificate of Need Review Manual. DaVita further claims the proposed project will have an adverse impact to surrounding ESRD facilities.

Need Criterion 6 - Access to the Facility or Service

- a. The Applicant states that medically underserved populations currently have access to Fresenius Kidney Care and will continue to have access to the expanded ESRD stations proposed in the Application. The Applicant states the facility currently provides services to medically underserved populations including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly and will continue to do so. The Applicant estimates that approximately 95% of its current are in this medically underserved category. The Applicant further states that this utilization is anticipated to remain consistent as patients generally reside in proximity to the unit and given that many ESRD patients also fall into the category of medically underserved. Charts of the most recent data from the United States Renal Data System ("USRDS") Annual Data Report was included in the application.
- 1. According to the Applicant, all patients of the health planning 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.
- 2. According to the Applicant residents will have access to the proposed services and/or facility as described in the application.
- 3. The following table shows the Gross Patient Revenues' historical year for 2023 and 2024, as well as the projected Year 1 and projected Year 2 for medically indigent/Charity Care patients:

Gross Patient Revenue							
	Medically Indigent (%)	Charity Care (%)	Medically Indigent (\$)	Charity Care (\$)			
Historical Year 2023	6%	1%	\$215,421.00	\$36,167.00			
Historical Year 2024	5%	1%	\$393,427.00	\$78,685.00			
Projected Year I	5%	1%	\$436,905.00	\$87,381.00			
Projected Year 2	5%	1%	\$481,965.00	\$96,393.00			

^{*}Patients without a payor source receive benefits after a 90-day waiting period. The 90-day waiting period results in what is considered by the Applicant as medically indigent/charity care.

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- This facility does not have existing obligations under any federal regulation requiring provision of uncompensated care, community service, or access by minority/handicapped persons.
 - I. The Applicant states this statement is not applicable to this project.
- c. The Applicant states all patients with ESRD must receive dialysis services. The Applicant further states expansion of stations at the existing facility will make these life-saving services more accessible for the Medicare, Medicaid and medically indigent ESRD patients residing in Jackson and the metro area.
- d. The Applicant states the facility's hours of operation are 6:00 a.m. to 5:00 p.m., six (6) days per week, however, alternate times will be available by arrangement. In addition, the Applicant states Medicaid recipients can receive transportation assistance for travel to dialysis appointments.
- e. i. The Applicant states the facility is conveniently located off 1-55 Frontage Road in Jackson, MS.
 - ii. The application includes a copy of the facility's admission's policy (Exhibit J).
 - iii. The Applicant further states that they will continue to provide care to medically indigent patients. The Applicant submits all patients not otherwise covered by insurance qualifies for Medicare/Medicaid after an initial ninety (90) day waiting period. The Applicant affirms that indigent/charity care provided by the Fresenius Kidney Care is calculated by estimating the percentage of patients who will be subject to the ninety (90) day qualification period. The Applicant does not anticipate receiving any reimbursement for those patients within this Ninety (90) day period.

Need Criterion 7 – Information Requirement:

The Applicant affirms they will record and maintain, at a minimum, the following information regarding charity care to the medically indigent, and Medicaid populations and make it available to the Department with in fifteen (15) business days of request: utilization data e.g., number of indigent, Medicaid, and charity admissions, and patient days of care; age race sex, zip code and county of origin of patient cost/charges per patient day and/or cost/charges per procedure, if applicable; and any other data pertaining directly or indirectly to the utilization of services by medically indigent, Medicaid, or charity patients which may be requested, i.e., discharge diagnosis, service provided, etc.

Need Criterion 8 – Relationship to Existing Health Care System:

b. The Applicant states the target population accesses dialysis treatment at the Applicant's facility and surrounding dialysis facilities in the Jackson metro area. See Attachment 3 for a list of ESRD facilities within a 30-mile radius of the proposed project.

