

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
OCTOBER 16, 2016**

**CON REVIEW: ESRD-NIS-0916-020
TOTAL RENAL CARE, INCORPORATED
D/B/A DAVITA ITAWAMBA COUNTY DIALYSIS
ESTABLISHMENT OF AN ESRD FACILITY IN ITAWAMBA COUNTY
CAPITAL EXPENDITURE: \$1,972,179
LOCATION: MANTACHIE, ITAWAMBA COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Total Renal Care, Inc. d/b/a DaVita Itawamba County Dialysis is a business corporation. Total Renal Care is a wholly-owned subsidiary of DaVita HealthCare Partners Incorporated. The applicant indicates that Total Renal Care Inc. is governed by 1 director and 3 officers.

The applicant provided a Certificate from the Secretary of State verifying that the corporation was issued a Charter/Certificate of Authority on March 9, 2004. The document indicates that the business is incorporated in the State of Mississippi.

B. Project Description

Total Renal Care, Inc. d/b/a DaVita Itawamba County Dialysis (DaVita Itawamba) requests Certificate of Need (CON) authority to establish an End Stage Renal Disease (ESRD) facility in Mantachie, Itawamba County, Mississippi. The applicant affirms that the proposed ESRD facility will consist of thirteen (13) staff assisted hemodialysis stations and two (2) home training rooms.

The applicant intends to renovate an existing structure and construct an 8,000 square foot facility (6,250 square feet build-out and 1,750 unfinished) on the proposed site. The proposed facility will be located at 3483 Mississippi Highway 371 N. Mantachie, MS 38855 (a .997 acre parcel, retail establishment). The applicant states that DaVita Itawamba will be a state-of-the-art facility. Features of this design include the following: a patient waiting room, patient prep area, patient treatment area, lab area, staff offices, staff lounge, storage room, water treatment room and a storage area for waste.

The applicant states that currently residents are forced out of necessity to travel from Fulton, Mantachie and surrounding communities to more distant facilities to receive renal dialysis services. The applicant suggests that DaVita Itawamba will be located in an area likely to attract patients from Itawamba, Lee, Prentiss and Tishomingo County. The applicant believes that many members of these underserved ESRD communities will choose to dialyze in a DaVita facility not only because of its geographical convenience but also because of the company's reputation for high quality of care.

The applicant provided a letter from Seakay Construction Corporation to verify the preliminary cost estimates for the desired shell building improvements for the proposed project.

The applicant expects to employ 4.2 full-time equivalent employees at a total personnel cost of \$52,000 during the first year of operation.

The total proposed capital expenditure for this project is \$1,972,179 that the applicant proposes to finance with cash reserves. The applicant anticipates that the project will commence within 3 months of CON approval and completion within one year.

II. TYPE OF REVIEW REQUIRED

This project for the establishment of an end stage renal disease facility is reviewed in accordance with Section 41-7-191(1)(a), of the Mississippi Code of 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 10 days of the publication of the staff analysis. The opportunity to request a hearing expires on October 26, 2016.

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

A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains criteria and standards which the applicant is required to meet before receiving CON authority to establish a fifteen-station ESRD facility. This application is in substantial compliance with applicable criteria and standards.

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. An ESRD Facility service area is defined as the area within a 30 mile radius of an existing or proposed ESRD facility. The applicant submits that currently there is one ESRD facility located in the proposed service area; RCG of Tupelo which is approximately 18.1 miles from the proposed ESRD facility.

The MS State Department of Health ESRD Utilization Data Survey (FY 2014) conveyed RCG of Tupelo, a 50 hemodialysis-station experienced 76% utilization. Per CON Review Number ESRD-NIS-0616-013, the CON application verifies that RCG of Tupelo experienced 83.4% utilization and their satellite facility (RCG of New Albany) experienced 62.0% utilization in less than 8 months.

According to RCG of Tupelo's utilization projections stated above their ESRD

facility has maintained a minimum annual utilization rate of 80 percent. The *FY 2015 State Health Plan* shows that there are not any ESRD facilities in Prentiss and Tishomingo Counties and the applicant affirms that presently there are not any ESRD facilities located in Itawamba County. The applicant asserts that the residents currently travel to other counties to receive ESRD services. MSDH staff determined that the ESRD facility located in Aberdeen, Monroe County, Mississippi is approximately 40 driving miles from the proposed facility. The applicant believes that the establishment of a thirteen-station ESRD facility will be the most efficient, effective, and accessible solution to meet the needs of ESRD patients in Itawamba County.

