

**DIVISION OF HEALTH PLANNING
AND RESOURCE DEVELOPMENT
OCTOBER 29, 2018**

**CON REVIEW NUMBER: ESRD-NIS-0918-010
FRESENIUS MEDICAL CARE DOGWOOD, LLC
D/B/A FRESENIUS KIDNEY CARE DOGWOOD
ESTABLISHMENT OF A SATELLITE ESRD FACILITY
LOCATION: FLOWOOD, RANKIN COUNTY, MISSISSIPPI
CAPITAL EXPENDITURE: \$3,865,678.62**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Fresenius Medical Care Dogwood, LLC d/b/a Fresenius Kidney Care Dogwood is a Delaware limited liability company, authorized to do business in the state of Mississippi. The application contains a Certificate from the Office of the Secretary of State, Jackson, Mississippi, indicating that as of September 12, 2018 the entity was in good standing with the State of Mississippi. Fresenius Medical Care Dogwood, LLC has four (4) officers.

B. Project Description

Fresenius Medical Care Dogwood, LLC d/b/a Fresenius Kidney Care Dogwood (“Kidney Care Dogwood”) requests certificate of need (CON) authority to establish a ten (10) station satellite end stage renal dialysis (“ESRD”) facility to be located at 205B Belle Meade Point in Flowood. According to the applicant, the proposed satellite location is less than seven (7) miles from Fresenius Medical Care Dialysis Services of Rankin County – Brandon (the “host facility”) located at 209 Mar Lyn Drive in Brandon, Mississippi.

The applicant submits that the host facility is experiencing access and crowding issues at its current occupancy rate of 63.46%. Therefore, the applicant proposes to offer a satellite facility for patients to receive necessary dialysis services in the Flowood, Rankin County area.

The applicant asserts that a developer will construct the shell of the building and Kidney Care Dogwood will undertake the interior build-out needed to provide ESRD services in the building. The proposed construction and build-out will include building the shell, interior studs, drywall, floor, wall and ceiling finishes, interior doors, casework, specialty items, plumbing, HVAC and electrical systems. According to the applicant, the total rentable area is 11,040 square feet.

The applicant affirms that Kidney Care Dogwood will comply with building codes, zoning ordinances and other appropriate regulatory authority. In addition, the

applicant confirms that it will comply with all applicable 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 contains a schematic drawing and a cost estimate from Donald C. Brown, Architect, authorized to do business in the State of Mississippi. In addition, the Bureau of Health Facilities Licensure and Certification approved the site for the satellite facility in Flowood on September 13, 2018.

The proposed capital expenditure of \$3,865,678.62 includes land cost - \$975,000, building cost - \$2,495,212, fixed and non-fixed equipment - \$219,675, and project development cost - \$175,792 (see the Financial Feasibility Section of this Staff Analysis for a complete breakdown of expenditures). The applicant anticipates that the capital expenditure will be obligated within six (6) months of final CON approval and that the proposed project will be complete within one (1) year of final CON approval.

Fresenius Kidney Care Dogwood projects that the project will require 12.1 full time equivalent personnel at an estimated annual cost of \$1,111,700.

The applicant submits that its final objective for the project is to provide Flowood and Rankin County area dialysis patients with an additional access point to receive necessary dialysis treatment and to relieve the patient load at other Fresenius-affiliated facilities in the area.

II. TYPE OF REVIEW REQUESTED

This project for the establishment of an end stage renal disease satellite facility is reviewed in accordance with Section 41-7-191(1)(a)-(b) of the Mississippi Code of 1972 Annotated, as amended. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual, April 9, 2017, Revision*; all adopted rules, procedures, and plans of the MSDH.

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 publication of the staff analysis. The opportunity to request a hearing expires November 8, 2018.

III. CERTIFICATE OF NEED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2018 Mississippi State Health Plan* (FY 2018 MSHP) contains policy statements, and service specific criteria and standards which the applicant is required to meet before receiving CON authority to establish a ten-station satellite ESRD facility. This application is in substantial compliance with applicable criteria and standards.

