Division of Health Planning and Resource Development November 2004

CON Review: ESRD-NIS-0904-031 RCG Mississippi, Inc. dba RCG-Belzoni

Establishment of a Six (6) Station ESRD Facility

Capital Expenditure: \$429,880

Location: Belzoni, Humphreys County, Mississippi

Staff Analysis

I. Project Summary

A. Applicant Information

According to the applicant, on February 5, 1974, Kidney Care became the first provider of outpatient End-Stage Renal Disease (ESRD) services in Mississippi, and throughout its history, Kidney Care has been the leader in the provision of ESRD services within Mississippi. In 1996, Kidney Care became affiliated with Renal Care Group, Inc., operating in Mississippi under the name of RCG Mississippi, Inc.(RCG). The company provides care to over 28,000 persons with kidney disease in 395 outpatient dialysis facilities, in addition to providing acute dialysis services at more than 190 hospitals nationwide. Today, RCG owns and operates 395 ESRD centers in 31 states. Thirty-eight of these centers are in Mississippi, making RCG the largest provider of ESRD services in Mississippi.

The applicant states that RCG is firmly committed to transplantation as a viable option for ESRD treatment. All patients are evaluated for potential transplant eligibility. Furthermore, RCG has 2,253, or 10.9 percent, of its Mississippi ESRD patients on home dialysis.

B. Project Description

The applicant, RCG Mississippi, Inc., requests Certificate of Need (CON) authority to establish a six-station ESRD facility in Belzoni, Mississippi to better serve the 32 ESRD patients identified by Network 8 as residing in Humphreys County. Currently 25 of these patients travel to RCG's facilities in Indianola and Lexington to receive dialyses. The other seven patients also travel out of Humphreys County for dialysis, but to facilities other than those operated by RCG. RCG anticipates that at least 29 of these patients will choose to dialyze at RCG-Belzoni, for an initial total patient count of 29. The number and type of stations to be established include:

Home Training	0
Self-Care Hemodialysis	0
Self-Care Peritoneal Dialysis	0
Staff Assisted Hemodialysis	6
Staff Assisted Peritoneal	0

In addition, one station will be available for backup.

RCG-Belzoni will purchase a 28 by 74 foot modular building that has been especially designed, built, and retrofitted for the provision of dialysis treatment services. RCG-Belzoni will contract for accounting, auditing, and legal services as needed. RCG operates its own dialysis filter reuse facility and is able to contract with support staff, including social workers and dieticians, who are able to work full time for RCG while providing care to patients in a variety of facilities. The total proposed capital expenditure for this project is \$429,880, 39 percent of which will be allocated to non-fixed equipment cost.

The application contained a letter from the Division of Health Facilities Licensure and Certification approving the Belzoni site.

RCG-Belzoni's staffing percentage breakdown is as follows:

Position Title	<u>Full-Time</u> Equivalent	Approximate <u>Salary</u>
Facility Manager (Registered Nurse)	1.00	\$ 55,000
Registered Nurse	1.00	45,000
Patient Care Technician	1.50	37,500
Unit Secretary	0.50	12,500
Dietician	0.20	9,000
Social Worker	0.20	10,000
Filter Reuse Technician	0.10	2,500
Bio-Med Technician	<u>0.10</u>	3,300
Total FTE and Salary	4.60	\$174,800

The 4.60 full-time equivalent staff will cost an estimated \$278,900 (including benefits) during the first year of operation.

The applicant expects the project to be completed within 180 days of CON approval.

The applicant is competing with two other applicants for the ESRD facility for Humphreys County, as authorized by the Mississippi State Board of Health through changes in regulations adopted July 14, 2004. Other applicants are Diversified Renal Group, requesting four stations, and Bio-Medical Applications of Mississippi, Inc., dba Fresenius Medical Care, Belzoni, requesting eight stations.

II. Type of Review Required

This project for the establishment of an end-stage renal disease facility is reviewed in accordance with Section 41-7-173 (h) and 41-7-191 (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, 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 6, 2004.

The Department received three applications competing for the ESRD facility in Humphreys County. These applications were deemed complete on October 1, 2004 and were entered into the October 2004 review cycle as competing applications.

III. Conformance with the State Health Plan and other Adopted Criteria and Standards

A. State Health Plan

The **FY 2005 Mississippi State Health Plan** contains policy statements, service specific criteria, and standards which must be met before an applicant may be granted CON authority to establish an ESRD facility, as set forth below.

State Health Plan Criterion 1 - Need

Pursuant to the revised rules as set forth in the FY 2005 State Health Plan, the ESRD Facility Service Area in question consists solely of Humphreys County, Mississippi. Since there are no ESRD Facilities located in this county, there are also no facilities in this service area. There are five other facilities located within thirty-five miles of the proposed location of the Belzoni facility. Four of these facilities are currently owned and operated by Renal Care Group and 76 percent of all ESRD patients who reside in Humphreys County currently dialyze at an RCG facility, according to the applicant.

