MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT NOVEMBER 2007

CON REVIEW ESRD-NIS-0907-024
RCG SOUTHAVEN, LLC D/B/A DESOTO COUNTY DIALYSIS CENTER
ESTABLISHMENT OF A 10-STATION ESRD FACILITY IN DESOTO COUNTY
CAPITAL EXPENDITURE: \$750,000
LOCATION: SOUTHAVEN, DESOTO COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

RCG Southaven, LLC d/b/a DeSoto County Dialysis Center is a Delaware limited liability company authorized to do business in the state of Mississippi. Fresenius Medical Care-North America is a parent of RCG Southaven, LLC. RCG Southaven, LLC has a four (4) member Board.

Renal Care Group-Southaven (RCG) currently operates a 40-station ESRD facility in Southaven.

B. Project Description

RCG Southaven, LLC d/b/a DeSoto County Dialysis Center proposes to establish a new, 10-station end stage renal disease (ESRD) facility in Southaven, DeSoto County, Mississippi, known as DeSoto County Dialysis Center. The applicant is a joint venture between Renal Care Group, Inc. (RCG) and four physicians (Gary Davis, MD, Jacinto Hernandez, MD, Julio Ruiz, MD, and Lynn Ebaugh, MD). RCG states that these stations will facilitate patient needs, patient access, and the population growth of DeSoto County.

RCG Southaven proposes to lease approximately 5,100 square feet of renovated space from Bio-Medical Applications of Mississippi (landlord) to house the 10-station ESRD facility. The applicant states that the landlord of the proposed site has shelled in space. RCG Southaven, LLC will renovate the shelled in space in order to make accommodations to provide ESRD services. The proposed renovation includes finishing out 5,100 square feet of shell space for the ten (10) station dialysis unit and related office. The work will include: interior studs, drywall, floor, wall and ceiling finishes, interior doors with hardware, specialty items casework; and complete plumbing, HVAC and electrical systems. Such renovation will comply with all local ordinance and regulations. The total proposed capital expenditure of the project is \$750,000.

The Mississippi State Department of Health, Division of Health Facilities Licensure and Certification, found the site acceptable for the stated use.

The applicant expects to obligate capital expenditure January 1, 2008, and expects the project to be complete by October 1, 2008.

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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, subparagraph (1)(a), 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 20 days of the publication of the staff analysis. The opportunity to request a hearing expires on December 5, 2007.

III. CONFORMANCE WITH THE <u>STATE HEALTH PLAN</u> AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The FY 2007 State Health Plan contains policy statements and service specific criteria and standards which must be met before an applicant is granted CON authority to establish an ESRD facility, as set forth below.

SHP Criterion 1 - Need

An applicant proposing the establishment of a limited care renal dialysis facility shall demonstrate that each individual ESRD facility in the proposed ESRD Facility Service Area has (a) maintained a minimum annual utilization rate of 80 percent or (b) that the location of the proposed ESRD facility is in a county which does not currently have an existing ESRD facility but whose ESRD relative risk score using current ESRD Network 8 data is 1.5 or higher.

An ESRD Facility Service Area is defined as the area within 30 highway miles from an existing or proposed ESRD facility. Currently, there is only one provider within the proposed facility's service area, Renal Care Group of Southaven (RCG Southaven).

The applicant proposes to establish a second facility in Southaven, DeSoto County, Mississippi, comprised of ten (10) ESRD stations. The applicant believes that these stations will facilitate patient needs, patient access, and the population growth of DeSoto County. Given the number of active dialysis patients reported by RCG Southaven for the past three years and the average number of stations, staff estimates the utilization rate of the facility to be as follows:

| Year | Average Number of Patients | Average Number of Stations | Average Number of Shifts/Days | Number of Treatments* | Utilization Percentage |
|------|-------------------------------------|----------------------------------|-------------------------------------|--------------------------|---------------------------|
| 2005 | 106 | 35 | 2 shifts/6 days | 16,536 | 50% |
| 2006 | 117 | 40 | 2 shifts/6 days | 18,252 | 49% |
| 2007 | 133 | 40 | 2 shifts/6 days | 20,748 | 55% |

*Note: Total treatments were calculated based on 3 treatments per patient per week, 156 treatments per year (3 x 52 weeks).

