

**DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT  
MAY 2006**

**CON REVIEW ESRD-NIS-0905-041  
HEALTHCARE ENGINEERS, LLC  
ESTABLISHMENT OF A 12 STATION ESRD FACILITY IN TALLAHATCHIE COUNTY  
CAPITAL EXPENDITURE: \$254,085  
LOCATION: CHARLESTON, TALLAHATCHIE COUNTY, MISSISSIPPI**

**STAFF ANALYSIS**

**I. PROJECT SUMMARY**

A. Applicant Information

Healthcare Engineers, LLC, a for-profit, Mississippi limited liability company owned by Ray Shoemaker, Missy Hutto, and Robert Corkern, was established for the purpose of providing end-stage renal disease (ESRD) services in Charleston, Tallahatchie County, Mississippi. The entity, whose governing board consists of the three owners, is an affiliate of Tri-Lakes Medical Center, Batesville, Mississippi.

B. Project Description

Healthcare Engineers, LLC requests Certificate of Need (CON) authority to establish a 12-station ESRD facility in Charleston, Tallahatchie County, Mississippi. The applicant proposes to lease a parcel of land containing 5.00 acres located on South Panola Street in Charleston, Tallahatchie County, with an option to purchase at a price of \$9,000. The ESRD facility will be housed in a modular building leased from Vanguard at a cost of \$18,000 per month, with an initial charge of \$100,000. The total proposed capital expenditure of the project is \$254,085.

The project will require four full-time (and one part-time) registered nurses, two full-time (and one part-time) licensed practical nurses, three full-time (and one part-time) certified nurse assistants, one office manager, one physician, and one consulting physician.

The proposed site for the project has not been zoned for commercial use for medical offices, and has not been approved by the MDH Division of Health Facilities Licensure and Certification. However, the applicant submitted evidence that suggests that it may overcome unfavorable conditions associated with the site.

The applicant expects to obligate capital expenditure upon CON approval and expects the project to be complete approximately three months thereafter.

**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), Section 41-7-191, subparagraph (1)(a), and Section 41-7-193 of the Mississippi Code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi 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 June 8, 2006.

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

#### A. State Health Plan (SHP)

The *FY 2006 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.

Tallahatchie County is identified by the State Health Plan as one of the counties meeting the need criterion (b) above. In accordance with the *FY 2006 State Health Plan*, ESRD Policy Statements 2, 4, 5, and 6 of the *Plan* do not apply to projects reviewed under 1(b).

The applicant states that there are 29 ESRD patients in Tallahatchie County and 21 of these patients drive 25 miles to facilities in Greenwood and Grenada.

**Note: Network 8, Inc. reported an incidence of less than 11 ESRD patients and a prevalence of 31 patients for Tallahatchie County for 2004. Based on the foregoing information, it appears that there are not enough patients in Tallahatchie County to justify an addition of 12 ESRD stations. It is also noted that the applicant's original application submitted on September 9, 2005, requested the approval of 6 ESRD stations. Information received from the applicant on December 30, 2005, upgraded the request to 12 stations. The remainder of this staff analysis will focus on six ESRD stations for Tallahatchie County.**

Based on the optimum utilization of 702 dialyses per station per year as contained in the *State Health Plan* and information *obtained* from Network 8, Inc., Tallahatchie County will need 6.89 ESRD stations to dialyze its 31 end-stage patients.

Number of dialyses per patient/year = 156  
Number of dialyses for 31 patients:  $156 \times 31 = 4,836$   
Optimum dialyses per station = 702  
Number of stations needed to dialyze 31 patients:  $4,836 / 702 = 6.89$

Optimum dialyses of 7 stations –  $(702 \times 7 \text{ stations}) = 4,914$  dialysis

**SHP Criterion 2 - Number of Stations**

The *FY 2006 State Health Plan* establishes a minimum of four ESRD stations that may be approved for establishment of an ESRD facility. Healthcare Engineers, LLC proposes to establish 12 ESRD stations; therefore, the applicant is in compliance with this criterion. However, based on the optimum utilization level, Tallahatchie County only needs 6.89 ESRD stations. As shown in the table below, six stations is a more conservative projection for the applicant to meet the needs of Tallahatchie County ESRD population and to fulfill the minimum utilization requirements of the *State Health Plan*.