According to Network 8, Inc., an average end-stage renal disease patient receives three dialysis sessions per week, or an average of 12 per month or 144 dialysis sessions per year. The FY 2005 State Health Plan defines optimum utilization of an ESRD station as 702 dialyses per year. Network 8, Inc. sets the prevalence of end-stage renal disease for Humphreys County at 32 as of April 30, 2004 as indicated below.

ESRD Incidence and Prevalence, Humphreys County, Mississippi 1999-April 2004

Year	Incidence	Prevalence
1999	9	50
2000	7	54
2001	2	52
2002	4	43
2003	6	40
2004 (as of April 30)	n/a	32

Source: Network 8, Inc., Jackson, Mississippi

Based on the optimum utilization of 702 dialyses per station per year as contained in the *State Health Plan*, Humphreys County will need nearly seven (6.56) ESRD stations to dialyze its 32 end-stage patients.

Number of dialyses per patient/year =144. Number of dialyses for 32 patients 144 x 32= 4,608 Optimum dialyses per station = 702 Number of stations needed to dialyze 32 patients 4,608/702 = 6.56

As indicated above, the prevalence of end-state renal disease has steadily decreased since the year 2000. Considering this decrease in the prevalence and the consequent decrease in the number of renal dialysis stations needed, the optimum number of ESRD stations needed to dialyze the renal patients of Humphreys County should be established at six.

Considering the fact that RCG presently serves 76 percent of these Humphreys County patients, staff is inclined to recommend approval of this application for six stations rather than one of the other competing applications requesting four and eight stations, respectively.

State Health Plan Criterion 2 - Minimum Number of Stations

The FY 2005 Mississippi State Health Plan establishes the minimum number of ESRD stations that can be approved per ESRD facility at four. The applicant, requesting six, is in compliance with this criterion.

State Health Plan Criterion 3 - Minimum Expected Utilization

The FY 2005 Mississippi State Health Plan requires that the applicant demonstrate that a proposed ESRD facility will reach a minimum utilization of 50, 65, and 75 percent during the first, second, and third years, respectively.

Renal Care Group estimates that 29 of the 32 dialysis patients who are currently being dialyzed at one of the surrounding dialysis facilities, but who reside in Humphreys County, will choose to dialyze at RCG-Belzoni. Of those 32 patients, RCG's Indianola and Lexington facilities currently dialyze 25. These patients live closer to the proposed Belzoni location and are expected to relocate to the Belzoni facility. The applicant expects that a portion of the remaining patients not being treated by RCG will also relocate to the proposed facility.

According to the 2005 population projections as found in the 2005 Mississippi State Health Plan, Humphreys County has a population of 10,798 – 26 percent of which is white and 74 percent is non-white (98 percent of the non-white population is African-American). According to Network 8 data, Mississippi experienced a statewide incidence rate of 242.70 per million for whites, 715.05 per million for non-whites, and 425.54per million for the state as a whole. Based on the statewide incidence rate, 0.68 new white patients and 5.73 non-white patients would be expected for Humphreys County per year.

According to the applicant, 10.9 percent of RCG's patients participate in a home dialysis program. Based on the number of patients expected to use RCG-Belzoni, one patient would be expected to begin home dialysis during the next three years. Each patient typically dialyzes three times per week or twelve times per month. Therefore, RCG-Belzoni expects to perform 3,996, 4,320, and 4,493 procedures for years one, two, and three, respectively, as indicated by the following display:

Projected Utilization For RCG-Belzoni

	Year 1	Year 2	Year 3
Initial Patient Load	29	30	31
New (Incidence)	6.0	7.0	7.0
Home Dialysis (5.5 percent)	0.0	<u>1.0</u>	0.0
Year End Total	35.0	36.0	38.0
Less: Mortality (19.0 percent)	5.0	5.0	6.0
Transplantation (1.5 percent)	0.0	0.0	<u>1.0</u>
Final Year Patient Load	<u>30.0</u>	<u>31.0</u>	<u>31.0</u>
Projected Treatments	3,996	4,320	4,493
Percent Utilization	77	79	79

State Health Plan Criterion 4 - Minimum Services

The applicant affirms that the facility will provide social, dietetic, and rehabilitative services through contractual arrangement with RCG-Mississippi.

State Health Plan Criterion 5 - Access to Needed Services

The applicant affirms that RCG-Belzoni will provide for reasonable access to equipment/facilities for such needs as vascular access and transfusion required by stable maintenance ESRD patients through transfer agreements with University Medical Center and local health care facilities.