Policy Statement No. 11 of the FY 2018 State Health Plan provides that any existing ESRD facility which reaches a total of 30 ESRD stations may establish a ten (10) station satellite facility. However, if the proposed ESRD facility is to be located more than one (1) mile from the existing facility, a CON must be obtained by the facility prior to the establishment of the satellite facility. The applicant indicates that the proposed satellite facility to be located in Flowood is located 6.3 miles from the host facility. Therefore, the applicant has submitted this CON application.

According to the applicant Fresenius Kidney Care-Rankin County, the host facility, operated thirty-six (36) ESRD stations during FY 2016.

SHP Need Criterion 3

If the proposed satellite facility will be established at a location between a five and thirty mile radius of the existing facility, the facility must demonstrate compliance with the following criteria:

- (a) Document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application;**

The Applicant asserts that the host facility is experiencing a 63.46% utilization rate on its thirty-six (36) stations, which includes the 10 stations to be relocated.

- (b) Justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility;**

According to Fresenius Kidney Care Dogwood, the satellite facility will provide ESRD patients an additional access point for dialysis services to help reduce crowding issues experienced at nearby facilities and the host facility, provide improved patient care and enable patients to have flexibility with appointment times. The applicant asserts that the proposed project will also improve the efficiency of services provided to patients utilizing the host facility.

- (c) Document that it is more cost effective to establish a satellite facility than to expand the existing facility; and**

The applicant asserts that in order to expand the existing facility, additional construction would need to be undertaken, which would disrupt patient care; therefore, the most cost effective solution is to establish the proposed satellite facility. The application contains a signed cost estimate for the project.

(d) Demonstrate that the proposed satellite facility's location is not within thirty miles of an existing facility without obtaining the existing facility's written support.

The applicant affirms that the proposed satellite facility is located within a five mile radius of the host facility. No letter of opposition were received for the proposed project.

SHP Need Criterion 4 – Number of Stations

The applicant proposes to establish a 10-station satellite ESRD facility.

SHP Need Criterion 5 – Minimum Utilization

Fresenius Kidney Care Dogwood confirms that the projected utilization will meet the minimum utilization requirements. Based on the applicant's projections of the number of treatments, staff determined that the facility will serve 32.5 patients the first year, 42.25 the second year and 48.75 the third year. Each patient is estimated to receive 144 treatments per year. Typically, an ESRD patient receives three (3) treatments per week or 156 treatments per year. The following table indicates the applicant's projections for the first three years of operation:

		Applicant's Projections	
Year	Stations	Treatments	Utilization Rate
1	10	4,680	50%
2	10	6,084	65%
3	10	7,020	75%

The *FY 2018 MSHP* recognizes that an applicant may not meet optimum utilization (65%) of 10 stations by the end of the first year; however, it requires an applicant to show that it will meet 50% utilization by the end of the first year and 65% utilization by the end of its third year. As demonstrated above, the applicant has met this requirement.

SHP Need Criterion 6 – Minimum Services

The applicant affirms that it will provide, at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.

SHP Need Criterion 7 – Access to Needed Services

The applicant states that it will provide reasonable access to equipment and facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Need Criterion 8 – Hours of Operation

According to the applicant, the normal facility hours of operation will be Monday through Saturday from 6:00 a.m. to 5:00 p.m. The applicant affirms that alternative arrangements will be made for those patients needing after-hours treatments.

SHP Need Criterion 9 – Home Training Program

The applicant affirms that a home-training program will be available, and it will counsel all patients on availability of and eligibility requirements to enter the home/self-dialysis program.

SHP Need Criterion 10 – Indigent/Charity Care

Fresenius Kidney Care Dogwood states that the proposed facility will not have admissions policies which will adversely affect access to care by indigents. It projects that it will provide approximately 2% indigent/charity care.

SHP Need Criterion 11 – Facility Staffing

The applicant asserts that staffing for the proposed facility will consist of 3.0 full time equivalent (FTE) registered nurses, 6.0 FTE aides, 0.5 FTEs dietician, 0.5 FTE technical/paramedical, 0.8 FTE social workers, and 1.3 FTE administrative/management.

SHP Need Criterion 12 – Staffing Qualifications

The applicant affirms that staff will meet, at a minimum, all requirements and qualifications as stated in 42 C.F.R., Subpart D. §494.140.

