

**DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2007**

**CON REVIEW: ESRD-NIS-1206-044
DIALYSIS SOLUTIONS, LLC
ESTABLISHMENT OF A SIX-STATION ESRD FACILITY IN MONTGOMERY COUNTY
CAPITAL EXPENDITURE: \$179,000
LOCATION: WINONA, MONTGOMERY COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Dialysis Solutions, LLC is a for-profit limited liability company formed on November 14, 2006. Dr. Walter Roberts is the owner and registered agent of the entity. Dr. Roberts is also the sole governing body of the entity.

B. Project Description

Dialysis Solutions, LLC requests Certificate of Need (CON) authority to establish a six-station end stage renal dialysis (ESRD) facility in Winona, Montgomery County, Mississippi. The applicant states that the establishment of an ESRD facility in Winona will enhance accessibility to those patients who are currently being treated at other facilities in Grenada, Greenwood, and Lexington, but who live closer to the proposed Winona location. The applicant proposes that 21 patients currently dialyzing at Grenada, Greenwood, and Lexington facilities live closer to and would be treated at the proposed facility.

The project will require two full-time Registered Nurses (one of which will serve as Facility Manager) and one full-time Patient Care Technician. The applicant projects to hire 4.35 full-time equivalent personnel at an estimated annual cost of \$266,830 the first year.

The proposed site for the project, which the applicant will lease from Tyler Holmes Memorial Hospital, has been zoned for use for medical offices, and has been approved by the MSDH Division of Health Facilities Licensure and Certification.

The applicant states that the capital expenditure will be obligated subsequent to receiving CON approval; estimated date for obligation of working capital is as soon as practicable after receiving CON approval; and estimated completion date for the project is three months after obligation of working capital.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Sections 41-7-173 (h),(v) 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, 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 STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The 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. This project is not in substantial compliance with the need criterion as discussed below.

SHP Criterion 1(a): An ESRD Facility Service Area is defined as the area within 30 highway miles from an existing or proposed ESRD facility. Currently, there are two providers within a 30-mile radius of Montgomery County – RCG-Grenada, Grenada County (26 miles) and RCG-Greenwood, Leflore County (28 miles). As shown in the table below, RCG Grenada and RCG-Greenwood reported utilization statistics far less than the required 80 percent for the period July 1, 2005, to June 30, 2006:

Facility	Average Number of Patients	Average Number of Stations	Average Number of Shifts/Days	Number of Treatments	Utilization Percentage
RCG-Grenada	88	27	2 shifts/6 days	13,007	51.0
RCG-Greenwood	98	27	2 shifts/6 days	14,570	58.0

Source: Annual ESRD Utilization Survey, Fiscal Year 2006.

SHP Criterion 1(b): An alternative to determining need for ESRD facilities was adopted in 2004 for Humphreys, Jefferson, Montgomery, and Tallahatchie counties. These counties were listed in the FY2006 State Health Plan as counties without an ESRD facility and whose relative risk score using current ESRD Network 8 data is 1.5 or higher. However, a CON was awarded in December 2004 to RCG-Winona, and is currently outstanding. Policy Statement 8 states that ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation.

In addition, Network 8, Inc. reported an incidence of 14 ESRD patients and a prevalence of 39 patients for Montgomery County for 2006 and an incidence of 5 and prevalence of 42 for the period January 1 through July 31, 2007. Based on the incidence and prevalence of ESRD patients in Montgomery County, it is estimated that the county can support a six-station ESRD facility. As stated above, a CON remains outstanding for RCG-Montgomery County, LLC for the establishment of a six-station ESRD facility in the county. No new facilities can be approved until the outstanding CON is revoked, rescinded, or until the facility is opened and operating at 80 percent utilization. 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 six ESRD stations. Therefore, the applicant is in compliance with this criterion.

SHP Criterion 3 - Minimum Utilization

Dialysis Solutions (DS) estimates that 25 of 29 dialysis patients who currently dialyze at one of the five surrounding dialysis facilities, but who reside in Montgomery County, will choose to dialyze at Dialysis Solutions, LLC. Out of those 25 patients, the Grenada, Greenwood, and Lexington facilities currently dialyze 21 patients. The applicant states that these patients live closer to the Winona location and are expected to relocate to a Montgomery County facility. In addition, Dialysis Solutions, LLC expects that a portion of patients treated elsewhere will also relocate to the proposed facility. The applicant projects to perform 4,032 treatments on 28 patients the first year of operation for an annual utilization of 72 percent. The table below gives a comparison of the applicant's projections with the MSDH requirements.