State Health Plan Criterion 6 - Hours of Operation

RCG-Belzoni will schedule three treatments per station per day, between the hours of 6:00 a.m. – 7:00 p.m. After-hour dialysis will be available to accommodate those patients who are working and need to dialyze after the patient's normal working hours.

State Health Plan Criterion 7 - Home Training Program

RCG-Belzoni affirms that it will make a home training/self dialysis program available to those patients who are medically eligible and receptive to such a program.

State Health Plan Criterion 8 - Indigent /Charity Care

The applicant certifies that RCG-Belzoni will provide a "reasonable amount" of indigent /charity care. Since almost all patients either qualify for Medicare or Medicaid, dialysis patients do not typically require a great amount or unreimbursed care. RCG-Belzoni expects to serve approximately 0.68 percent indigent/charity care patients. No patient is denied services due to an inability to pay.

State Health Plan Criterion 9 - Facility Staffing

The application contains documentation of the proposed facility's staffing by category, including minimum education and experience requirements, specific duties, and full-time equivalents.

State Health Plan Criterion 10 - Staffing Qualifications

The applicant affirms that the staff of the proposed facility shall, at minimum, meet all requirements and qualifications as stated in 42 CFR, Chapter IV, Subpart U.

State Health Plan Criterion 11 - Staffing Time

RCG-Belzoni affirms that when the facility is in operation, at least one Registered Nurse will be on duty. There shall be a minimum of two persons for each dialysis shift (one of which will be an RN). The proposed facility's Medical Director or designated physician shall be onsite or on-call at all times when the facility is in operation. The applicant further states that at all times when the facility is not in operation, the Medical Director or designated physician and a Registered Nurse shall be on-call.

State Health Plan Criterion 12 - Data Collection

The applicant affirms that utilization data will be recorded and made available as required by the Department.

State Health Plan Criterion 13 - Staff Training

RCG-Belzoni will provide an on-going program of training and dialysis techniques for nurses and technicians at the facility. The applicant also affirms that in-service training sessions will be held at least monthly.

State Health Plan Criterion 14 - Scope of Privileges

The applicant affirms 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.

State Health Plan Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirmed that it shall, within one year of commencing operation of the facility, enter into an affiliation agreement with a transplantation center. The written agreement shall describe the relationship between the transplantation facility and the ESRD facility and the specific services that the transplantation center will provide to the patients of the ESRD facility. The agreement will comply with all requirements of this criterion. The application contains a proposed agreement between the applicant and University of Mississippi Medical Center.

B. General Review Criterion

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, revision 2000, contains general review criteria which all Certificate of Need applications must meet.

General Review Criterion 3 – Availability of Alternatives

The applicant states that the proposed project resulted from planning and identification of long-range goals of RCG-Mississippi and the community it serves. The applicant contends that the project, as proposed, is the most efficient and cost-effective method of meeting the needs of the health care community served by RCG Mississippi.

General Review Criterion 4 - Economic Viability

The applicant expects that the immediate and long-term financial feasibility of the project to be excellent. The net income is projected to be \$4,100, \$58,100, and \$62,500 during the first, second, and third years of operation, respectively. The Medicare reimbursement rate has been set at a maximum of \$122.25 per treatment session.

General Review Criterion 5 - Need

The State Health Plan establishes the optimum utilization of an ESRD station as 702 dialyses per year. Network 8, Inc. has identified 32 ESRD patients residing in Humphreys County. Also, according to Network 8, the average ESRD patient receives 12 dialyses per month or 144 per year. Humphreys County needs 6.56 ESRD stations to dialyze its 32 dialysis patients. (144 x 32 = 4,608 dialyses per year. 4,608/702 = 6.56). The applicant, requesting six stations, is the most appropriate proposal to serve the dialysis needs of Humphreys County.

General Review Criterion 6 - Access to Facility/Services

The applicant affirms that RCG does not discriminate against the poor, the handicapped, women, the elderly, or members of racial and ethic minorities with regard to the delivery of health care services. Patients are provided health care services without regard to physical conditions, age, or ethic background.

General Review Criterion 7 – Information Requirement

RCG-Belzoni affirmed that it will maintain the required information and make it available to the Department within 15 days of request.

General Review Criterion 8 - Relationship to Existing Health Care Services

The applicant states that the proposed services will meet the needs of RCG patients who are presently receiving dialysis services in contiguous counties. There will be no adverse impact on existing providers of ESRD services, particularly since most of the patients to be served by this proposal are presently RCG patients. This facility will enhance the health care services in Humphreys County, a health care services scarcity area.

