DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT NOVEMBER 2004

CON REVIEW: ESRD-NIS-0804-040
DIVERSIFIED RENAL GROUP, PLLC DBA
DRG DIALYSIS UNIT, FAYETTE
ESTABLISHMENT OF A FOUR (4) STATION ESRD FACILITY
LOCATION: FAYETTE, MISSISSIPPI, JEFFERSON COUNTY

CAPITAL EXPENDITURE: \$309,825.70

STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

Diversified Renal Group, PLLC dba DRG Dialysis Unit (DRGDU) is a for-profit limited liability company that will be located in Jeffferson County in the city of Fayette, Mississippi. Historically, Diversified Renal Group, PLLC has been a provider of outpatient End Stage Renal Disease (ESRD) services in Mississippi since January 5, 1998. Presently, Diversified Renal Group, PLLC is in a joint venture with Renal Care Group of Southaven, Mississippi, and operates 30 ESRD stations.

The applicant indicates that DRGDU of Fayette, Mississippi, is governed by two corporate officers and managed by three physicians. The applicant provided a Certificate of Formation indicating that Diversified Renal Group, PLLC is authorized by the Secretary of State to do business in the state of Mississippi and the company is in good standing. The facility will be certified to participate in the Medicare and Medicaid programs. The company submitted a letter to the Mississippi State Department of Health, Division of Licensure and Certification, requesting site approval.

B. PROJECT DESCRIPTION

The Diversified Renal Group, PLLC, Fayette, Mississippi, requests Certificate of Need authority to establish a four station End Stage Renal Dialysis (ESRD) facility in the city of Fayette, Mississippi, Jefferson County. The four station ESRD will provide accessible services to patients who travel to ESRD facilities in Natchez, Greenwood, Port Gibson, and Brookhaven but live closer to the Fayette area.

The applicant states that they will enter a lease agreement with the City of Fayette to occupy 3,000 square feet of space on the lower North Wing of the building. The applicant states that they will renovate and make capital improvements to 2,000 square feet of space to be used as a medical clinic, medical offices, and related facilities. The renovation will involve modifying the space to install dialysis machines and plumbing, and provide the correct electrical wiring to support the dialysis facility. Also, adequate parking at the site will be available to ESRD patients and employees. Thus, there is no new construction involved in this proposed project.

DRGDU affirms that they will provide a home training program to patients who are receptive and medically eligible to participate in the program. Also, the applicant states that they will offer counseling and make available the requirements for patients desiring to enter the home/self dialysis program. Based on the projected patient population, DRGDU anticipates that two patients will begin home dialysis during the first three years of operation. Thus, the applicant will request one home training station for ESRD patients who will be home trained. The applicant provided a list of non-fixed equipment totaling \$188,396.00.

The applicant states that DRGDU of Fayette will hire required staff, management personnel, and support staff to provide ESRD services to patients. In addition, the applicant will use available funds for capital and operating needs to support the proposed ESRD services. The applicant states that DRGDU will employ 4.35 full-time employees at an annual estimated cost of \$163,375. As an alternative, the applicant contemplates hiring outside trained staff to serve as contract employees. DRGDU includes a capital expenditure summary and a Three Year Projected Operating Statement. The applicant provided letters from financial institutions stating the company's sources/ amounts of non-debt and debt financing along with a 15 year amortization schedule for all loans. The total proposed expenditure for this project is \$309,825.70. Funding and financing from an incorporated company will be used to finance the project. Upon the approval of the project, the completion date will take place six to eight months after the working capital has been obligated.

II. TYPE OF REVIEW REQUESTED

The Mississippi State Department of Health reviews applications for the establishment of an end stage renal disease facility in accordance with Section 41-7-173 (h) and 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 publication of the staff analysis. The opportunity to request a hearing expires December 6, 2004.

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

A. State Health Plan (SHP)

The FY 2005 State Health Plan contains criteria and standards which the applicant is required to meet before receiving CON authority to establish a four station ESRD facility. This application is in substantial compliance with applicable criteria and standards.

SHP Criterion 1- Need

As shown in the *Fiscal Year 2005 Mississippi State Health Plan*, the Mississippi State Board of Health authorized the Department of Health to issue a CON for the construction or expansion of end stage renal facilities having a need in the following Mississippi counties: Humphreys, Jefferson, Montgomery, and Tallahatchie Counties.

According to the FY 2005 State Health Plan, there are seven ESRD facilities located 20 to 48 miles from Jefferson County. The ESRD facilities are as follows: Renex DFI-Port Gibson, Claiborne County (20 miles); FMC and RCG-Hazlehurst, Copiah County (48 miles); RCG-Brookhaven, Lincoln County (42 miles); Magnolia Dialysis-Meadville, Franklin County (27 miles); and RCG-Natchez, Adams County (24 miles).