C.

i. Complement Existing Systems

The Applicant states that they have experienced an increase in utilization over the past year and anticipates increased patient use. The Applicant further states to ensure patients continue to receive quality access to care, the increase in station authority is needed. The Applicant asserts the proposed expansion is not an unnecessary duplication of services due to the increased utilization at the facility. The Applicant states Fresenius Kidney Care anticipates at least twenty-five (25) new patients will start

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each year in this size facility. The Applicant states these patients must receive life-saving dialysis treatment, and it is essential to their overall health that they receive appropriate access to care. The Applicant states patients receiving dialysis have been diagnosed with ESRD and further states, patients with ESRD receive Medicaid and Medicare coverage. The Applicant states the proposed project will not increase the cost of dialysis services to patients or Medicaid, and the addition of stations does not increase the patient population. The Applicant further states the expansion of stations does not increase the ESRD diagnosis.

ii. Provide Alternate or Unique Service

The Applicant asserts its relationship with Fresenius Kidney Care greatly benefits the proposed expansion due to Fresenius Kidney Care's integrated delivery and service model. The Applicant states that this association will also ensure quality of care to residents of Jackson, Hinds County, and the surrounding area. The Applicant further states that each dialysis patient will benefit from the expertise and experience of the nation's largest dialysis provider and its extensive clinical network. The Applicant submits this affiliation also helps provide and promote the delivery of health care services in a cost-effective manner.

iii. Provide a Service for a Specific target Population

The Applicant states the target population accesses dialysis treatment at the Applicant's facility and surrounding dialysis facilities in the Jackson metro area. The Applicant states only patients with ESRD receive services at the Applicant.

vi. Provide Services for which there is an unmet need.

The Applicant states all patients with ESRD must receive dialysis services. The Applicant states the expansion of stations at the existing facility will ensure that these services are available for the Applicant's patients and those that will be diagnosed with ESRD in the future.

Need Criterion 9 – Availability of Resources:

- a. The Applicant states other ESRD facilities affiliated with the Applicant have successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of their current facilities. The Applicant states Fresenius Kidney Care proposes to continue to use this method. The Applicant further states its facility is currently sufficiently staffed and already has relationships with adequate nephrologists to support the expansion of stations. The Applicant states in the event there is a shortage of staff at the facility, the affiliation with the closest facilities will allow the Applicant and other facilities to supplement and share staff if ever necessary.
- b. The Applicant states this statement is not applicable to this proposed project.
- c. The Applicant states other ESRD facilities affiliated with the Applicant have successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of their current facilities. The Applicant further states that they propose to continue to use this method. The Applicant states its facility is currently sufficiently staffed and already has relationships with adequate nephrologists to support the expansion of stations. The Applicant further states in the event there is a shortage of staff at the facility, the affiliation with the closest facilities will allow the Applicant and these other facilities to supplement and share staff if necessary.

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d. The Applicant states that this statement is not applicable to this proposed project.

Need Criterion 10– Relationship to Ancillary or Support Services:

- a. The Applicant (and its affiliates) affirms to have necessary support and ancillary services for the facility's proposed expansion. The Applicant states due to the relationship with Fresenius Kidney Care and the surrounding medical community, all ancillary services will be sufficiently available including laboratory services, drugs and any necessary services related to the method in which a patient chooses to receive dialysis services.
- b. The Applicant states that this statement is not applicable to this proposed project.
- c. The Applicant states that this statement is not applicable to this proposed project.

Need Criterion 11– Health Professional Training Programs:

The Applicant affirms it cooperate with health professional training programs in the surrounding area.

Need Criterion 12- Access by Health Professional Schools:

The Applicant agrees to cooperate to meet the clinical needs of health professional trainings in the surrounding area.

Need Criterion 13 - Access to Individuals Outside Service Area:

The Applicant states this statement is not applicable to this proposed project.

Need Criterion 14– Construction Projects:

The Applicant states this statement is not applicable to this proposed project.

Need Criterion 15 – Competing Applications:

As of June 9, 2025, there are no competing applications on file with the Department.

Need Criterion 16– Quality of Care

a. The Applicant states that every patient receiving dialysis has at least one (1) serious and chronic disease, ESRD, for which there is no cure other than a transplant. The Applicant states meeting the criteria for a transplant is not only difficult for the patient and their caregiver, but there are also a limited number of kidneys available for a transplant. The Applicant states that they seek to provide the best quality of care to a life-long condition. The Applicant states that they meet the Mississippi average for removing enough waste from the patient's blood and balancing calcium levels. The Applicant further state they exceed national standards, where Mississippi specific standards are not provided, for the use of fistulas; preventing hospital admission and readmission; patient deaths; transplants and transplant waiting list; preventing bloodstream infections; preventing emergency department visits; and preventing emergency visits within thirty (30) days of hospital discharge. The Applicant states continuous provision of services and these national, Medicare metrics demonstrate quality of care at the facility.

