

**Division Of Health Planning and Resource Development
November 2004**

**CON Review: ESRD-NIS-0804-039
Diversified Renal Group dba DRG-Belzoni
Establishment of a Four Station ESRD Facility
Capital Expenditure: \$309,826
Location: Belzoni, Humphreys County, Mississippi**

Staff Analysis

I. Project Summary

A. Applicant Information

Diversified Renal Group (DRG) is a Mississippi professional limited liability company with good standing with the Mississippi Secretary of State's office. The home office is located in Jackson, Mississippi.

B. Project Description

DRG requests Certificate of Need (CON) authority to establish a four-station ESRD facility in Belzoni, Mississippi to better serve the 32 ESRD patients identified by Network 8, Inc., as residing in Humphreys County. Currently, these patients travel 20 to 40 miles to other facilities in Greenville, Indianola, Lexington, Rolling Fork, and other places to receive dialysis.

The number and type of stations to be established include:

Hemodialysis Stations	4
Peritoneal Dialysis Stations	0
Limited Care	0
Staff Care	0
Home Training	1 (included above)

DRG-Belzoni proposes to convert 2,100 square feet of leased clinic space into a four-station renal dialysis facility in Belzoni. The applicant has requested a site approval from the Division of Health Facilities Licensure and Certification, but as of November 16, 2004, no letter of approval has been submitted. The total proposed capital expenditure for this project is \$309,826, 61 percent of which will be allocated to non-fixed equipment cost.

DRG-Belzoni's staffing estimate is as follows:

Position Title	Full-Time Equivalent	Approximate Salary
Medical Director	0.25	\$ 16,000
Registered Nurse	2.00	\$ 50,875
Licensed Practical Nurse	2.00	\$ 33,750
Chief Dialysis Technician	0.50	\$ 25,000
Clerical	0.20	\$ 12,500
Dietitian	0.25	\$ 10,625
Social Worker	0.25	\$ 11,250
Machine Technician	0.10	\$ 2,375
Total FTE and Salary	6.35	\$162,375

The 6.35 full-time equivalent staff will cost an estimated \$162,375 during the first year of operation.

The applicant expects the project to be completed within six to eight months of approval.

The applicant is competing with two other applicants for the ESRD facility recently approved by the Mississippi State Board of Health for Humphreys County. The other applicants are Renal Care Group-Mississippi dba RCG-Belzoni, requesting six 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 MSDH.

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 35 miles of the proposed location of the Belzoni facility.

According to Network 8, Inc., the 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-stage renal disease has steadily decreased since the year 2000. Considering this decrease in the prevalence and the corresponding 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.

The four stations proposed by the applicant will not adequately satisfy the need for Humphreys County dialysis patients.

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 stations. The applicant, requesting four, 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 minimum utilization of 50, 65, and 75 percent during the first, second, and third years, respectively. The applicant projects the following utilization for Humphreys County :

Projected Utilization For DRG-Belzoni			
	Year 1	Year 2	Year 3
Initial Patient Population	8	16	19
Estimated New Patients	12	8	8
Less: New Patient Home Training (20 percent)	(2)	(2)	(3)
Mortality of Remaining Patients (12 percent)	(1)	(2)	(3)
Net New Patients Added During Year	9	4	2
Less: Mortality Among Estimated Patients	(1)	(1)	(1)
Total Patients at End of Year	16	19	21
Treatments*	1,872	2,808	3,198
Percent Utilization**	67.0	83.0	87.5

* Applicant's Projections

** Staff calculated utilization percentages at 50.0, 75.0, and 85.5 during the first, second, and third years, respectively.

State Health Plan Criterion 4 – Minimum Services

The applicant affirms that the facility will provide social, dietetic, and rehabilitative services on a part-time basis.

State Health Plan Criterion 5 – Access to Needed Services

The applicant affirms that a reasonable access to equipment/facilities for such needs as vascular access and transfusions required for the facility's stable maintenance ESRD patients will be provided and shall be a standard provision of this proposed DRG Dialysis Unit.

State Health Plan Criterion 6 – Hours of Operation

Applicant states that the normal facility hours will be from 7:00 A.M. to 3:30 P.M. Monday, Wednesday, and Friday. A late shift, operating from 5:30 to 9:00 P.M., will be offered to accommodate those patients in need of after hour services.

State Health Plan Criterion 7 – Home Training Program

DRG affirms that it shall make a home training/self dialysis program available to those patients who are medically eligible and receptive to such a program. DRG affirms that it will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program and their different modality options. These limitations include:

- | | |
|-----------------|---|
| Home Training | 1) suitable home environment
2) patient desire
3) medical stability
4) helper availability |
| Transplantation | 1) age
2) patient desire
3) medical stability
4) medical history |

State Health Plan Criterion 8 – Indigent /Charity Care

The applicant anticipates ten percent bad debt.

State Health Plan Criterion 9 – Facility Staffing

The application includes 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 a minimum, meet all requirements and qualifications as stated in 42 CFR, Chapter IV, Subpart U.

State Health Plan Criterion 11 – Staffing Time

DRG 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 on-site or on-call at all times when the facility is in operation. A second physician will be available to supplement the services of the medical director.

