

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
OCTOBER 1, 2018**

**CON REVIEW NUMBER: ESRD-NIS-0618-008
FRESENIUS MEDICAL CARE EAST MCCOMB DIALYSIS, LLC
ESTABLISHMENT OF SATELLITE ESRD FACILITY
CAPITAL EXPENDITURE: \$4,010,432.35
LOCATION: MCCOMB, PIKE COUNTY, MISSISSIPPI**

STAFF ANALYSIS

PROJECT SUMMARY

A. Applicant Information

Fresenius Medical Care East McComb Dialysis, LLC (FMC East McComb) is a limited liability company. The applicant indicates that FMC East McComb is governed by a two member Board of Directors and has fourteen officers.

The applicant provided a Certificate from the Secretary of State, verifying that the corporation was issued a Charter/Certificate of Authority on May 16, 2018. 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

Fresenius Medical Care East McComb Dialysis, LLC (FMC East McComb) requests Certificate of Need (CON) authority to establish a ten (10) station, satellite End Stage Renal Disease ("ESRD") facility in Pike County.

The applicant states that the proposed ten-stations will be relocated from RCG McComb, an affiliated thirty-two (32) station ESRD facility. RCG McComb is located at 1404 White Street in McComb, MS.

The applicant indicates that the proposed satellite facility will be located on Lots one (1) and two (2) of the Parklane Business Center off of Business Center Drive in McComb, Pike County, MS. The applicant declares that the proposed satellite ESRD facility will be located less than five (5) miles from RCG McComb (the host facility). The applicant affirms that the host facility's occupancy rate is sixty-four percent (64%) which has led to overcrowding and scheduling conflicts for its patients. The applicant states that the proposed facility will provide additional access to high quality ESRD services for residents of Pike County.

The applicant asserts that the developer will construct a new shell building for the satellite and will be responsible for the costs associated with the exterior construction. The applicant confirms that FMC East McComb will be responsible for costs associated with the interior build-out. The applicant states that FMC East McComb will lease approximately 8,160 square feet from PCI HealthDev (the developer) at an annual cost of \$138,720 for a lease term of ten (10) years.

The applicant states that the proposed build-out will include interior studs, drywall, floor, wall and ceiling finishes, interior doors, casework, specialty items, plumbing, HVAC and electrical systems. The construction will comply with all ordinances and regulations with a gross square footage of 8,160.

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

During the first year of operation the applicant expects to employ 6.6 full-time equivalent employees. The capital expenditure for the proposed project is \$4,010,432.35. The applicant indicates cash reserves will be used to fund the project.

The applicant states that the establishment of a satellite facility in Pike County will provide better opportunities for Pike County area patients to receive necessary dialysis services closer to home.

The applicant foresees that the anticipated date for obligation of capital expenditure of the proposed project is within six (6) months of final CON approval and the proposed completion of the proposed project within one (1) year of the start date.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Section 41-7-191(1)(a)-(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 10 days of the publication of the staff analysis. The opportunity to request a hearing expires on October 11, 2018. However, since October 11, 2018 is a Sunday, requests for a hearing will be accepted until Monday – October 12, 2018.

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

A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains policy statements and service specific criteria and standards which the applicant is required to meet before receiving CON authority to establish a ten-station satellite ESRD facility. This application is in substantial compliance with applicable criteria and standards.

Policy Statement No. 14 of the 2015 State Health Plan states “Any existing ESRD facility which reaches a total of 30 ESRD stations, may establish a ten (10) station satellite facility. If a proposed satellite ESRD facility is to be located more than one (1) mile from the existing facility, a certificate of need must be obtained by the facility prior to the establishment of the Satellite”.

According to the *FY 2015 State Health Plan*, RCG McComb, an affiliated facility has 32 certified and CON approved stations.

The applicant declares that the proposed satellite ESRD facility will be located within 5 (five) miles from RCG McComb. The applicant states that the proposed satellite facility will be located on Lots One (1) and Two (2) of the Parklane Business Center on Business Center Drive in McComb, Pike County, MS. The application contained a map demonstrating the distance between the proposed facility and RCG McComb.

The applicant is requesting CON approval for the establishment of a ten (10) station satellite ESRD facility in Pike County.

SHP Criterion 3- Need

Need Criterion for Establishment of ESRD Satellite Facilities: In order for a 30 station ESRD facility to be approved for the establishment of a ten (10) station satellite facility through the transfer and relocation of existing stations within a five mile radius or less from the existing facility, the facility must (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; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility. If the proposed satellite facility will be established at a location between a five and twenty-five mile radius of the existing facility, the facility must (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; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility; and (d) demonstrate that the proposed satellite facility's location is not within 30 miles of an existing facility without obtaining the existing facility's written support. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the establishment of satellite ESRD facilities. An ESRD satellite facility established under this Need Criterion 3 shall not be used or considered for purposes of establishing or determining an ESRD Facility Service Area.