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The applicant asserts that the increase in actual utilization at RCG Southaven, the need of dialysis patients for easy access, and the projected increase in utilization due to the population growth in DeSoto County supports the need for this project. The average patient receives 12-13 ESRD treatments per month or a maximum of approximately 156 treatments per year. Based on the 2006 and 2007 utilization data stated in the application, the number of treatments performed at RCG-Southaven increased by 1,584 from 2005 to 2006 and by 2,304 from 2006 to 2007. However, the number of stations at the facility also increased from 35 to 40 stations. According to the *State Health Plan*, full utilization (100%) is defined as an average of 936 dialysis per station per year. Full utilization of 40 stations yields 37,440 possible ESRD treatments per year. Given the applicants stated number of patients served during 2007, the applicant performed between 19,152 (133x144) and 20,748 (133x156) treatments during 2007, yielding an average utilization of 51-55 percent.

In addition, Network 8, Inc. reported an incidence of 45 ESRD patients and a prevalence of 133 patients for DeSoto County for 2006. For the period January 1, 2007, to July 31, 2007, Network 8, Inc. reported an incidence of 31 ESRD patients and a prevalence of 141 patients for DeSoto County. Based on the number of patients reported by RCG Southaven and the fact that it is the only facility in the area, it appears that all patients are being dialyzed at RCG Southaven. It also appears that there are not enough patients in the service area to justify an addition of 10 ESRD stations. Furthermore, criterion (a) requires 80 percent utilization for the past fiscal year; according to the applicant, Renal Care Group of Southaven's utilization was 63.75 percent for FY 2007. Therefore, the applicant is not in compliance with this criterion.

SHP Criterion 2 - Number of Stations

The FY 2007 State Health Plan establishes a minimum of four ESRD stations that may be approved for establishment of an ESRD facility. The applicant proposes to establish 10 ESRD stations. RCG Southaven, LLC is in compliance with this criterion.

SHP Criterion 3 - Minimum Utilization

The applicant projects to perform 5,195 treatments on 34 patients the first year of operation for an annual utilization of 55.50 percent. The table below gives a comparison of the applicant's projections with the MSDH requirements.

| Projected Utilization | | | | | | | |
|-----------------------|----------|-------------|----------|-----------------|-------------|-------------------|-------------|
| | | | | RCG Projections | | MSDH Requirements | |
| | Patients | Treatments | | | Utilization | | Utilization |
| Year | | per Station | Stations | Treatments | Rate | Treatments | Rate |
| 1 | 34 | 520 | 10 | 5,195 | 55.50% | 4,680 | 50% |
| 2 | 46 | 646 | 10 | 6,458 | 68.90% | 6,084 | 65% |
| 3 | 51 | 716 | 10 | 7,160 | 76.50% | 7,020 | 75% |

SHP Criterion 4 - Minimum Services

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

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SHP Criterion 5 - Access to Needed Services

RCG Southaven, LLC affirmed 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 Criterion 6 - Hours of Operation

The applicant proposes that the normal facility hours of operation will be from 6:30 a.m. to 6:00 p.m., six days per week. Alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 7 - Home Training Program

The applicant affirmed that a home training program will be made available.

SHP Criterion 8 - Indigent/Charity Care

The applicant certified that the proposed facility will not have any admission policies which will adversely affect access to care by indigents, and that it will provide indigent/charity care. The applicant anticipates its percentage of indigent/charity care to be two percent.

SHP Criterion 9 - Facility Staffing

According to the applicant, the facility's medical director will be Jacinto Hernandez, MD. The application includes documentation for qualifications and specific duties of the proposed facility's staff.

SHP Criterion 10 - Staffing Qualifications

RCG Southaven, LLC asserts that its staff will meet, at a minimum, all requirements and qualifications as stated in the Medicare Conditions for Coverage of Suppliers of ESRD Services, 42 CFR, Chapter IV, Subpart U.

SHP Criterion 11 - Staffing Time

RCG Southaven, LLC affirmed that when the unit is in operation, at least one (1) RN will be on duty. There will be a minimum of two persons for each dialysis shift, one of which will be an RN.

The applicant affirmed that a medical director or a designated physician will be on-site or oncall at all times when the facility is in operation.

The applicant further affirmed that when the unit is not in operation the medical director, or designated physician, and a RN will be on-call.

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SHP Criterion 12 - Data Collection

RCG Southaven, LLC affirmed that it will record and maintain all utilization data and data regarding services provided to indigent patients and shall make such information available to the MSDH as required.

SHP Criterion 13 - Staff Training

The applicant affirmed that it will provide an ongoing program of training for nurses and technicians in dialysis techniques.

SHP Criterion 14 - Scope of Privileges

The applicant affirmed that it shall 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.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirmed that it will enter into an affiliation agreement with at least one transplantation center upon CON approval in accordance with stated requirements. The application contains an agreement between the applicant and the University of Mississippi Medical Center, Jackson. The applicant also affirmed 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, revised November 2006,* addresses general criteria by which all CON applications are reviewed. The applicable criteria are discussed below.