Medicare certification records (maintained by the Mississippi State Department of Health, Division of LIcensure and Certification), Health Care Financing Administration (HCFC), and ESRD Network 8, Incorporated determine current and projected utilization of services. Based on 2003 data provided by ESRD Network 8, the applicant states that Mississippi had an ESRD incidence rate of 11 and a prevalence rate of 26. Presently, ESRD patients in Jefferson County must drive more than 34 miles to other ESRD facilities in surrounding counties. If a CON is approved, the applicant estimates that 24 Jefferson County ESRD patients will be able to dialyze at DRG Dialysis Unit.

For the past 12 months, surrounding ESRD facilities had an annual utilization rate of less than 60 percent. The applicant would not be in compliance with this criteria based on the previous year Criteria and Standards listed in the *Plan*; however, the *FY 2005 State Health Plan* Addendum, adopted by the Mississippi Board of Health on July 14, 2004, waives the utilization criteria because there is not a facility in Jefferson County and its ESRD relative risk score is 1.5 or higher.

SHP Criterion 2 - Number of Stations

The applicant states the ESRD facility will establish four hemodialysis stations in the city of Fayette, Mississippi, Jefferson County.

SHP Criterion 3 - Minimum Utilization

DRGDU states that each patient will dialyze three (3) times per week and the facility will be open from 7:00 AM to 3:30 PM and 5:30 PM to 9:00 PM, 3 days per week. The chart below indicates how many procedures will be performed within the first three years after the DRGDU of Fayette is approved for a CON.

Minimum Utilization					
	Year 1	Year 2	Year 3		
Projected Utilization Rate	67%	83%	87.5%		

Number of dialysis is based on year end data. Utilization Rate is based on Optimum 75% utilization being defined as an average of 702 dialyses/station per year as per page XIII-28 of the FY 2005 State Health Plan.

Based on 2003 data provided by ESRD Network 8, the applicant states that Jefferson County experienced a growth rate of 11 patients. The applicant expects DRGDU of Fayette to have 16, 20, and 21 patients respectively, at the end of each year following approval and expects one patient per year to expire. As a result, DRGDU of Fayette will be fully utilized and will maintain a sufficient utilization rate during the first three years of operation.

Also, 20.0% of all DRGDU patients will participate in the home dialysis and transplantation programs based on requirements and medical factors. Consequently, the applicant anticipates that two patients will begin home dialysis during the first three years of operation.

The proposed facility will be located in Fayette, Mississippi (Jefferson County) which is from 20 to 48 miles from Claiborne, Copiah, Lincoln, Franklin, and Adams County facilities. ESRD facilities in four counties except Copiah County experienced an annual utilization rate less than 60 percent, far less than the required 75 or 80 percent annual utilization rate. However, the utilization standard is waived based on the recent adoption of the Criteria and Standards listed in the FY 2005 State Health Plan.

SHP Criterion 4 - Minimum Services

DRGDU affirms that the facility will provide extensive professional support from social workers and other such trained staff members.

SHP Criterion 5 - Access to Needed Services

DRGDU of Fayette affirms that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required for stable maintenance ESRD patients. The applicant provides a copy of a transfer agreement with the University of Mississippi Medical Center. In addition, once a CON has been approved, DRGDU of Fayette states that there will be referral and transfer agreements with area hospitals.

SHP Criterion 6 - Hours of Operation

The DRGDU of Fayette will open between the hours of 7:00 AM to 3:30 PM, three 3 days per week. Patients who work each day and can not dialyze between regular hours will be accommodated from 5:30 PM to 9:00 PM.

SHP Criterion 7 - Home Training Program

Patients who have obtained services for the first time at the DRGDU facility in Mississippi will be counseled on the availability of the home-training program and the requirements to enter the home/self-dialysis program. One self/home training station is being requested to service 20.0% of DRGDU's proposed patient population.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirms that DRGDU of Fayette will provide a "reasonable amount" of indigent/charity care and will serve approximately 10 percent indigent/charity care patients. The majority of all DRGDU patients will be Medicare or Medicaid recipients; however, no patient will be denied services due to an inability to pay. Any unreimbursed needs will be addressed by the social worker through referrals and services will be provided by pharmaceutical companies to help with medication cost.

SHP Criterion 9 - Facility Staffing

The proposed facility, DRGDU, included a personnel list documenting each staffing category and the qualification guidelines (minimum education and experience requirements), specific duties, and full time equivalents. Therefore, the applicant affirms that 4.35 FTEs will be hired based on the applicant's expected utilization rate.

SHP Criterion 10 - Staffing Qualifications

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

SHP Criterion 11 - Staffing Time

When the unit is in operation, the applicant affirms that 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 affirms that the medical director or a designated physician and one R.N. will be on call.