(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 indicates that RCG McComb is currently experiencing 63.9% utilization.

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

The applicant believes that establishing a satellite facility will help improve efficiency at RCG McComb by decreasing utilization and provide ESRD patients in Pike County and surrounding areas a new access point for dialysis services. The applicant further suggests that the proposed project will provide improved patient care and enable patients to have flexibility with their appointment times.

(c) Document that it is more cost effective to establish a satellite facility than to expand the existing facility.

The applicant confirms that in order for the expansion of RCG McComb, additional construction would have to be undertaken, which would disrupt patient care. The applicant states that expansion of the host facility is not an option due to the host facility being landlocked and unavailability of space for lease. Therefore, the applicant suggests that the most cost effective and only solution is to establish the proposed satellite facility.

SHP Criterion 4 - Number of Stations

RCG McComb has 32 hemo-dialysis ESRD stations and will transfer ten (10) ESRD hemo-dialysis stations to the proposed satellite facility. The applicant affirms that the satellite ESRD facility will contain ten (10) hemo-dialysis stations. The applicant is in compliance with this criterion.

SHP Criterion 5 - Minimum Utilization

The applicant projects 32.5 patients in year one, 42.25 patients in year two, and 48.75 patients in year three for the proposed ten-station satellite ESRD facility. The applicant estimates that each patient would receive 144 treatments per year. Typically, an ESRD patient receives three treatments per week or 156 treatments per year. The following table compares the applicant's projections with the Department's requirements:

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

Based on MSDH's utilization requirements in the *FY 2015 MSHP* and numbers provided by applicant, staff determined the number of treatments for the first through third year of operation will be as follows:

MSDH Projections			
Year	Stations	Treatments	Utilization Rate
1	10	4,680	50%
2	10	6,084	65%
3	10	6,084	65%

SHP Criterion 6 - Minimum Services

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

SHP Criterion 7 - Access to Needed Services

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

SHP Criterion 8 - Hours of Operation

The applicant states that the normal facility hours will be Monday through Saturday between the hours of 6:00 a.m. to 4:00 p.m. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

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

SHP Criterion 10 - Indigent/Charity Care

The applicant affirms that the proposed facility will not have admission policies which adversely affect access to care by indigents, and will provide indigent/charity care. Furthermore, the applicant states that if the Applicant determines that a patient does not have insurance coverage, steps will be taken to determine whether viable coverage options exist.

The applicant states it will serve all ESRD patients, including Medicaid and Medicare recipients and approximately 1.5% indigent/charity care patients.

SHP Criterion 11 - Facility Staffing

The applicant proposes to hire the following: 1 FTE RN, 1 FTE licensed practical nurse, 2.5 FTE patient care and technical/paramedical which include 2 Patient Care Techs and 0.5 technical personnel, 0.3 FTE social worker, 0.3 FTE dietician, and 1.5 FTE administrative assistants. The applicant included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements), and specific duties. If the proposed project is CON approved, the applicant affirms that 6.6 full time equivalents will be utilized to operate the satellite ESRD facility.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D, Section 494.140.

SHP Criterion 13 - Staffing Time

The applicant affirms that when the unit is in operation, at least one (1) R.N. will be on duty and at least two (2) persons will be present for each dialysis shift, one of which will be an R.N. In addition, the applicant affirms that the medical director or a designated physician will be on site or on call at all times when the unit is in

operation. When the ESRD facility is not in operation, the applicant states that the medical director or a designated physician and one R.N. will be on call.

SHP Criterion 14 - Data Collection

The applicant affirms that it shall record and maintain all required data listed under SHP Criterion 14 and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 15 - Staff Training

The applicant asserts that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility. Specifically, the applicant states that Fresenius and the Applicant will offer comprehensive training program for all direct patient care staff. The allocated training includes didactic and clinical training with qualified preceptors to build clinical skills and includes OSHA and mandatory compliance training.