GR Criterion 1 - State Health Plan

This application is not in compliance with the need criterion stated in the FY 2007 *State Health Plan*. It is a policy of the Mississippi State Department of Health that no CON shall be issued unless it substantially complies with the projection of need as reported in the State Health Plan which is in effect at the time the application is received by the Department.

GR Criterion 2 - Long Range Plan

The applicant indicates that the project will provide easy access and convenient dialysis services to its patients in the Southaven and DeSoto County area. RCG Southaven believes that establishing a second location will ensure its current and future patients have access to dialysis services.

GR Criterion 3 - Availability of Alternatives

RCG Southaven, LLC submits that there is no less costly or more effective available alternative to the application. No other alternatives were presented in the application.

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GR Criterion 4 - Economic Viability

Based on the applicant's three-year projections, this project will realize a net income of \$238,087 the first year, \$313,596 the second year, and \$367,200 the third year of operation, respectively. Staff contends that the project cannot be viable without impacting on the viability of the existing provider.

- a. Proposed Charge: The applicant projects charges of \$311.92 per dialysis treatment for the first three years of operation for the proposed project. The applicant projects cost of \$266.09 per dialysis treatment for the first three years of operation for the proposed project.
- b. **Projected Levels of Utilization**: RCG Southaven, LLC makes the following projections of dialysis treatment to be performed during the first three years of operation: 5,195; 6,458 and 7,160, respectively.
- c. **Project's Financial Feasibility Study**: The capital expenditure for this project is \$750,000; therefore, a feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 - Need for the Project

- a. Access by Population Served: The applicant asserts that the population of DeSoto County is growing at an outstanding rate. With the increase in population necessarily comes the increase in the need for dialysis services. The applicant asserts that the existing ESRD facility in Southaven is operating at near capacity.
- b. **Relocation of Services**: This application is for the establishment of a ten station ESRD facility in DeSoto County.
- c. Probable Effect on Existing Facilities in the Area: The applicant asserts that the proposed second location will offer a familiar alternative to current patients and provide increased accessibility for DeSoto County's residents. The applicant believes that the availability of another, high quality, related provider of dialysis services will ensure all dialysis patients are timely served, increasing the over-all health of DeSoto County and Mississippi residents. However, RCG-Southaven, the only provider of ESRD services within 30 miles from the proposed facility, had a utilization rate of 50 percent for the fiscal year 2005, 49 percent for fiscal year 2006 and 55 percent for fiscal year 2007.

Staff contends that the proposed project would create an unnecessary duplication of a health service.

d. **Community Reaction**: The application contains 14 letters of support for the proposed project.

The Department received no letters of opposition concerning the proposed project.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, all patients of the ESRD service area, including Medicaid

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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 | \$36,425 (2%) | | |
| 2 | \$45,720 (2%) | | |

GR Criterion 7 - Information Requirement

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

GR Criterion 8 - Relationship to Existing Health Care System

As previously mentioned, the only provider of ESRD services in DeSoto County is Renal Care Group-Southaven. Based on utilization data stated in RCG Southaven, LLC application, the existing dialysis facility had a utilization rate of 63.75 percent for fiscal year 2007, which is far less than the 80 percent utilization rate required before an additional provider can be approved.

RCG Southaven believes that the project will give its patients an alternative location to seek services from a familiar provider and ensure adequate ESRD services are available for the ever-increasing population of DeSoto County.

The Department received no letters of opposition concerning the proposed project.

GR Criterion 9 - Availability of Resources

The applicant states it has successfully recruited, through advertising and word-of-mouth, and maintained the personnel necessary for the efficient operation of its current facility, and will take the same approach for its second location.

The applicant projects to hire 11.7 full-time equivalent personnel at an estimated annual cost of \$301,310 the first year.

GR Criterion 10 – Relationship to Ancillary or Support Services

RCG Southaven, LLC submits that it currently has all necessary support and ancillary services for its facility and does not anticipate any problems with such at its proposed second location.

GR Criterion 11 – Health Professional Training Programs

According to the applicant, RCG Southaven will cooperate with health professional training programs in the area.