**SHP Criterion 3 - Minimum Utilization**

The applicant projects to perform 4,032 treatments the first year of operation, based on use of 6 stations, for an annual utilization of 72%. Mississippi Department of Health requires that an applicant perform at a utilization rate of 50% the first year of operation; therefore, the applicant's projections exceed the minimum utilization requirement during the first year. Likewise, the projected numbers of treatments for years 2 and 3 exceed the minimum utilization of 65% and 75%, respectively.

| Projected Utilization |          |                        |          |                      |                  |             |                  |
|-----------------------|----------|------------------------|----------|----------------------|------------------|-------------|------------------|
|                       |          |                        |          | Healthcare Engineers |                  | SHP Minimum |                  |
| Year                  | Patients | Treatments per Station | Stations | Treatments           | Utilization Rate | Treatments  | Utilization Rate |
| 1                     | 26       | 672                    | 6        | 4,032                | 72%              | 2,808       | 50%              |
| 2                     | 28       | 720                    | 6        | 4,320                | 77%              | 3,650       | 65%              |
| 3                     | 29       | 744                    | 6        | 4,464                | 79%              | 4,212       | 75%              |

Although the number of stations needed was calculated at 6.89 at the optimum utilization level, the projected number of treatments for seven stations would yield 62% in the first year, 66% in the second year, and 68% in the third year, with the third year utilization falling below the 75% minimum utilization requirement. The projection of six stations is a more conservative projection and will result in the applicant's meeting the optimum utilization requirement in the Plan for year three.

**SHP Criterion 4 - Minimum Services**

The applicant affirmed that it will provide extensive professional support from social workers and other such trained staff members.

**SHP Criterion 5 - Access to Needed Services**

The applicant 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 6:00 a.m. to 7:00 p.m. five days a week. Alternate arrangements will be made for those patients needing after-hour 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 a reasonable amount of indigent/charity care.

#### **SHP Criterion 9 - Facility Staffing**

The applicant states that there will be four full-time (and one part-time) registered nurses, two full-time (and one part-time) licensed practical nurses, three full-time (and one part-time) certified nurse assistants, one office manager, one physician, and one consulting physician for the project.

#### **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**

Healthcare Engineers affirmed that when the unit is in operation, at least one (1) RN will be on duty and at least two persons will be present 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**

Healthcare Engineers 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 MDH 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 a transplant center within one year after the facility is opened and operating. The applicant further 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 2000*, 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 in compliance with Need Criterion 1(b) stated in the *FY2006 State Health Plan*.

### **GR Criterion 2 - Long Range Plan**

The applicant states that its long range development plan is to operate a facility that provides hemodialysis to patients who must dialyze during scheduled times during the week and on an outpatient basis.

### **GR Criterion 3 - Availability of Alternatives**

The applicant submits that presently the patients who live in the Charleston area are traveling at least 25 miles to use the services offered at the Renal Care Group facilities in Grenada, Greenwood, and Lexington. According to the applicant, this facility, if approved, would give patients the opportunity to use a facility in the Charleston area, therefore, eliminating the travel distance. The applicant states that there are no other available alternatives to provide health resources and cost containment.

### **GR Criterion 4 - Economic Viability**

The applicant projects a net loss of \$19,031 for the first year of operation of the project, net income of \$47,899 for the second year, and net income of \$54,989 for the third year of operation.

The proposed charge per dialysis patient is \$200.36 for the first year, \$203.50 for the second year, and \$214.04 for the third year of operation of this project.