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

DRG will provide an on-going program of training and dialysis techniques for nurses and technicians at the facility.

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 and 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 the Mississippi Medical Center Renal Transplantation Program has offered to serve as the renal transplant program of record if the CON is granted.

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

Applicant states that the proposed dialysis facility will make available and accessible a less costly and effective method of treating end-stage renal disease within the locality of the proposed services.

General Review Criterion 4 – Economic Viability

The applicant expects the immediate and long-term financial feasibility of the project to be excellent. The net income is projected to be loss of \$7,491 during the first year of operation but a gain of \$12,942 and \$40,877 during second and third years of operation, respectively. However, the applicant did not demonstrate the ability to operate at a deficit for two years as requested by the Department.

General Review Criterion 5 – Need

Network 8, Inc. reported a prevalence of 32 ESRD patients residing in Humphreys County as of April 30, 2004. These 32 patients will require approximately 4,608 dialyses per year (12 dialyses per month x 12 months). Operating at an optimum level of 702 dialyses per station per year, the county will need six ESRD stations to generate the optimum number of dialyses. DRG is seeking approval for four stations, less than six needed for the Humphreys County ESRD patients.

General Review Criterion 6 – Access to Facility/Services

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

General Review Criterion 7 – Information Requirement

DRG 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 provision of a dialysis facility will complement the services provided by the community health center and several local outpatient clinics and offices. The facility may enhance broadening of the health services to be provided at the local hospital and increase utilization of the hospital by the ESRD population.

A letter of opposition to this project was submitted by RCG, Inc.

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 review cycle as competing applications. Comparison among the three 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 currently 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 the proposed project will foster improvement and innovations in the financing and delivery of ESRD services, thereby fostering competition. The applicant contends that the system of delivering ESRD services proposed by this application will ensure quality assurance and cost effectiveness as well as patient satisfaction. The applicant does not have a history of past ESRD facility operation.

IV. Financial Feasibility

A. Capital Expenditure Summary

New Construction Cost	\$ 0
Renovation Cost, 2,000 Square feet at \$25.00 per Square foot	50,000
Capital Improvement Cost	60,000
Non-Fixed Equipment Cost	188,396
Fixed Equipment Cost	0
Site Preparation Cost	0
Fees (Contractual, legal, etc.)	0
Contingency Reserve Cost	5,000
Capitalized Interest	6,430
Other Cost	<u>0</u>
Total Capital Expenditure	<u><u>\$ 309,826</u></u>

B. Method of Financing

The applicant affirms that financing is available through Statewide Physical Medicine Group and Premier Dialysis, Inc. However, the applicant did not explain the relationship of Statewide Physical Medical Group and Premier Dialysis, Inc. to Diversified Renal Group.

C. Effect on Operating Cost

Attachment 1 contains the applicant’s projections of expenses, utilization, and results from operating for the first three years following completion of this project.

D. Cost to Medicare/Medicaid

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 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 FY 2005 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 the application submitted on behalf of Renal Care Group Mississippi, Inc., dba, RCG-Belzoni is the most appropriate application to provide ESRD dialysis services in Humphreys County. Therefore, since only one application can be approved for Humphreys County, the Division of Health Planning and Resource Development recommends disapproval of the application submitted on behalf of Diversified Renal Group.

Attachment 1

DRG-Belzoni Three Year Projected Operating Statement			
	First Year	Second Year	Third Year
Total Treatments	1,872	2,808	3,198
Revenue			
Routine Patient Care	\$ 362,513	\$ 543,769	\$ 619,293
Doubtful Accounts Allowance	<u>(72,503)</u>	<u>(108,754)</u>	<u>(123,859)</u>
Net Revenue	<u>\$ 290,010</u>	<u>\$ 435,015</u>	<u>\$ 495,434</u>
Patient Care Cost			
Clinical Salaries Cost	\$ 133,875	171,635	178,500
Facility Cost and Rent	48,236	51,225	51,225
Supplies	<u>50,752</u>	<u>76,128</u>	<u>86,701</u>
Total Patient Care Cost	\$ 232,863	\$ 298,988	\$ 316,426
General and Administrative Expense			
Directors and Clerical Salaries	\$ 28,500	\$ 28,500	\$ 28,500
Supplies and Other Cost	1,200	3,700	4,400
Depreciation and Amortization	28,509	53,827	53,827
Interest Expense	<u>6,429</u>	<u>18,816</u>	<u>18,062</u>
Total General and Admin. Expense	\$ 64,638	\$ 104,843	\$ 104,789
Total Expense	<u>\$ 297, 501</u>	<u>403,831</u>	<u>421,215</u>
Net Income (Loss) Before Taxes	\$ (7,491)	\$ 31,184	\$ 74,219
Taxes	0	\$18,242	\$ 33,342
Net Income (Loss)	\$ (7,491)	\$ 12,942	\$ 40,877
Treatments*	1,872	2,808	3,198
Cost per Treatment (Applicant)	\$ 150.00	\$ 150.00	\$ 150.00
Cost per Treatment (Staff Calculations)	\$ 158.92	\$ 143.81	\$ 131.71
Net Income (Loss) per Treatment	\$ (4.00)	\$ 4.61	\$ 12.78

* Based on full utilization of 936 dialyses per year per station