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GR Criterion 16 - Quality of Care

The applicant submits that the quality of care offered to RCG Southaven patients has exceeded patient and physician expectations as a result of organization and leadership. The second location will offer a familiar alternative to current patients and provide increased accessibility of DeSoto County's residents.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

| Cost Item | Projected Cost | % of Total |
|-----------------------------|----------------|------------|
| Construction Cost – New | 0 | 0.0% |
| Renovation | \$594,000 | 79.20% |
| Capital Improvements | 0 | 0.0% |
| Total Fixed Equip Cost | 31,940 | 4.25% |
| Total Non-Fixed Equip Cost | 97,330 | 12.99% |
| Land Cost | 0 | 0.0% |
| Site Prep Cost | 0 | 0.0% |
| Fees | 26,730 | 3.56% |
| Contingency Reserve | 0 | 0.0% |
| Capitalized Interest | 0 | 0.0% |
| Other Cost | 0 | 0.0% |
| Total Proposed Expenditures | \$ 750,000 | 100.0% |

B. Method of Financing

The applicant proposes to finance this project through cash reserves.

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C. Effect on Operating Cost

RCG Southaven, LLC projects the following expenses, revenues, and utilization for the first three years of operation:

| RCG Southaven, LLC Three-Year Operating Statement | | | | | |
|---|--------------------|---------------------|---------------------|--|--|
| | Year I | Year 2 | Year 3 | | |
| | | | | | |
| Revenue | | | | | |
| Patient Revenue: | | | | | |
| Inpatient | \$1,620,424 | \$2,033,894 | \$2,275,691 | | |
| Outpatient | -0- | -0- | -0- | | |
| Total Gross Patient | <u>\$1,620,424</u> | <u>\$ 2,033,894</u> | <u>\$ 2,275,691</u> | | |
| Revenue | | | | | |
| | | | | | |
| Charity Care | -0- | -0- | -0- | | |
| Deductions | -0- | -0- | -0- | | |
| | | | | | |
| | | | | | |
| Net Patient Revenue | \$1,620,424 | \$2,033,894 | \$2,275,691 | | |
| Other Operating | -0- | -0- | -0- | | |
| Revenue | | | | | |
| Total Operating | <u>\$1,620,424</u> | <u>\$2,033,894</u> | <u>\$2,275,691</u> | | |
| Revenue | | | | | |
| | | | | | |
| Expenses | | | | | |
| Salaries | \$301,310 | \$378,192 | \$423,154 | | |
| Benefits | 75,328 | 94,548 | 105,788 | | |
| Supplies | 497,993 | 618,872 | 685,591 | | |
| Lease | 121,979 | 149,973 | 164,353 | | |
| Depreciation | 79,951 | 98,712 | 108,639 | | |
| Other | <u>305,778</u> | <u>380,000</u> | <u>420,967</u> | | |
| Total Expenses | <u>\$1,382,338</u> | <u>\$1,720,298</u> | <u>\$1,908,492</u> | | |
| | **** | 4040 500 | **** | | |
| Net Income (Loss) | <u>\$238,087</u> | <u>\$313,596</u> | <u>\$367,200</u> | | |
| | | | | | |
| Utilization Rate | 55.50% | 68.90% | 76.50% | | |
| Total treatments | 5,195 | 6,458 | 7,160 | | |
| Patients | 37 | 46 | 51 | | |
| Charge Per Treatments | \$311.92 | \$314.94 | \$317.83 | | |
| Cost Per Treatment | \$266.09 | \$266.38 | \$266.54 | | |
| Charge Per Outpatient Day | -0- | -0- | -0- | | |
| Charge Per Inpatient Day | -0- | -0- | -0- | | |
| Cost Per Outpatient Day | -0- | -0- | -0- | | |
| Cost Per Inpatient Day | -0- | -0- | -0- | | |

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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. However, no comments were received as of this writing.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with criteria and standards for establishment of end stage renal disease facilities, as contained in the FY 2007 State Health Plan; the Mississippi Certificate of Need Review Manual, revised November 2006; and all adopted rules, procedures, and plans of the Mississippi State Department of Health. Specifically, the project does not comply with SHP Criterion 1 and GR Criterion 5 – Need. Policy Statement 5 of the FY 2007 State Health Plan states: "A CON application for the establishment of an ESRD facility shall be considered for approval only when each individual facility within an applicant's proposed ESRD Facility Service Area has maintained, at a minimum, an annual or prorated utilization rate of 80 percent as verified by the MSDH. The 12 months prior to the month of submission of the CON application shall be used to determine utilization." Staff found that there is only one ESRD facility within 30 highway miles of the proposed facility. That facility had a utilization rate of 63.75 percent, less than the required 80 percent. Given the low utilization rate of the existing provider, staff questions the viability of the applicant's proposal and contends that the proposal, if approved, will be an unnecessary duplication of a health service.

Consequently, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by RCG Southaven, LLC d/b/a DeSoto County Dialysis Center for the establishment of a 10-station ESRD facility in DeSoto County.