The applicant projects utilization of 72% in the first year of operation, 77% in the second year and 79% in the third year.

The capital expenditure for this project is \$254,082; therefore, no feasibility study is required for the project. Based on information provided, the project appears to be financially feasible.

#### **GR Criterion 5 - Need**

The applicant states that it is the policy of Healthcare Engineers, LLC to admit patients to the dialysis program and make services available to all patients regardless of race, creed, color, age, and/or ability to pay.

The applicant proposes to establish a new 12-station ESRD facility in Tallahatchie County, Charleston, Mississippi. No relocation of services is required. However, based on information received from Network 8, Inc. and staff calculations of projected utilization, Tallahatchie County can only support 6.89 ESRD stations at optimum utilization. Based on applicant's projected treatments, staff determined that six stations is a more conservative projection for meeting the needs of Tallahatchie County. Staff further determined that optimum utilization of six stations furthers the goal of cost containment.

The current utilization of ESRD facilities in the ESRD service area is less than the required 80 percent utilization before another ESRD facility can be approved; however, the State Health Plan waives this requirement for the establishment of an ESRD facility in Tallahatchie County.

The application contained no letters of support or opposition for the project from physicians or others in the area.

#### **GR Criterion 6 - Access to Facility/Service**

The applicant assures that all patients will have access to the ESRD services. The applicant projects that the majority of its patients will be Medicare or Medicaid eligible.

#### **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**

Currently, there are no ESRD providers located in Tallahatchie County. The *FY 2006 State Health Plan* lists Tallahatchie County as one of the counties eligible to receive CON approval based on a relative risk score using current ESRD Network 8, Inc. data of 1.5 or higher.

#### **GR Criterion 9 - Availability of Resources**

The applicant states that the required staff will include an Administrative Registered Nurse

who will be named from within the existing nursing personnel at Tri-Lakes Medical Center, an affiliate of Healthcare Engineers. In addition, Healthcare Engineers proposes to recruit Registered Nurses and Licensed Practical Nurses from area colleges, universities, and local community colleges.

**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.

**GR Criterion 11 – Health Professional Training Programs**

The applicant believes that the establishment of an ESRD facility in Charleston will enhance the training opportunities available in the Charleston area by allowing the facility to be open to required staff and students for the purpose of training, lectures, job opportunities, etc.

**GR Criterion 14 – Construction Projects**

The applicant does not propose any construction; however, the site on which the modular unit will be placed has not received approval from the MDH Division of Health Facilities Licensure and Certification.

**GR Criterion 16 - Quality of Care**

Healthcare Engineers, LLC will be a new provider of ESRD services in Mississippi; and therefore no track record has been established.

**IV. FINANCIAL FEASIBILITY**

A. Capital Expenditure Summary

| <b>Cost Item</b>                   | <b>Projected Cost</b> | <b>% of Total</b> |
|------------------------------------|-----------------------|-------------------|
| Construction Cost - New            | \$ 0                  | 0.0%              |
| Renovation                         | 0                     | 0.0%              |
| Capital Improvements               | 0                     | 0.0%              |
| Total Fixed Equip Cost             | 0                     | 0.0%              |
| Total Non-Fixed Equip Cost         | 204,085               | 80.0%             |
| Land Cost                          | 0                     | 0.0%              |
| Site Prep Cost                     | 0                     | 0.0%              |
| Fees                               | 25,000                | 10.0%             |
| Contingency Reserve                | 25,000                | 10.0%             |
| Capitalized Interest               | 0                     | 0.0%              |
| Other Cost -                       | 0                     | 0.0%              |
| <b>Total Proposed Expenditures</b> | <b>\$254,085</b>      | <b>100.0%</b>     |

The above capital expenditure is proposed for the purchase of 12 ESRD stations. The facility will be housed in a modular building to be leased from Vanguard, and located on land to be leased from Darnell and Martha Heffner. The applicant has an option to purchase the property for the sum of \$9,000.