General Review Criterion 15 - Competing Applications

Applicants competing for the ESRD facility for Humphreys County are as follows:

Diversified Renal Group proposing four stations, Renal Care Group of Mississippi proposing six stations, and Bio-Medical Applications of Mississippi proposing eight stations. Each application was adjudged to be complete on October 1, 2004, and entered into the October 2004 review cycle as competing applications. Comparison of the three applicants indicates the following:

Number of Stations Needed

Network 8, Inc. has determined that as of April 30, 2004, 32 chronic kidney failure patients resided in Humphreys County. This number of patients will require six stations to maintain an optimally operated renal dialysis facility. Renal Care Group is requesting six stations, the desired number for Humphreys County patients. The four requested by Diversified Renal Group is inadequately low, and the eight requested by Bio-Medical would generate excess capacity.

Present ESRD Provider for Humphreys County Patients

Twenty-five of Humphreys County's renal patients are current being dialyzed in renal dialysis facilities operated by Renal Care Group in their Indianola and Lexington facilities. The transfer of these patients to another provider would require a likely switch of nephrologist, social worker, dietitian, staff nurses, and support staff, professionals with whom these patients have probably established a close working therapeutic relationship. DRG does not operate a dialysis facility in the area. Fresenius' nearest facility is located in Yazoo City. The transfer of the majority of Humphreys County patients to a facility in Humphreys County would probably be less traumatic to the patients if their present kidney care providers remained the same, particularly their nephrologist, social worker, and dietician.

General Review Criterion 16 - Quality of Care

The applicant states that with a 30-year history of providing high quality dialysis services to the end-stage renal patients of Mississippi, RCG Mississippi evidences compliance with this criterion.

IV. Financial Feasibility

A. Capital Expenditure Summary

New Construction Cost	\$ 0
Renovation Cost	0
Capital Improvement Cost	0
Non-Fixed Equipment Cost	170,000
Fixed Equipment Cost	0
Land Cost	12,000
Site Preparation Cost	74,880
Fees (Contractual, legal, etc.)	25,000
Contingency Reserve Cost	25,000
Other Cost (Specify)	
Purchase of 28X84 Modular Building	42,059
Build-Out Cost	72,941
Misc. Building Cost	8,000
Total Proposed Capital Expenditure	<u>\$429,880</u>

B. Method of Financing

The applicant affirms that the RCG-Belzoni project will be financed through operating funds of RCG-Mississippi.

C. Effect on Operating Cost

The applicant projects the following expenses, utilization, and results from operating for the first three years following completion of this project.

RCG-Belzoni Three Year Projected Operating Statement			
Expenses	<u>First Year</u>	Second Year	Third Year
Salaries, Wages, and Benefits	\$ 278,900	\$ 239,100	\$ 248,700
Supplies and Misc. Expense	351,600	380,200	395,400
Int., Depreciation, and Other	52,000	52,000	52,000
Bad Debt Allowance	27,200	29,400	30,600
Facility Expense	<u>191,000</u>	<u>183,500</u>	<u>189,400</u>
Total Expenses	<u>\$ 900,700</u>	\$ 884,200	<u>\$916,100</u>
Revenue			
Gross Revenue	\$ 3,796,200	\$ 4,104,000	\$ 4,268,350
Contractual Adjustments	<u>2,888,700</u>	3,122,900	3,248,050
Total Net Revenue	907,500	981,100	1,020,300
Income Before Income Taxes	6,800	96,900	104,200
Provisions For Income Taxes	<u>2,700</u>	38,800	41,700
Net Income	<u>\$ 4,100</u>	<u>\$ 58,100</u>	<u>\$ 62,500</u>
Assumptions			
Treatments	3,996	4,320	4,493
Charge per Treatment	\$ 950	\$ 950	\$ 950
Cost Per Treatment*	\$ 225	\$ 205	\$ 204
Net Income per Treatment	\$ 1.03	\$ 13.45	\$ 13.91

^{*} Staff Calculations

D. Cost to Medicare/Medicaid

ESRD treatment is a Medicare entitlement program. 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 the proposed application, and does not oppose the project.

VI. Conclusion and Recommendation

This project is in substantial compliance with criteria and standards for the establishment of end-stage renal disease facilities, as contained in the FY2005 State Health Plan; the *Mississippi Certificate of Need Review Manual*, revised 2000; and adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Department received three competing applications, all requesting Certificate of Need authority to establish ESRD services in Humphreys County. The three applications were deemed complete on October 1, 2004, and entered into the October Review Cycle.

All projects were found to be in substantial compliance with the ESRD Certificate of Need criterion. However, with competing applications, the Department must determine which applicant, if any, is the most appropriate applicant for providing the proposed services. Staff has determined that this application submitted on behalf of Renal Care Group Mississippi, Inc., dba RCG-Belzoni, for reasons as contained in this staff analysis, is the most appropriate to provide ESRD dialysis services in Humphreys County. Therefore, the Division of Health Planning and Resource Development recommends approval o this application submitted by RCG Mississippi, Inc.