SHP Need Criterion 13 – Staffing Time

The applicant affirms that: (a) when the unit is in operation, at least one (1) RN will be on duty and that there will be a minimum of two (2) persons for each dialysis shift; (b) a medical director or a designated physician will be on-site or on-call at all times when the unit is in operation; and (c) when the unit is not in operation the medical director or designated physician and an RN will be on call.

SHP Need Criterion 14 – Data Collection

The applicant affirms that it shall record and maintain required utilization data and data regarding services provided to indigent patients and shall make such information available as required by the Department.

SHP Need Criterion 15 – Staff Training

The applicant affirms that it will provide an ongoing program of training for nurses

and technicians in dialysis techniques at the facility. It states that specifically, Fresenius and the Applicant will offer a comprehensive training program for all direct patient care staff, to include didactic and clinical training with qualified preceptors to build clinical skills and includes OSHA and mandatory Fresenius compliance training.

SHP Need 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 governing body of the facility. The applicant asserts that it has existing relationships with nephrologists in the area who currently treat the applicant's patients and will continue to treat the patients at the proposed facility.

SHP Need Criterion 17 – Affiliation with a Renal Transplant Center

Fresenius Kidney Care Dogwood affirms that it will enter into an affiliation agreement with at least one transplantation center within one (1) year of commencing operation in accordance with the above-stated requirements. The applicant further affirms its understanding and agreement that failure to comply with this criterion may, after due process, result in revocation of the CON.

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

The application is in compliance with the policy statements and service specific criteria and standards contained in the *FY 2018 State Health Plan* pertaining to the establishment of a ten (10) station satellite ESRD facility.

GR Criterion 2 - Long Range Plan

Fresenius Kidney Care Dogwood states that its long-range plan is to provide high quality, easy access to care for Mississippi residents in need of dialysis services in and near Rankin County. The applicant believes that the proposed satellite facility will offer a less congested environment for patients and greater accessibility for patients to receive necessary dialysis services at more flexible times in the Rankin County area.

GR Criterion 3- Availability of Alternatives

The applicant states that it considered not establishing a satellite facility in Flowood and continuing to treat patients at its existing host facility; however, it was determined that expansion at the host facility was not the best option. The applicant believes that the satellite facility will create another access point, and is still close enough to the host facility to not significantly disrupt patients' weekly schedules. Therefore, the applicant deems the creation of the satellite a more efficient and cost-effective solution for crowding issues than expanding the host facility. Furthermore, the applicant states that the satellite facility will increase the availability of more desirable appointment times in a less crowded environment.

GR Criterion 4 - Economic Viability

Based on the applicant's projections, the project will have a net income of \$789,611 the first year, \$1,177,480 the second year and \$1,451,172 the third year of operation.

- a. **Proposed Charge.** Fresenius Kidney Care Dogwood states that the charges will be substantially the same as the applicant's affiliates in the area.
- b. **Projected Levels of Utilization.** The applicant states that the projected utilization was determined by reviewing current ESRD patients receiving treatment at the host facility. Dialysis patients receive on average three (3) treatments per week. The applicant estimates that each patient will receive approximately 144 treatments since patients at time miss appointments, are in the hospital, or receive transplants. The applicant projects 50% utilization the first year, 65% utilization the second year and 75% utilization the third year of operation.
- c. **Projects Financial Feasibility Study.** The applicant asserts that it has the financial strength to operate the facility at a loss, if necessary. The application contains a letter from the Vice President of Finance for Fresenius, attesting to the financial feasibility of this project.

Further, the applicant states that the project will not increase the cost of dialysis services to patients or Medicaid. The applicant asserts that the experience gained by Fresenius 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 health care as it is associated with this project.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served.** The applicant submits that Fresenius Kidney Care provides dialysis services and will continue to provide dialysis services to low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly.

- b. Relocation of Service.** The applicant proposes to relocate ten (10) ESRD stations from the Brandon facility to the Flowood location. The applicant states that the proposed project seeks to provide dialysis patients with another access point in Rankin County.
- c. Probable Effect on Existing Facilities in Area.** The applicant states that the establishment of the satellite facility will slightly decrease the utilization at other surrounding, affiliated facilities as those Fresenius dialysis patients in the area will seek services at the satellite facility since it will be more accessible for certain patients and not as crowded.
- d. Community Reaction.** The Applicant received eight (8) letters of support from physicians and ten (10) letters from patients in support of the proposed project.