Projected Utilization							
				DS Projections		MSDH Requirements	
Year	Patients	Treatments per Station	Stations	Treatments	Utilization Rate	Treatments	Utilization Rate
1	28	672	6	4,032	72%	2,808	50%
2	30	720	6	4,320	77%	3,650	65%
3	31	744	6	4,464	79%	4,212	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.

SHP Criterion 5 - Access to Needed Services

Dialysis Solutions, 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 to schedule three treatments per station per day between the hours of 6:00 a.m. and 7:00 p.m. After-hours dialysis will be available to accommodate those

patients who are working and need to dialyze after the patient's normal working hours.

SHP Criterion 7 - Home Training Program

The applicant affirmed that a home training program will be made available to those patients who are medically eligible and receptive to such a program.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirmed that it will provide a "reasonable amount" of indigent/charity care. Since almost all patients qualify for Medicaid or Medicare, dialysis patients do not typically require a great deal of uncompensated care. Dialysis Solutions, LLC expects that it will serve approximately .68% indigent/charity care patients. Applicant states that no patient will be denied services due to an inability to pay.

SHP 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.

SHP Criterion 10 - Staffing Qualifications

The applicant affirmed that the staff of the facility shall, at a minimum, meet 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

Dialysis Solutions, 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 on-call 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 an RN will be on-call.

SHP Criterion 12 - Data Collection

Dialysis Solutions, 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 12, 2006*, contains general review criteria which all CON applications must meet. The applicable criteria are discussed below.

GR Criterion 1 – Compliance with the *State Health Plan*

The project is not in compliance with the need criterion stated in the *FY 2007 State Health Plan*.

GR Criterion 2 - Long Range Plan

Dialysis Solutions, LLC states that it is dedicated to improving the quality of life and to care for those patients with chronic and acute renal disease. It is committed to the philosophy that optimal care is attained through the application of state-of-the-art technology, continual quality improvement, and patient/family education. The applicant seeks to achieve superior patient outcomes and to provide the best value in patient care.

GR Criterion 3 - Availability of Alternatives

The applicant submits that the project is the result of planning and the identification of long-range goals. According to the applicant, the project as proposed is the most efficient and cost-effective method of meeting the needs of the health care community.

GR Criterion 4 - Economic Viability

The applicant projects earnings/(losses) before income taxes of (\$19,031) the first year, \$47,899 the second year, and \$54,909 the third year.

The proposed charge per dialysis patient is \$200.36 for the first year, \$203.50 the second year, and \$214.04 the third year of operation of this project. Proposed charges are comparable to those proposed by like facilities.

The applicant projects utilization of 72 percent for the first year of operation. There are currently no operational ESRD facilities in Montgomery County; however, one facility holds an outstanding CON for a six-station ESRD facility. There are approximately five facilities in

surrounding counties that ranged in utilization from 51 to 61 percent.

GR Criterion 5 - Need

Dialysis Solutions, LLC states that it does not discriminate against low income persons, racial and ethnic minorities, elderly, women, handicapped persons, or underserved groups in the provision of its services.

The applicant submits that the establishment of an ESRD facility in Montgomery County by Dialysis Solutions, LLC would provide a more convenient location for approximately 21 existing patients who are currently being dialyzed at other facilities, as well as any other patients who may present to the facility.

The application contained three letters of support for the project from the Montgomery County Board of Supervisors, Winona Manor, and an ESRD patient.

In addition, a letter of opposition to the project was received from RCG-Montgomery County, LLC.

GR Criterion 6 - Access to Facility/Service

The applicant assures that all patients will have access to the ESRD services. It states that individuals of any age who receive dialysis or renal transplantation for ESRD are eligible for Part A coverage if they file an application and they (1) meet the work requirements for insured status under the Social Security or railroad retirement program, (2) are entitled to monthly Social Security benefits of an annuity under the Railroad Retirement Act, or (3) are the spouses or dependent children of such insured or entitled persons. Medicare-qualified government employees are also eligible for ESRD benefits.

The applicant estimates that less than one percent of its patients will be medically indigent.