SHP Criterion 2 – Expansion of Existing ERSRD Facilities

The proposed project is not for the expansion of an existing ESRD facility; therefore, Criterion 2 is not applicable.

SHP Criterion 3 – Establishment of ESRD Satellite Facilities

The proposed project is not for the establishment of a new ESRD satellite facility; therefore, Criterion 3 is not applicable.

SHP Criterion 4 - Number of Stations

The applicant states that the ESRD facility will consist of thirteen staff assisted hemodialysis stations and two home training rooms stations in Itawamba County.

SHP Criterion 5 - Minimum Utilization

The following table below gives a comparison of the applicant’s projections with the MSDH requirements.

| Year | Stations | Applicant’s Projections | | | MSDH Requirements | |
|------|----------|-------------------------|------------|------------------|-------------------|------------------|
| | | Patients | Treatments | Utilization Rate | Treatments | Utilization Rate |
| 1 | 13 | 43 | 6,192 | 50.9% | 6,084 | 50% |
| 2 | 13 | 50 | 7,200 | 59.2% | N/A | N/A |
| 3 | 13 | 55 | 7,920 | 65.1% | 7,909 | 65% |

SHP Criterion 6 - Minimum Services

The applicant affirms that the facility will provide social, dietetic, and rehabilitative services.

SHP Criterion 7 - Access to Needed Services

The applicant affirms that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

SHP Criterion 8 - Hours of Operation

The applicant states that DaVita Itawamba County Dialysis hours of operation will be limited to Monday, Wednesday & Friday during the initial phase of operation and will gradually increase to Monday – Saturday from 6:00 a.m. to 6:00 p.m. The applicant affirms alternate arrangements will be made for those patients needing after-hours treatments.

SHP Criterion 9 - Home Training Program

The applicant affirms that patients who would like to participate in the home training program will be counseled on the availability of the home-training program and the requirements to enter the home/self-dialysis program.

SHP Criterion 10 - Indigent/Charity Care

The applicant affirms that they will treat all patients regardless of ability to pay and provide a reasonable amount of indigent/charity care. The applicant states that government-based programs represent approximately 69 percent of all dialysis and related lab services revenues for DaVita and its affiliates in Mississippi, with commercial payors comprising the rest. The applicant states that unreimbursed care, including indigent care represents one percent (1%) or less of these revenues.

SHP Criterion 11 - Facility Staffing

The applicant included a proposed list of staff by category, position qualification guidelines (minimum education and experience requirements) and specific duties. If the proposed project is CON approved, the applicant affirms that 4.2 full time equivalents will be utilized to operate the ESRD facility.

SHP Criterion 12 - Staffing Qualifications

The applicant asserts that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in the Medicare Conditions for Coverage of Suppliers of ESRD Services.

SHP Criterion 13 - Staffing Time

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

SHP Criterion 14 - Data Collection

The applicant affirms that it shall 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 15 - Staff Training

The applicant asserts that it will provide an ongoing training program for nurses and technicians in dialysis techniques at the facility.

SHP Criterion 16 - Scope of Privileges

The applicant affirms that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the proposed governing body of the facility.

SHP Criterion 17 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center within one (1) year after the facility is opened and operating.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011* addresses general criteria by which all CON applications are reviewed. The applicable criteria are discussed below.

The Department received two letters of opposition concerning the proposed project from Nephrology and Hypertension Associates, Ltd. and Renal Care Group Tupelo.

GR Criterion 1 – State Health Plan

This application is in compliance with the overall objectives of the *FY 2015 State Health Plan*. The applicant seeks Certificate of Need authority to establish thirteen hemodialysis stations and two home training rooms in Mantachie, Itawamba County, Mississippi.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, easily accessible ESRD services for those residents in need of dialysis services in Itawamba County.

GR Criterion 3 – Availability of Alternatives

The applicant states that due to the fact that there are no existing ESRD facilities in Itawamba County, no other alternatives to the proposed facility were considered. Mantachie is located within an area in North East Mississippi where many patients must drive extended distances for dialysis treatments at a very large facility. The applicant suggests that the establishment of a smaller ESRD facility benefits not only the patients but also the system as a whole by providing access and a wider-range of ESRD service providers. The applicant affirms that the health care delivery system for ESRD patients in this region will benefit from the location of a DaVita ESRD facility in the projected service area.

The applicant believes that the establishment of a thirteen-station and two home

training rooms ESRD facility will be the most efficient, effective and accessible solution to meet the needs of ESRD patients in Itawamba County.

GR Criterion 4 – Economic Viability

Based on the applicant's three-year projections, this project will have a net operating income (losses) of (\$571,740) the first year, (\$327,252) the second year, and (\$246,255) the third year of operation. The applicant shows losses for three years after the proposed project is implemented.