B. Method of Financing

The applicant proposes that the project will be financed from operating revenue.

C. Effect on Operating Cost

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

**Three-year Projected Operating Statement  
 (Based on Six Stations)**

| <u>Item</u>                          | <u>Year 1</u>      | <u>Year 2</u>     | <u>Year 3</u>     |
|--------------------------------------|--------------------|-------------------|-------------------|
| <b>Revenue</b>                       |                    |                   |                   |
| <b>Total Revenue</b>                 | <b>\$ 807,840</b>  | <b>\$879,120</b>  | <b>\$955,470</b>  |
| <b>Expenses</b>                      |                    |                   |                   |
| Salaries, Wages, and Benefits        | \$ 266,830         | \$ 221,180        | \$ 240,390        |
| Supplies and Misc. Expenses          | 326,070            | 354,840           | 385,660           |
| Interest Depreciation & Amortization | 15,811             | 15,811            | 15,811            |
| Bad Debt                             | 24,240             | 26,370            | 28,660            |
| Facility Rent                        | 20,580             | 16,940            | 17,380            |
| Other Expenses                       | 173,340            | 165,670           | 177,450           |
| <b>Total Expenses</b>                | <b>\$ 826,871</b>  | <b>\$ 800,811</b> | <b>\$ 865,351</b> |
| Income Before Income Taxes (loss)    | \$ (19,031)        | \$ 78,309         | \$ 90,119         |
| Provision for Income Taxes           | 0                  | \$ 30,410         | \$ 35,130         |
| <b>Net Income</b>                    | <b>\$ (19,031)</b> | <b>\$ 47,899</b>  | <b>\$ 54,989</b>  |
| <b>Utilization Statistics</b>        |                    |                   |                   |
| Total Patients                       | 26                 | 28                | 29                |
| Total Treatments                     | 4,032              | 4,320             | 4,464             |
| Utilization Rate                     | 72%                | 77%               | 79%               |
| Cost per Treatment                   | \$ 200.36          | \$ 185.37         | \$ 193.85         |
| Charge per Treatment                 | \$ 205.08          | \$ 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. Outpatient services are paid as outlined in the Medicaid State Plan. The Division of Medicaid took no position on this project.



## **VI. CONCLUSION AND RECOMMENDATION**

This project is in substantial compliance with criteria and standards for establishment of end stage renal disease facilities, as contained in the *FY 2006 State Health Plan*; the *Mississippi Certificate of Need Review Manual, revised 2000*; and all adopted rules, procedures, and plans of the Mississippi Department of Health. However, the applicant requests the establishment of 12 ESRD stations in Tallahatchie County. The proposal was initially submitted as a request for 6 ESRD stations and was subsequently revised to request 12. Based on information received from Network 8, Inc. and staff calculations of projected utilization, Tallahatchie County can only support 6.89 ESRD stations at optimum utilization. Staff determined that six stations is a more conservative projection for meeting the needs of Tallahatchie County and that optimum utilization of six stations furthers the goal of cost containment.

In addition, the site on which the applicant proposes to place the ESRD facility has not received approval by the MDH Division of Health Facilities Licensure and Certification. Regulations stipulate that the State Health Officer shall not approve an application in which the site has not been approved. Therefore, final consideration is contingent upon satisfying this requirement.

Section 41-7-195 subparagraph 5 provides that the State Department of Health may approve or disapprove a proposal for a Certificate of Need as originally presented in final form, or it may approve a certificate of need by modification, by reduction only, of such proposal provided the proponent agrees to such modification.

Consequently, the Division of Health Planning and Resource Development recommends approval of the application submitted by Healthcare Engineers, LLC for the establishment of a 12-station ESRD facility in Tallahatchie County, by reduction to 6 stations at a capital expenditure cost of \$254,085, provided the applicant agrees to such reduction, and provided the site has received MDH approval prior to a decision by the State Health Officer.