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- b. The Applicant states that patients in and around the Jackson metro area will continue to receive quality life-saving treatment from the provider. The Applicant further states the expansion will ensure that overcrowding does not occur and that patients continue to receive care with the least amount of disruption to their treatment routines as possible.
- c. The Applicant states there are no accreditation and/ or certifications held for the proposed project.

IV. FINANCIAL FEASIBILITY

A. <u>Capital Expenditure Summary</u>

Cost Item	Projected Cost	Percentage (%) of Total
Construction Cost – New	\$0	0%
Construction Cost - Renovation	\$1,258,261.00	67.14%
Capital Improvements	\$0	0%
Total Fixed Equipment Cost	\$220,000.00	6.86%
Total Non-Fixed Equipment Cost	\$65,027.00	9.10%
Land Cost	\$0	0%
Site Prep Cost	\$0	0%
Fees	\$128,550.00	11.74%
Contingency Reserve	\$170,368.00	3.46%
Capitalized Interest	\$0	0%
Other	\$31,845.00	1.70%
Total Proposed Expenditures	\$1,874,051.00	100.00%

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

The Applicant submitted a Financial Analysis with the application (Exhibit L). The Applicant states 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 of this Staff Analysis. Utilization, cost, and charges are also included in the applicant's Three-Year Projected Operating Statement (Exhibit M).

D. Cost to Medicaid/Medicare

Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson provides the following gross patient revenue projections with the proposed project for each payor source category listed below.

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Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson					
Payor Source	Utilization Percentage*	First Year Revenue			
Medicare	51.34%	\$ 1,613,071.00			
Medicaid	3.43%	\$ 107,778.00			
Commercial	27.80%	\$ 873,512.00			
Self-Pay	0.49%	\$ 15,507.00			
Charity	1.00%	\$ 31,420.00			
Other	15.94%	\$ 500,755.00			
Total	100.00%	<u>\$ 3,142,043.00</u>			

^{*}Utilization Percentages were rounded.

V. Recommendation of Other Affected Agencies

The Division of Medicaid was provided a copy of this application for review and comment. The Division has not commented on the project as of June 2025.

VI. Conclusion and Recommendation

This project is in substantial compliance with the criteria and standards for the expansion of an existing ESRD facility as contained in the FY 2022 State Health Plan; the Mississippi Certificate of Need Review Manual, Revised November 11, 2023; 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 Kidney Care North Jackson for expansion of stations at its existing ESRD facility.

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Attachment 1 Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson Three-Year Operating Statement with Project

	Year 1		Year 2		Year 3
\$	0	\$	0	\$	0
	•	1.	•	1 '	3,604,262
\$		1 '	3,369,237	\$	3,604,262
\$	31,420	\$	33,692	\$	36,043
	157,102		168,462		180,213
\$	2,953,521	\$	3,167,083	\$	3,388,006
\$	0	\$	0	\$	0
\$	2,953,521	\$	3,167,083	\$	3,388,006
\$	795,602	\$	853,130	\$	912,641
	223,970		240,165		256,918
	623,580		668,669		715,313
	0		0		0
	0		0		0
	165,435		165,435		165,435
	0		0		0
	0		0		0
\$	1,808,587	\$	1,927,399	\$	2,050,307
\$	1,144,934	\$	1,239,684	\$	1,337,699
ı	Proposed Year 1		Proposed Year 2	ı	Proposed Year 3
	0		0		0
	0		0		0
	· · · · · · · · · · · · · · · · · · ·				9,288
					0
	-		-		0
					388
	~				0
\$	215	\$	218	\$	0 221
	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$	\$ 0 \$ 3,142,043 \$ 3,142,043 \$ 31,420 157,102 \$ 2,953,521 \$ 0 \$ 2,953,521 \$ 795,602 223,970 623,580 0 0 \$ 1,808,587 \$ 1,144,934 Proposed Year 1 0 0 8,424 \$ 0 \$ 373 \$ 0 \$ 0	\$ 0 \$ 3,142,043 \$ \$ 3,142,043 \$ \$ 157,102 \$ 2,953,521 \$ \$ 0 \$ \$ 2,953,521 \$ \$ \$ 795,602 \$ 223,970 \$ 623,580 \$ 0 0 \$ 165,435 \$ 0 \$ \$ 1,808,587 \$ \$ 1,144,934 \$ \$ Proposed Year 1 \$ 0 \$ 0 \$ 8,424 \$ 0 \$ \$ 0 \$ \$ 3,73 \$ \$ 0 \$ \$ \$ 3,73 \$ \$ 0 \$ \$ \$ 0 \$ \$	\$ 0 \$ 0 \$ 3,142,043 \$ 3,369,237 \$ 3,142,043 \$ 33,692 157,102 168,462 \$ 2,953,521 \$ 3,167,083 \$ 0 \$ 0 \$ 2,953,521 \$ 3,167,083 \$ 795,602 \$ 853,130 223,970 240,165 623,580 668,669 0 0 0 0 0 165,435 165,435 0 0 0 165,435 1,927,399 \$ 1,808,587 \$ 1,927,399 \$ 1,144,934 \$ 1,239,684 Proposed Year 1 2 0 0 0 0 8,424 8,856 \$ 0 \$ 0 \$ 0 \$ 0 \$ 373 \$ 380 \$ 0 \$ 0 \$ 0 \$ 0	\$ 0 \$ 0 \$ 3,369,237 \$ \$ 3,142,043 \$ 3,369,237 \$ \$ 31,42,043 \$ 33,692,237 \$ \$ \$ 157,102 \$ 168,462 \$ 2,953,521 \$ 3,167,083 \$ \$ \$ 0 \$ 0 \$ \$ \$ 2,953,521 \$ 3,167,083 \$ \$ \$ \$ 0 \$ 0 \$ \$ \$ 223,970 \$ 240,165 \$ 623,580 \$ 668,669 \$ 0 \$ 0 \$ 0 \$ \$ 165,435 \$ 0 \$ 0 \$ \$ 1,808,587 \$ 1,927,399 \$ \$ \$ 1,144,934 \$ 1,239,684 \$ \$ \$ Proposed Year 1 2 \$ 0 0 0 \$ 0 \$ 0 \$ 0 \$ 0 \$ 0 \$ 0 \$ 0 \$