The applicant submits that DaVita Itawamba will cover all expenses through company-wide operating revenues if the project fails to meet projected revenues.

- a. **Proposed Charge:** The applicant submits that the proposed project will not increase the cost of dialysis services to patients or Medicaid. The applicant believes that the proposed charges and projected profitability of the facility is comparable to similar services in the state provided by other ESRD providers.

The applicant projects charges of \$280 per dialysis treatment for the first year, \$313 for the second year, and \$309 for the third year of operation. The applicant projects cost of \$783 per dialysis treatment for the first year, \$397 for the second, and \$346 for the third year of operation for the proposed project.

- b. **Projected Levels of Utilization:** The applicant makes the following projections of dialysis treatments to be performed during the first three years of operation: 50.9%, 59.2%, and 65.1% respectively.
- c. **Project's Financial Feasibility Study:** The capital expenditure for this project is \$1,972,179; therefore, a financial feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 – Need for Project

- a. **Access by Population Served:** The applicant asserts that dialysis services will be offered to all ESRD patients, including without limitation, to the underserved population
- b. **Relocation of Services:** This application does not entail the relocation of services or replacement of an ESRD facility.
- c. **Probable Effect on Existing Facilities in the Area:** As previously stated above, the applicant submits that currently there is one ESRD facility located in the proposed service area; RCG of Tupelo which is approximately 18.1 miles from the proposed ESRD facility. The applicant further suggests that all ESRD services in areas surrounding Itawamba County are provided by a single ESRD service provider that has recorded significant growth over the years. The applicant believes that due to the relatively small size of DaVita Itawamba and its location in a small town that it is not likely to have an adverse impact on the financial viability of RCG Tupelo.

- d. **Community Reaction:** The application contained letters of support for the proposed project from the Mississippi State Senate, Itawamba County Board of Supervisors Member, a Mississippi State Representative, Itawamba County Development Council, nephrologists, clinical directors, and ESRD patients.

GR Criterion 6 – Access to the Facility or Service

According to the applicant, all patients of the ESRD service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The applicant submits the following percentage of gross patient revenue (GPR) and actual dollar amount of health care provided to medically indigent care patients for the projected amounts for the two years following completion of the proposed project:

**Medically Indigent Care Patients
Gross Patient Revenue**

| | Medically Indigent | Charity Care | GPR Dollar Amount |
|------------------|---------------------------|---------------------|--------------------------|
| Projected Year 1 | 1.5% | 1.5% | \$4,652 |
| Projected Year 2 | 1.5% | 1.5% | \$15,706 |

The applicant states that DaVita Itawamba hours of operation will be limited to Monday, Wednesday & Friday during the initial phase of operation and will gradually increase to Monday – Saturday from 6:00 a.m. to 6:00 p.m.

GR Criterion 7 – Information Requirement

The applicant affirms that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 – Relationship to Existing Health care System

The applicant states that there are no ESRD facilities in Itawamba County. Currently residents have to travel to other counties to receive ESRD services. The applicant submits that currently there is one ESRD facility located in the proposed service area, RCG of Tupelo, which is approximately 18.1 miles from the proposed ESRD facility. The applicant affirms that prior to commencing operation of the facility; they will enter into an affiliation agreement with a renal transplant center and an emergency back-up agreement.

Based on the information presented in the application, the applicant asserts that RCG of Tupelo is within a 30 miles radius of the proposed ESRD facility in Mantachie, MS; however, RCG of Tupelo's satellite facility in New Albany and the ESRD facility in Aberdeen, MS are outside of the 30 mile radius.

The applicant believes that an existing single provider of ESRD services will not

allow patients to have the option of treatment at another facility with more desirable shifts for patients.

The applicant believes that failure to implement this project will restrict access to the growing ESRD patient population in Itawamba County.

GR Criterion 9 – Availability of Resources

The applicant affirms that a number of board certified nephrologists who, based upon initial contacts, have expressed an interest in serving as medical director for the proposed facility. DaVita also plans to grant privileges to qualified nephrologists who currently treat patients at the existing facility in the service area, who would also like to treat patients at the proposed facility. The applicant states that the facility shall provide access to all doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the physicians. The applicant suggests that Registered Nurses, Licensed Practical Nurses, Social Workers, Dieticians and Dialysis Technicians will be recruited from area colleges and universities and local advertisement.