GR Criterion 6 –Accessibility

Fresenius Kidney Care Dogwood submits that all residents of the health planning service area, hospital service area or patient service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly have access to the services of the existing facility and will continue to have access. A copy of the applicant’s admissions policy is included in the application.

The percentage of gross patient revenue and actual dollar amount of health care projected to be provided to medically indigent and charity care patients are presented below:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$1,351.98 (2%)
2	\$1,781.30 (2%)

The applicant states that 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.

The applicant submits that all patients with ESRD must receive dialysis services. According to the applicant, establishment of the satellite facility in Flowood will make these life-saving services more accessible and convenient for Medicare, Medicaid and medically indigent ESRD patients residing in Flowood and the surrounding area.

GR Criterion 7- Information Requirement

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

GR Criterion 8 - Relationship to Existing Health Care System

Fresenius Kidney Care Dogwood submits that the target population currently accesses dialysis treatment services at the applicant's host facility (FMC Dialysis Services of Rankin County – Brandon). The Applicant states that if the project is not implemented, current and future ESRD patients residing in the area will continue to travel to the host facility three times a week to receive necessary dialysis services.

The application contains copies of transfer agreements between the Applicant and The University of Alabama; The University of Mississippi Medical Center; Mississippi Baptist Medical Center; and Central Mississippi Medical Center, n/k/a Merit Health-Central.

The application contains eight (8) letters of support from practicing nephrologists and ten (10) letters of support from patients.

GR Criterion 9 - Availability of Resources

The Applicant asserts that 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 that the surrounding area has sufficient nephrologists to support the proposed facility; however, in the event there is a shortage of staff at the new facility, the affiliation with the closest facilities, will allow the Applicant and these other facilities to supplement and share staff if necessary.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant asserts that its affiliates have necessary support and ancillary services for their facilities, and the applicant will likewise provide all necessary support and ancillary services.

GR Criterion 11- Health Professional Training Programs

The applicant states that Kidney Care Dogwood will cooperate with health professional training programs in the surrounding area.

GR Criterion 12 – Access by Health Professional Schools

The applicant states it will cooperate to meet the clinical needs of health professional training programs in the surrounding area.

GR Criterion 13 – Service to Residents Outside Service Area

According to the applicant, this criterion is not applicable to this project.

GR Criterion 14 – Construction Projects

This project is not for construction. Therefore, this criterion is not applicable.

GR Criterion 15 – Competing Applications

There are no competing projects on file with the Department; therefore, this criterion is not applicable.

GR Criterion 16 - Quality of Care

The applicant asserts that affiliated facilities provide quality of care to their patients. The applicant further asserts that the target population currently receives dialysis treatment at the host facility (FMC Dialysis Services of Rankin County – Brandon). Fresenius Kidney Care Dogwood states that as the host facility is experiencing increased utilization, the proposed establishment of a satellite facility in Flowood will provide area patients with more convenient time slots to receive necessary dialysis treatment closer to home. The applicant states that their relationship with Fresenius will greatly benefit the proposed facility due to Fresenius’ integrated delivery and service model.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage (%) of Total*
Construction Cost - New	\$2,067,949	54.00%
Construction Cost - Renovation	\$ 0	0.00%
Capital Improvements	\$ 0	0.00%
Total Fixed Equipment Cost	\$ 205,500	5.00%
Total Non-Fixed Equipment Cost	\$ 14,175	*%
Land Cost	\$ 975,000	25.00%
Site Prep Cost	\$ 0	0.00%
Fees (architectural, consultant)	\$ 179,667	5.00%
Contingency Reserve	\$ 247,595	6.00%
Capitalized Interest	\$ 0	0.00%
Other : Legal & Acct. Fees	\$ 175,792	5.00%
Total Proposed Expenditures	\$3,865,678	100.00%

Note: Percentages have been rounded. * Insignificant amount (.4%).