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Attachment 2 Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson Nephrologists and Physicians

Below is a list of Nephrologists and Physicians

Central Nephrology Clinic 1010 Lakeland Square Ext Ste A Flowood, Mississippi 39232

Mark N.A. Klein, M.D.
Ami R. Patel, M.D.
F.M. Phillippi IV, M.D.
Mohit Ahuja, M.D.
Derrick H. Tesseneer, M.D.
Naveen S. Sandhu, M.D.
Daphne M. Bilbrew, M.D.
Lee M. Ferguson, M.D.
Lindsey T. Norris, M.D.
Steven J. Wagner, M.D.
Karthikeyan Venkatachalam, M.D.
Vipin S. Patel, M.D.

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Attachment 3 Bio-Medical Applications of Mississippi, Inc. d/b/a Fresenius Kidney Care North Jackson ESRD Facilities within a 30-mile Radius

The Applicant listed below fourteen (14) ESRD Facilities in Service Area 5.

ESRD Facilities in Service Area

Fresenius Kidney Care Central Dialysis 381 Medical Drive Jackson 39216 (-4.1 miles)

Fresenius Kidney Care Southwest Jackson 1856 Hospital Drive Jackson 39204 (-13.1 miles)

Fresenius Kidney Care Rankin County - Brandon 209 Mar Lyn Drive Brandon 39042 (-16.7 miles)

Fresenius Medical Care - Lakeland Home Program 1010 Lakeland Square Ext., Suite A Flowood 39232 (-6.3 miles)

Fresenius Medical Care - Mid Mississippi 656 North State Street Jackson 39202 (-6.7 miles)

Fresenius Medical Care - Southwest Jackson Home 1421 North State Street, Suite 501 Jackson 39202 (-5.5 miles)

Fresenius Medical Care- West Hinds 105 Johnston Place Clinton 39056 (-18.0 miles)

NRI - Brandon 101 Christian Drive Brandon 39042 (-16.7miles)

NRI-Canton 620 East Peace Street Canton 39046 (~20.5 miles)

NRI-Jackson North 571 Beasley Road Jackson 39206 (~2.1 miles)

NRI - Jackson South 1015 I-20 Frontage Road Jackson 39204 (~9.5 miles)

NRI - Jackson Southwest 1828 Raymond Road Jackson 39204 (~13.7 miles)

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University Pediatric & ESRD Adult Outpatient Clinic 2500 North State Street
Jackson 39216 (~4.5miles)

University Hospital and Clinics Outpatient Dialysis -Jackson 350 Woodrow Wilson Ave, Suite 479 Jackson 39213 (~6.3 miles)