Furthermore, the applicant states that they will enter a contract with a refuse carrier, janitorial service and a laboratory service provider on an annual basis. The applicant also anticipates entering into a medical director agreement with a nephrologist before the facility opens. The applicant states that the suggested contracts are not finalized at this time.

GR Criterion 10– Relationship to Ancillary or Support Services

The applicant affirms that all necessary ancillary or support services will be available.

GR Criterion 11– Health Professional Training Programs

According to the applicant, DaVita Itawamba plans to be open for student tours, lectures, training, and clinical placement opportunities for fellows, residents, and other allied health professionals.

GR Criterion 16– Quality of Care

The applicant states that DaVita leads the industry with 98 percent of their centers rated in the top clinical performance tier for the CMS Quality Incentive Program. The applicant believes that the DaVita's CMS Five Star Quality Rating System is a significant indicator of facility quality and service.

The applicant submits that Itawamba County currently does not have an ESRD facility. The applicant believes that the proposed project will improve the access to all ESRD patients in Itawamba County

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

| Cost Item | Projected Cost | % of Total |
|--|-----------------------|-------------------|
| Construction Cost - New | \$ 0 | 0% |
| Construction Cost - Renovation | \$1,108,900 | 56.22% |
| Capital Improvements | \$ 0 | 0% |
| Total Fixed Equip Cost | \$ 660,099 | 33.47% |
| Total Non-Fixed Equip Cost | \$ 0 | 0% |
| Land Cost | \$ 0 | 0% |
| Site Prep Cost | \$ 0 | 0% |
| Fees - architectural, consulting, etc. | \$ 93,000 | 4.72% |
| Fees - legal and accounting | \$ 82,250 | 4.17% |
| Contingency Reserve | \$ 0 | 0% |
| Capitalized Interest | \$ 27,930 | 1.42% |
| Other Cost | \$ 0 | 0% |
| Total Proposed Expenditure | \$1,972,179 | 100% |

B. Method of Financing

The applicant proposes that the project will be financed from cash reserves.

C. Effect on Operating Cost

Attachment 1 lists Total Renal Care, Incorporated d/b/a DaVita Itawamba County Dialysis projections of expenses, revenues, and utilization for the first three years of operation.

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. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application and the Department received written comments from the agency. For the establishment of an ESRD facility, the Division of Medicaid does not foresee any increase in allowable costs to Medicaid as a result of the project and does not oppose the transaction.

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 2015 State Health Plan*; the *Mississippi Certificate of Need Review Manual, revised September 1, 2011*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the

application submitted by Total Renal Care, Inc. d/b/a DaVita Itawamba County Dialysis for the establishment of a thirteen- station ESRD facility in Itawamba County, with two (2) training stations.

Total Renal Care, Inc.
 d/b/a Davita Itawamba County Dialysis

Three-Year Projected Operating Statement

| | Year 1 | Year 2 | Year 3 |
|------------------------------------|---------------------|----------------------|---------------------|
| Revenue | | | |
| Inpatient Care Revenue | 0 | 0 | 0 |
| Outpatient Revenue | 310,142 | 1,047,048 | 1,521,939 |
| Gross Patient Revenue | \$ 310,142 | \$1,047,048 | \$1,521,939 |
| Charity | 9,304 | 31,411 | 45,658 |
| Deductions from Revenue | 5,427 | 13,088 | 19,024 |
| Net Patient Care Revenue | 295,411 | 1,002,549 | 1,457,257 |
| Other Operating Revenue | 0 | 0 | 0 |
| Total Operating Revenue | \$ 295,411 | \$1,002,549 | \$1,457,257 |
| Operating Expenses | | | |
| Salaries | \$ 200,652 | \$ 263,961 | \$ 341,327 |
| Benefits | 78,254 | 102,945 | 133,117 |
| Supplies | 76,011 | 225,983 | 333,154 |
| Services | 84,375 | 100,000 | 100,000 |
| Lease Expenses | 88,000 | 90,640 | 93,359 |
| Depreciation | 182,131 | 185,919 | 189,784 |
| Interest | 0 | 0 | 0 |
| Other | 157,727 | 360,352 | 512,771 |
| Total Operating Expenses | \$ 867,150 | \$1,329,800 | \$1,703,512 |
| Net Operating Income (Loss) | (\$ 571,740) | (\$ 327,252) | (\$ 246,255) |
| | Proposed | Proposed Year | Proposed |
| | Year 1 | Year 2 | Year 3 |
| Procedures | 1,107 | 3,349 | 4,926 |
| Charge per outpatient day | \$ 280 | \$ 313 | \$ 309 |
| Cost per outpatient day | \$ 783 | \$ 397 | \$ 346 |