B. Cost to Medicaid/Medicare

ESRD treatment is a Medicare entitlement. As such, the Medicare program will absorb a majority of the costs associated with this project. The cost to the Medicaid

program will be negligible.

The applicant's projections of gross patient revenue percentage and actual dollar amount to Medicare and Medicaid payor sources for the first year of operation is presented below:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)
Medicare	71.00%	\$2,373,401
Medicaid	1.00%	\$ 34,085
Commercial	26.00%	\$ 849,083
Self Pay	0.00%	\$ 6,465
Charity Care	0.00%	\$ 0
Other	2.00%	\$ 67,599
Total	100.00%	\$3,330,633

C. Effect on Operating Cost

The Applicant's projections of gross revenues for the first, second, and third years 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).

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. The Division asserts that no foreseeable increase in allowable costs to Medicaid will result as it relates to the proposed project. The Division of Medicaid does not oppose this project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of a satellite ESRD facility as contained in the *FY 2018 Mississippi State Health Plan*; Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2017, Revised*; and all adopted rules, procedures, and plans of the Mississippi Department of Health.

The Division of Health Planning and Resource Development recommends approval of this application submitted by Fresenius Medical Care Dogwood, LLC, d/b/a Fresenius Kidney Care Dogwood for the establishment of a satellite ESRD facility in Flowood.

ATTACHMENT 1
Fresenius Medical Care Dogwood, LLC d/b/a Fresenius Kidney Care Dogwood
Establishment of Satellite ESRD Facility
Three-Year Projected Operating Statement
(With Project)

	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient	\$	\$	\$
Outpatient	\$ 3,330,633	\$ 4,395,341	\$ 5,147,718
Gross Patient Revenue	\$ 3,330,633	\$ 4,395,341	\$ 5,147,718
Charity Care	-	-	-
Deductions from Revenue	-	-	-
Net Patient Revenue	\$ 3,330,633	\$ 4,395,341	\$ 5,147,718
Other Operating Revenue	-	-	-
Total Operating Revenue	\$ 3,330,633	\$ 4,395,341	\$ 5,147,718
Operating Expenses			
Salaries	\$ 808,744	\$ 1,072,520	\$ 1,262,239
Benefits	302,956	401,766	472,835
Supplies	572,107	751,264	875,488
Services	-	-	-
Lease	213,720	213,720	213,720
Depreciation	212,086	212,086	212,086
Interest	-	-	-
Other	431,408	566,505	660,178
Total Expenses	\$ 2,541,021	\$ 3,217,861	\$ 3,696,546
Net Income (Loss)	\$ 789,612	\$ 1,177,480	\$ 1,451,172
Assumptions			
Inpatient days			
Outpatient days			
Procedures	4,680	6,084	7,020
Charge per outpatient Procedure	\$712	\$722	\$733
Cost per Procedure	\$543	\$529	\$527

ATTACHMENT 2
Fresenius Medical Care Dogwood, d/b/a Fresenius Kidney Care Dogwood
Establishment of Satellite ESRD Facility
Computation of Construction and Renovation Cost

Cost Component	Total	New Construction	Renovation
New Construction Cost	\$2,067,949	\$2,067,949	
Renovation Cost	\$0		\$0
Total Fixed Equipment Cost	\$205,500	\$205,500	
Total Non-Fixed Equipment Cost	\$14,175	\$14,175	
Capital Improvement	\$0	\$0	
Land Cost	\$975,000	\$975,000	
Site Preparation Cost	\$0	\$0	
<i>Fees (Architectural, Consultant, etc.)</i>	\$179,667	\$179,667	\$0
<i>Contingency Reserve</i>	\$247,595	\$247,595	\$0
<i>Capitalized Interest</i>	\$0	\$0	\$0
<i>Other</i>	\$175,792	\$175,792	
Total Proposed Capital Expenditure	\$3,865,678	\$3,865,678	\$0

Square Footage	11,040	11,040	
<i>Allocation Percent</i>		100.00%	0.00%

Costs Less Land, Non-Fixed Eqt.& Cap. Improvement	\$2,876,503	\$2,876,503	\$0
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Cost Per Square Foot	\$244.63	\$244.63	\$0.00
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