SHP Criterion 16 -Scope of Privileges

The applicant affirms that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the proposed governing body of the facility. The applicant states that their affiliated facilities within the service area have 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 Criterion 17 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center within one (1) year of commencing operation. The application included an affiliation agreement between UMMC and FMC McComb. The applicant states that FMC East McComb anticipates substantially similar agreements for the proposed satellite facility.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2017, Revision*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 – State Health Plan

This application is in compliance with the overall objectives of the *FY 2015 State Health Plan*.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, easy access ESRD services for those residents in need of dialysis services near Pike County area. The applicant believes, a satellite facility will allow for greater accessibility and opportunity for Pike County residents to receive necessary dialysis treatment.

GR Criterion 3 – Availability of Alternatives

The applicant affirms that the establishment of the proposed ESRD facility is the only effective alternative. The applicant considered not establishing a satellite facility in McComb and continuing to service those patients through its existing facility. However, the applicant states that in order for the expansion of RCG McComb, additional construction would have to be undertaken, which would disrupt patient care. The applicant affirms that creating a satellite facility is more efficient and cost effective for solving the overcrowding issues at RCG McComb verses other alternatives such as relocating and expanding the host facility.

The applicant states that the selected site for the satellite facility is close enough to the host facility so the patient's weekly schedule will not be significantly disrupted all while providing an additional access point for treatment.

The applicant believes that the establishment of a ten (10) station satellite ESRD facility in Pike County will be the most efficient, effective, and accessible alternative to meet the needs of the patients in Pike County.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net income of \$1,034,310 the first year, \$1,504,708 second year, and \$1,838,454 the third year of operation, respectively.

- a. **Proposed Charge:** The applicant submits that the proposed project will not increase the cost of dialysis services to patients or Medicaid. The applicant deems that the 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.
- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 50%; 65%; and 75%, respectively.
- c. **Project's Financial Feasibility Study:** The application contained a letter attesting to the financial feasibility of the proposed project.

GR Criterion 5 – Need for Project

- a. **Access by Population Served:** The applicant states that dialysis services will continue to be offered to all ESRD patients including the underserved population.
- b. **Relocation of Services:** The applicant states that while ten stations from the RCG McComb facility will be relocated to create the proposed satellite facility, services will continue to be provided at the existing location. Therefore, this application does not entail the relocation of services or replacement of an ESRD facility.
- c. **Probable Effect on Existing Facilities in the Area:** RCG Brookhaven and Tylertown Dialysis Unit are both located within RCG McComb and the proposed satellite's ESRD Facility Service Area. The proposed facility does

not seek to increase utilization but to increase the availability of treatment times for patients. As previously stated, the applicant affirms that while ten stations from the RCG McComb facility will be relocated to create the proposed satellite facility, services will continue to be provided at the existing location. The applicant anticipates that the host facility's utilization will slightly decrease as patients seek more convenient treatment times at the proposed facility.

- d. **Community Reaction:** The application contained letters of support for the proposed project from physicians and various patients in the community. No letters of opposition for the proposed project were received.

GR Criterion 6 – Access to the Facility or Service

According to the applicant, all patients of the ESRD service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The following table shows the projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$2,728.76 (2%)
2	\$3,602.58 (2%)

The applicant states that patients without a payor source will 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 confirms that the proposed facility will be conveniently located off Business Center Drive and Parklane Road in McComb. The applicant suggests that this location is near US 98 and I-55 which makes travel to the satellite easily accessible for patients.

The proposed facility will operate Monday through Saturday from 6:00 a.m. to 4:00 p.m.

GR Criterion 7 – Information Requirement

The applicant affirms that it will record and maintain all requested information required under GR Criterion 7 and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 – Relationship to Existing Health Care System

The applicant states that the most significant impact should be on the host facility. The host facility will cooperate to transfer patients to the proposed facility to facilitate continuity of care. Currently, area residents travel to multiple clinics including the host facility to receive ESRD services. The applicant insists that failure to implement the proposed project will result in ESRD patients residing in

or near Pike County continuing to travel three times a week to the host facility as well as other locations, farther away from their homes to receive necessary dialysis services.

The application contained a transfer/referral/affiliation agreement that RCG McComb currently has with the University of Mississippi Medical Center. The applicant states that new transfer/referral/affiliation agreements will be entered into with local hospitals upon the establishment of the satellite ESRD facility.

GR Criterion 9 – Availability of Resources

The applicant states that its affiliates have successfully recruited physicians and professional staff members through advertising and word of mouth, as well as maintained the personnel necessary for the efficient operation of its current facilities.

The applicant affirms that the allocated service area has sufficient nephrologists to support the proposed satellite facility. The applicant further affirms that due to the applicant's existing presence in the area, relationships with nearby nephrologists who will support the proposed facility has been established.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that RCG McComb and its affiliates will provide the necessary ancillary and support services.