SHP Criterion 12 - Data Collection

The applicant affirms that DRGDU of Fayette will record and maintain the required data and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 13 - Staff Training

DRGDU of Fayette affirms that the applicant will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

SHP Criterion 14 -Scope of Privileges

The applicant affirms that DRGDU 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.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

Upon the approval of the CON, the applicant affirms that they will enter into an agreement with a transplant center. The applicant provided a copy of the transfer agreement with the University of Mississippi Medical Center.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000 revisions,* addresses general criteria by which all CON applications are reviewed. Based on the Addendum, adopted on July 14, 2004, by the Mississippi Board of Health, the *FY 2005 State Health Plan* authorizes the Department of Health to issue a CON for the construction or expansion of end stage renal facilities having a need in the following Mississippi counties: Humphreys, Jefferson, Montgomery, and Tallahatchie Counties. This application is in substantive compliance with general review criteria.

GR Criterion 2 - Long Range Plan

Through a need identified in the FY 2005 State Health Plan, the applicant states that their goal is to fulfill the Plan's need to enhance the accessibility and availability of ESRD services to renal care patients who live in Jefferson County where there are no ESRD facilities located in that county.

GR Criterion 3- Availability of Alternatives

Presently, ESRD patients who live in Jefferson County are traveling more than 20 miles to use services offered at ESRD facilities in Claiborne, Copiah, Lincoln, Franklin, and Adams Counties. A CON would give patients the opportunity to use a facility in the Fayette area, therefore, eliminating the traveling distance. The applicant states there are no other alternatives to provide health resources and cost containment.

GR Criterion 4 - Economic Viability

Three year operating projections reflect a first year net loss of \$7,491, a second year profit of \$12,942, and a third year profit of \$40,877. The proposal reflects a capital expenditure of \$309,825.70. An incorporated company will fund and finance the project. Also, the applicant's financial institution will make available a line credit as needed to DRGDU based on their eight year history and current account standing. Once the ESRD facility is operating, the applicant will use net income to continue ongoing ESRD operations. The applicant also believes that the financial statements contained in the application provide evidence that DRGDU has the monetary means to provide the same.

GR Criterion 5 - Need for the Project

As shown in the *Fiscal Year 2005 Mississippi State Health Plan*, the Mississippi State Board of Health authorized the Department of Health to issue a CON for the construction or expansion of end stage renal facilities having a need in the following Mississippi counties: Humphreys, Jefferson, Montgomery, and Tallahatchie Counties.

According to the FY 2005 State Health Plan, there are seven ESRD facilities located 20 to 48 miles from Jefferson County. The ESRD facilities are as follows: Renex DFI-Port Gibson, Claiborne County (20 miles); FMC and RCG-Hazlehurst, Copiah County (48 miles); RCG-Brookhaven, Lincoln County (42 miles); Magnolia Dialysis-Meadville, Franklin County (27 miles); and RCG-Natchez, Adams County (24 miles).

Medicare certification records (maintained by the Mississippi State Department of Health, Division of Licensure and Certification), Health Care Financing Administration (HCFC), and ESRD Network 8, Incorporated determine current or projected utilization of services. Based on 2003 data provided by ESRD Network 8, the applicant states that Mississippi had an ESRD incidence rate of 11 and a prevalence rate of 26. Presently, ESRD patients in Jefferson County must drive more than 34 miles to other ESRD facilities in surrounding counties. If a CON is approved, the applicant estimates that 24 Jefferson County ESRD patients will be able to dialyze at DRG Dialysis Unit.

The community officials recognize that DRGDU of Fayette complies with all federal regulations regarding community service and supports the DRGDU's efforts to serve all patients in the service area regardless of race, creed, sex, race, or ability to pay.

GR Criterion 6 - Access to the Facility of Service

The applicant affirms that all patients will be served without regard to race, sex, age, physical abilities, or ability to pay. Also, DRGDU of Fayette proposes to serve approximately 10 percent indigent care patients.

GR Criterion 7- Information Requirement

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

GR Criterion 8 - Relationship to Existing Health Care System

The proposed service will meet the needs of current DRGDU patients. The project is not expected to have a significant adverse impact on existing providers of ESRD services.

GR Criterion 9 - Availability of Resources

The applicant affirms that the facility will adhere to this criterion by providing access to all qualified and required staff as identified in the *FY 2005 State Health Plan* and Federal Register 42 CFR, Chapter IV, Subpart U. The applicant states that DRGDU will employ 4.35 full-time employees at an annual estimated cost of \$163,375. As an alternative, the applicant contemplates hiring outside trained staff to serve as contract employees. Diversified Renal Group, PLLC is in a joint venture with Renal Care Group of Southaven, Mississippi, and currently operates 30 ESRD stations. The applicant has maintained a satisfactory staffing history at this facility.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant affirms there will be no adverse impact on any ancillary or support services.