GR Criterion 7 - Information Requirement

The applicant affirmed that it will maintain the required information and make it available to the Department within 15 business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

As stated earlier, there are no current ESRD providers in Montgomery County; however there are two facilities within a 30-mile radius of the county and additional facilities within a 33-45 mile radius of the county. One additional provider (RCG-Montgomery County, LLC) holds a CON to establish a six-station ESRD facility in Montgomery County. RCG-Montgomery has submitted a letter in opposition of the approval of this project.

GR Criterion 9 - Availability of Resources

The applicant submits that registered and licensed practical nurses will be recruited from area colleges and universities, dialysis technicians will be recruited locally, and social workers and dietician services will be provided on a contractual basis.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant submits that there will be no adverse impact on any ancillary or support services offered.

GR Criterion 11 – Health Professional Training Programs

The applicant believes that the establishment of the six-station ESRD facility by Dialysis Solutions, LLC will enhance the training opportunities available in the Winona area. Dialysis Solutions proposes to hold the facility open for student tours, lectures, training, and clinical placement opportunities for fellows, residents, and other allied health professionals.

GR Criterion 16 - Quality of Care

Dialysis Solutions, LLC is a proposed new provider of ESRD services and thus does not have a record by which to measure quality of care.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	% of Total
Construction Cost - New	\$ 0	0.00%
Renovation	0	0.00%
Capital Improvements	0	0.00%
Total Fixed Equip Cost	0	0.00%
Total Non-Fixed Equip Cost	124,000	69.27%
Land Cost	0	0.00%
Site Prep Cost	0	0.00%
Fees	30,000	16.76%
Contingency Reserve	25,000	13.97%
Capitalized Interest	0	0.00%
Other Cost - Testing Services	0	0.00%
Total Proposed Expenditures	\$ 179,000	100.00%

The above capital expenditure is for the purchase of six ESRD stations to be located on space leased from Tyler Holmes Memorial Hospital in Montgomery County. The applicant will lease a GE modular building to house the six stations.

B. Method of Financing

The applicant proposes that the project will be financed from member assets. The financial information contained in the application does not identify whether funds are available for the project.

C. Effect on Operating Cost

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

Three-year Projected Operating Statement

Item	Year 1	Year 2	Year 3
Revenue			
Clinical Revenue			
EPO Revenue			
Ancillary Revenue			
Total Revenue	\$ 807,840	\$ 879,120	\$ 955,470
Expenses			
Salaries, Wages and Benefits	\$ 266,830	\$ 221,180	\$ 240,470
Supplies & Miscellaneous Expense	326,070	354,840	385,660
Interest, Depreciation & Amortization	15,811	15,811	15,811
EPO Cost (w/o Acute)			
Other Med-No Equip Leasing (w/o Acute)			
Other Med- Equip. Leasing (w/o Acute)			
Housekeeping (w/o Acute)			
Adm Exclude Regional & BU Allocation			
Bad Debt	24,240	26,370	28,660
Depr./Amort. (with Acute)			
Property/Insurance (with Acute)			
Rent (with Acute)	20,580	16,940	17,380
Other Expenses	173,340	165,670	177,450
Total Expenses	\$ 826,871	\$ 800,811	\$ 865,431
Earnings Before Income Taxes	\$ (19,031)	\$ 78,309	\$ 90,039
Provision for Income Taxes	\$ 0	\$ 30,410	\$ 35,130
Income After Taxes	\$ (19,031)	\$ 47,899	\$ 54,909
Utilization Statistics			
Total Patients	28	30	31
Total Treatments	4,032	4,320	4,464
Utilization Rate	72.0%	77.0%	79.0%
Cost per Treatment	\$205.08	\$185.37	\$193.87
Charge per Treatment	\$200.36	\$203.50	\$214.04

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. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of the proposed application for comment; however, no written comments had been received from the Division of Medicaid 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 12, 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 are two ESRD facilities within 30 highway miles of the proposed facility. Those facilities had utilization rates of 51-58 percent, less than the required 80 percent. SHP Criterion 1(b) excludes counties without ESRD facilities from the requirement of 1(a); however, a CON for ESRD services remains outstanding in Montgomery County. Therefore, the applicant cannot qualify for the exclusion under this criterion. Given the low utilization rate of the existing providers and the outstanding CON, 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 Dialysis Solutions, LLC for the establishment of a six-station ESRD facility in Montgomery County.