GR Criterion 11– Health Professional Training Programs

The applicant asserts that the proposed facility will cooperate with area health professional training programs in the surrounding area.

GR Criterion 12– Access by Health Professional Schools

The applicant affirms that the proposed facility will cooperate to meet the clinical needs of health professional training programs in the surrounding area.

GR Criterion 13 – Access to Individuals Outside Service Area

The applicant affirms that FMC East McComb is not proposing to provide access to individuals outside the allocated service area; therefore, Criterion 13 is not applicable.

GR Criterion 14– Construction Projects

The applicant asserts that the developer will construct a new shell building for the satellite and will be responsible for the costs associated with the exterior construction. The applicant confirms that FMC East McComb will be responsible for costs associated with the interior build-out. Therefore, Criterion 14 is not applicable.

GR Criterion 15 – Competing Applications

The applicant states that FMC East McComb is not aware of any competing applications.

GR Criterion 16– Quality of Care

The applicant states that while this application does not concern an existing ESRD facility, the applicant’s affiliates have consistently provided quality of care to their patients. The applicant affirms 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 suggests that this affiliation will also help to ensure quality of care delivery of health care services, staff training and expectations.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage% of Total
Construction Cost - New	\$ 1,142,400	28.49%
Construction Cost - Renovation	\$ 0	0.00%
Capital Improvements	\$ 0	0.00%
Total Fixed Equip Cost	\$ 205,500	5.12%
Total Non-Fixed Equip Cost	\$ 21,574	0.54%
Land Cost	\$ 148,000	3.69%
Site Preparation and improvement	\$ 1,754,400	43.75%
Fees (Legal and Accounting)	\$ 0	0.00%
Fees (Architectural/Consultant/etc.)	\$ 260,712	6.50%
Contingency Reserve	\$ 289,680	7.22%
Capitalized Interest	\$ 0	0.00%
Other	\$ 188,166	4.69%
Total Proposed Expenditures	\$ 4,010,432	100.00%

The applicant provided a letter attesting to the feasibility of the proposed project.

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves.

C. Effect on Operating Cost

Attachment 1 lists RCG McComb projections of expenses, gross revenue, net income and utilization for the first three years of operation.

D. 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.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. The Division asserts that no foreseeable increase in allowable costs to Medicaid will result as it relates to the proposed project. The Department 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 2015 State Health Plan*; the *Mississippi Certificate of Need Review Manual, Revised 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 Fresenius Medical Care East McComb Dialysis, LLC for the establishment of a ten (10) station, satellite End Stage Renal Disease ("ESRD") facility in Pike County.

Attachment 1

Fresenius Medical Care East McComb Dialysis, LLC
Establishment of Satellite ESRD Facility

Three-Year Operating Statement with Project

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	\$ 0	\$ 0	\$ 0
Outpatient Revenue	\$ 3,791,861	\$ 5,002,550	\$ 5,858,821
Gross Patient Revenue	\$ 3,791,861	\$ 5,002,550	\$ 5,858,821
Charity	\$ 0	\$ 0	\$ 0
Deductions from Revenue	\$ 0	\$ 0	\$ 0
Net Patient Care Revenue	\$ 3,791,861	\$ 5,002,550	\$ 5,858,821
Other Operating Revenue	\$ 0	\$ 0	\$ 0
Total Operating Revenue	\$ 3,791,861	\$ 5,002,550	\$ 5,858,821
Operating Expenses			
Salaries	\$ 813,805	\$ 1,079,013	\$ 1,269,915
Benefits	229,543	304,348	358,194
Supplies	816,964	1,072,582	1,249,970
Services	0	0	0
Lease Expenses	213,720	213,720	213,720
Depreciation	221,184	221,184	221,184
Interest	0	0	0
Other	462,336	606,995	707,383
Total Operating Expenses	\$ 2,757,551	\$ 3,497,842	\$ 4,020,366
Net Operating Income	\$ 1,034,310	\$ 1,504,708	\$ 1,838,454
	Proposed Year 1	Proposed Year 2	Proposed Year 3
Inpatient Days	0	0	0
Outpatient Visits	0	0	0
Number of ESRD Procedures	4,680	6,084	7,020
Charge per Outpatient Day	\$ 0	\$ 0	\$ 0
Charge per Inpatient Day	\$ 0	\$ 0	\$ 0
Charge per Procedure	\$ 810	822	\$ 835
Cost per Inpatient Day	\$ 0	\$ 0	\$ 0
Cost per Outpatient Day	\$ 0	\$ 0	\$ 0
Cost per Procedure	\$ 589	\$ 575	\$ 573