GR Criterion 14- Construction Projects

The applicant will renovate 2,000 square feet of space by modifying the area to install dialysis machines, plumbing, and provide the correct electrical wiring to support the dialysis facility. The cost to renovate 2,000 square feet will be \$61 per square foot. Also, adequate parking at the site will be available to ESRD patients and employees. Thus, there is no new construction involved in this proposed project. The applicant included a schematic drawing of the proposed facility, a letter requesting site approval from the Department, and affirms that they will adhere to local and state standards.

GR Criterion 15 - Competing Applications

The Department received one application for ESRD services in Jefferson County, the south western central portion of Mississippi. Therefore, there are no competing applications for this service.

GR Criterion 16 - Quality of Care

Diversified Renal Group, PLLC is in a joint venture with Renal Care Group of Southaven, Mississippi and currently operates 30 ESRD stations. DRGDU affirms they will continue to provide quality care to the residents of Mississippi.

IV. FINANCIAL FEASIBILITY

A. CAPITAL EXPENDITURE SUMMARY

A. CAPITAL EXPENDITURE SUMMARY				
Construction Cost -New	\$0.00			
Construction Cost-Renovation	\$50,000.00			
Capital Improvements, i.e. (minor painting and repairs, refurbishing)	\$60,000.00			
Total Fixed Equipment Cost	\$0.00			
Total Non-Fixed Equipment Cost	\$188,396.00			
Land Cost	\$0.00			
Site Preparation Cost	\$0.00			
Fees (Architectural, Consultant, etc.)	\$0.00			
Contingency Reserve	\$5,000.00			
Capitalized Interest	\$6,429.70			
Other Cost (Specify)	\$0.00			
TOTAL PROPOSED CAPITAL EXPENDITURE	\$309,825.70			

NOTE: There is no new construction associated with this project; however, the applicant will renovate 2,000 square feet at a cost of \$61 per square foot.

B. Method of Financing

The applicant provided letters from financial institutions stating the company's sources/ amounts of non-debt and debt financing along with a 15 year amortization schedule for all loans. Statewide Physical Medicine Group, Incorporated and Premier Dialysis, Incorporated will fund and finance the proposed project. Statewide Physical Medicine Group, Incorporated is the parent company of Premier Dialysis, Incorporated.

C. Effects on Operating Costs

The applicant projects the following expenses, utilization, and results from operation for the first three years of operation:

	First Year	Second Year	Third Year
Revenue			
Routine Patient Care	362,513	543,769	619,293
Allowance for Doubtful Accounts	(72,503)	(108,754)	(123,859)
Total Net Revenue	\$290,010	\$435,015	\$495,434
Expenses			
Clinical Salaries, Wages, and Benefits	133,875	171,635	178,500
Other Facility Costs (Rent, Ins,)	48,236	51,225	51,225
Supplies	50,752	76,128	86,701
Directors and Clerical Salaries, Wages, Benefits	28,500	28,500	28,500
Supplies and Other	1,200	3,700	4,400
Depreciation and Amortization	28,509	53,827	53,827
Interest Expense	6,429	18,816	18,062
Total Expenses	\$297,501	\$403,831	\$421,215
Net Income (Loss) Before Taxes	(7,491)	31,184	74,219
Taxes at 40%	0	18,242	33,342
Net Income (Loss)	(\$7,491)	\$12,942	\$40,877
Total Treatments	1,872	2,808	3,198
Cost/Treatment	\$158.92	\$143.81	\$131.71
Charge/Treatment	\$193.65	\$193.65	\$193.65

D. Cost to Medicaid/Medicare

ESRD treatment is a Medicare entitlement. The current Medicare reimbursement charge is \$122.55 per dialysis.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application and the Division of Health Planning and Resource Development received written comments from the Division stating that ESRD facility services will be paid based upon utilization once the facility is in operation. In addition, the Division of Medicaid states cost to Medicaid cannot be determined at this time.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of an end stage renal disease facility/service as contained in the FY 2005 Mississippi State Health Plan; Chapter 8 of the Mississippi Certificate of Need Review Manual, 2000; and all adopted rules, procedures, and plans of the Mississippi State Department of Health. Specially, the proposed facility will be located in Fayette, Mississippi (Jefferson County), which is from 20 to 48 miles from Claiborne, Copiah, Lincoln, Franklin, and Adams County facilities. ESRD facilities in four counties except Copiah County experienced an annual utilization rate less than 60 percent, far less than the optimum 75 percent annual utilization rate. However, the utilization standard is waived based on the recent adoption of the Criteria and Standards listed in the FY 2005 State Health Plan.

The Division of Health Planning and Resource Development recommends approval of this application submitted by Diversified Renal Group, PLLC dba DRG Dialysis Unit for the establishment of a four-station ESRD facility in Fayette, Mississippi (Jefferson County).